K152842

Boston Scientific

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28th September, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: **Traditional 510(k) Notification**
WALLSTENT™ RP Endoprosthesis Tracheobronchial
WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Sir or Madam:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 807 Subpart E, Boston Scientific Corporation (BSC) hereby submits the enclosed Traditional 510(k) Premarket Notification for the WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial Device.

This tracheobronchial self-expanding stent is a Class II device per 21 CFR 878.3720, Product Code JCT. Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial devices are self-expanding stents indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. The predicate device is the WALLSTENT Tracheobronchial Endoprosthesis, cleared via K992510 on November 18th, 1999. There have been no prior NSE determinations, deleted or withdrawn 510(k)s, IDEs, or PMAs for the subject device.

The proposed modification is to the Magnetic Resonance (MR) Safety section of the DFU, updating wording to align with current guidance recommendations for "MR Conditional". This labeling modification does not alter the indications for use or the fundamental scientific technology of the devices from that of the predicate device. As recommended in the FDA Guidance for Industry and FDA Staff, *Format for Traditional and Abbreviated 510(k)s,* August 12, 2005, the principal design and use factors of the device are tabulated below:

1/4

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device ?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further information is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah J Kucharski

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
Fax: 763.494.2222
E-mail: carah.kucharski@bsci.com

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA
01752

Check No. : (b)(4)

Date
02/12/2015

Account # : (b)(4)

FOOD AND DRUG ADMINISTRATION
US BANK
1005 CONVENTION PLAZA
SAINT LOUIS MO 63101

Document	Reference Document	Date	Deductions	Gross Amount
(b)(4)				
Sum total			0.00	(b)(4)

Payment document	Check number	Date	Currency	Payment amount
(b)(4)	(b)(4)	(b)(4)	USD	(b)(4)

THE FACE OF THIS DOCUMENT HAS A COLORED BACKGROUND ON WHITE PAPER

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA
01752

(b)(4)

(b)(4)

AMOUNT

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PAY TO THE ORDER OF FOOD AND DRUG ADMINISTRATIO
US BANK
1005 CONVENTION PLAZA
SAINT LOUIS MO 63101

AUTHORIZED SIGNATURE

(b)(4)

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BOSTON SCIENTIFIC CORP One Scimed Place Regulatory Affairs, MS: A380 Maple Grove Hennepin MN 55311-1566 US	Carah Kucharski 2.1 E-MAIL ADDRESS carah.kucharski@bsci.com 2.2 TELEPHONE NUMBER (include Area code) 763-255-0565 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 510-
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA   [X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES   [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)   09-Feb-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

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Acceptance Checklist for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments:		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.*		
Comments: This question is Not Applicable, because there was not a Request for Designation.		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments:		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments:		

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Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		X
Comments: This question is Not Applicable, because there are no clinical studies.		

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*			
	Yes	**No**	**Page #**
a. Submission contains Table of Contents	X		2
b. Each section is labeled (e.g., headings or tabs designating Device Description section,	X		N/A
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	X		N/A
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	X		1
Comments: Organizational Elements b & c are evident throughout.			

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)
Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

			Yes	N/A	No	Page #
A	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			N/A
		Comments: English content is evident throughout.				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			CDRH Form 3514
		a. Device trade name or proprietary name	X			
		b. Device common name	X			
		c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*	X			3 & Appx A
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*	X			4 & Appx B
		a. Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	X			
		b. Statement contains all elements per 21 CFR 807.93	X			
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*	X			5 & Appx C
		Comments:				
	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*		X		6
		Comments: This Section is not applicable because the submission is not a Class III 510(k).				
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A"is selected, parts a and b below are omitted from the checklist.*		X		7

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		Yes	**N/A**	**No**	**Page #**
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators*				
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*				
	Comments: This section is not applicable because there is no clinical data provided with this submission.				
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*	X			8 & Appx D
	Comments:				
9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*	X			CDRH Form 3514 & Cover Letter

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		Yes	**N/A**	**No**	**Page #**
a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*		X		
Comments: See CDRH Cover Sheet and Cover Letter; No prior submissions for this device.					
B Device Description					
10. a. If there are requirements regarding the device description, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*			X		15
b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted*			X		15
Comments: Per the guidance referenced on Page 15, there are no device-specific requirements for device description.					
11. Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:		X			11
a. A description of the principle of operation and mechanism of action for achieving the intended effect.		X			13

Contains Nonbinding Recommendations

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
			Yes	**N/A**	**No**	**Page #**
		b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			11
		c. A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	X			11
		Comments:				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*	X			11 & Appx G
		Comments:				
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*		X		15
		a. Submission includes a list of all components and accessories to be marketed with the subject device.		X		
		b. Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*		X		
		c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*		X		15
		Comments: This section is Not Applicable, because there device is not marketed with multiple components, accessories, or systems.				
C.	**Substantial Equivalence Discussion**					
	14	Submitter has identified a predicate(s) device	X			9

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	Yes	**N/A**	**No**	**Page #**
a. Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm).*	X			
b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			N/A
Comments: Part B is evident throughout submission.				
15. Submission includes a comparison of the following for the predicate(s) and subject device				
a. Indications for use	X			16
b. Technology, including features, materials, and principles of operation	X			9 16
Comments:				
16. Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE, affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			9 16
Comments:				
D. Proposed Labeling (see also 21 CFR part 801) *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*				
17. Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	X			30 & Appx H Appx J Appx K
a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	X			
b. Submission includes directions for use that • include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** • Includes directions for layperson (see 21 CFR 801.5) **OR** • submission states that device qualifies for exemption per 21CFR 801 Subpart D	X			

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		Yes	**N/A**	**No**	**Page #**
	Comments:				
18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*	X			30 & Appx H Appx J
	Comments:				
19.	General labeling provisions				
a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X			30 & Appx H Appx J
b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*		X		N/A
	Comments: Part B is Not Applicable, because the device is for prescription use only.				
20. a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		X		15
b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*		X		

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)
Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

			Yes	N/A	No	Page #
	c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*		X		
	Comments: The Device-Specific Guidance noted on Page 15 does not have special labeling requirements.					
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*			X		N/A
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) **X** provided sterile provided non-sterile but sterilized by the end user non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist. If information regarding the sterility status of the device is not provided, select "No."*					31
	Comments: Device is Provided Sterile.					
22.	Assessment of the need for sterilization information					
	a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X			31
	b.	Identification of device, and/or accessories, and/or components that are end user sterilized		X		
	c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.		X		
	Comments: The entire device is provided sterile and is single-use.					
23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*					
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X			31

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	Yes	**N/A**	**No**	**Page #**
b. A description of method to validate the sterilization parameters is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X			
c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	X			
d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			14
e. Sterility Assurance Level (SAL) stated.	X			
Comments:				
24. If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*		X		N/A
a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)				
b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*				
c. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)				
d. Submission includes sterilization instructions for end user				
Comments: This Section is N/A, because the entire device is provided sterile.				
25. a. If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		X		15

Contains Nonbinding Recommendations

				Yes	N/A	No	Page #
Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*		X		
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*		X		
		Comments: The Device-Specific Guidance noted on Page 15 does not have special labeling requirements.					
F	**Shelf Life**						
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*		X			32
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*		X			
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		X			
		Comments:					

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	Yes	**N/A**	**No**	**Page #**
G. Biocompatibility *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				
Submission states that there: (*one of the below must be checked*) **X** are are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*				33
29. Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			33
30. Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	X			34
31. Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			33
Comments:				
H. Software				
Submission states that the device: (*one of the below must be checked*) Does **X** Does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				35
32. Submission includes a statement of software level of concern and rationale for the software level of concern	X			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)
Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

		Yes	N/A	No	Page #
33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).		X		
	Comments: This Section is N/A, as there is no software associated with the device.				
I.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) Does **X** Does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				36
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		X		
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		X		
	Comments: This Section is N/A, as there are no electric components associated with the device.				
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*				

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		Yes	**N/A**	**No**	**Page #**
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*	X			37 & Appx L
	Comments: Full test reports supporting the change are provided in Appendicies L2-L6.				
37. a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		X		15
b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*		X		
c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*		X		15

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	Yes	**N/A**	**No**	**Page #**
Comments: The Device-Specific Guidance noted on Page 15 does not have special testing requirements applicable to the proposed device				
38. If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				Appx L
a. Legible reprints or a summary of each article	X			
b. Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X			
Comments:				
39. For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*		X		N/A
a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120				
b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185				
c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.				
Comments: This section is Not Applicable because there were no animal studies conducted for this device.				
K. Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))		X		
Submission indicates that device: (*one of the below must be checked*) is **X** is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*				11
40. Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:		X		
a. Precision/reproducibility				

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		Yes	**N/A**	**No**	**Page #**
b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.					
c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device					
d. Analytical specificity					
41. a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*					
b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			X		11
c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*					
Comments: This section is Not Applicable because the device is not an In Vitro Diagnostic Device.					

Boston Scientific

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28th September, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: **Traditional 510(k) Notification**
WALLSTENT™ RP Endoprosthesis Tracheobronchial
WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Sir or Madam:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 807 Subpart E, Boston Scientific Corporation (BSC) hereby submits the enclosed Traditional 510(k) Premarket Notification for the WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial Device.

This tracheobronchial self-expanding stent is a Class II device per 21 CFR 878.3720, Product Code JCT. Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial devices are self-expanding stents indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. The predicate device is the WALLSTENT Tracheobronchial Endoprosthesis, cleared via K992510 on November 18th, 1999. There have been no prior NSE determinations, deleted or withdrawn 510(k)s, IDEs, or PMAs for the subject device.

The proposed modification is to the Magnetic Resonance (MR) Safety section of the DFU, updating wording to align with current guidance recommendations for "MR Conditional". This labeling modification does not alter the indications for use or the fundamental scientific technology of the devices from that of the predicate device. As recommended in the FDA Guidance for Industry and FDA Staff, *Format for Traditional and Abbreviated 510(k)s,* August 12, 2005, the principal design and use factors of the device are tabulated below:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device ?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further information is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah J Kucharski

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
Fax: 763.494.2222
E-mail: carah.kucharski@bsci.com

Boston Scientific

WALLSTENT™ RP™ Endoprosthesis Tracheobronchial Self-Expanding Stent

WALLSTENT™ Endoprosthesis Tracheobronchial Self-Expanding Stent

Traditional 510(k) Submission

September 28th, 2015

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1.0 Indications for Use Statement

The Indications for Use Statement is found in **Appendix A.**

2.0 510(k) Summary

The 510(k) Summary is found in **Appendix B**.

3.0 Truthful and Accurate Statement

The Truthful and Accurate Statement is found in **Appendix C.**

4.0 Class III Summary and Certification

This section is not applicable to this submission as the device is Class II.

5.0 Financial Certification or Disclosure Statement

This section is not applicable to this submission as there is no clinical data associated with this submission.

6.0 Declarations of Conformity and Summary Reports

6.1. Declaration of Conformity

Currently no FDA mandated or voluntary performance standards exist for this device. However, to assess and ensure product safety and performance, Boston Scientific (BSC) has relied on several recognized standards for Magnetic Resonance Imaging (MR) labeling changes to the WALLSTENT™ RP Endoprosthesis Tracheobronchial Self-Expanding Stent and WALLSTENT™ Endoprosthesis Tracheobronchial Self-Expanding Stent (Hereby "WALLSTENT Endoprosthesis Tracheobronchial"). These standards are identified in **Section 6.4**. FDA Form 3654 for these standards can be found in **Appendix D**.

6.2. Design Requirements

The design and development of the WALLSTENT Endoprosthesis Tracheobronchial was conducted in accordance with Design Controls as outlined in 21 CFR 820. Boston Scientific has an established Quality System which consists of procedures that outline the conduct of design and development activities discussed within the Quality System regulations. These include design and development planning, design inputs and outputs, design reviews, design verification and validation activities, risk management, and the transfer of the design to commercial manufacturing. Design changes are managed in accordance with Boston Scientific's Quality System procedures.

6.3. Risk Management

A risk analysis was performed based on the requirements of ISO 14971:2012 *Medical devices - Application of risk management to medical devices* to identify any risks to safety or effectiveness specific to the new MRI Safety information in the WALLSTENT Endoprosthesis Tracheobronchial Directions for Use (DFU). The risks identified have been mitigated through the testing summarized in **Section 15**, **Table 15-1**.

6.4. Reliance on Standards

The following standards were used to perform Magnetic Resonance Imaging Safety testing:

ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ASTM F2052-14	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
ASTM F2119-07	Standard Test Method for Evaluation for MR Image Artifacts from Passive Implants

FDA Form 3654 for each standard can be found in **Appendix D**.

7.0 Summary of Changes

7.1. Executive Summary of Changes

The purpose of this submission is to modify the MR safety section of the Directions for Use (DFU) for the WALLSTENT Endoprosthesis Tracheobronchial cleared for marketing under K992510 (November 18th, 1999). Note that this 510(k) was for the modification of the 5-10mm diameter delivery systems; reference device K980163 (cleared March 13th, 1998) introduced the same change for the 12-24mm diameter delivery systems, all of which are within the scope of this proposed submission.

The proposed WALLSTENT Endoprosthesis Tracheobronchial has the same intended use, scientific technology, design, critical materials, sterilization method, and packaging materials as the applicable predicate device.

Predicate device labeling approved in K992510 did not include MR safety information (though language was added as part of cumulative changes, below). New MR safety information states "MR Conditional" and lists the conditions that the device is safe to be scanned within. Submission DFU wording aligns with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11th, 2014. The MRI language in the proposed DFU was finalized through Real-Time Reviews of the WALLSTENT Endoprosthesis TIPS (P930031) and WALLSTENT Endoprosthesis Venous (P980033) products, which share a DFU with WALLSTENT Endoprosthesis Tracheobronchial. The Real-Time Reviews were approved under P930031/S054 and P980033/S043 on August 12th, 2015.

7.2. Cumulative Changes

Changes to the WALLSTENT Endoprosthesis Tracheobronchial that have occurred since the previous 510(k) that did not require a submission when assessed in accordance with FDA Guidance Document, *Deciding When to Submit a 510(k) for a Change to an Existing Device,* dated January 10, 1997 include:

(b) (4)

4. **Tear-Tab Closure Strip:** The packaging for the WALLSTENT Endoprosthesis Tracheobronchial device has incorporated a business tool of a vertical tear-tab closure strip. The closure strip is not responsible for keeping the carton closed, and is used as a restocking aid only. Applicable packaging verification, shelf life verification and sterilization evaluations were completed to demonstrate that packaging continues to meet specifications.
5. **Carton Paperboard Tolerance:** The specification tolerance for carton paperboard thickness of packaging the 8-24mm stent sizes was updated to remove the micron tolerance requirement. Paperboard is now accepted to the standard tolerance of 0.001 inch. No verification or validation was required because the specification has not changed, only the tolerance requirements.
6. **Branding Updates:** As a corporate branding alignment initiative, minor DFU and label dimension updates were implemented. No material or supply grade changes occurred, and all design verification testing remains valid.
7. **DFU and Labeling Updates:** Because all DFU and labeling changes are to content only, no design verification, sterilization, or biocompatibility testing was required to ensure that products continue to meet required specifications. See **Table 9-2** for a detailed DFU comparison between predicate and proposed DFUs, and **Appendicies I** and **J** for the predicate and proposed DFUs and proposed labels, respectively.
    a. **Consolidated DFUs:** The WALLSTENT Endoprosthesis Tracheobronchial, Transhepatic Biliary, TIPS (P930031), and Venous (P980033) DFU's were consolidated into one combined DFU for all four indications. As a result, a common section at the front of the DFU was created to include a general device description, table of UPNs by indication, sizing matrix and principles of operation. Per conversations with FDA (**Appendix E**), this change was evaluated as a 510k letter to file.
    b. **Benign Indication Removal:** Per FDA request (**Appendix F**), the benign indication portion of the WALLSTENT Endoprosthesis Tracheobronchial indications for use ("or in benign strictures after all alternative therapies have been exhausted") was removed from the indications for use. This change narrowed the indications for use, and does not raise questions of comparative safety and/or effectiveness as compared to the predicate.
    c. **Vascular Indications Warnings and Preparation Instructions:** Per FDA request (**Appendix F**), warnings against vascular use for non-vascular UPNs were added to the DFU and product labels for UPNs that are not cleared for a vascular (venous) indication. Additionally, instructions for vascular and non-vascular preparation were added to the DFU.
    d. **MRI Language:** MRI language was added based on current testing to indicate that the device shows no deflection or torque in a 1.5T MR machine, as well as expected image artifact information (see **Table 9-2**). This language is removed in the proposed device and replaced with the language proposed below in **Section 15.**
    e. **General Formatting:** General formatting and clarification updates to the DFU and labels were implemented, including UDI implementation and a legal manufacturer address change.

8.0 Device Description

8.1. General Description and Product Matrix

The WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

There are no device-specific regulations that are applicable to the proposed device; this device is not an in-vitro diagnostic device.

The WALLSTENT™ device is offered in both a standard profile (8-12 French) and Reduced Profile (RP) system, for 6-7 French systems (see **Table 8-1**). Both systems are comprised of two components: The implantable metallic stent and the UNISTEP™ Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self- expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque markerbands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm diameter) have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035in (0.89mm) guidewire. See **Figure 8-1** below.

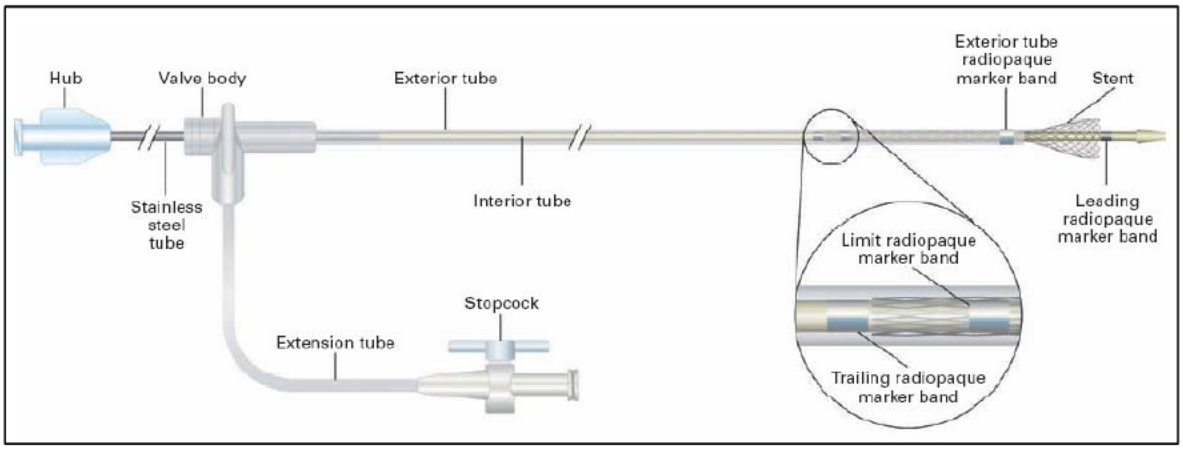

Figure 8-1: WALLSTENT Endoprosthesis Tracheobronchial

Immediately prior to the procedure, sterile saline or contrast media is passed through the stopcock and extension tube into the valve body and allowed to displace air in the coaxial tubing assembly. After flushing, the system is positioned at the lesion site, and the outer tube is retracted, releasing the stent and allowing it to self-expand. With the stent partially released, the system can be reconstrained by the outer tube of the delivery system if repositioning is desired.

Table 8-1: UPNs for WALLSTENT Endoprosthesis Tracheobronchial

US Product Code	Stent Diameter	Stent Length	Catheter OD	Catheter Working Length	Catheter Total Length
	[mm]	[mm]	[FR]	[cm]	[cm]
M001711000	5	20	6	75	100
M001711010	5	20	6	135	160
M001711020	5	40	6	75	100
M001711030	5	40	6	135	160
M001711040	5	55	6	75	100

US Product Code	Stent Diameter [mm]	Stent Length [mm]	Catheter OD [FR]	Catheter Working Length [cm]	Catheter Total Length [cm]
M001711050	5	55	6	135	160
M001711060	5	80	6	75	100
M001711070	5	80	6	135	160
M001711080	6	20	6	75	100
M001711090	6	20	6	135	160
M001711100	6	45	6	75	100
M001711110	6	45	6	135	160
M001711120	6	60	6	75	100
M001711130	6	60	6	135	160
M001711140	6	90	6	75	100
M001711150	6	90	6	135	160
M001711160	7	20	6	75	100
M001711170	7	20	6	135	160
M001711180	7	40	6	75	100
M001711190	7	40	6	135	160
M001711200	7	60	6	75	100
M001711210	7	60	6	135	160
M001711220	7	90	6	75	100
M001711230	7	90	6	135	160
M001711240	8	20	6	75	100
M001711250	8	20	6	135	160
M001711260	8	40	6	75	100
M001711270	8	40	6	135	160
M001711280	8	60	6	75	100
M001711290	8	60	6	135	160
M001711300	8	80	6	75	100
M001711310	8	80	6	135	160
M001711320	10	20	6	75	100
M001711330	10	20	6	135	160
M001711340	10	42	7	75	100
M001711350	10	42	7	135	160
M001711360	10	68	7	75	100
M001711370	10	68	7	135	160
M001711380	10	94	7	75	100
M001711390	10	94	7	135	160
H965402100	12	20	9	75	100
H965412000	12	20	9	135	160
H965412010	12	40	9	75	100
H965402120	12	40	9	135	160
H965412020	12	60	9	75	100
H965412020	12	60	9	135	160
H965402130	12	90	9	75	100
H965412030	12	90	9	135	160
H965403100	14	20	10	75	100
H965403110	14	40	10	135	160
H965403120	14	60	10	75	100
H965403130	14	90	10	75	100
H965403300	16	20	10	75	100
H965403310	16	40	10	75	100
H965403320	16	60	10	75	100

US Product Code	Stent Diameter [mm]	Stent Length [mm]	Catheter OD [FR]	Catheter Working Length [cm]	Catheter Total Length [cm]
H965403330	16	90	10	75	100
H965404110	18	40	11	75	100
H965404120	18	60	11	75	100
H965404130	18	90	11	75	100
H965404300	20	40	11	75	100
H965404310	20	55	11	75	100
H965404320	20	80	11	75	100
H965404500	22	35	11	75	100
H965404510	22	45	11	75	100
H965404520	22	70	11	75	100
H965405100	24	35	12	75	100
H965405110	24	45	12	75	100
H965405120	24	70	12	75	100

8.2. Device Components

The proposed WALLSTENT Endoprosthesis Tracheobronchial is constructed with the following components, unchanged from the predicate:

• Hub	• Stainless Steel Tube	• Extension Tube	• Stopcock	• Valve Body
• Exterior Tube	• Interior Tube	• Stent	• Marker Bands	• Tip

See **Appendix G** for finished good drawings of the device and packaging.

8.3. Principle of Operation

The WALLSTENT Endoprosthesis Tracheobronchial exterior tube is easily retracted by immobilizing the stainless steel tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constrainment. A single operator can thus control deployment and implant the stent. The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. (The stent deployment threshold or point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band [Figure A]). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

8.4. Packaging Description

The WALLSTENT Endoprosthesis Tracheobronchial is packaged in two different packaging configurations, known as the long pack and short pack. All 6 and 7 Fr sizes utilize the short pack configuration. All remaining codes utilize the long pack configuration. See **Table 8-2** for packaging component details.

Short Pack Packaging Configuration

(b)(4)

(b)(4) See **Figure 8-3** for an image of the packaging configuration.

(b)(4)

Figure 8-3: Short Pack Packaging Configuration (from FGM0017xxx; see **Appendix G**).

Long Pack Packaging Configuration

(b)(4)

(b)(4) See **Figure 8-4** for an image of the packaging configuration.

(b)(4)

Figure 8-3: Long Pack Packaging Configuration (from FGM001731xxx; see **Appendix G**).

(b) (4)

Accessories
The WALLSTENT Endoprosthesis Tracheobronchial device is not packaged with any accessories.

Labeling
See **Section 10.0** for proposed labeling.

8.5. Device-Specific Guidance

FDA Guidance Document Guidance *For Industry - Guidance For The Content Of Premarket Notifications For Esophageal And Tracheal Prostheses* (April 29th, 1998) was considered during the course of developing these updates. No recommendations outlined in this guidance apply to the proposed labeling modification; this submission instead follows the FDA guidance *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11, 2014).

9.0 Substantial Equivalence Discussion

9.1. Substantial Equivalence Statement

The proposed WALLSTENT Endoprosthesis Tracheobronchial is substantially equivalent to the currently marketed predicate K992510, WALLSTENT Endoprosthesis Tracheobronchial, cleared November 18, 1999. Note that this 510(k) was for the modification of the 5-10mm diameter delivery systems; reference device K980163 was the last submission for the 12-24mm diameter stent sizes of this product family, all of which are covered in this submission. See **Table 9-1** below for a history of this product family.

Table 9-1: History of WALLSTENT Endoprosthesis Tracheobronchial 510(k) submissions

510(k) #	Stent Size	Purpose of Submission	Clearance Date
K992510 *Predicate*	5-10mm	Lower Profile (reduced French Size) delivery system	11/18/99
K980163 *Reference Device*	12-24mm	New Delivery System allowing for Reconstrainment	03/13/98
K964121	5-10mm	New Delivery System allowing for Reconstrainment	12/04/96
K961296	12-14mm	Increase Radial Force	07/10/96
K945494	5-12mm	Increase Radiopacity	03/03/95
K934116	5-24mm	Initial clearance	06/02/94

The proposed WALLSTENT Endoprostheses Tracheobronchial have the same intended use and fundamental scientific technology, design, materials (except for the stopcock handle resin; see **Section 7.2.1**), sterilization method, and packaging as the predicates. The purpose of this submission is to modify the labeling of the device only; no technological changes are proposed. Because no technological changes are proposed as a part of this submission, the predicate comparison of the device is found in **Table 9-2**.

9.2. Predicate Comparison Tables

Table 9-2 provides a listing of the changes made to the DFU labeling in a comparative format between the WALLSTENT Endoprosthesis Tracheobronchial predicate and the proposed DFU.

Table 9-2: Comparison to Predicate Device – Directions for Use (Cumulative and Proposed Changes to Directions for Use)
Note: N/A indicates that no labeling for this section existed in the predicate DFU. See **Appendicies I** and **J** for the predicate and proposed directions for use.

DFU Section	Predicate (K992510)	Proposed	Comparison
Common Section of DFU			
Warning	N/A	Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.	**Cumulative Change:** Clarification that contents are supplied sterile through the EO cycle
	N/A	For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious diseases(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.	**Cumulative Change:** Addition of warning to not reuse/reprocess

DFU Section	Predicate (K992510)	Proposed	Comparison
Device Description	N/A	The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis are comprised of two components: The implantable metallic stent and the UNISTEP Plus delivery system (reference Figure A). The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89mm) guidewire.	**Cumulative Change:** Clarification of device description
User Information	N/A	This system is intended for use by physicians who have received appropriate training.	**Cumulative Change:** Clarification that use is for trained physicians only
Contents	N/A	One (1) WALLSTENT RP Endoprosthesis or One (1) WALLSTENT Endoprosthesis	**Cumulative Change:** Clarification based on combined DFU
Tables 1 and 2	N/A	Size and indication information by UPN and sizing chart	**Cumulative Change:** Clarification based on combined DFU

DFU Section	Predicate (K992510)	Proposed	Comparison
Principle of operation	N/A	The exterior tube is easily retracted by immobilizing the stainless steel tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constrainment. A single operator can thus control deployment and implant the stent. The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. (The stent deployment threshold or point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band [Figure A]). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.	**Cumulative Change:** Addition of device principles of operation
Warning	N/A	A stent cannot be repositioned or removed after the deployment threshold has been exceeded	**Cumulative Change:** Clarification of warning that device may not be repositioned after deployment
Precaution	N/A	The system is intended for use by physicians who have received appropriate training	**Cumulative Change:** Clarification that use is for trained physicians only

DFU Section	Predicate (K992510)	Proposed	Comparison
Preparation of the Delivery System for Insertion-- Vascular Indications	N/A	1. Initial Preparation of the Delivery System • Carefully remove the delivery system from its protective packaging. • Visually inspect the entire device for damage or defects. • Visually check that the leading end of the stent is covered by the exterior tube. • Ensure that no stent wires have perforated the exterior tube. 2. Flushing the delivery system • Attach a 10ml (cc) syringe filled with sterile saline to stopcock on extension tube. • Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system • After flushing the delivery system, close the stopcock and remove the syringe. • Re-verify that the leading end of the stent is covered by the exterior tube. Do not use device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant and such use may cause lumen injury	**Cumulative Change:** Per FDA feedback, addition of vascular indication preparation instructions

DFU Section	Predicate (K992510)	Proposed	Comparison
Preparation of the Delivery System for Insertion--Non-Vascular Indications	N/A	1. Initial Preparation of the Delivery System • Carefully remove the delivery system from its protective packaging. • Visually inspect the entire device for damage or defects. • Visually check that the leading end of the stent is covered by the exterior tube. • Ensure that no stent wires have perforated the exterior tube. 2. Flushing the delivery system • Attach a 10ml (cc) syringe filled with sterile saline to stopcock on extension tube. • Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system • After flushing the delivery system, visually check that any excess saline is drained from the delivery system. • Re-verify that the leading end of the stent is covered by the exterior tube. Do not use device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant and such use may cause lumen injury	**Cumulative Change:** Per FDA feedback, addition of non-vascular indication preparation instructions
How Supplied	N/A	The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis are supplied sterile and intended for single use only. The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis	**Cumulative Change:** Clarification that contents are supplied sterile through the EO cycle

DFU Section	Predicate (K992510)	Proposed	Comparison
		are sterilized by ethylene oxide gas. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.	
Handling & Storage	N/A	Do not expose delivery catheter to organic solvents, e.g., isopropyl alcohol. Such an exposure can cause delivery catheter to become brittle. Rotate inventory such that products are used prior to the "Use By" date on package label. Store in a cool, dry place.	**Cumulative Change:** Clarification of content handling and storage
Tracheobronchial Section			
Indications for use/Intended use	The Schneider WALLSTENT Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.	The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. With the exception of the following WALLSTENT Codes which are approved for Venous or TIPS indications, the safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death: H965402100, H965402110, H965402120, H965402130, H965403100, H965403110, H965403120, H965403130, H965403300, H965403310, H965403320, H965403330, M001711320, M001711340, M001711360, M001711380.	**Cumulative Change:** Brand division of the 5-10mm into the "WALLSTENT RP Endoprosthesis" name. **Cumulative Change:** Per FDA Feedback, remove indication for benign strictures and addition of warning for vascular system use. See **Appendix F**

DFU Section	Predicate (K992510)	Proposed	Comparison
Contraindications	Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial include: • Use of the device in very small bronchials which could impede catheter removal • All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system.	Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial include: • Use of the device in very small bronchials which could impede catheter removal • All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system.	Same
Warnings	• Stenting across a major bifurcation may prevent or hinder future access or other procedures. • Use of the device across bifurcations or side branches could impede airflow to the affected portion of the lung • Stents cannot be repositioned after the deployment threshold has been exceeded. • Stents should not be placed near or across the cricopharyngeus. • Use of a laser on or around the surface of the stent may results in damage to the stent.	• Stenting across a major bifurcation may prevent or hinder future access or other procedures. • Use of the device across bifurcations or side branches could impede airflow to the affected portion of the lung • Stents cannot be repositioned after the deployment threshold has been exceeded. • Stents should not be placed near or across the cricopharyngeus. • Use of a laser on or around the surface of the stent may results in damage to the stent.	Same
Precautions	• The device is intended for use by physicians who have received appropriate training. • The device should not be resterilized. • The sterile packaging and device should be inspected prior to use. If sterility or performance	• The device is intended for use by physicians who have received appropriate training. • The device should not be resterilized. • The sterile packaging and device should be inspected prior to use. If sterility or performance	**Cumulative Change:** Added MR wording to DFU based on testing and standards available at the time.

DFU Section	Predicate (K992510)	Proposed	Comparison
	of the device is suspect to compromise, it should not be used. • The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system. • ***MRI Safe:** The WALLSTENT Self-Expanding Stent has shown no deflection or torque in the area of maximum spatial gradient (450 gauss centimeter) of a 1.5 tesla MRI system under conditions that produced a Specific Absorption Rate (SAR) of 1.3 W/Kg. Imaging artifacts affect the region of interest at the location of the device (artifact ratio 0.8 to 7.0), while areas away from the device appear unaffected by their presence. ***Note:** This MRI wording was added as part of cumulative changes since predicate device clearance. This wording is removed and replaced with common wording in the section below in the proposed device labeling	of the device is suspect to compromise, it should not be used. • The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.	
Magnetic Resonance Imaging (MRI) Safety Information	N/A	*See **Section 15.3.1** for Proposed MRI Conditional Wording*	**Proposed Change:** Approval of MR Conditional Wording based on current bench test results

DFU Section	Predicate (K992510)	Proposed	Comparison
Complications	Complications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial may include the usual complications reported for conventional tracheobronchial stents such as infection, stent misplacement, stent migration, and stent obstructions secondary to tumor or granuloma ingrowth through the stent, tumor or granuloma overgrowth at the stent ends, or mucous occlusion or perforation.	Complications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial may include the usual complications reported for conventional tracheobronchial stents such as infection, stent misplacement, stent migration, and stent obstructions secondary to tumor or granuloma ingrowth through the stent, tumor or granuloma overgrowth at the stent ends, or mucous occlusion or perforation.	Same
Operational Instructions	**Recommended material for implant** Prepare the following material using sterile technique: • 10ml (cc) syringe filled with sterile saline • 0.035 in guidewire of appropriate length **Device selection** Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant. After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.	**Recommended material for implant** Prepare the following material using sterile technique: • 10ml (cc) syringe filled with sterile saline • 0.035 in (0.89mm) guidewire of appropriate length **Device selection** Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant. After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.	**Cumulative Change:** Addition of 0.89mm measurement for guidewire Same

DFU Section	Predicate (K992510)	Proposed	Comparison
	Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.	Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.	Same
Step 1	Place a 0.035in exchange guidewire through the stricture **Note:** Predilitation, with an appropriate dilator, of the stricture may be performed prior to stent implantation at the option of the physician.	Place a 0.035in (0.89mm) exchange guidewire through the stricture **Note:** Predilitation, with an appropriate dilator, of the stricture may be performed prior to stent implantation at the option of the physician.	**Cumulative Change:** Addition of 0.89mm measurement for guidewire Same
Step 2	Having prepared the delivery system as described, insert it over the guidewire.	Having prepared the delivery system as described, insert it over the guidewire.	Same
Step 3	**Guidelines for stent positioning:** • Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment. • The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary. • Maintain the delivery system as straight as possible during deployment of the stent.	**Guidelines for stent positioning:** • Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment. • The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary. • Maintain the delivery system as straight as possible during deployment of the stent.	Same

DFU Section	Predicate (K992510)	Proposed	Comparison
Step 4	To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.	To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.	Same
Caution	Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 7.	Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 7.	Same
Step 5	Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts. As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire	Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts. As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire	Same

DFU Section	Predicate (K992510)	Proposed	Comparison
	delivery system back.	delivery system back.	
Step 6	To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.	To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.	Same
Caution	A stent cannot be repositioned after the deployment threshold has been exceeded.	A stent cannot be repositioned after the deployment threshold has been exceeded.	Same
Step 7	To remove a partially deployed stent, first reconstrain the stent (see step 5). The entire delivery system can be pulled back. The delivery system can then be removed, with the guidewire left in place. As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.	To remove a partially deployed stent, first reconstrain the stent (see step 5). The entire delivery system can be pulled back. The delivery system can then be removed, with the guidewire left in place. As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.	Same
Step 8	After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.	After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.	Same
Step 9	The implanted stent length should allow for adequate overlapping into the non-stricured area to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.	The implanted stent length should allow for adequate overlapping into the non-stricured area to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.	Same
Step 10	When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath	When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath	Same

DFU Section	Predicate (K992510)	Proposed	Comparison
	to protect the balloon or delivery system.	to protect the balloon or delivery system.	
Device Sizes	The Schneider WALLSTENT Tracheobronchial Endoprosthesis is avaialable in the following diameters: 5, 6, 7, 8, 10, 12, 14, 16, 18, 20, 22, 24 mm.	The WALLSTENT RP Endoprosthesis Tracheobronchial is available in the following diameters: 5, 6, 7, 8, & 10mm. The WALLSTENT Endoprosthesis Tracheobronchial is available in the following diameters: 12, 14, 16, 18, 20, 22 & 24 mm.	**Cumulative Change:** Brand division of the 5-10mm into the "WALLSTENT RP Endoprosthesis" name.
Related Articles	1. Rousseau, H, et al. Self-expandable prostheses in the tracheobronchial tree. Radiology 1993; 188: 199-203.	1. Rousseau, H, et al. Self-expandable prostheses in the tracheobronchial tree. Radiology 1993; 188: 199-203.	Same

9.3. Conclusion

In summary, the proposed WALLSTENT Endoprosthesis Tracheobronchial contains the same technological characteristics and critical materials, same intended use, sterilization method, and packaging materials as the identified predicate devices. The identified differences do not constitute a new intended use and do not raise different or new questions of safety and efficacy. Based on these similarities and differences, the proposed device may be considered substantially equivalent to the identified predicates.

10.0 Proposed Labeling

10.1. Labeling

The labeling for the proposed WALLSTENT Endoprosthesis Tracheobronchial consists of the content and artwork for the following components:

- Pouch Labels and Artwork
- Carton Labels and Artwork
- Directions for Use (DFU)
- Patient Implant Card

The graphics and design modifications incorporate BSC's corporate master branding. The labeling is designed to comply with applicable labeling standards and global regulatory requirements along with internal BSC requirements.

See **Appendix H** for a representative Pouch and Carton Label from a short pack (M001711000) and Long Pack (M001711010) UPN. All labels are available upon request. See **Appendicies I** and **J** for the predicate and proposed DFU. See **Appendix K** for the patient implant card (common implant card across multiple indications).

11.0 Sterilization and Shelf Life

11.1. Sterilization Method

(b)(4)

11.2. Sterility Assurance Level

Boston Scientific qualifies devices for sterilization by using product models (b)(4)

(b)(4)

Sterilization validation is conducted per ISO 11135-1:2007, *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*, using overkill (half-cycle) methodology.

11.3. EO Residuals

The residual levels of the WALLSTENT Endoprosthesis Tracheobronchial are at acceptable levels to meet the Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) residual limits as specified in *ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*. The WALLSTENT Endoprosthesis Tracheobronchial is in the permanent contact category per ISO 10993-7. The WALLSTENT Endoprosthesis Tracheobronchial has met ISO10993-7 average daily dose requirements as follows:

Limited Exposure Device:

- **Average Daily Dose (ADD):** The WALLSTENT Endoprosthesis Tracheobronchial has met the EN ISO10993-7 requirement of EO ≤ 4 mg and ECH ≤ 9 mg after 0 days of additional ambient aeration following 1X and 2X sterilization cycles.

Permanent Contact Device:

- **Average Daily Dose (ADD):** The WALLSTENT Endoprosthesis Tracheobronchial has met the EN ISO10993-7 ADD requirement of EO ≤ 0.1 mg/day and ECH ≤ 0.4 mg/day after 0 days of additional aeration following 1X and 2X sterilization cycles.
- **24 Hour Period:** The WALLSTENT Endoprosthesis Tracheobronchial has met the EN ISO10993-7 first 24 hour requirement of EO ≤ 4 mg and ECH ≤ 9 mg after 0 days of additional aeration following 1X and 2X sterilization cycles.
- **30 Day Period:** The WALLSTENT Endoprosthesis Tracheobronchial has met the EN ISO10993-7 first 30 days requirement of EO ≤ 60 mg and ECH ≤ 60 mg after 0 days of additional aeration following 1X and 2X sterilization cycles.
- **Lifetime Period:** The WALLSTENT Endoprosthesis Tracheobronchial has met the EN ISO10993-7 lifetime requirement of EO ≤ 2,500mg and ECH ≤ 10,000mg after 0 days of additional aeration following 1X and 2X sterilization cycles.

Tolerable Contact Limit (TCL): The WALLSTENT Endoprosthesis Tracheobronchial has met the EN ISO10993-7 TCL requirement of ≤ 10 µg/cm2 and ECH < 5 mg/cm2 after 0 days of additional aeration following 1X and 2X sterilization cycles.

11.4. Bacterial Endotoxin

The WALLSTENT Endoprosthesis Tracheobronchial will be provided non-pyrogenic. Representative finished product is tested to assure non-pyrogenicity and to verify the product neither inhibits nor enhances the Limulus Amoebocyte Lysate (LAL) test.
It is the policy of Boston Scientific to follow the applicable requirements of AAMI ST72, *Bacterial Endotoxin- Test methodologies, routine monitoring and alternatives to batch testing*. Limits are set and verified according to USP<85> (*Bacterial Endotoxins Test*) and <161> (*Transfusion and Infusion Assemblies*) and the CDRH 1987 Guideline: *Validation of Limulus Amoebocyte Lysate Test as an End-Product Endotoxin Test for Medical Devices.*

11.5. Product and Package Shelf Life

The packaging used for the proposed WALLSTENT Endoprosthesis Tracheobronchial device is identical to the predicate WALLSTENT Endoprosthesis Tracheobronchial device and contains a double sterile barrier Tyvek package intended to protect the device through 2x EO sterilization, distribution, handling, and storage, and to maintain a sterile barrier for its labeled shelf life. WALLSTENT devices are packaged individually.

The shelf life for the proposed WALLSTENT Endoprosthesis Tracheobronchial is unchanged from the predicate K992510 device's 2 year (24 month) shelf life. Shelf life testing for the vertical tear-tab closure strip restocking aid (**Section 7.2**) was performed and demonstrates that the strip meets specifications for a 24 month shelf life. (b) (4) Therefore, the stopcock handle resin change does not impact predicate shelf life testing and all predicate (K992510) shelf life testing remains valid.

12.0 Biocompatibility

12.1. General Biocompatibility Information

The proposed WALLSTENT Endoprosthesis Tracheobronchial incorporate the same device materials as the predicate WALLSTENT Endoprosthesis Tracheobronchial device (b)(4) Patient-contacting components, materials, and colorants are listed in **Table 12-1**. To Boston Scientific's knowledge, there have been no changes in colorants between the Predicate K992510 and proposed WALLSTENT Endoprosthesis Tracheobronchial devices. All colorants and materials have a history of safe use in both the reference device, as well as other BSC class II and III devices.

Table 12-1: Patient-Contacting Materials

Component Name	Direct/ Indirect Contact	Chemical Name/ Formulation/Grade	Color Additive Present
(b) (4)			

12.2. Biocompatibility Testing

(b) (4)

12.3. Biocompatibility Conclusion

No additional testing was required for the MRI labeling change to confirm that the WALLSTENT Endoprosthesis Tracheobronchial device remains biocompatible for its intended use as per ISO 10993-1 categories:

Stent:

- Category: Implant
- Contact Duration: Permanent (>30 days)
- Body Contact: Tissue/Bone

Delivery Device:

- Category: Externally Communicating
- Contact Duration: Limited (≤ 24 hours)
  Body Contact: Tissue/Bone/Dentin

13.0 Software

This section is not applicable to this submission as there is no software associated with the device.

14.0 Electromagnetic Compatibility and Electrical Safety

This section is not applicable to this submission as the device does not include any electrical or electronic components.

15.0 Performance Testing - Bench

15.1. General Bench Test Information

The performance testing presented in this section aligns with the FDA guidance *"Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment"*, December 11, 20144. Boston Scientific conducted verification testing on models that are representative of the entire WALLSTENT family, including the WALLSTENT Endoprosthesis Tracheobronchial, Transhepatic Bilary (K993232), TIPS (P930031), Venous (P980033), Iliac (P940019), and WALLSTENT Uni (OUS only) devices. This testing demonstrates that the WALLSTENT Endoprosthesis Tracheobronchial device is MR Conditional, and that the proposed labeling modifications do not provide any new or incremental increase in risk.

The risks associated with the proposed changes have been evaluated. The modifications to the DFU are to a more conservative MR safety status based on existing test data, current standards, and FDA guidance, and are not related to any complaints or field actions.

No changes to the indications, contraindications, sterilization, or packaging/labeling methods were made as the result of this change. The design, performance specifications, and manufacturing of the device have not changed. There are no requirements regarding performance data or special controls for this submission, nor is there device-specific guidance for the WALLSTENT Endoprosthesis Tracheobronchial device.

15.2. MRI Status Bench Test Results

Per the FDA guidance *"Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment"*, December 11, 2014, non-clinical testing was completed in order to support the classification of the devices as MR Conditional. Testing included Radio Frequency (RF) heating in 1.5 and 3 Tesla systems and displacement force, torque, and image artifacts in a 3 Tesla MR system, as this represents a worst-case scenario compared to 1.5 Tesla. This testing utilized the test methods referenced in the guidance above (See **Table 15-1**, below, and **Appendix D**). Where a previous revision of the test method was used during testing, a gap analysis is also presented (in **Appendix D**) to justify that the differences do not affect the integrity of the testing results. Testing for all products utilized the same ASTM version.

Table 15-1: Utilized Test Methods

ASTM F2052-14	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
ASTM F2119-07	Standard Test Method for Evaluation for MR Image Artifacts from Passive Implants

15.2.1. Test Sample Device Size Justifications

The WALLSTENT MR Technical Report **(Appendix L)** completed testing for all WALLSTENT products marketed by Boston Scientific, including those with the Reduced Profile (RP), Uni, and Endoprosthesis systems. While these versions of the WALLSTENT brand may differ in stent sizes and indications, all WALLSTENT models utilize the same (b)(4) All stents are (b)(4) Therefore, a worst-case size selection across any of these product versions will represent a worst-case for all models, as they utilize the same materials and processing methods.

WALLSTENT Endoprosthesis Tracheobronchial device testing of RF heating and image artifact utilized the 24mm X 70mm size of the WALLSTENT Uni Endoprosthesis model. WALLSTENT Endoprosthesis Tracheobronchial testing for displacement force and torque leveraged testing from the 10mm X 90mm Boston Scientific Placehit Biliary Wallstent. The Placehit Wallstent device utilizes nearly the same wire materials (b)(4) , and nearly identical processing methods as described above. The only difference in materials is that the Wallstent Placehit Device contains a (b)(4) (b)(4) is non-magnetic, and thus torque is not affected. To evaluate the potential difference in displacement force between the Placehit Wallstent and WALLSTENT Uni products, additional in-house comparison testing was performed. See **Section 6.2.2** of technical report (b)(4) (**Appendix L**) for these results. Justifications for these products as worst-case scenarios are located in **Section 9.2** of technical report (b)(4) (**Appendix L**).

(b) (4)

Labeling terminology was chosen that complies with ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, in order to clearly present the MR conditions under which a patient may be

safely scanned. FDA Guidance *"Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment"*, December 11, 2014, was also considered.

Results of all testing support an MR safety status of MR Compatible within specified conditions. The conditions that each device has been evaluated under are defined within the proposed DFU wording, presented below in **Section 15.3**

15.3. Proposed DFU Wording

The proposed DFU for for WALLSTENT Endoprosthesis Tracheobronchial (Bundled DFU with Tracheobronchial, Transhepatic Biliary, TIPS, and Venous indications) is included in **Appendix J**. Please note that the format of the MR section presented below aligns with those in the TIPS and Venous Class III indication sections of the common DFU, approved 12 Aug, 2015 in P930031/S054 and P980033/S043 as a Real-Time Review).

15.3.1. WALLSTENT® (RP) Endoprosthesis DFU MRI Section

(to also be included on symbol definition page on the last page of the DFU)

Non-clinical testing has demonstrated that WALLSTENT™ TracheoBronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

15.4. Conclusion

Bench test results provided above support the conclusion that the proposed WALLSTENT Endoprosthesis Tracheobronchial is MR Conditional and significantly equivalent to the predicate device, K992510.

16.0 Performance Testing - Animal

This section is not applicable to this submission as there are no animal studies used to support substantial equivalence.

17.0 Performance Testing-Clinical

This section is not applicable to this submission as there are no clinical trials associated with this submission.

510k Summary

Per 21 CFR §807.92

Common or Usual Name	Self-Expanding Stent	
Trade Name(s)	Boston Scientific WALLSTENT™ RP Endoprosthesis Tracheobronchial and Boston Scientific WALLSTENT™ Endoprosthesis Tracheobronchial	
Product Code	JCT – Prosthesis, Tracheal, Expandable	
Classification of Device	The WALLSTENT Endoprosthesis Tracheobronchial device has been classified as Class II devices according to 21 CFR 878.3610 – Esophageal Prosthesis.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	**Owner /Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 3005099803
	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
Predicate Devices	WALLSTENT™ Tracheobronchial Endoprosthesis K992510 cleared November 18, 1999.	

Intended Use/ Indications for Use	The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
Description of Device	The WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial are comprised of two components: The implantable metallic stent and the UNISTEP Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89mm) guidewire.
Comparison of Required Technological Characteristics	The proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial is substantially equivalent to the existing Wallstent Endoprosthesis Tracheobronchial cleared by FDA under premarket notification K992510 (November 18, 1999). WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has the same intended use, scientific technology, design, sterilization method, and packaging as the applicable predicate device. The only difference is to the MR Safety labeling information within the Directions for Use. Bench testing in accordance with current FDA guidance supports a labeling as MR Conditional.
Summary of Non-Clinical Test Summary	Bench testing was performed in accordance with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11, 2014) to support labeling as MR Conditional. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALSLTENT Endoprosthesis Tracheobronchial (K992510).

Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(k), I certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Regulatory Affairs Specialist for Boston Scientific Corporation, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Carah Kucharski
Regulatory Affairs Specialist
Boston Scientific Corporation

9/25/15
Date

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

F2503-13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-349	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

F2503-13 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

ASTM F2503-13 defines the terminology for marking medical devices for MR Safety. This ASTM was utilized to define the terminology for labeling devices "MR Conditional". No testing was required to conform with this standard.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under “justification.” Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under “type of deviation or option selected,” “description” and “justification” on the report. More than one page may be necessary.

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2052-14, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-381	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2052-14, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Attachment to Appendix D, Utilized Test Methods and Gap Assessment, for gap assessment between recognized F2052-14 and the tested F2052-06e1. Additionally, see Appendix L2 for the test report, which highlights any ASTM deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-128	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Appendix L3 for the test report, which highlights any ASTM deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Attachment to Appendix D, Utilized Test Methods and Gap Assessment, for gap assessment between recognized F2182-11a and the tested F22182-02a. Additionally, see Appendicies L4 and L5 for the test report, which highlight any ASTM deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Office of Chief Information Officer
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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

See Appendix L6 for the test report, which highlights any ASTM deviations.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Appendix D, Attachment

Utilized Test Methods and Gap Assessment

Current Standardized Test Method	Method Used	Gap Assessment (where required)
ASTM F2052-14 Measurement of Magnetically Induced Displacement Force	**ASTM F2052-06e1**	**Test Location (8.1):** F2052-14, Section 8.1 requires the test location to be at the center of the MR system bore, on the X and Y axis. However, F2052-06e1 calls for test location where deflection is a maximum. Testing utilized the standards in F2052-06e1, placing the device left of center on the X axis, at the location of highest technically accessible spatial magnetic gradient. Because this represents a worst-case scenario, this deviation is acceptable. **Report Requirements (10.1.7, 10.1.12, and 10.1.13):** F2052-14 requires the calculation of field strength and spatial gradient, weight of holding material, and calculated deflection force for angles greater than 45° to be noted in the test report, while F2052-06e1 does not. Both applicable test reports do present field strength, spatial gradient, and note lack of holding material; deflection angles were under 45°, so no calculation is required. Therefore, this gap does not create a protocol deviation.
ASTM F2213-06 Measurement of Magnetically Induced Torque	**ASTM F2213-06**	N/A
ASTM F2182-11a Measurement of Radio Frequency Induced Heating Near Passive Implants	**ASTM F2182-02a**	**Phantom Container Size (8.1):** F2182-11a defines phantom container dimensions different than those specified in F2182-02a. As a result, RF heating was measured in a phantom container of slightly different dimensions than current standard. However, the total volume of the phantom container is within 12% of recommended volume; this is not enough to affect probe measurements or SAR calculations, so this deviation is acceptable. **Gelled Saline Conductivity (8.2.1):** F2182-11a requires conductivity of the phantom material to be 0.47 ±10% S/m, while F2182-02a listed a wider range of permissible values. For the test reports discussed below, the measured conductivity of the saline was between 0.29 and 0.32 S/m, which is within the range permitted in F2182-02a. However, the RF heating values are conservative, as they do not take the effects of perfusion due to blood flow into accout. As a result, the margin of conductivity difference is well within both the margin of measurement error within the experiment, as well as the conservative values reported for RF Heating. Therefore, this deviation does not affect the integrity of testing results. **Phantom Material Recipe (8.3):** F2182-11a and -02a differ in their prescribed recipe for gelled saline. Testing utilized the following gel recipe:

		• 40 Liters distilled water acc. to VDE 0510 (Phonix, Bergneustadt, Germany) • 5.85 g/L polyacrylic acid, partial sodum salt, lightly crosslinked, Catalog number 436364 (Aldrich, St. Louis, MO, USA) • 0.8 g/L NaCL (Merck, GR for analysis, Darmstadt, Germany) All materials in the utilized recipe are identical to those in F2182-11a. This recipe aligns with the one required in F2182-02a, and thus creates the difference in conductivity justified above. **Worst Case Phantom Location (8.4.1):** F2182-11a now requires justification of worst case implant configuration. MR Comp (the testing lab) has determined the worst case location in the phantom for both 1.5 and 3.0 Tesla scanners used in testing. Per test reports PO090408-1 and PO090408-2 (**See Appendicies B15** and **B16**), the evaluation of SAR distribution has been done to determine the worst case location. Therefore, this gap does not create a protocol deviation. **Implant Holder (8.5):** F2182-11a requires the presence of a non-metallic implant holder to keep devices in place during testing; F2152-02a does not include this requirement, but implants were held in place during testing with non-metallic string. This string is an acceptable alternative to the requirement, so this deviation does not affect the results. **Minimum Whole Body SAR (8.9):** F2182-11a requires a minimum whole body SAR of 2 W/kg. F2182-02a requires only 1 W/kg. The protocol described in the test reports produces a value of greater than 2 W/kg for all test results, so this gap does not create a protocol deviation. **Sample Frequency (8.12):** F2182-11a requires a temperature sample at last once every 5 seconds, while -02a only requires one sample every 12 seconds. Test protocols sampled temperature 60 times per minute for all tests, so this gap does not create a protocol deviation. **Determining Whole Body SAR Through Calorimetry (9):** F2182-11a requires the determination of whole body SAR through calorimetric methods in the phantom, while this is only recommended in -02a. All testing calculated whole body SAR in this manner, so this gap does not create a protocol deviation.
ASTM F2119-07 Evaluation of MR Image Artifacts	**ASTM F2119-07**	N/A
ASTM F2503-13 Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	**ASTM F2503-13**	N/A

FDA Contact Report

FDA Contact(s)	Nicole Wolanski Dr. Kenneth Cavanaugh
Office/Branch	ODE - Program Operations
Telephone Number	301-594-2186 x141 (Nicole Wolanski) 301-443-8517 x170 (Dr. Kenneth Cavanaugh)
BSC Contact	Angie Byland
Product/Subject	Wallstent TIPS & Venous Special PMA Supplement (Wallstent Biliary and Trach Bronch premarket notifications)
Submission Number	TIPS (P930031) Venous (P980033)
Date of Initial Contact	October 18, 2004 (email)

Summary of Discussion(s)

Initial FDA Contact

On October 18, 2004, Nicole Wolanski from FDA sent an email to me regarding the Wallstent Venous and TIPS Special PMA Supplement which was submitted on October 13, 2004 to request approval to reformat the Directions for Use (DFU). Currently, there are separate DFUs for each indication and the change proposed is to combine the DFUs into one document to reduce the potential for packaging errors. The email stated that this change could potentially be documented via annual report.

I then called Nicole to discuss further. I explained that we had contacted the agency (Judith Danielson) about 18 months ago and had documented that FDA recommended full supplements and traditional 510(k)s for this change. Also, I said that we thought that this may be an annual report type item, but we didn't want to disregard the initial read from FDA. To compromise, we decided to submit a special PMA/S and special 510(k)s. I did mention to the FDA reviewer that we would be combining class III and class II indications so that FDA would fully realize what we are doing. Nicole cautioned that we have to be careful when we make changes to the class II devices in that it would need to meet the requirements for class III devices. I thanked her for pointing this out and mentioned that we typically review changes with the class III requirements in mind because the devices are all the same design, etc. I told her that I would forward this information to the team as a 'heads up".

I then mentioned to Nicole that we were ready to submit special 510(k)s for the class II devices and asked her if we should hold off. Nicole agreed that we should hold the 510(k)s submissions while she did some checking with the acting branch chief at the Office of Device Evaluation.

FDA Follow Up

After consulting with the branch chief, the FDA reviewer (Nicole Wolanski) said that she would delete this special PMA supplement and have it logged in an annual report type item. The annual report will then be forwarded to the ODE staff for review.

Because of this, the special 510(k)s will not be submitted and instead be documented as 'letters to file".

ODE Review of Submission Logged in as an Annual Report

Dr. Kenneth Cavanaugh contacted me via phone and confirmed that the submission report looked fine and that we could proceed with making the change. He also mentioned that we would not receive any formal correspondence from FDA regarding the completion of review of this report.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

FEB - 1 2006

RECEIVED
FEB 0 8 2006
Per

Boston Scientific
Plymouth Technology Center
Regulatory Affairs Office
5905 Nathan Lane
Minneapolis, Minnesota 55442

Re: K003100
Device Name: Wallstent
K992510
Device Name: Wallstent Tracheobronchial Endoprosthesis and Unistep Plus Delivery System

To Whom It May Concern:

The Office of Device Evaluation (ODE) is issuing this letter today to all firms with premarket notification submissions (510(k)s) for metallic stents for use in the tracheobronchial system. We are addressing two issues with the use of metallic tracheal stents, one regarding on-label use, for which we have issued a FDA Public Health Notification, and one regarding the off-label use of these stents.

First, ODE has recognized the recent safety concerns regarding the safety of metallic tracheal stents for the treatment of benign tracheobronchial strictures. As part of our preparation for the FDA Public Health Notification, "Complications from Metallic Tracheal Stents in Patients with Benign Airway Disorders" dated July 29, 2005 (http://www.fda.gov/cdrh/safety/072905-tracheal.html), we again considered the documentation that was provided in the above-referenced premarket notifications. We are asking you to address the following concerns:

We request that you review the recent safety concerns regarding the removability of metallic stents that have been raised by Gaissert HA *et al.*, Complication of benign tracheobronchial strictures by self-expanding metal stents, *The Journal of Thoracic and Cardiovascular Surgery*, 2003, 126(3), pp. 744-7. This paper concludes that the use of metallic stents should be avoided in benign conditions. The adverse events identified in the clinical literature include life-threatening complications such as in-growth of granulation tissue causing airway obstruction and risk of irreparable structural damage due to tissue reaction to the stent. These complications have made it difficult or impossible to completely remove implanted stents, and, in some cases, appear to have diminished or precluded the success of subsequent surgical treatment of the original airway disorder. We believe that the complications arising from the use of metallic stents in benign airway disorders is a serious safety concern as shown by the recent public health notice referenced above. Therefore, we believe the following information should be addressed.

If your device is indicated for use in benign conditions, we believe the removability of your

device should be addressed. We are asking all firms with 510(k)s to address:

a. If your device is intended to be removed, please indicate this in your device labeling and provide data that demonstrates the device can be safely removed. Your data should address the length of time your device can be implanted and still be safely removed. This data should be able to substantiate the implant duration of your device, which should include proper bench testing, animal models, and clinical evaluation. If you do not have evidence to support the safe removal of your stent at this time, we believe the most appropriate action is to revise your device labeling and remove the indication for "benign strictures."

b. If your device is intended to be permanently implanted, please indicate this in your device labeling and provide data that demonstrates your device can be permanently implanted safely. Your data should be able to substantiate the implant duration of your device, which should include proper bench testing, animal models, and clinical evaluation. If you do not have evidence to support the permanent implantation of your device in patients with benign strictures, we believe the most appropriate action is to revise your device labeling and remove the indication for "benign strictures."

c. We are unaware of complications associated with silicone stents in patients with benign strictures. If there is a benign stricture patient population that you believe cannot be treated with silicone stents, and must be treated with metallic stents, please identify this patient population and provide supporting information.

d. If you are able to identify a benign stricture patient population that must be treated with metallic tracheal stents, we recommend you add the following statement to your warnings in your package insert and to the carton pouch labeling in a font-size that is easy to read.

> **Warning: The use of metallic tracheal stents may preclude the success of subsequent surgical procedures and should be considered only for patients after all alternative therapies have been exhausted. Please consider the use of tracheal surgical procedures or placement of silicone stents before using metallic tracheal stents.**

Secondly, the Center for Devices and Radiological Health has evaluated the medical device reports (MDRs) associated with tracheal stent devices and has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Specifically, a recent review of the MDR database for the time period October 22, 1996, through November 15, 2005, identified 71 reports (representing 67 separate events) associated with use of metallic tracheal stents in the cardiovascular system. These included 7 deaths and 29 injuries. We are requesting that you make the following labeling modifications, as appropriate, to provide essential information to clinicians about the use of your metallic tracheal stent:

a. Removal of all vascular terminology from your device labeling (e.g., heparinized saline, angioplasty); and

b. Adding the following limitation to appear immediately following the Indications for Use section, and on the carton pouch labeling in a font-size that is easy to read.

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

We are recommending these modifications to help you ensure that your device continues to satisfy section 502 of the Federal Food, Drug, and Cosmetic Act (the Act). In the future, we do not plan to clear any additional 510(k)s for metallic stents without the above labeling modifications (in accordance with section 513(i)(1)(E) of the Act).

Please let us hear from you within 30 days from the date of this letter regarding our concerns with the on-label and off-label use of your tracheal stents. Please reference your 510(k) numbers in your response and submit it as an add-to-file, in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If we do not hear from you within the 30 days, we will follow-up with your firm.

It may be useful for you to discuss these issues with us. If you wish to meet with us or have any questions concerning the contents of the letter, please contact CDR Stephen P. Rhodes, USPHS, Branch Chief, Plastic and Reconstructive Surgery Devices, at (301) 594-3090.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

(b)(4) Device Engineering Drawing

(b)(4) Device Engineering Drawing

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(b)(4) Device Engineering Drawing

Wallstent RP Endoprosthesis Pouch Label (representative)

Boston Scientific

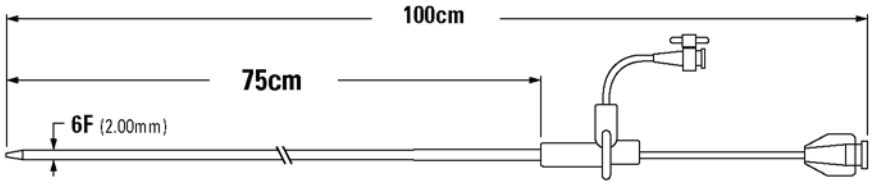
8mm x 20mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

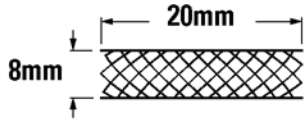
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	29mm
6mm	36mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406358	LOT	12345678
REF Catalog No.	M001711240	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322708-01H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

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WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

(01)08714729406358(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number:L322708-01H

Wallstent RP Endoprosthesis Carton Label (representative)

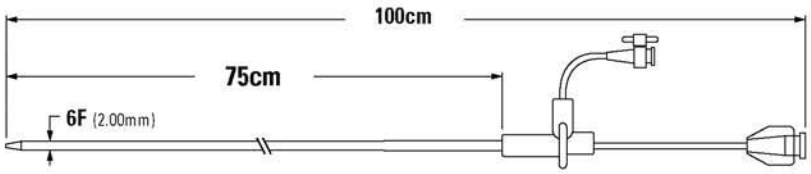
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

Self-Expanding Stent, Stent Auto-expansível

8mm x20mm 75cm

Contents **(1)**



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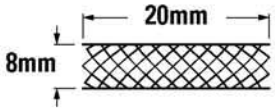

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Lumen Diameter	Stent Length
7mm	29mm
6mm	36mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406358	LOT	12345678
REF Catalog No.	M001711240	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 20 mm | 75 cm
GS1
2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY 8 mm | 20 mm | 75 cm

90499465-01

Internal BSC Bar Code
L322707-01H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

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LOT 12345678

(01)08714729406358(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 20 mm | 75 cm
GS1
2010-12-31

Label Specification Part Number:L322707-01H

Wallstent Endoprosthesis Pouch Label (representative)

Boston Scientific

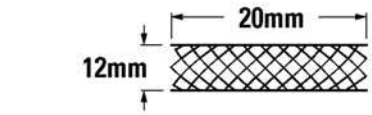
12mm x20mm 75cm

WALLSTENT® Endoprosthesis

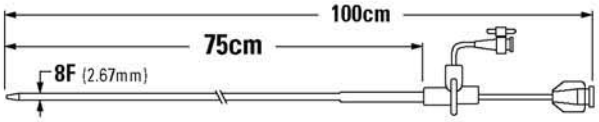
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	26mm
10mm	31mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **9F** (3.00mm) Recommended Introducer Sheath

GTIN 08714729203940

REF Catalog No. H965402100

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
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12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

90478733-01

Internal BSC Bar Code
L322690-01G

{01)08714729203940(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number:L322690-01G

Wallstent Endoprosthesis Carton Label (representative)

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

GS1

12 mm 20 mm 75 cm

2010-12-31

Boston Scientific

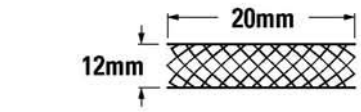
12mm x20mm 75cm

WALLSTENT® Endoprosthesis

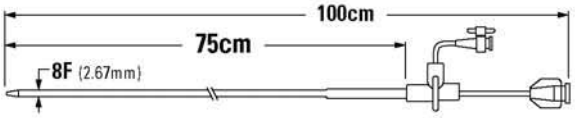
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	26mm
10mm	31mm



GW R 0.035in (0.89mm) Recommended Guidewire

IS R 9F (3.00mm) Recommended Introducer Sheath

GTIN 08714729203940

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90478732-01

Internal BSC Bar Code

L322689-01H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number:L322689-01H

WALLSTENT®

TRACHEOBRONCHIAL ENDOPROSTHESIS

INSTRUCTIONS FOR USE

LA0181-001 REV. B

INDICATIONS
The Schneider WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

CONTRAINDICATIONS
Contraindications associated with the use of the WALLSTENT® Tracheobronchial Endoprosthesis include:

- Use of the device in very small bronchials which could impede catheter removal.

- All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system.

WARNINGS
- Stenting across a major bifurcation may prevent or hinder future access or other procedures.

- Use of the device across bifurcations or side branches could impede airflow to the affected portion of the lung.

- Stents cannot be repositioned after the deployment threshold has been exceeded.

- Stents should not be placed near or across the cricopharyngeus.

- Use of a laser on or around the surface of the stent may result in damage to the stent.

PRECAUTIONS
- The device is intended for use by physicians who have received appropriate training.

- The device should not be resterilized.

- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.

- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

COMPLICATIONS
Complications associated with the use of the WALLSTENT® Tracheobronchial Endoprosthesis may include the usual complications reported for conventional tracheobronchial stents such as infection, stent misplacement, stent migration, and stent obstruction secondary to tumor or granuloma ingrowth through the stent, tumor or granuloma overgrowth at the stent ends, or mucous occlusion or perforation.

RECOMMENDED MATERIAL FOR IMPLANT

Prepare the following material using sterile technique:

- 10 cc syringe filled with sterile saline.

- 0.035" guidewire of appropriate length.

LENGTH SELECTION

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant.

After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

PROCEDURE
TRACHEOBRONCHIAL

1. Place a 0.035" exchange guidewire through the stricture.

NOTE: Predilatation, with an appropriate dilator, of the stricture may be performed prior to stent implantation at the option of the physician.

2. Having prepared the delivery system as described, insert it over the guidewire.

3. Guidelines for stent positioning:

- Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.

- The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.

- Maintain the delivery system as straight as possible during deployment of the stent.

4. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and *gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.*

CAUTION: *Do not push* on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 7.

5. Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

6. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

CAUTION: A stent cannot be repositioned after the deployment threshold has been exceeded.

7. To remove a partially deployed stent, first reconstrain the stent (see step 5). The entire

delivery system can be pulled back. The delivery system can then be removed, with the guidewire left in place.

As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

8. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.

9. The implanted stent length should allow for adequate overlapping into the non-strictured area to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.

10. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

RELATED ARTICLES

1. **Rousseau, H, et al.** Self-expandable prostheses in the tracheobronchial tree. *Radiology* 1993; 188: 199-203.

DEVICE SIZES

The Schneider WALLSTENT® Tracheobronchial Endoprosthesis is available in the following diameters: 5, 6, 7, 8, 10, 12, 14, 16, 18, 20, 22, 24 mm.

Schneider (USA) Inc
• 5905 Nathan Lane North
• Plymouth, MN 55442
• Tel 612-550-5500 • 1-800-822-6822
• Fax 1-800-325-9106

Boston Scientific

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRANSHEPATIC BILIARY

TRACHEOBRONCHIAL

TIPS

VENOUS

Self-Expanding Stent

DRAFT

This artwork is not ready for release until this note is removed. The Date-of-Issue will not be populated until this draft note is removed.

91079000-01

2015-08

Boston Scientific (Master Brand DFU Template 3in x 9in Global, 90106040AP), DFU, MB, WALLSTENT ENDO, ENVPT 91079000-01A_pretrans

CW01

Black (K) ΔE ≤5.0

TABLE OF CONTENTS

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

Self-Expanding Stent

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus delivery system (reference Figure A). The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5 mm–12 mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89 mm) guidewire.

User Information

This system is intended for use by physicians who have received appropriate training.

Contents

One (1) WALLSTENT RP Endoprosthesis

Or

One (1) WALLSTENT Endoprosthesis

WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis with UNISTEP™ Plus Delivery System

Table 1. Size and Indication Information

UPN	Order Number	Stent Diameter Compatibility	Stent Length	Sheath Diameter	Effective Length	Total	Indications
		mm	mm	F(mm)	cm	cm	
M001711000	71-100	5	20	6 (2.0)	75	100	1
M001711010	71-101	5	20	6 (2.0)	135	160	1
M001711020	71-102	5	40	6 (2.0)	75	100	1
M001711030	71-103	5	40	6 (2.0)	135	160	1
M001711040	71-104	5	55	6 (2.0)	75	100	1
M001711050	71-105	5	55	6 (2.0)	135	160	1
M001711060	71-106	5	80	6 (2.0)	75	100	1
M001711070	71-107	5	80	6 (2.0)	135	160	1
M001711080	71-108	6	20	6 (2.0)	75	100	1
M001711090	71-109	6	20	6 (2.0)	135	160	1
M001711100	71-110	6	45	6 (2.0)	75	100	1
M001711110	71-111	6	45	6 (2.0)	135	160	1
M001711120	71-112	6	60	6 (2.0)	75	100	1
M001711130	71-113	6	60	6 (2.0)	135	160	1
M001711140	71-114	6	90	6 (2.0)	75	100	1
M001711150	71-115	6	90	6 (2.0)	135	160	1
M001711160	71-116	7	20	6 (2.0)	75	100	1
M001711170	71-117	7	20	6 (2.0)	135	160	1
M001711180	71-118	7	40	6 (2.0)	75	100	1
M001711190	71-119	7	40	6 (2.0)	135	160	1
M001711200	71-120	7	60	6 (2.0)	75	100	1
M001711210	71-121	7	60	6 (2.0)	135	160	1
M001711220	71-122	7	90	6 (2.0)	75	100	1
M001711230	71-123	7	90	6 (2.0)	135	160	1
M001711240	71-124	8	20	6 (2.0)	75	100	1, 3
M001711250	71-125	8	20	6 (2.0)	135	160	1
M001711260	71-126	8	40	6 (2.0)	75	100	1, 3
M001711270	71-127	8	40	6 (2.0)	135	160	1
M001711280	71-128	8	60	6 (2.0)	75	100	1, 3
M001711290	71-129	8	60	6 (2.0)	135	160	1
M001711300	71-130	8	80	6 (2.0)	75	100	1, 3
M001711310	71-131	8	80	6 (2.0)	135	160	1
M001711320	71-132	10	20	6 (2.0)	75	100	1, 3, 4
M001711330	71-133	10	20	6 (2.0)	135	160	1
M001711340	71-134	10	42	7 (2.3)	75	100	1, 2, 3, 4
M001711350	71-135	10	42	7 (2.3)	135	160	1
M001711360	71-136	10	68	7 (2.3)	75	100	1 2 3 4
M001711370	71-137	10	68	7 (2.3)	135	160	1
M001711380	71-138	10	94	7 (2.3)	75	100	1, 2, 3, 4
M001711390	71-139	10	94	7 (2.3)	135	160	1
H965402100	40210	12	20	9 (3.0)	75	100	1, 3, 4
H965412000	41200	12	20	9 (3.0)	135	160	1
H965402110	40211	12	40	9 (3.0)	75	100	1, 2, 3, 4
H965412010	41201	12	40	9 (3.0)	135	160	1
H965402120	40212	12	60	9 (3.0)	75	100	1 2 3 4
H965412020	41202	12	60	9 (3.0)	135	160	1
H965402130	40213	12	90	9 (3.0)	75	100	1, 2, 3, 4
H965412030	41203	12	90	9 (3.0)	135	160	1
H965403100	40310	14	20	10 (3.3)	75	100	1, 4
H965403110	40311	14	40	10 (3.3)	75	100	1, 4
H965403120	40312	14	60	10 (3.3)	75	100	1, 4
H965403130	40313	14	90	10 (3.3)	75	100	1, 4
H965403300	40330	16	20	10 (3.3)	75	100	1, 4
H965403310	40331	16	40	10 (3.3)	75	100	1, 4
H965403320	40332	16	60	10 (3.3)	75	100	1, 4
H965403330	40333	16	90	10 (3.3)	75	100	1, 4
H965404110	40411	18	40	11 (3.7)	75	100	1
H965404120	40412	18	60	11 (3.7)	75	100	1
H965404130	40413	18	90	11 (3.7)	75	100	1
H965404300	40430	20	40	11 (3.7)	75	100	1
H965404310	40431	20	55	11 (3.7)	75	100	1
H965404320	40432	20	80	11 (3.7)	75	100	1
H965404500	40450	22	35	11 (3.7)	75	100	1
H965404510	40451	22	45	11 (3.7)	75	100	1
H965404520	40452	22	70	11 (3.7)	75	100	1
H965405100	40510	24	35	12 (4.0)	75	100	1
H965405110	40511	24	45	12 (4.0)	75	100	1
H965405120	40512	24	70	12 (4.0)	75	100	1

Indication Key
1 Tracheobronchial
2 Transjugular Intrahepatic Portosystemic Shunt (TIPS)
3 Transhepatic Biliary
4 Venous

Table 2. Sizing Chart

Fully Open Dimension (As labelled on box)	Approximate Implanted Stent Length						Delivery System
Diameter x Length	Nominal Lumen Diameter	Stent Length	Nominal Lumen Diameter	Stent Length	Nominal Lumen Diameter	Stent Length	Catheter Size
mm	mm	mm	mm	mm	mm	mm	F (mm)
5 x 20	4.0	26	3.0	30	2.0	33	6 (2.00)
5 x 40		54		63		68	
5 x 55		78		89		97	
5 x 80		116		134		145	
6 x 20	5.0	25	4.0	29	3.0	32	6 (2.00)
6 x 45		52		60		65	
6 x 60		74		85		93	
6 x 90		111		128		139	
7 x 20	6.0	25	5.0	28	4.0	30	6 (2.00)
7 x 40		50		57		63	
7 x 60		72		82		90	
7 x 90		108		123		134	
8 x 20	7.0	29	6.0	36	5.0	41	6 (2.00)
8 x 40		49		56		61	
8 x 60		70		79		86	
8 x 80		105		119		130	
10 x 20	9.0	27	8.0	33	7.0	38	6 (2.00)
10 x 42	9.0	48	8.0	54	7.0	58	7 (2.33)
10 x 68		69		77		83	
10 x 94		103		115		124	
12 x 20	11.0	26	10.0	31	9.0	36	8 (2.67)
12 x 40		47		51		55	
12 x 60		66		73		79	
12 x 90		100		110		119	
14 x 20	13.0	27	12.0	33	11.0	38	9 (3.00)
14 x 40		46		50		54	
14 x 60		65		72		77	
14 x 90		98		107		115	
16 x 20	15.0	23	14.0	28	13.0	32	9 (3.00)
16 x 40		45		49		52	
16 x 60		64		70		75	
16 x 90		97		105		112	
18 x 40	17.0	45	16.0	48	15.0	51	10 (3.33)
18 x 60		64		69		73	
18 x 90		95		103		110	
20 x 40	19.0	40	18.0	44	17.0	47	10 (3.33)
20 x 55		57		63		68	
20 x 80		86		94		102	
22 x 35	21.0	35	20.0	40	19.0	44	10 (3.33)
22 x 45		50		57		62	
22 x 70		75		85		93	
24 x 35	23.0	35	22.0	39	21.0	43	11 (3.67)
24 x 45		50		56		61	
24 x 70		75		84		92	

INDICATION: Tracheobronchial: 5-24 mm stents
Transhepatic Biliary: 8-12 mm stents
Venous: 10-16 mm stents
TIPS: 10-12 mm stents

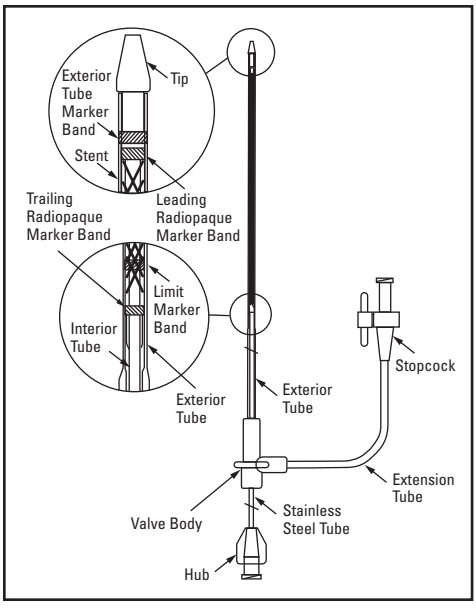

Figure A. UNISTEP™ Plus Delivery System

PRINCIPLE OF OPERATION

The exterior tube is easily retracted by immobilizing the stainless steel tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constrainment. A single operator can thus control deployment and implant the stent.

The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. (The stent deployment threshold or point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band [Figure A]). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

WARNING

A stent cannot be repositioned or removed after the deployment threshold has been exceeded.

PRECAUTION

The system is intended for use by physicians who have received appropriate training.

PREPARATION OF THE DELIVERY SYSTEM FOR INSERTION - VASCULAR INDICATIONS

1. **Initial Preparation of the Delivery System**
   - Carefully remove the delivery system from its protective packaging.
   - Visually inspect the entire device for damage or defects.
   - Visually check that the leading end of the stent is covered by the exterior tube.
   - Ensure that no stent wires have perforated the exterior tube.

2. Flushing the Delivery System

- Attach a 10 ml (cc) syringe filled with sterile saline to stopcock on extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After flushing the delivery system, close the stopcock and remove the syringe.
- Re-verify that the leading end of the stent is covered by the exterior tube. Do not use device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant and such use may cause lumen injury.

PREPARATION OF THE DELIVERY SYSTEM FOR INSERTION -NON VASCULAR INDICATIONS

1. Initial Preparation of the Delivery System

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire device for damage or defects.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

2. Flushing the Delivery System

- Attach a 10 ml (cc) syringe filled with sterile saline to stopcock on extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After flushing the delivery system, visually check that any excess saline is drained from the delivery system.
- Re-verify that the leading end of the stent is covered by the exterior tube. Do not use device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant and such use may cause lumen injury.

HOW SUPPLIED

The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis are supplied sterile and intended for single use only. The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis are sterilized by ethylene oxide gas.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling & Storage

Do not expose delivery catheter to organic solvents, e.g., isopropyl alcohol. Such an exposure can cause delivery catheter to become brittle. Rotate inventory so that products are used prior to the "Use By" date on package label.

Store in a cool, dry, dark place.

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRANSHEPATIC BILIARY

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary are indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

CONTRAINDICATIONS

Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary include:

- Use of the device in very small intrahepatic ducts.
- Stenting of a perforated duct, where leakage from the duct could be exacerbated by the prosthesis and leakage could occur across the mesh of the stent.
- All of the customary contraindications associated with the percutaneous transhepatic manipulation of 6-9F (2.0-3.0 mm) caliber catheters (e.g.: bleeding disorders unresponsive to vitamin K or blood product therapy).

WARNINGS

- The safety and effectiveness for use in the vascular system have not been established except for the following WALLSTENT product codes that are also indicated for improving central venous luminal diameter in the innominate and subclavian veins following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract: M001711320, M001711340, M001711360, M001711380, H965402110, H965402120, H965402130, H965402100.
- Stenting across a major bifurcation may prevent or hinder future endoscopic access or other procedures.
- Stents cannot be repositioned after the deployment threshold has been exceeded.
- Final stent placement resulting in an excessive length of stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The device should not be re-sterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT™ Transhepatic Biliary is MR Conditional for single and overlapping lengths up to 94 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT Transhepatic Biliary is expected to produce a maximum in-vivo temperature rise of 0.64°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

COMPLICATIONS

Complications associated with the use of the WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary may include the usual complications reported for conventional biliary stents and transhepatic procedures such as infection, stent misplacement, stent migration, and stent obstruction secondary to tumor in-growth through the stent, tumor overgrowth at the stent ends, or sludge occlusion.

OPERATIONAL INSTRUCTIONS

Recommended Material for Implant

Prepare the following material using sterile technique:

- 10 ml (cc) syringe filled with sterile saline.
- Non-hemostatic introducing sheath, approximately 10-12 cm long (6F (2.0 mm) for 6F (2.0 mm) delivery system, 7F (2.3 mm) for 7F (2.3 mm) delivery system and 9F (3.0 mm) for 8F (2.7 mm) delivery system).
- 0.035 in (0.89 mm) guidewire of appropriate length.

Device Selection

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant.

After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

TRANSHEPATIC PROCEDURE

1. Place a 0.035 in (0.89 mm) exchange guidewire transhepatically into the duodenum and remove the drainage catheter. Dilate the liver tract if indicated.
2. Dilate the biliary stricture with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
3. Remove the balloon catheter, leaving the guidewire in place.
4. Having prepared the delivery system as previously described, insert it into the introducer sheath and over the guidewire.
5. Use the radiopaque marker bands to identify the area to be dilated and stented.

Note: Always use an introducer sheath for the implant procedure, to protect both the liver tract and the puncture site, in the event a partially deployed stent were to be removed.

6. Guidelines for stent positioning:
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   - The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radiographic visualization of the stent itself is necessary.
   - Maintain the delivery system as straight as possible during deployment of the stent.
7. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Caution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible duct damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 10.

8. Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.
9. To complete stent deployment immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Caution: A stent cannot be repositioned after the deployment threshold has been exceeded.

10. To remove a partially deployed stent, first reconstrain the stent (see step 8). The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

    As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.
11. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
12. Using standard operative procedures, perform routine cholangiography to demonstrate location and patency of the stent.
13. The implanted stent length should allow for adequate overlapping into the non-strictured duct to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.
14. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery catheter.

DEVICE SIZES

The WALLSTENT™ RP Endoprosthesis Transhepatic Biliary is available in the following diameters: 8 & 10 mm.

The WALLSTENT™ Endoprosthesis Transhepatic Biliary is available in the following diameter: 12 mm.

RELATED ARTICLES

1. Adam A, Chetty N, Roddie M, Yeung E, Benjamin IS. Self expandable stainless steel endoprosthesis for treatment of bile duct obstruction. AJR 1991; 156:321-325.
2. Dick R, Gilliams A, Dooley JS, Hobbs KEF. Stainless steel mesh stents for biliary strictures. Journal of Interventional Radiology 1989; 4:95-98.
3. Gilliams A, Dick R, Dooley JS, Wallsten H, El-Din A. Self expandable stainless steel braided endoprosthesis for biliary strictures. Radiology 1990; 174:137-140.
4. LaBerge JM, Doherty M, Gordon RL, Ring EJ. Hilar malignancy: treatment with an expandable metallic transhepatic biliary stent. Radiology 1990; 177:793-797.
5. Lammer J, Klein GE, Kleinert R, Hausegger K, Einspieler R. Obstructive jaundice: use of expandable metal endoprosthesis for biliary drainage. Radiology 1990; 177: 789-792.
6. Neuhaus H, Hagenmüller F, Griebel M, Classen M. Percutaneous cholangioscopic or transpapillary insertion of self-expanding biliary metal stents. Gastrointestinal Endoscopy 1991; 37:31-37.

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRACHEOBRONCHIAL

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

With the exception of the following WALLSTENT Codes which are approved for Venous or TIPS indications, the safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death: H965402100, H965402110, H965402120, H965402130, H965403100, H965403110, H965403120, H965403130, H965403300, H965403310, H965403320, H965403330, M001711320, M001711340, M001711360, M001711380.

CONTRAINDICATIONS

Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial include:

- Use of the device in very small bronchials which could impede catheter removal.
- All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system.

WARNINGS

- Stenting across a major bifurcation may prevent or hinder future access or other procedures.
- Use of the device across bifurcations or side branches could impede airflow to the affected portion of the lung.
- Stents cannot be repositioned after the deployment threshold has been exceeded.
- Stents should not be placed near or across the cricopharyngeus.
- Use of a laser on or around the surface of the stent may result in damage to the stent.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The device should not be resterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT Tracheobronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned

safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT™ Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

COMPLICATIONS

Complications associated with the use of the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial may include the usual complications reported for conventional tracheobronchial stents such as infection, stent misplacement, stent migration, and stent obstruction secondary to tumor or granuloma ingrowth through the stent, tumor or granuloma overgrowth at the stent ends, or mucous occlusion or perforation.

OPERATIONAL INSTRUCTIONS

Recommended Material for Implant

Prepare the following material using sterile technique:

- 10 ml (cc) syringe filled with sterile saline.
- 0.035 in (0.89 mm) guidewire of appropriate length.

Device Selection

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant.

After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

TRACHEOBRONCHIAL PROCEDURE

1. Place a 0.035 in (0.89 mm) exchange guidewire through the stricture.

   Note: Predilatation, with an appropriate dilator, of the stricture may be performed prior to stent implantation at the option of the physician.

2. Having prepared the delivery system as described, insert it over the guidewire.
3. Guidelines for stent positioning:
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   - The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these

markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.

- Maintain the delivery system as straight as possible during deployment of the stent.

4. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Caution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 7.

5. Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

6. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Caution: A stent cannot be repositioned after the deployment threshold has been exceeded.

7. To remove a partially deployed stent, first reconstrain the stent (see step 5). The entire delivery system can be pulled back. The delivery system can then be removed, with the guidewire left in place.

   As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

8. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
9. The implanted stent length should allow for adequate overlapping into the non-strictured area to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.
10. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

DEVICE SIZES

The WALLSTENT™ RP Endoprosthesis Tracheobronchial is available in the following diameters: 5, 6, 7, 8 & 10 mm.

The WALLSTENT™ Endoprosthesis Tracheobronchial is available in the following diameters: 12, 14, 16, 18, 20, 22 & 24 mm.

RELATED ARTICLES

1. Rousseau, H, et al. Self-expandable prostheses in the tracheobronchial tree. Radiology 1993; 188: 199-203.

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TIPS

DEVICE DESCRIPTION

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transjugular Intrahepatic Portosystemic Shunt (TIPS) are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus delivery system. The stent is composed of biomedical superalloy wire with a radiopaque core, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, highly radiopaque and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035 in (0.89 mm) guidewire. The delivery system may be inserted through a 7F (2.3 mm) sheath (10 mm stent) or 9F (3.0 mm) sheath (12 mm stent).

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS are indicated for creation of intrahepatic shunt connections between the portal venous system and the hepatic vein for prophylaxis of variceal bleeding in the treatment of portal hypertension and its complications in patients who have previously failed conventional treatment techniques.

CONTRAINDICATIONS

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS are contraindicated for use in:

- Patients with associated occlusion of the portal or hepatic vein.
- Patients with gastric varices secondary to splenic vein thrombosis.

WARNING

Treatment may exacerbate pulmonary hypertension or congestive heart failure in patients with severely compromised cardiovascular or pulmonary function.

PRECAUTIONS

- A stent cannot be repositioned or removed after the deployment threshold has been exceeded.
- The device is intended for use by physicians who have received appropriate training in interventional radiological techniques involving the liver and biliary tree. TIPS should be done by a physician who performs this procedure regularly and who is prepared to follow and monitor patients for shunt patency on a long term basis. In addition the TIPS procedure should be performed only at facilities adequate to manage critically ill patients and where surgical expertise is available if needed.

- The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis TIPS are intended for single use only. The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS should NOT be resterilized.
- Ultrasonographic or angiographic follow-up is recommended for post-TIPS monitoring of shunt status.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT TIPS is MR Conditional for single and overlapping lengths up to 94 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT TIPS is expected to produce a maximum in-vivo temperature rise of 0.64°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS

Adverse events recorded during the clinical trial of the WALLSTENT TIPS Endoprosthesis included:

- Death – <30 days 15% & >30 days 15%
- Encephalopathy – 30% increased
- Hepatic Artery Thrombosis/Liver Failure – 1%
- Hepatic Lobe Infarction – 1%
- Hepatic or Portal Vein Occlusion or Stenosis – 1%
- Hyperbilirubinemia secondary to bile duct puncture – 1%
- Intra-abdominal Hemorrhage secondary to: liver capsule/ vessel puncture – 3%
- Pulmonary hypertension/edema/Adult Respiratory Distress Syndrome – 1%
- Puncture Site Hematoma – 1%
- Recurrence of Esophageal Varices – 10%
- Sepsis/Infection – 6%
- Shock – 5%
- Shunt Stenosis or Occlusion – 17%

Additional adverse events associated with TIPS, although not observed in the clinical study include:

- Disseminated Intravascular Coagulation
- Pneumonia
- Pulmonary Embolism
- Stent Migration
- Stent Misplacement
- Vessel Rupture

The risks associated with the use of contrast media angiography (allergic type reactions, hypertension, shock, death) should also be considered, as fluoroscopy and angiography are recommended during the stent implant procedure.

CLINICAL SUMMARY

A multicenter trial at eight USA centers in 101 patients was conducted to evaluate the safety and efficacy of the 10 mm diameter WALLSTENT™ TIPS Endoprosthesis when implanted to create an intrahepatic shunt. This shunt connected the portal venous system and the hepatic vein for the treatment of portal hypertension in patients who had previously failed conventional treatment techniques.

Results for major endpoints were compared to sclerotherapy and surgery historical controls. Key patient demographic data for study patients are summarized in **Table 1** with **Figure 1** illustrating the liver status by both Child's and Child-Pugh classification schemes. Class A patients have less advanced liver disease, Class B are moderate risk patients with significantly compromised liver function and Class C are severely compromised patients, with minimal remaining liver function.

Table 1. Demographics (n=97)*

Age (Yrs)†	56 ± 13 (22 – 86)	
Gender (%)	61 Male; 39 Female	
Karnofsky Score†,§	77 ± 20 (20 – 100)	
Varice (#pts) ✍	93 Esophageal 54 Gastric	
Liver Status (%)	Child's A 27, B 51, C 22 Child-Pugh A 26, B 40, C 34	
# Treatments Pre-TIPS	3, Range 1 – 12	
Pre-TIPS Treatments	Sclerotherapy Sclero + Other Medical Balloon Banding Laser None	37% 43% 7% 4% 2% 1% 5%
Etiology	Alcohol Only ETOH + Other Cryptogenic Hepatitis Other	40% 26% 17% 9% 8%
Pre-TIPS (mmHg)†	23.3 ± 6.9 (7.0 – 42.0)	
Flow Direction‡	67 Hepatopetal 25 Hepatofugal	

* Analysis on 97/101 patients. Four excluded for not meeting study inclusion/exclusion criteria.
† Mean ± SD, (range).
§ Karnofsky scale ranges from 10 = moribund to 100 = normal.
‡ Flow unknown in five patients.
✍ Many patients exhibited both esophageal and gastric varices.

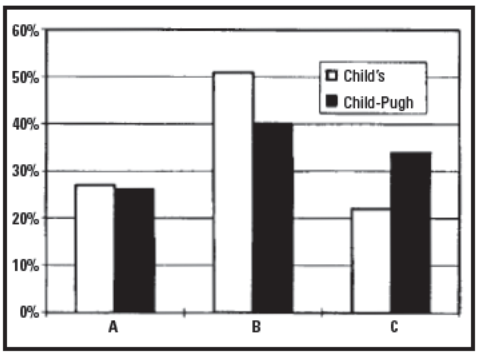

Figure 1. Liver Status

Table 2 presents the effectiveness data. Procedure success addresses the issues of successful creation of a TIPS with variceal decompression, as evidenced by a portosystemic gradient <20 mm Hg. Shunt success was measured by maintenance of shunt patency, a portosystemic gradient <20 mm Hg or the absence of renewed filling of varices at six months post-implant. Maintenance of shunt patency is also reflected in the frequency of intervention required post-TIPS.

Table 2. Effectiveness Measures*

Procedure Success		
Initial†	93 (96%)	
At Discharge	96 (99%)	
Adjunctive Embolization	25 (26%)	
Portocaval Pressure Gradients		
Pre Device	23.2 ± 6.9 mmHg	
Post Device	9.7 ± 4.8 mmHg	
Gradient Decrease		
Initial	13.2 ± 5.1 mmHg	
Six Months	10.2 ± 3.9 mmHg	
Shunt Success		
Patency‡	30 Days	180 Days
Primary	0.90 ± 0.06	0.69 ± 0.11
Primary Assisted	0.98 ± 0.03	0.92 ± 0.06
Secondary	0.99 ± 0.02	0.98 ± 0.04
Intervention Post TIPS		
0 interventions	57 patients (59%)	
1 intervention	28 patients (29%)	
2 interventions	10 patients (10%)	
3 interventions	2 patients (2%)	
Average Interventions/pt	0.6/patient	
Average Time to Intervention	97 days	

Numbers are mean ± SD or number (%) for the indicated group.
* A total of 101 patients enrolled, four excluded from analysis, N=97.
† Three patients required shunt modification prior to discharge.
‡ Life table analysis: value given is life table estimate ± 1.96 (SE).

Figures 2-4 illustrate the Kaplan-Meier analysis for primary, primary assisted and secondary patency. The dashed lines on the figures represent the upper and lower 95% confidence interval boundaries. Primary patency is defined as the time until shunt intervention; primary assisted as the time until shunt occlusion; and secondary as the time until loss of shunt function.

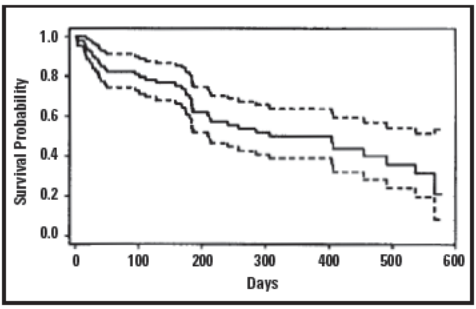

Figure 2. Primary Patency: Kaplan-Meier Survival Analysis (with 95% CI)

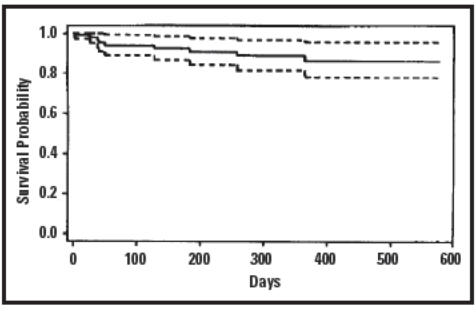

Figure 3. Primary Assisted Patency: Kaplan-Meier Survival Analysis (with 95% CI)

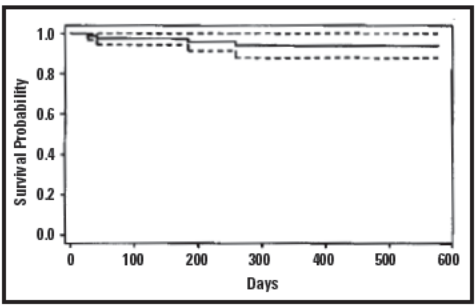

Figure 4. Secondary Patency: Kaplan-Meier Survival Analysis (with 95% CI)

Table 3 presents the safety data. The safety measures of survival and rebleeding were assessed using meta analysis comparing sclerotherapy and surgery historical controls to the study population.

Table 3. Safety Measures Meta Analysis to Literature*

Survival	Survival Rate	p value
TIPS vs Surgery @ 108 days	75.4 vs 61.2	0.02
TIPS vs Sclerotherapy @ 106 days	74.9 vs 69.8	0.33
Freedom from Rebleeding	**Success Rate**	**p value**
TIPS vs Surgery @ 151 days	85.1 vs 94.4	0.014
TIPS vs Sclero @ 182 days	82.7 vs 63.2	0.00005

* Comparison of study data to sclerotherapy and surgery literature using weighted average.

There are statistically significant differences between classification groups with Class A survival being greater than Class B, which is greater than Class C. **Table 4** presents patient survival information.

Table 4. Patient Survival and Associated Events Description (n=97)

Category	Child-Pugh Class	n	%	Clinical Course	n	%
Early† (<30 days)	A	1	1	• Systemic Disease Progression	7	7
	B	2	2	• Gastrointestinal Bleeding	5	5
	C	12	12	• TIPS-Related	2	2
	Overall	15	15	• Incarcerated Bowel Loop Sepsis	1	1
Late‡ (>30 days)	A	1	1	• Systemic Disease Progression	9	9
	B	5	5	• Sepsis or Septic Shock	3	3
	C	9	9	• Bronchial Bleed or Pneumonia	2	2
	Overall	15	15	• Brain Abscess	1	1
Overall		30	31			

†Mean time to early death was 13.4 days, range 2 – 29 days.
‡Mean time to late death was 139.1 days, range 31 – 375 days.

Rebleeding did not occur in 84% of the study population. **Table 5** details the frequency and events description of those patients with rebleed episodes. There were no statistically significant differences between classification groups for rebleed.

Table 5. Rebleed (n=97)

Episodes	n	%	Events Description	n	%
None	81	84	• Shunt intervention, sclerotherapy or embolization	10	10
One	10	10			
Two	2	2	• No intervention	4	4
Three	3	3	• Bronchial Bleed	1	1
Four	1	1	• Death	1	1
Overall	16	16			

Mean time to rebleed was 59 days, range 6 – 185 days.

Figures 5 and **6** illustrate the Kaplan-Meier estimates of the time to death and rebleed, respectively for all study patients. The dashed lines on the figures represent the upper and lower 95% confidence interval boundaries.

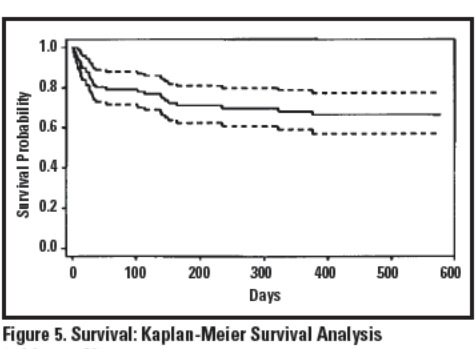

Figure 5. Survival: Kaplan-Meier Survival Analysis (with 95% CI)

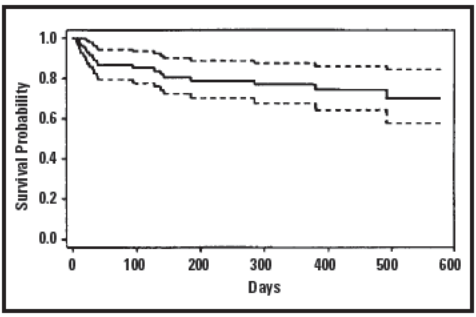

Figure 6. Rebleeding: Kaplan-Meier Survival Analysis (with 95% CI)

Table 6 presents information on the 29 patients with increased encephalopathy post-TIPS. Encephalopathy (Hepatic) is characterized as apathy, somnolence, psychic irritative symptoms, or coma associated with cirrhosis of the liver and attributed to the passage of toxic nitrogenous substances from the portal to systemic circulation. Encephalopathy patients are categorized as mild, moderate or severe and **Figure 7** illustrates the distribution of patients with increased encephalopathy post-TIPS by category and the percentage controlled with standard medical therapy. Of the 29 patients, 22 (76%) were controlled with standard medical therapy.

Table 6. Post TIPS Increased Encephalopathy (n=97)

Category	n	%	Clinical Sequelae	n	%
Mild	8	8	• Controlled	8	8
Moderate	12	12	• Controlled • Controlled ⌧Systemic Disease Progression ⌧Death	10 2	10 2
Severe	9	9	• Controlled/improved • Controlled ⌧Systemic Disease Progression ⌧Death • Uncontrolled ⌧Systemic Disease Progression ⌧Death • Bronchial Bleeding (non-TIPS related) ⌧Death	4 3 1 1	4 3 1 1
Overall	29	30			

Thirty-one of the 97 patients exhibited some level of encephalopathy pre-TIPS, of which six died predischarge and of the remaining 25 patients, 20 improved or where unchanged.

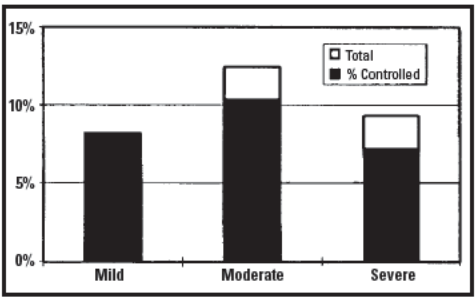

Figure 7. Post TIPS Encephalopathy Patients Treatment Outcome

Two patient characteristics typically associated with portal hypertension are encephalopathy and ascites. Encephalopathy was previously defined, and ascites is the accumulation of serous fluid in the peritoneal cavity. **Figure 8** illustrates the change in occurrence of these characteristics over time post-TIPS.

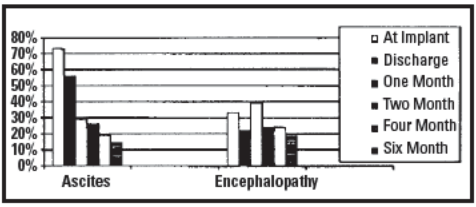

Figure 8. Encephalopathy and Ascites Over Time

Table 7 presents TIPS procedure portography related complications and the clinical sequela. In 22 reported events 16 (70%) required no medical treatment.

Table 7. Portography-Related Complications* (n=97)

Complication	n	%	Clinical Sequelae	n	%
Liver Capsule Puncture	15	16	• None • Transfusion Only • Transfusion ⌧Surgery ⌧Death	12 2 1	12 2 1
Bile Duct Puncture	11	11	• None	11	11
Hepatic Artery Puncture	3	3	• None • Puncture ⌧Thrombosis ⌧Systemic Disease Progression ⌧Death (Shunt was Patent)	2 1	2 1
Main Portal Vein Puncture	1	1	• None	1	1
Hematoma	1	1	• None	1	1
Overall	22	23			
Delivery System Failures (210 delivery system attempts in 97 pts., n=210)					
Per Delivery System Attempt	15	7	• Stent would not deploy • Would not prime or hold pressure	11 4	5 2

Thirty-one events occurred in 22 patients.

OPERATIONAL INSTRUCTIONS

Preparation of the Delivery System for Insertion

1. **Recommended Material for Implant**

   Prepare the following material using sterile technique:

   - 10 ml (cc) syringe filled with sterile saline.
   - Contrast media.
   - 0.035 in (0.89 mm) extra stiff guidewire of appropriate length. (eg. 180 cm).
   - 9F (3.0 mm) sheath with a check valve (eg. 40 cm).
   - Curved angiographic catheter.
   - Transjugular catheter (eg.-45 cm long, 9F (3.0 mm) catheter; 55 cm curved, 16 gauge needle).
   - 8 mm diameter balloon catheter (10 mm stent) or 10 mm diameter balloon catheter (12 mm stent).

2. **Device Selection**

   Having calculated the distance between the hepatic vein and portal vein segments and allowing for post-implant stent shortening (due to continued expansion), determine the stented length necessary to adequately connect the target vein segments.

   Should multiple stents be required, place the distal stent (i.e.-portal vein segment) first followed by the proximal (i.e.-hepatic vein segment) stent. Both stents should have the same diameter and length. Allow for generous stent overlapping, to avoid extension of the proximal stent end into the vena cava.

3. **Initial Preparation of the Delivery System**
   - Carefully remove the delivery system from its protective packaging.
   - Visually inspect the entire device for damage or defects.
   - Visually check that the leading end of the stent is covered by the exterior tube.
   - Ensure that no stent wires have perforated the exterior tube.
4. **Flushing the Delivery System**
   - Attach a 10 ml (cc) syringe filled with sterile saline to the extension tube stopcock.
   - Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
   - After flushing the delivery system, close the stopcock and remove the syringe.
   - Reverify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved proximally exposing the ends of the stent wires.

TIPS PROCEDURE

Catheterization

Note: The exact technique used to gain catheter access to the targeted placement site is selected at the discretion of the implanting physician. One proposed access technique is outlined as follows:

- With the patient in a slight Trendelenburg position, the right internal jugular vein is accessed percutaneously.
- An appropriate size sheath with a check valve is placed through the right atrium to the origin of the inferior vena cava.
- A curved angiographic catheter is manipulated into a large hepatic vein (either the right or middle hepatic vein). The sheath is advanced over the catheter into the hepatic vein.
- The angiographic catheter is exchanged for a transjugular catheter with curved 16 gauge needle.
- The needle is advanced from the hepatic vein, through the parenchyma, into a portal vein branch using external ultrasound guidance.
- A rigid guidewire is advanced down to the mesenteric or splenic vein.
- The 16 gauge needle is removed and a 65 cm long, 5F (1.7 mm) catheter is introduced through the transjugular catheter.
- Portal pressure and a portal venogram are obtained.
- The 5F (1.7 mm) catheter is exchanged over the guidewire for an appropriate size balloon.
- The balloon is inflated across the parenchymal tract with sufficient pressure to eliminate the waist in the balloon.
- The sheath is advanced as far as possible into the parenchymal track and the catheter and dilating balloon are removed, leaving the rigid guidewire in the mesenteric or splenic vein.
- Having prepared the delivery system as previously described, insert it over the rigid guidewire.
- Once the stent has been advanced into the portal vein, the length of the segment to be shunted is mapped by injecting contrast through the check flow sheath in the hepatic vein, and through the central lumen of the delivery system in the portal vein.

Device Deployment Procedure

Guidelines for Stent Positioning

1. Position the leading marker band so that the leading end of the stent releases into the main or right portal vein just proximal to its bifurcation.
2. The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. In order to assure precise stent placement, fluoroscopic visualization of the stent itself is necessary.
3. Maintain the delivery system as straight as possible during deployment of the stent.
4. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and *gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.*

Caution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see **step 7**.

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5. Assess stent position and reposition if desired. To reposition, reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

Note: To facilitate reconstrainment, the delivery system may be flushed with heparinized saline.

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6. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Caution: A stent cannot be repositioned after the deployment threshold has been exceeded.

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7. To remove a partially deployed stent, first reconstrain the stent (see **step 5**). The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

   As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.
8. After the stent is correctly positioned and fully deployed, an injection of contrast media may be made through the internal tube lumen to confirm adequate proximal and distal positioning of the stent.

If little or no flow is seen through the shunt, an injection through the check flow side arm determines how much additional shunt length is required to reach the hepatic vein.

If necessary, a second stent may be deployed an appropriate distance within the first so that its proximal end opens into the hepatic vein. The diameter and length of the second stent should equal that of the first.

9. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
10. Repeat portal pressures and venography following removal of the delivery system.
11. If the pressure gradient reads between 15 and 20 mm Hg and variceal filling occurs (i.e. the coronary vein is visualized on venography), the shunt may be dilated with an appropriately sized high pressure balloon. If the pressure gradient remains between 15 and 20 mm Hg, and variceal filling persists after balloon dilation of the tract, additional embolization therapy may be indicated. If, after balloon dilation and embolization therapy have been performed, the pressure gradient is still above 20 mm Hg and massive filling of varices is noted, a second parallel TIPS should be placed.

    The instructions for a second TIPS procedure are identical to the preceding instructions.
12. After demonstrating adequate portal decompression, reverse the Trendelenburg position and remove the catheters.

DEVICE SIZES

The WALLSTENT™ RP Endoprosthesis TIPS is available in the following diameter and deployed length (nominal):

Diameter	Deployed Length
mm	mm
10	42

The WALLSTENT™ Endoprosthesis TIPS is available in the following diameters and deployed lengths (nominal):

Diameter	Deployed Length
mm	mm
10	68
10	94
12	40
12	60
12	90

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction.

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WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

VENOUS

DEVICE DESCRIPTION

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus Delivery System.

- The stent is composed of biomedical superalloy wire with a radiopaque core braided in a tubular mesh configuration.
- The delivery system is composed of co-axial tubes which allow reconstrainment as indicated by the limit marker and has radiopaque marker bands which aid in accurate placement of the stent.

The WALLSTENT RP Endoprosthesis Venous is available in the following diameter: 10 mm.

The WALLSTENT Endoprosthesis Venous is available in the following diameters: 12, 14 & 16 mm.

Stent diameter selected should be approximately 1.0 mm to 2.0 mm larger than the vessel diameter desired. Deployed lengths reflect expansion to desired vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction. On average, a 0.5 mm change in diameter yields a 10-15% change in length. Once the desired vessel diameter is reached, no additional reduction in stent length should occur.

Table 1. Stent Sizing Specifications

WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous Vessel Diameter and Approximate Implanted Stent Length						
Order Number	Fully Opened Stent Diameter/Length		Stent Length When Implanted in Specified Vessel Diameter			
	Diam.	Length	Nominal Vessel Diam.	Stent Length	Nominal Vessel Diam.	Stent Length
	mm	mm	mm	mm	mm	mm
71-132	10	20	8	33	9	27
71-134	10	42	8	54	9	48
71-136	10	68	8	77	9	69
71-138	10	94	8	115	9	103
40210	12	20	10	31	11	26
40211	12	40	10	51	11	47
40212	12	60	10	73	11	66
40213	12	90	10	110	11	100
40310	14	20	12	33	13	27
40311	14	40	12	50	13	46
40312	14	60	12	72	13	65
40313	14	90	12	107	13	98
40330	16	20	14	28	15	23
40331	16	40	14	49	15	45
40332	16	60	14	70	15	64
40333	16	90	14	105	15	97

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Venous are indicated for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥30% for a vein ≤10 mm in diameter or ≥50% for a vein >10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are the innominate and subclavian veins, ranging from 8.0 mm to 15 mm in diameter.

CONTRAINDICATIONS

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are contraindicated for use in patients with bleeding disorders unresponsive to vitamin K or blood product therapy.

WARNINGS

- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The long-term outcome following repeat dilation of venous stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.
- Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration. Refer to Table 1 for sizing information.

PRECAUTIONS

Stent Placement Precautions

- The target lesion should be predilated with a conventional balloon angioplasty catheter prior to stent placement.
- Do not release the stent if unusual force is required. If the stent does not deploy easily, use another device.
- Do not advance the delivery catheter without the guidewire extending from the tip.
- Do not fully deploy the stent if it is not properly positioned in the vessel.
- Do not advance a partially (≤50%) deployed stent. Reconstrain and then move distally. Partially deployed stents can be pulled proximally, if necessary.
- Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see step 10 in the Procedure Section.
- A stent cannot be repositioned after the deployment threshold has been exceeded.
- Implanting a stent may lead to dissection of the vessel distally, and/or proximally, to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., surgery, further dilation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by the stenting of the more proximal lesion(s). Stenting in this order obviates the need to cross the proximal stent in the placement of the distal stent and reduces the chance for dislodging the proximal stent.

- Stenting across a major side branch could obstruct the side branch and prevent or hinder percutaneous access or future interventions.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma or pseudoaneurysm.

Stent/System Removal Precautions

- If Stent/System removal is required prior to full deployment, and when the stent is ≤50% deployed, first attempt to reconstrain the stent and remove as described in step 8 of the Procedure Section. If the stent cannot be reconstrained, remove the entire Stent/System as follows:

  Hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.
- Failure to follow these steps could potentially result in loss of, or damage to, the stent or delivery system.

Post Implant Precautions

- Care must be exercised when crossing a newly deployed stent with intravascular ultrasound (IVUS), or a guidewire, or a balloon catheter to avoid disrupting the stent geometry.
- Be aware of the location of stented venous lesions. Dislodging stents with catheters or other transluminal devices may produce unexpected stent migration.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT™ Venous is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or lessGauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤1 W/kg for patient landmarks above the umbilicus (patient navel) and ≤2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus

RF Heating

Under the scan conditions defined above, WALLSTENT Venous is expected to produce a maximum in-vivo temperature rise of 3.1°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS

Observed Adverse Events

A total of 42 patients were enrolled in the multi-center study of WALLSTENT™ Venous Endoprosthesis for central lesions. This study was conducted at 12 investigational sites.

Patients from the WALLSTENT Venous Endoprosthesis study form the basis of the observed events described in Table 2.

Five (5) patients enrolled in the WALLSTENT Venous Endoprosthesis Study died during the trial. None of these deaths occurred in the first 6 months following the WALLSTENT procedure and none were considered device related. The cause of death was reported as follows: (1) hyperkalemia 475 days post procedure; (2 and 3) cardiac arrest at 343 and 631 days post procedure; (4) septicemia with peripheral vascular disease and gangrene 902 days post procedure; (5) stomach cancer 276 days post procedure.

Table 2. Safety Results, WALLSTENT Venous Endoprosthesis Central Patients (n=42)

Adverse Event	Result	95% C.I.
General Events		
Death	11.9% (5/42)	[4.0%, 25.6%]
Surgical Revision	4.8% (2/42)	[0.6%, 16.2%]
Access abandoned from central lesion	40.5% (17/42)	[25.6%, 56.7%]
Access abandoned from peripheral graft	21.4% (9/42)	[10.3%, 36.8%]
Non-Stent-Related Events		
Graft Occlusion/Restenosis	45.2% (19/42)	[29.8%, 61.3%]
Pseudoaneurysm	16.7% (7/42)	[7.0%, 31.4%]
Infection	14.3% (6/42)	[5.4%, 28.5%]
Hematoma	4.8% (2/42)	[0.6%, 16.2%]
Stent-Related Events		
Stent Restenosis	76.2% (32/42)	[60.5%, 87.9%]
Stent Thrombosis	50.0% (21/42)	[34.2%, 65.8%]
Migration	2.4% (1/42)	[0.1%, 12.6%]
Edema	40.5% (17/42)	[25.6%, 56.7%]

Results are percent (count/sample size) of all patients experiencing the event, and reflect each patient's entire study experience regardless of length of follow-up.

Mean ± SD (sample size) (min, max) length of follow-up in days; 350.5±299.4 (42) (4.0, 1434). Confidence intervals are based on exact limits.

Note: Surgical revision refers to those events where the graft was revised, but not abandoned. Patients reporting edema are a subset of patients with stent restenosis/thrombosis.

Additional clinical safety data were retrospectively obtained on 12 patients enrolled in a physician's registry study of the WALLSTENT Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. Four deaths were reported among these 12 patients. The reported cause and time of occurrence of these deaths is: sepsis at 16 days post-procedure, aspiration pneumonia at 32 days post-procedure, myocardial infarction/subdural hematoma at 81 days post-procedure, and hypotension at 240 days post procedure.

Adverse events related to either the stent or the stent implant procedure included stent thrombosis (5), stent restenosis (8), stent migration (3), and an allergic reaction to contrast media (1). The three stent migrations in this physician single-center study and the one stent migration in the multi-center WALLSTENT Venous Endoprosthesis central lesion study were attributed to incorrect sizing of the stent and/or dislodgment with the guide catheter. All of the stent migration cases were treated with a percutaneous procedure and none resulted in abandonment of the access site.

Potential Adverse Events

Potential adverse events associated with use of the WALLSTENT™ Venous Endoprosthesis may include the usual adverse events reported for conventional percutaneous transluminal angioplasty such as: hemorrhage, infection, contrast media reactions, dissection, distal emboli, graft rupture, graft/vein thrombosis or occlusion, perforation of the vein, suture disruption of the anastomosis, thromboembolism or transient spasm.

Potential adverse events associated with the WALLSTENT Venous Endoprosthesis are stent misplacement, stent migration, or vein perforation.

Observed Device Malfunctions

Two incidents of stent malfunction were reported in the central venous lesion study. In one incident, the delivery system failed to deploy. In the second incident, the stent did not fully expand.

CLINICAL STUDIES

A total of 42 patients at 12 investigational sites within the United States were enrolled in a prospective, multi-center, non-randomized study with a historical percutaneous transluminal angioplasty (PTA) control cohort to investigate the safety and efficacy of the WALLSTENT Venous Endoprosthesis for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis.

Primary Endpoint: The primary endpoint for the WALLSTENT Venous Endoprosthesis trial was circuit secondary patency at 6 months. Circuit Secondary Patency is defined as the proportion of patients, over time, that have an occluded vessel that is successfully opened. Failure of circuit secondary patency occurs at the time the dialysis site is abandoned due to the inability to treat the stenosis, or occlusion of either the central lesion under consideration or any other peripheral or de novo central lesion.

Other endpoints evaluated include:

Stent Primary Patency, defined as the proportion of patients, over time, that have had uninterrupted (intervention-free) patency since the initial procedure. Primary patency ends at the first occurrence of one of the following: initial re-intervention for the purpose of treating patency of the central lesion; anatomical failure (50% or greater stenosis) of the central lesion; or when the dialysis site is abandoned due to the inability to treat the original central lesion. If percent stenosis of the central lesion is undetermined, the occurrence of arm/face edema indicates the end of primary patency.

Stent Secondary Patency, defined as the time to failure of the access site due to stenosis or occlusion of the stented central lesion. Anatomical failure (>50% stenosis) of the central lesion which is not successfully reopened is also considered failure of stent secondary patency. Patients failing circuit secondary patency due to other peripheral lesions, problems at the access site (e.g. pseudoaneurysm, infection), or a de novo central lesion that does not involve the stent margin, do not fail stent secondary patency. These patients are censored from analysis at the date of the last follow-up documenting patency of the stent.

Patency rates were estimated by means of Kaplan-Meier Survival Analysis.

Patient Eligibility: Patients were eligible for the study if they were on chronic hemodialysis and had a central venous stenosis which was treatable with PTA. If the PTA failed to reduce the stenosis to less than 50% in patients with a vein >10 mm in diameter, or 30% in a vein ≤10 mm in diameter, the patient received a WALLSTENT Venous Endoprosthesis. If the PTA was successful, but the stenosis recurred within 4 months, the patient received a WALLSTENT Venous Endoprosthesis.

Study Methods: Clinical follow-up was obtained at 1 week, 2 months, 6 months, and every 6 months thereafter until study conclusion, or the graft site was abandoned. Baseline quantitative

angiography was performed pre-procedure, following balloon angioplasty, following device deployment, and at the 2-month and 6-month visit. The stent primary patency, stent secondary patency, and circuit secondary patency were analyzed.

Results: Among the 42 patients enrolled in the study, lesions involved the innominate vein in 14, subclavian vein in 23, and both subclavian and innominate veins in 5 patients. The mean lesion length was 25.8 mm (±18.8, range = 2.0-81.6 mm). Multiple stents were implanted in 5 patients (11.9%). A total of 28.6% of the patients (12/42) had occluded (100% stenosis) veins at the time of the study enrollment.

Initial intraoperative success, as measured by the reduction in stenosis to <30%, or angiographic demonstration of an increase in venous outflow, was achieved in 100% of patients. Analysis of the clinical data demonstrated a 74.3% circuit secondary patency rate at six months for the WALLSTENT™ Venous Endoprosthesis study group, compared to a 50% secondary patency rate for the historical control of percutaneous transluminal angioplasty (PTA), resulting in a highly significant statistical difference ($p<0.0003$). The WALLSTENT Venous Endoprosthesis was found to provide superior efficacy in the central venous patient cohort when compared to the historical control (PTA).

Baseline demographic and lesion characteristics were individually regressed on time to loss of circuit secondary patency to assess possible predictors of clinical outcome (univariate analysis). Presence of an occluded lesion pre-procedure was significantly associated with circuit secondary patency ($p=0.022$). The same variables were analyzed using stepwise selection to identify a multivariate predictor model. Presence of a totally occluded lesion pre-procedure was the only variable associated with time to loss of circuit secondary patency ($p=0.0072$). Implantation of multiple stents approached significance in the multivariate model ($p=0.062$).

Principal Efficacy and Safety results are summarized in Table 3.

Table 3. Principal Efficacy and Safety Results, BSC Patients (n=42)

Efficacy Measures	Result	95% C.I.
Device Success	100.0% (42/42)	[91.6%,100.0%]
Initial Intraoperative Success:		
Criterion 1: 30% Residual Stenosis	64.3% (27/42)	[48.0%,78.4%]
Criterion 2: Increased Venous Flow	90.5% (38/42)	[77.4%,97.3%]
Met Either Criteria	100.0% (42/42)	[91.6%,100.0%]
Acute Procedure Success	64.3% (27/42)	[48.0%,78.4%]
Initial Clinical Success	95.8% (23/24)	[78.9%,99.9%]
Pre-PTA RVD (mm)	12.6±3.7 (42) (3.0,20.1)	[11.5,13.7]
Post-Stent MLD (mm)	8.8±2.8 (39) (3.7,20.2)	[7.9,9.7]
Post-Stent %DS	24.1±18.4 (42) (0.0,63.0)	[18.5,29.6]
6-Month RVD (mm)	10.4±3.3 (25) (4.0,18.3)	[9.1,11.7]
6-Month MLD (mm)	3.0±2.7 (26) (0.0,11.0)	[1.9,4.0]
6-Month %DS	67.9±29.1 (26) (9.0,100.0)	[56.7,79.1]
Patency		
6-Month Stent Primary Patency (K-M)24.4%		[9.8%,39.0%]
6-Month Stent Secondary Patency (K-M)82.5%		[69.7%,95.2%]
6-Month Circuit Secondary Patency (K-M)74.3%		[60.6%,88.1%]
Stent Restenosis	76.2% (32/42)	[60.5%,87.9%]
Arm-Face Edema	40.5% (17/42)	[25.6%,56.7%]
Safety Measures	**Result**	**95% C.I.**
Major In-Hospital Event	0.0% (0/42)	[0.0%,8.4%]
Out-of-Hospital (Stent-Related) Event		
Stent Thrombosis	50.0% (21/42)	[34.2%,65.8%]
Migration	2.4% (1/42)	[0.1%,12.6%]
Death	11.9% (5/42)	[4.0%,25.6%]

Results are mean ± SD (sample size) (min, max) for continuous variables, and percent (count/sample size) for binary variables.

Confidence intervals for binomial proportions are based on exact limits.

Patency rates are Kaplan-Meier estimates at 180 days; confidence intervals based on Greenwood standard errors.

RVD = Reference Vessel Diameter.

MLD = Minimum Lumen Diameter.

%DS = percent diameter stenosis which refers to "within lesion" measurement technique.

Device Success = Stent(s) deployed completely.

Initial Intraoperative Success, Criterion 2 = angiographic demonstration of an increase in venous outflow (visualization of less collateral flow, more rapid rate of contrast media clearing or less reflux flow post-procedure).

Acute Procedure Success = ≤30% residual stenosis and absence of major in-hospital event.

Initial Clinical Success = <20% recirculation fraction one week post-procedure. (Note: incomplete number of assessments (n=24) reflects a change in clinical practice during the course of the study in which many institutions stopped using recirculation fractions to monitor patients.)

Stent Restenosis = within stent %DS of 50% or greater, or in the absence of angiography, the presence of arm-face edema.

Stent Thrombosis = total thrombotic stent occlusion documented by angiography. (Note: Stent Thrombosis is a subset of stent restenosis).

Additional clinical efficacy data was also retrospectively obtained on 12 patients enrolled in a physician's registry study of the WALLSTENT™ Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. The enrollment criteria for this study were similar to the multi center WALLSTENT Venous Endoprosthesis central lesion study. A Kaplan-Meier Survival analysis estimated the six-month circuit secondary patency, stent primary patency, and stent secondary patency rates at 68.6%, 33.8%, and 75%, respectively, for this patient cohort.

PATIENT SELECTION AND TREATMENT

Individualization of Treatment

The risks and benefits of using the WALLSTENT Venous Endoprosthesis should be carefully considered for each patient before use. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., bleeding disorders unresponsive to Vitamin K or blood product therapy, see Contraindications.)

Premorbid conditions that increase the risk of a poor initial result should also be considered. The relationship of baseline and procedural variables to failure of circuit secondary patency was examined. Presence of an occluded lesion pre-procedure was the only statistically significant predictor for failure of circuit secondary patency. Implantation of multiple stents approached significance in one analysis.

Use in Special Population

The safety and effectiveness of the WALLSTENT Venous Endoprosthesis have not been established for the following:

- Veins that are smaller than 8.0 mm or larger than 15 mm.
- Where stenting would not allow for sufficient puncture sites of the hemodialysis access.
- Where damage to a diseased or injured vessel may occur due to the self-expanding nature of the stent.
- Veins other than the innominate or subclavian.
- Lesions at or within 5 mm of the arterial anastomosis.
- When significant intraluminal thrombus is present after thrombolytic therapy.
- Multiple lesions greater than 4 cm apart.
- Patients for longer than 6 months.

OPERATIONAL INSTRUCTIONS

Preparation of the Delivery System for Insertion

1. **Recommended Material for Implant:**

   Prepare the following material using sterile technique:

   - 10 ml (cc) syringe filled with sterile saline.
   - 6F (2 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 6F (2 mm) delivery system.
   - 7F (2.3 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 7F (2.3 mm) delivery system.

- 9F (3.0 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 8F delivery system.
- 10F (3.3 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 9F delivery system.
- 0.035 in (0.89 mm) guidewire of appropriate length.

2. Device Selection

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant. After considering the nominal implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. (See Table 1) Should two stents be required to cover the lesion, place the distal stent first, followed by the proximal stent, and allow for generous overlapping. Deployed lengths reflect expansion to nominal vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

3. Initial Preparation of the Instrument:

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire device for damage or defects.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

4. Flushing the Delivery System:

- Attach a 10 ml (cc) syringe filled with sterile saline to the stopcock on the extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After priming the delivery system, close the stopcock and remove the syringe.
- Verify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the trailing end, exposing stent wires. Proper device function cannot be assured during implant, and such use may cause vessel injury.

VENOUS PROCEDURE

1. Use radiopaque marker bands to identify the area to be dilated and stented.
2. Place a 0.035 in (0.89 mm) exchange guidewire percutaneously into the vessel to be treated.
3. Dilate the venous lesion with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
4. Remove the balloon catheter, leaving the guidewire in place.
5. Having prepared the delivery system as previously described, insert the delivery system into the appropriate size introducer sheath and over the guidewire.

Note: Always use an introducer sheath for the implant procedure, to protect the puncture site, in the event a partially deployed stent were to be removed.

6. Guidelines for Stent Positioning:
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.

- The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.
- Maintain the delivery system as straight as possible during deployment of the stent.

7. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Precaution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see step 10.

---

8. Assess stent position and reposition if desired. To reposition, reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

Note: To facilitate reconstrainment, the delivery system may be flushed with heparinized saline.

---

9. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Precaution: A stent cannot be repositioned after the deployment threshold has been exceeded.

---

10. To remove a partially deployed stent, first reconstrain the stent (see step 8). If the stent cannot be reconstrained, remove the entire Stent/System as follows: Hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

    As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

11. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed. If desired, repeat balloon dilation inside the implanted stent may be performed to achieve nominal stent diameter. For this procedure, a new balloon dilatation catheter is recommended.

12. Using standard operative procedures, perform routine venography to demonstrate location and patency of the stent.

13. The implanted stent length should allow for adequate overlapping into the non-strictured vessel to compensate for further stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.

    If, prior to initial stent implantation, it is expected that a second stent will be necessary to cover the lesion, cover the distal end of the lesion with the first stent and use the second stent to cover the proximal portion of the lesion. This will minimize interference with placement of the second stent by the previously deployed stent.
14. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

PATIENT INFORMATION

Physicians will be provided, separately, copies of a Patient Guide that includes information on Venous stenosis, the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Venous, and the stent implant procedure.

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Consulte as Instruções de Utilização


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Magnetic Resonance Conditional
Ressonância magnética - utilização condicional

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MR **Magnetic Resonance Conditional**

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Patient Information Card

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Patient Name	Emergency Contact Number
Implanting Physician's Name	Stent Material
Physician's Phone Number	Date of Implant

PLEASE CARRY YOUR CARD AT ALL TIMES.

Before you have a Magnetic Resonance Imaging (MRI) scan, or for questions regarding your Stent System or procedure, please contact the implanting physician.

Boston Scientific, Patient Implant CardTemplate 3.375in x 6.3125in, Card, Patient, MB, Wallstent

Black (K) ΔE ≤5.0

Magnetic Resonance Conditional

Non-clinical testing has demonstrated the WALLSTENT™ system is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla
- Spatial gradient field of 1900 Gauss/cm
- Normal operating mode only with a maximum whole body (WB) averaged specific absorption rate (SAR) of ≤1 W/kg for patient landmarks above the umbilicus (patient navel) and ≤2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus

Score & Fold

MRI at 3 T or 1.5 T may be performed immediately following the implantation of the WALLSTENT. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

Score & Fold

Boston Scientific, Patient Implant Card Template 3.375in x 6.3125in, Card, Patient, MB, Wallstent

Stent Identification Information

Product Name	Product Name
Product Code	Product Code
Product Lot Number	Product Lot Number
Stent Location	Stent Location

Black (K) ΔE ≤5.0

Document Title	MRI WALLSTENT Endoprosthesis*
Document Number	(b)(4)
Project Name	WallStent Recertification
Project Number	(b)(4)
Author(s)	
Contributor(s)	

** This Technical Report includes MR Safety testing data for the WallStent Uni device and supports the MR Safety labeling for the* WallStent RP Endoprosthesis, WallStent Endoprosthesis, and WallStent Uni Endoprosthesis. *Refer to* (b)(4) *(US & IC, OUS),* (b)(4) *, and* (b)(4) *for UPN's in the scope of this Technical Report.*

Refer to Technical Report (b)(4) ***for MR Safety testing data for the Carotid WallStent (product specification documents*** (b)(4) ***and*** (b)(4) ***).***

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Test Report

Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging according to ASTM F2182-02a

MR system: 1.5 Tesla, Intera, Philips Medical Systems (PMS)

Test object: WALLSTENT® UNI

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Test Report

Evaluation of MR Image Artifacts from Passive Implants
according to ASTM F2119-07

MR system: 3 Tesla, Achieva, Philips (PMS)

Test object: WALLSTENT® UNI

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3.2.1.2 SE sequence, test object long axis parallel to B_0, transversal view, cross section

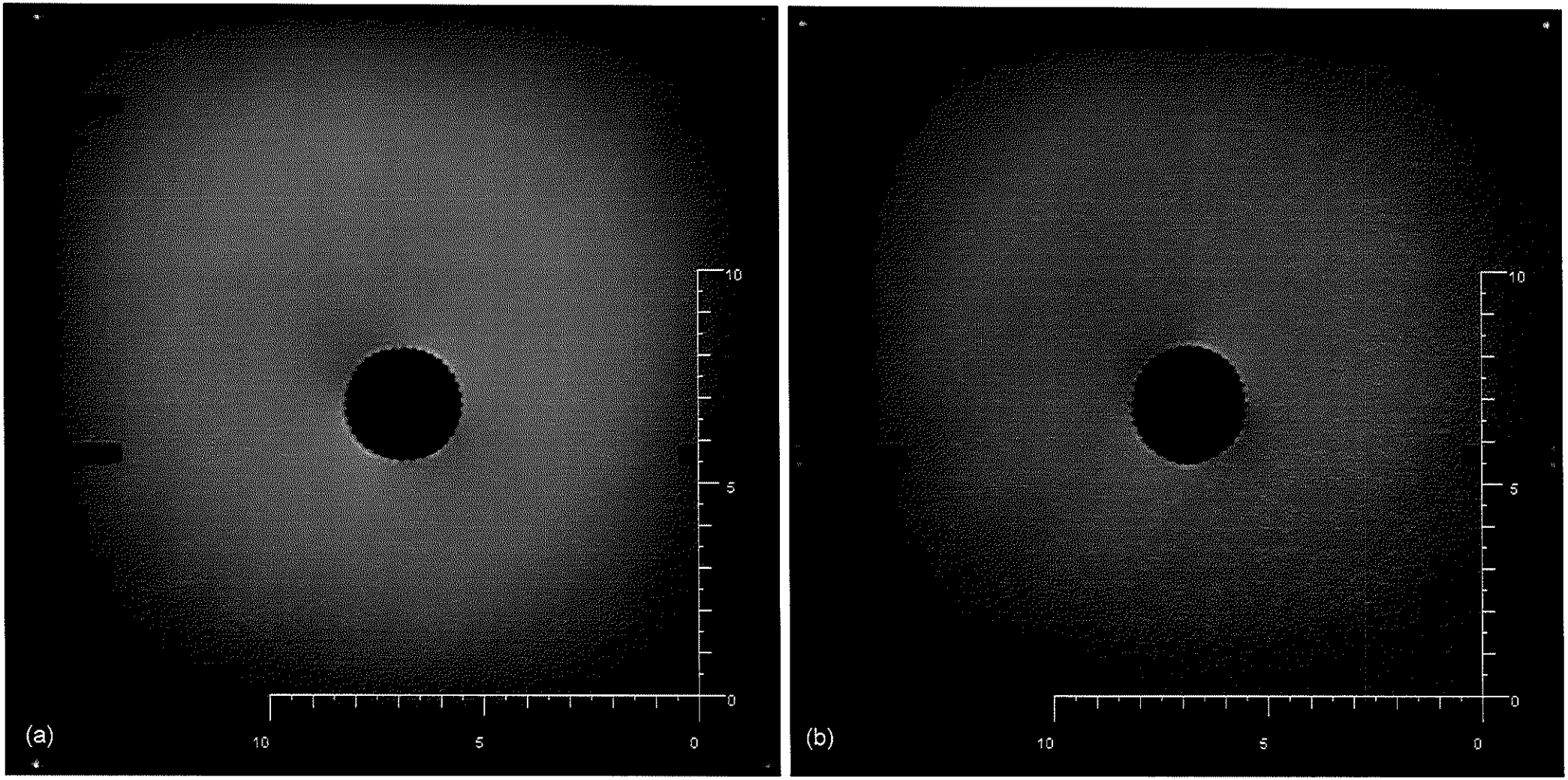

FIG. 7: Phase encode AP (a), RL (b)

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Technologie Zentrum AG

Technical Protocol
MR protocol for in-vitro testing of geometry artifacts on stents

Document # (b)(4) **-MR-protocol-for-in-vitro-testing-of-geometry-artifacts-on-stents_A.doc**

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Report

Numerical and Metrological Evaluation of SAR Distribution within a Gel Filled Body Phantom of ASTM Standard F2182-02a

MR system: MR system: 1.5 Tesla, Intera, Philips Medical Systems (PMS)

Purchaser:

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Report

Numerical and Metrological Evaluation of SAR Distribution within a Gel Filled Body Phantom of ASTM Standard F2182-02a

MR system: 3 Tesla, Magnetom Trio, Siemens Medical Solutions (SMS)

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healthsciences

Summary, conclusions and recommendations: adverse temperature levels in the human body

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(*Received 14 January 2003*)

In the spring of 2002, The World Health Organization workshop 'Adverse Temperature Levels in the Human Body' brought together scientists with expertise in biological effects of hyperthermia to review the data and determine the evidence that could be used to evaluate potential adverse effects from human exposures to radiofrequency (RF) electromagnetic radiation in the range of 10–300 GHz. Standards for RF exposure in this frequency range are based currently on thermal effects. Information was reviewed on the ability of hyperthermia, either to the whole body or to part of the body to affect physiology, particularly the heart and circulatory system, to induce other thermoregulatory responses such as sweating, to affect the performance of simple and complex mental tasks, to induce various heat-related disorders such as heat stroke and to damage body tissue. Risks to a variety of organs were considered. In addition, thresholds for effects on developing embryos and foetuses and possible carcinogenic effects were also examined. These findings were discussed in the context of known cellular and biochemical responses of cells and tissues to hyperthermia. The experts judged the relevance of each study for informing decision-makers on the scientific basis for establishing safe exposure levels. The consensus was that standards should consider both temperature and time of exposure, whenever possible.

Key words: Hyperthermia, normal tissue, carcinogenesis, embryo, threshold risk.

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MODELING RF HEATING OF ACTIVE IMPLANTABLE MEDICAL DEVICES DURING MRI USING SAFETY INDEX

A THESIS
SUBMITTED TO THE DEPARTMENT OF ELECTRICAL AND ELECTRONICS ENGINEERING
AND THE INSTITUTE OF ENGINEERING AND SCIENCES
OF BILKENT UNIVERSITY
IN PARTIAL FULLFILMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
MASTER OF SCIENCE

By
Halise Irak
August 2007

I certify that I have read this thesis and that in my opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Science.

Prof. Dr. Ergin Atalar (Supervisor)

I certify that I have read this thesis and that in my opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Science.

Prof. Dr. Nevzat Gençer

I certify that I have read this thesis and that in my opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Science.

Assist. Prof. Dr. Vakur Ertürk

Approved for the Institute of Engineering and Sciences:

Prof. Dr. Mehmet B. Baray
Director of Institute of Engineering and Sciences

ABSTRACT

MODELING RF HEATING OF ACTIVE IMPLANTABLE MEDICAL DEVICES DURING MRI USING SAFETY INDEX

Halise Irak

M.S. in Electrical and Electronics Engineering

Supervisor: Prof. Dr. Ergin Atalar

August 2007

Magnetic Resonance Imaging (MRI) is known as a safe imaging modality that can be hazardous for patients with active implantable medical devices, such as a pacemakers or deep brain stimulators. The primary reason for that is the radio frequency (RF) heating at the tips of the implant leads. In the past, this problem has been analyzed with phantom, animal and human experiments. The amount of temperature rise at the lead tip of these implants, however, has not been theoretically analyzed. In this thesis, a simple approximate formula for the *safety index* of implants, which is the temperature increase at the implant lead tip per unit deposited power in the tissue without the implant in place, was derived.

For that purpose, an analytical quadrature birdcage coil model was developed and the longitudinal incident electric field distribution inside the body was formularized as follows:

$$E_z(R) = -\omega \mu H_- \mathrm{R}$$

in which ω is the angular frequency, μ is the magnetic permeability of the tissue, H_- is the left hand rotating component of the RF magnetic field and R is the radial distance from the center of the body. This formula was examined by simulations and phantom experiments. The analytical, simulation and experimental results of that model are in good agreement.

Then, depending on the quadrature birdcage coil model safety index (SI) formula for active implants with short leads was derived as shown below:

$$SI = \frac{\Delta T_{\max}}{SAR_{\text{peak}}} = \frac{1}{2\alpha c_t R_b^2}\left|Rl + Ae^{j\theta}\right|^2 f(Dv)$$

where ΔT_{max} is the maximum temperature increase in the tissue, SAR_{peak} is the maximum deposited power in the body when there is no implant in the body, α is the diffusivity of the tissue, c_t is the heat capacity of the tissue, R_b is radius of the body, R is the radial distance from the center of the body, l is the length of the implant lead, A is the area of the curvature of the lead, θ is the angle that curvature of the implant makes with the radial axis, and $f(Dv)$ is the perfusion correction factor, which is function of the diameter of the electrode and perfusion. The safety index formula was tested by simulations. Simulation results showed that the theoretical safety index formula approximates and identifies the RF heating problem of active implants with short leads accurately.

The safety index formula derived in this thesis is valid for only short wires. However, the formulation for long wires is currently under investigation. Despite the fact that the results obtained for short leads can not be generalized for the safety of patients with active implants, it is believed that this study is the first step towards safety of these patients. Using safety index as a measure of safety is very beneficial to ensure the safety of patients with active implants. Because, it uses the MR scanner-estimated deposited power that does not take the existence of the implant in the patient body into account. This formulation is the first study illustrating the advantage of the safety index metric for RF heating studies of active implants.

Keywords: MRI, RF heating, Active Implants, RF Safety, Safety Index, Quadrature Birdcage Coil

ÖZET

VÜCUDA TAKILABİLEN TIBBİ ELEKTRONİK ÜRETEÇLERİN MR GÖRÜNTÜLENMESİNİN GÜVENLİK İNDEKSİ KULLANILARAK RADYO FREKANS MODELLENDİRİLMESİ

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MR görüntüleme güvenli bir görüntüleme tekniği olarak bilinmektedir. Fakat kalp pili ve derin beyin uyarıcıları gibi tıbbi elektronik üreteçler taşıyan hastalar için tehlikeli olabilir. Bunun temel nedeni elektronik üreteçlerin kablolarında bulunan elektrotların radyo frekans (RF) dalgalar nedeniyle ısınmasıdır. Geçmişte bu problem insan modelleri, hayvanlar ve insanlar üzerinde yapılan deneylerle analiz edilmiştir. Ancak bu üreteçlerin elektrotlarında meydana gelen sıcaklık artışı teorik olarak analiz edilmemiştir. Bu tezde, üreteçlerin *güvenlik indeks'*ini yaklaşık olarak hesaplayan basit bir formül türetilmiştir. *Güvenlik indeks'*i vücutta üreteç varken meydana gelen sıcaklık artışının, üreteç olmadığı zaman dokuda depolanan birim enerjiye oranı olarak tanımlanmaktadır.

Bu amaçla, analitik çeyrek evre kuş kafesi sargı modeli geliştirilmiş ve vücuda boylamsal düşen elektrik alan dağılımı aşağıdaki gibi formülleştirilmiştir:

$$E_z(R) = -\omega \mu H_- \mathrm{R}$$

bu formülde ω açısal frekansı, μ dokunun manyetik geçirgenliğini, H. RF manyetik alanın sol el kuralına göre dönen bileşenini ve R vücudun merkezinden olan radyal uzaklığı simgelemektedir. Bu formül simulasyonlar ve

insan modeli deneyleriyle sorgulanmıştır. Bu modelin analitik, simulasyon ve deney sonuçları büyük oranda uyuşmaktadır.

Bu formülasyona dayanarak kısa kablolu elektronik üreteçlerin Güvenlik İndeks (Gİ) formülü aşağıdaki gibi türetilmiştir:

$$SI = \frac{\Delta T_{\max}}{SAR_{\text{peak}}} = \frac{1}{2\alpha c_t R_b^2} \left| Rl + Ae^{j\theta} \right|^2 f(Dv)$$

Bu formülde ΔT_{max} dokudaki maksimum sıcaklık artışını, SAR_{peak} vücutta üreteç yokken biriken maksimum gücü, α dokudaki yayılma gücünü, c_t dokunun sıcaklık kapasitesini, R_b vücudun yarı çapını, R vücudun merkezinden olan radial uzaklığı, l üretecin kablo uzunluğunu, A kablonun eğrilik alanını, θ üretecin kablo eğrisinin radyal eksenle yaptığı açıyı ve $f(Dv)$ elektrot çapına ve perfüzyona bağlı olan perfüzyon düzeltme faktörünü simgelemektedir. Güvenlik indeks formülü simulasyonlarla test edilmiştir. Simulasyon sonuçları teorik güvenlik indeks formülünün yaklaşık olarak kısa kablolu üreteçlerin RF ısınma problemini açıkladığını göstermiştir.

Bu tezde türetilen güvenlik indeks formülü kısa kablolar için geçerlidir. Uzun kablolar için olan formül üzerinde çalışmalar devam etmektedir. Kısa kablolarla elde edilen sonuçlar üreteçleri olan hastaların güvenliği için genellenemese de, inanıyoruz ki bu çalışma bu hastaların güvenliği için yapılacak olan çalışmalara öncü nitelik taşımaktadır. Güvenlik indeksini güvenlik ölçütü olarak kullanmak, MR tarayıcının tahmin ettiği vücutta üreteç yokken depolanan gücü kullanarak hesaplandığı için elektronik üreteçleri olan hastaların güvenliğini sağlamak açısından oldukça faydalıdır. Bu formülasyon güvenlik indeksini güvenlik ölçütü olarak almanın ne kadar faydalı olduğunu göstermek açısından elektronik üreteçlerin RF ısınması üzerine yapılan ilk çalışmadır.

Anahtar Kelimeler: MR Görüntüleme, RF Isınma, Elektronik Üreteçler, RF Güvenlik, Güvenlik İndeksi, Çeyrek Evre Kuş Kafesi Sargısı.

To my father Hamdullah and Prof. Ergin Atalar

for giving me a chance.

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Chapter 1

Introduction

1.1 Motivation and Literature Survey

There is an increasing demand for MRI exams of patients with active implantable medical devices (AIMD) such as pacemakers and deep brain stimulators. Unfortunately, these patients are barred from MRI exams primarily due to the possibility of hazardous RF heating at the lead tips of the implants. Despite the fact that most of the studies on the RF heating of implants are limited by testing of leads with phantom [1-3], animal [4] and human [5] experiments, there are a small number of quantitative studies [6-8]. These assessments focus on the heating of a straight wire as a good approximation for the RF heating of an implant with insulation [6], without insulation[6, 7], and insulation with exposed tips [7, 8]. Furthermore, the effects of loops constructed by leads were computed [9] and observed experimentally with phantom experiments [3, 10-12]. In the literature, there is no study with the aim of finding an analytical formula for the problem of AIMD heating. Such formula will enable us 1) to understand the parameters affecting the tip heating; 2) to determine the maximum power that can be safely applied during an MRI examination; and 3) to develop novel and effective methods to reduce coupling between AIMD and the MRI scanner.

It was reported [13] that just after an MRI examination of the head at 1 Tesla (T), a 73-year-old patient with bilateral implanted deep brain stimulator electrodes for Parkinson disease showed dystonic and partially ballistic movements of the left leg. Despite the fact that MR imaging of patients with deep brain stimulators was performed many times at 1.5 T with no side effects

before this incident, this incident shows that the generalization of the same conditions even at lower field strengths, i.e. 1 T, can be dangerous. Consequently, it is suggested [14-17] that each MRI system and update of the same system needs a specific safety regulation assessed with a preclinical study for the RF heating of the specific implant leads during MRI examinations. According to these studies [14-18], since MRI scanner calculated SAR does not take the existence of the active implants in the body into account, it is not reliable to use it for ensuring the safety of patients. Therefore, safety recommendations developed for a certain system, i.e. type of implant, body coil, MRI system and field strength, especially when the estimated SAR of the system is concerned may not be implemented across different MRI systems.

As it is seen, there is a doubt in the literature for the reliability of SAR (when there is an implant, people do not speak much on SAR but they focus on temperature) for the RF safety of patients with active implant. All of these controversies imply that all parameters of the RF heating problem should be clearly determined and put in a comprehensible form such that it becomes easier to develop universal RF safety limits. To achieve such practical format, the RF heating of active implants should be analytically analyzed. Considering the variety of the MRI scanners and active implants, and how regularly they are updated, it is more realistic to search for a consistent solution in which the type of the MRI system is not a parameter.

In this study, the MRI-related RF heating problem of active implantable medical devices (AIMDs) with a single short lead considering the curvature of the lead was theoretically analyzed at 1.5 T. The *safety index* [6] of active implants; the temperature rise at the implant lead tip per unit deposited power in the tissue without the implant in place, was also formulated. For that purpose, an active implant was placed in an infinitely long cylindrical human body model. It is assumed to lie coaxial with the transmit body coil. Then, the incident electric field on the implant was analytically found under the quasistatic assumption.

Next, the induced current, the SAR amplification and the resultant temperature increase in the tissue was formulated in terms of the electrical and thermal characteristics of the tissue and the characteristics of the implant configuration such as radius of the tip, length of the lead, area of the lead curvature and the position of the implant. Finally, the resultant temperature at the tip was normalized with the peak SAR in the body to find the safety index of the active implant. As a result of this analysis, it was aimed to explain how important and practical to use *safety index* metric in order to ensure the RF heating safety of active implants. Thus, this study shows that RF heating can be analytically identified and the safety index formula helps the standardization of the MRI-related RF heating problem. Besides, since it is required to calculate the safety index, scanner estimated SAR was shown to be vital for the RF safety of patients with active implants.

1.2 The Objective and Scope of the Thesis

In this thesis, an analytical analysis of the RF heating problem of AIMDs was done with the purpose of deriving a general formulation for the safety index of AIMDs. After calculating the induced electrical field on the cylindrical human model, the amplified absorbed power at the tip of the AIMD was found. Next, the temperature increase in the tissue was studied and finally the safety index of the AIMD was calculated by normalizing the temperature rise with respect to the absorbed power in the tissue when the AIMD is not in place.

This thesis has been divided into six chapters. Chapter 1 is devoted to the introduction and motivation. Chapter 2 explains the RF heating model of AIMDs during MRI scans with its implementation on an AIMD inside a cylindrical human body model under the quasistatic assumption. Chapter 3 contains the materials and methods used for the testing of the analysis. Chapter 4 is devoted the obtained results whereas Chapter 5 goes into the discussions of the results. Finally, Chapter 6 includes the conclusions of the thesis with the future work.

In the appendix, additional information about the Fourier transform convention and the special integral identities used during the calculations are presented.

Chapter 2

Theory

2.1. Introduction

A typical active implantable medical device (AIMD) with a single lead is shown in Figure 1. In order to analyze the RF heating of these types of implants, a general configuration was developed. The length of the lead was shortened despite the fact that it is very long. Also, the lead was considered as curved rather than looped around itself.

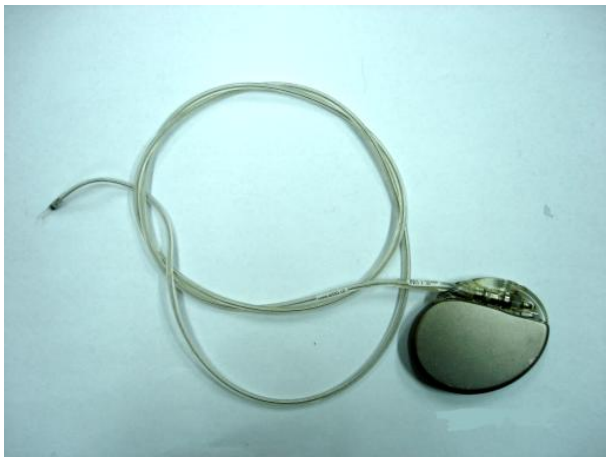

Figure 1. The photography of a typical active implantable medical device. The device shown in the figure is a pacemaker (Regency SC+ 2402L, Pacesetter, Switzerland).

In that chapter, first an early proposed RF heating model was explained. Also, the safety index of an AIMD was calculated based upon that model with underlined simplifying assumptions. The same derivations for the safety index were overviewed and simplified with a novel quadrature birdcage body coil model.

2.2. RF Heating Model

When a body undergoes an MRI examination, the body heats up due to the RF fields transmitted by the MRI scanner. The underlying mechanism behind the RF heating was modeled by Bottomley et al [19] and formulated what happens when there is an implant by Yeung et al [6]. This model was developed at 1.5 T for two cases; when there is an implant in the body and there is not an implant in the body. The detailed explanations are given in the following subsections.

2.2.1. RF Heating Model without Implants

RF heating of a body without an implant is the most common case. The body is exposed to the RF power of a transmitting body coil when there is no metallic implant in the body [20]. As shown in Figure 2, P is the time-averaged input power and determined by the applied RF pulse of the imaging sequence. This input power causes power deposition, characterized by specific absorption rate (SAR) and a function of position $\vec{r}$, in the body with respect to the electromagnetic properties of the tissue. Afterwards, this SAR distribution is converted into temperature distribution, which is a function of position $\vec{r}$ as well, depending on the thermal properties of the body [21].

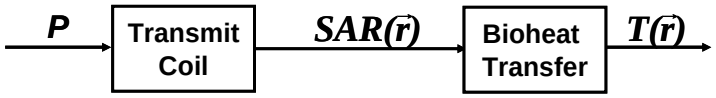

Figure 2. Flow-chart model of RF heating in MRI when there is no implant in the body. This figure is copied from reference [21].

The SAR is calculated from the electric field distribution in the body according to the following equation:

$$SAR = \frac{\sigma}{\rho_t} |E|^2 \quad \textbf{(1)}$$

where σ is the electrical conductivity of the tissue , ρ_t is the mass density of the tissue, and E is the rms amplitude of the RF electric field transmitted by the body coil. This can be calculated by using Maxwell's equations.

The temperature distribution in the body can be calculated by the bioheat equation first proposed by Pennes [22].

$$\frac{dT(\bar{r},t)}{dt} = \alpha \nabla^2 T(\bar{r},t) - \frac{\alpha \rho_b c_b m}{c_t}\left(T(\bar{r},t) - T_b\right) + \frac{1}{c_t} SAR(\bar{r},t) + Q \qquad \textbf{(2)}$$

in which c_t and α are the heat capacity and thermal diffusivity of the tissue respectively, c_b, ρ_b and T_b in that order are the heat capacity, mass density and temperature of the perfusing blood, m is the volumetric flow rate of blood per unit mass, Q is the heat generated by normal chemical processes in the body, ∇ is the Laplacian operator, and $\bar{r}$ is the position vector. When it is assumed that metabolic heat generation keeps the core body temperature steady with the perfusing blood temperature [21], the Eq.(2) can be written as follows:

$$\frac{d\Delta T(\bar{r},t)}{dt} = \alpha \nabla^2 \Delta T(\bar{r},t) - \alpha v^2 \Delta T(\bar{r},t) + \frac{1}{c_t} SAR(\bar{r},t) \qquad \textbf{(3)}$$

where $\Delta T = T - T_b$ and *v,* defined as $v = \sqrt{\rho_b c_b m / \alpha c_t}$, is the lumped perfusion constant. Notice that with that assumption the effect of the thermoregulation constant, Q, is assumed to be zero.

Even if the analytical solution of Eq. (3) is not possible, in case of local heating, it is possible to achieve an approximate solution with the following simplifying assumptions. First, the thermal parameters are assumed to be constant around the point of interest over a small temperature range. Next, the local region is assumed to be small with respect to whole body and not near the surface of any boundary. With these assumptions, Green's function of the bioheat equation can be used to find the spatial temperature distribution [21] as the following equation:

$$\Delta T(\bar{r}) = SAR(\bar{r}) * G(\bar{r}) \qquad \textbf{(4)}$$

where '*' denotes convolution and $G(\bar{r})$ is the Green's function of the bioheat equation as a function of position vector.

Green's function of the bioheat equation in the cylindrical (line source) and spherical (point source) coordinates for steady state are given respectively in Eq. (5) and Eq.(6).

$$G(R) = \frac{1}{2\pi\alpha c_t} K_0\left(vR\right) \quad \textbf{(5)}$$

$$G(r) = \frac{1}{\alpha c_t} \frac{e^{-vr}}{4\pi r} \quad \textbf{(6)}$$

where R is the distance from line source, r is the distance from point source, v is a lumped perfusion parameter, α is the diffusivity of the tissue, c_t is the heat capacity of the tissue, and K_0 is the modified Bessel function of the second kind and order zero.

The time-dependent Green's function of the bioheat equation in cylindrical in and spherical in coordinates are given in [21].

2.2.2. RF Heating Model with Implants

RF heating of a body with an implant is a very complex case because of the coupling of the transmitting coil with the metallic implant [20]. When there is an implant in the body during an MRI procedure, the absorbed power (SAR) in the body is amplified around the implant. This amplification is quantified with SAR gain as shown in Figure3A. With current technology it is not possible to know the resultant amplified SAR, denoted SAR' in Figure3A in the body. Yet, the deposited power when there is no implant in the body, that is SAR, can be estimated because the current MRI scanners are designed in a way that the applied power level is always lower than the patient safety limits. Therefore, it is reasonable to combine the raw SAR gain with the bioheat transfer into one unit, safety index [6], so that we can have a system with an estimated input, SAR, in

order to be able find the resultant temperature distribution in the body as shown in Figure3B. This helps to ensure safety of patients with implants by setting limits on the applied SAR of the imaging pulse sequence.

Thus, the safety index expresses the temperature increase as a consequence of the existence of an implant in the body for each unit of peak applied SAR when there is no implant in the body.

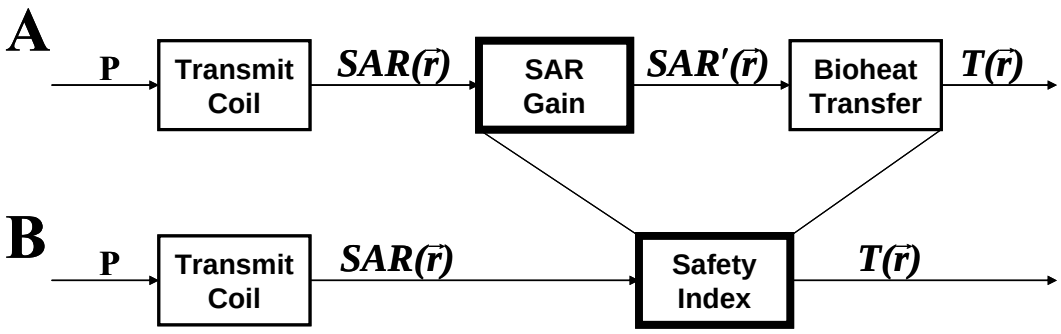

Figure 3. Flow-chart model of RF heating in MRI in case there exists an implant in the body. This figure is copied from reference [6].

2.3. Safety Index of Active Implants

With the proposed RF heating model for the existence of an implant in the body exposed to MRI-related RF fields, in that section, the safety index of active implants is obtained analytically by implementing each system in the RF heating model.

The analysis for the coupling of the transmit coil with a metallic implant in the body during an MRI examination is rather complicated despite the fact that it is straightforward for an electromagnetic solver software to analyze. Therefore, the theoretical analysis of the implant lead tip heating problem is not possible without some simplifying assumptions.

In order to make the first order approximation for the RF heating of an AIMD lead tip, the human body was assumed to be an infinitely long cylindrical object with uniform electromagnetic properties as in earlier studies [19, 23-25]. It was assumed to be lying coaxial with the transmit body coil. Besides, similar to these studies, the diameter of the body was assumed to be small compared to the wavelength.

On the other hand, considering the variety of AIMD configurations, the implant in Figure 1 was simplified for the analysis as shown in Figure 4. The common structure of an AIMD includes at least one insulated lead with a bare lead tip and a generator with a metallic case. Besides, the size of the implant including its leads was assumed to be significantly smaller than the wavelength; hence quasistatic RF fields can be used around the implant during the analysis.

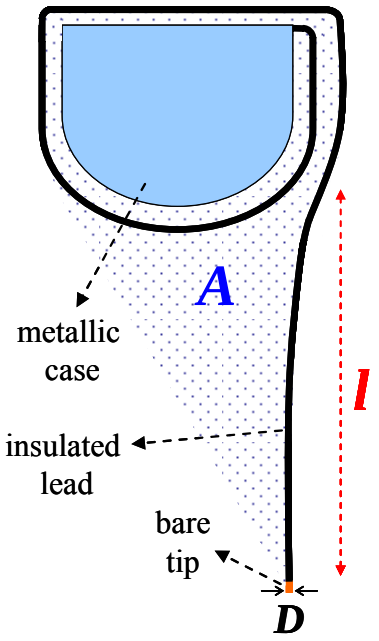

Figure 4. Model of an active implantable medical device. In this figure, D is the diameter of the tip; A is the area of the curvature; and l is the z-component of the distance between the metallic case and the electrode tip.

2.3.1. Calculation of SAR at the Implant Tip

The transmitted RF magnetic and electric fields of the body coil are coupled with the active implant in a way that a potential difference between the metallic case and the bare tip is induced. This gives rise to a current induction on the implant lead. This current is scattered from the bare tip to the tissue. Since tissue is a lossy medium, this scattered current amplifies the absorbed power already induced by the transmitted RF magnetic field in the body.

2.3.1.1. Calculation of Induced Current

There are two sources of voltage induction between the metallic case and the bare tip; the transmitted RF magnetic field and electric field. The resultant potential difference gives rise to a current induction at the lead tip of the implant depending on the impedance of the tip in a way that will be explained next. The equivalent circuit of an implant shown in Figure 5 illustrates the parameters affecting the current induction at the tip.

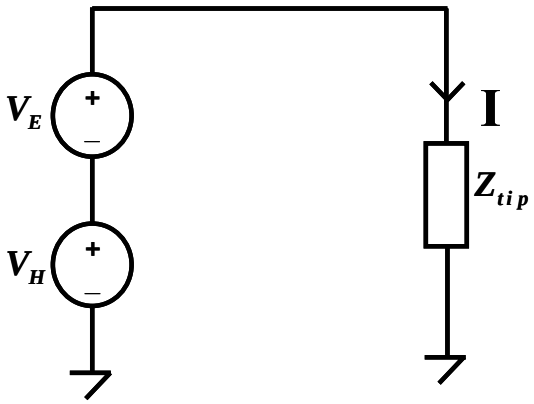

Figure 5. Equivalent circuit of the active implant model. V_E is the voltage source due to the coupling of the transmitted electric field with the straight part of the lead. V_H represents the voltage source because of the coupling of the transmitted magnetic field with the curvature of the lead. Z_{tip} is the impedance of the tip.

The first source comes from the coupling of the straight part of the lead with the incident electric field. It is calculated as follows:

$$V_e = \bar{E}_z(R) \cdot \bar{l} \qquad \textbf{(7)}$$

where $E_z(R)$ is the transmitted electric field in longitudinal direction and varies only in the radial direction on the body, and l is the distance between the metallic case and the tip in z-direction. In most of the studies calculating the deposited power around a straight wire [6, 7]; the maximum coupling between the electric field and the straight wire was achieved when the electric field is incident parallel to the wire. In our case, the transmitted electric field was also parallel to the straight part of the lead for maximum coupling. Then, Eq.(7) is reduced to the following:

$$V_e = E_z(R)l \quad \textbf{(8)}$$

Reilly and Diamant [26] used the same idea for the excitation of a nerve fiber by an external electric field to analyze the peripheral nerve stimulation.

On the other hand, the second source comes from the coupling of the curvature constructed by the lead with the RF magnetic field. This source of voltage induction can be calculated by Maxwell's Faraday's law of induction as shown below:

$$V_h = -j\omega \overline{B}_1 . \overline{n}_A A \quad \textbf{(9)}$$

in which A is the area of the loop and $\overline{n}_A$ is the normal vector of the loop and B_1 is the RF magnetic field. In fact, in many studies [3, 9-11, 27], it is mentioned that the effect of the existence of loops or curvature of leads can be calculated as shown in Eq. (9). Here, B_1 can be written in vector form depending on the left-hand rotation (this is the only one exciting the spins) convention as follows:

$$\overline{B}_1 = B_1\left(\hat{a}_x + j\hat{a}_y\right) \quad \textbf{(10)}$$

For a general analysis of the implant structure, it was assumed that the normal of the loop makes an angle of β with x-axis as shown in Figure 6; therefore, it can be expressed in vector form as follows:

$$\overline{n}_A A = \hat{a}_x A\cos\beta + \hat{a}_y A\sin\beta \quad \textbf{(11)}$$

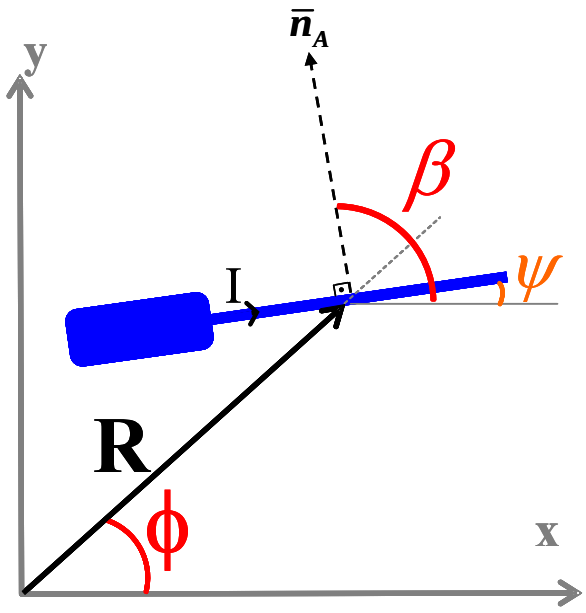

Figure 6. Axial view of the implant on the cylindrical human torso. I is the induced current flowing from the metallic case through the bare tip, that determines the direction of the normal vector $\bar{n}_A$ of curvature. Φ is the angle of the line connecting the center of the implant curvature to the origin of the cylindrical body. β is the angle between the normal of the loop and the x-axis. ψ is the angle that curvature of the implant makes with the x-axis.

Thus, the resultant induced voltage due to the curvature of the leads can be written as the following:

$$V_h = -j\omega B_1 A e^{j\beta} \quad \textbf{(12)}$$

As a result, the total induced voltage between metallic case and the tip can be written as follows:

$$V_{total} = E_z(R)l - j\omega B_1 A e^{j\beta} \quad \textbf{(13)}$$

We can write Eq. (13) in a more appropriate form as follows:

$$V_{total} = E_z(R)l + \omega B_1 A e^{j\psi} \quad \textbf{(14)}$$

in which ψ is defined as $\psi = \beta - \pi/2$ shown in Figure 6.

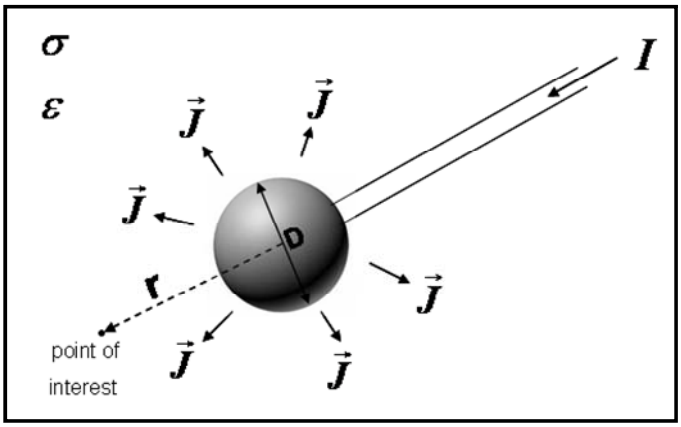

Figure 7. RF heating model of an insulated lead with bare tip, which is a very thin wire with spherical PEC tip. When current I is injected, current density J is distributed spherically symmetric to the tissue.

So as to find the induced current, call that current I, at the tip using the voltage difference between the bare tip and the metallic case, the impedance of the body to the tip should be calculated. For that purpose, the potential of the tip with respect to the lossy medium around it can be calculated by assuming a current I is induced at the tip. For simplicity, the metallic case and the tip were assumed as perfect electric conductor (PEC). While the insulated wire was assumed to be very thin, the tip was assumed to be a sphere with diameter D in order to take advantage of the spherical symmetry of the tip as shown in Figure 7. This assumption enabled to treat the bare tip as a point source, scattering current density around it. Thus, it became possible to use Green's function for a point source of the bioheat equation to calculate the heat transfer to the tissue. Assuming the bare tip as a PEC enabled the worst-case heating, because the small resistivity of the tip gives rise to maximum SAR amplification at the tip [28].

In a lossy medium, there are two types of current density in the system; conduction and displacement current densities as giving in Eq.(15). Due to the spherical symmetry, the current density is defined as in Eq. (16). Next, the scattered electric field can be found as in Eq. (17).

$$\bar{J} = \left(\sigma + j\omega\varepsilon\right)\bar{E} \qquad \textbf{(15)}$$

$$J = \frac{I}{4\pi r^2} \tag{16}$$

$$E_r = \frac{\mathrm{I}}{(\sigma + j\omega\varepsilon)4\pi r^2} \tag{17}$$

Then, we can find the potential of the tip by integrating the scattered electric field with respect to the radial distance to the tip as shown below:

$$V_{tip} = -\int_{\infty}^{D/2} \bar{E} \cdot \bar{dr} \tag{18}$$

Thus, the potential of the tip becomes the following:

$$V_{tip} = \frac{\mathrm{I}}{2\pi(\sigma + j\omega\varepsilon)D} \tag{19}$$

Then, the impedance of the tip modeled as a spherical PEC in a dielectric medium can be formulated as follows:

$$Z_{tip} = \frac{1}{2\pi(\sigma + j\omega\varepsilon)D} \tag{20}$$

Notice that in Eq. (19) the potential of the tip decreases as the diameter of the tip increases. Therefore, we can consider the metallic case with a very large diameter so that its potential with respect to tip becomes negligible. Then, the voltage difference between the tip and the case can be approximated as the potential of the tip with respect to the dielectric medium around it. Then, the induced current at the tip can be found as the following:

$$\mathrm{I} = 2\pi(\sigma + j\omega\varepsilon)D\left(E_z(R)l + \omega B_1 A e^{j\psi}\right) \tag{21}$$

Using induced current on the lead, we can formulate the scattering electric field at the tip and consequently the amplified SAR at the tip. Thus, from Eq.(17), the induced electric field at the tip can be formulated in terms of the incident RF fields and the properties of the active implant as follows:

$$E_r(r) = \frac{D}{2r^2}\left(E_z(R)l + \omega B_1 A e^{j\psi}\right) \tag{22}$$

Next, the amplified deposited power at the tip of the implant can be calculated as a function of radial distance r as follows:

$$SAR'(r) = \frac{\sigma}{\rho_t}\left(\frac{D}{2r^2}\right)^2 \left|E_z(R)l + \omega B_1 A e^{j\psi}\right|^2 \quad \textbf{(23)}$$

Then, maximum amplified power can be written like this:

$$SAR'_{\max} = SAR'(r = D/2) = \frac{\sigma}{\rho_t}\left(\frac{2}{D}\right)^2 \left|E_z(R)l + \omega B_1 A e^{j\psi}\right|^2 \quad \textbf{(24)}$$

2.3.2. Calculation of Temperature Increase in the Tissue

With the known amplified SAR distribution, the temperature rise distribution can be calculated in terms of induced current I at the tip using Green's function averaging technique [21] to take into account the bioheat transfer effects.

Notice that, in this study only the temperature increase due to the existence of the implant, in other words the amplified SAR (SAR') at the tip will be calculated. Even if there is no implant in the body, body temperature increases due to the deposited power (baseline SAR) during an MRI procedure. However, this increase is kept limited by the MRI system, i.e. pulse sequences are adjusted in a way that the applied power is always lower than the safety limits. Therefore, the temperature rise due to the baseline SAR is not a safety concern and much lower compared to the one caused by the deposited power due to the existence of an implant (SAR'). SAR' causes such a high temperature increase at the tissue that the tissue might burn. Thus, only the effect of scattered electric field on the temperature rise in the tissue was calculated by neglecting the one cause by the transmitted electric field.

From Eq. (23) , the amplified SAR at the tip can be formulated as follows:

$$SAR'(r) = \begin{cases} \dfrac{\sigma}{\rho_t}\left(\dfrac{D}{2}\right)^2 \left|E_z(R)l + \omega B_1 A e^{j\psi}\right|^2 \dfrac{1}{r^4}, & for\ r > \dfrac{D}{2} \\ 0, & for\ r < \dfrac{D}{2} \end{cases} \quad \textbf{(25)}$$

In steady-state, the Green's function of the tissue bioheat equation in spherical coordinates [21] for a point source is given as:

$$G(r) = \frac{1}{\alpha c_t}\frac{e^{-vr}}{4\pi r} \quad \textbf{(26)}$$

where c_t and α are the heat capacity and thermal diffusivity of the tissue respectively and v is a lumped perfusion constant and r is the distance from point source. Lumped perfusion constant is defined as $v = \sqrt{\rho_b c_b m / \alpha c_t}$, in which ρ_b and c_b are in that order the mass density and heat capacity of blood, and m is the volumetric flow rate of blood per unit mass of tissue [21].

Then, the amplified SAR can be convolved with the Green's function of the bioheat equation as it is given in Eq. (4). However, a different methodology suggested by Gao et al. [29] was followed for our calculations. That is, while calculating the resulting temperature distribution, the Fourier transform and its properties like convolution property given in Eq.(83) were used for simplicity rather than using convolution in computations directly. Thus, the Fourier transform of the amplified SAR was multiplied with the Fourier transform of the Green's function of the bioheat equation, and then their spherical inverse Fourier transform was taken to find the temperature increase.

The Fourier transform of spherically symmetric $SAR'(r)$ distribution was calculated using (81) in this way:

$$SAR'(q) = \frac{\sigma}{\rho_t}\left(\frac{D}{2}\right)^2 \left|E_z(R)l + \omega B_1 A e^{j\psi}\right|^2 \frac{4\pi}{q}\int_{\frac{D}{2}}^{\infty} \frac{\sin(qr)}{r^3} dr \quad \textbf{(27)}$$

The spherical Fourier transform (81) of Green's function can be found using the identity in Eq. (84) in this way:

$$G(q) = \frac{1}{\alpha c_t} \frac{1}{v^2 + q^2} \tag{28}$$

Using (82) and (83),

$$\Delta T(r) = \frac{1}{(2\pi)^3} \int_0^\infty SAR'(q) G(q) \frac{\sin(qr)}{qr} 4\pi q^2 dq \tag{29}$$

Yet, r in $SAR'(q)$ is not the same as r in $\Delta T(r)$, so the notation of $SAR'(q)$ was changed as r'.

$$\Delta T(r) = \frac{\sigma}{\rho_t} \left(\frac{D}{2} \right)^2 \left| E_z(R) l + \omega B_1 A e^{j\psi} \right|^2 \frac{1}{\alpha c_t} \frac{2}{\pi} \frac{1}{r} \int_0^\infty \left\{ \int_{\frac{D}{2}}^\infty \frac{\sin(qr')}{r'^3} dr' \right\} \frac{1}{v^2 + q^2} \sin(qr) dq \tag{30}$$

Here, a trick was made by changing the order of integrals.

$$\Delta T(r) = \frac{\sigma}{\rho_t} \left(\frac{D}{2} \right)^2 \left| E_z(R) l + \omega B_1 A e^{j\psi} \right|^2 \frac{1}{\alpha c_t} \frac{2}{\pi} \frac{1}{r} \int_{\frac{D}{2}}^\infty \frac{1}{r'^3} \left\{ \int_0^\infty \frac{\sin(qr')\sin(qr)}{v^2 + q^2} dq \right\} dr' \tag{31}$$

Using the trigonometric identity $2\sin(A)\sin(B) = \cos(A - B) - \cos(A + B)$

$$\Delta T(r) = \frac{\sigma}{\rho_t} \left(\frac{D}{2} \right)^2 \left| E_z(R) l + \omega B_1 A e^{j\psi} \right|^2 \frac{1}{\alpha c_t} \frac{2}{\pi} \frac{1}{r} \int_{\frac{D}{2}}^\infty \frac{1}{r'^3} \left\{ \int_0^\infty \frac{\cos(q\,|\,r' - r\,|) - \cos(q(r' + r))}{2(v^2 + q^2)} dq \right\} dr' \tag{32}$$

Using the integral identity in Eq. (85), the temperature increase can be written as follows:

$$\Delta T(r) = \frac{\sigma}{\rho_t} \left(\frac{D}{2} \right)^2 \left| E_z(R) l + \omega B_1 A e^{j\psi} \right|^2 \frac{1}{\alpha c_t} \frac{1}{2rv} \left\{ \int_{\frac{D}{2}}^\infty \frac{e^{-|r' - r|v}}{r'^3} dr' - \int_{\frac{D}{2}}^\infty \frac{e^{-(r' + r)v}}{r'^3} dr' \right\} \tag{33}$$

After using the definition of the absolute value,

$$\Delta T(r)=\frac{\sigma}{\rho_t}\left(\frac{D}{2}\right)^2\left|E_z(R)l+\omega B_1 A e^{j\psi}\right|^2\frac{1}{\alpha c_t}\frac{1}{2rv}\left\{\int_{\frac{D}{2}}^{r}\frac{e^{(r'-r)v}}{r'^3}dr'+\int_{r}^{\infty}\frac{e^{-(r'-r)v}}{r'^3}dr'-\int_{\frac{D}{2}}^{\infty}\frac{e^{-(r'+r)v}}{r'^3}dr'\right\}$$

(34)

When $r=\frac{D}{2}$, maximum temperature increase on the tip was obtained. Then, the first integral in Eq. (34) disappears. After some arrangements in the arguments of exponentials by taking the common term D*v*/2 out of the parenthesis, the following equation can be observed:

$$\Delta T_{\max}=\frac{\sigma}{\rho_t}\left(\frac{D}{2}\right)^2\left|E_z(R)l+\omega B_1 A e^{j\psi}\right|^2\frac{1}{\alpha c_t}\frac{1}{Dv}\left\{\int_{\frac{D}{2}}^{\infty}\frac{e^{-(\frac{2r'}{D}-1)\frac{Dv}{2}}}{r'^3}dr'-\int_{\frac{D}{2}}^{\infty}\frac{e^{-(\frac{2r'}{D}+1)\frac{Dv}{2}}}{r'^3}dr'\right\}$$

(35)

By making a change of variable $\frac{2r'}{D}=r''\Rightarrow dr'=\frac{D}{2}dr''$

$$\Delta T_{\max}=\frac{\sigma}{\rho_t}\left|E_z(R)l+\omega B_1 A e^{j\psi}\right|^2\frac{1}{2\alpha c_t}\frac{2}{Dv}\left\{\int_{1}^{\infty}\frac{e^{-(r''-1)\frac{Dv}{2}}}{r''^3}dr''-\int_{1}^{\infty}\frac{e^{-(r''+1)\frac{Dv}{2}}}{r''^3}dr''\right\}$$

(36)

Here, we call the numerical integral part of that expression *Perfusion Correction Factor* that is plotted in Figure 8.

$$f(Dv)=\frac{2}{Dv}\left\{\int_{1}^{\infty}\frac{e^{-(r''-1)\frac{Dv}{2}}}{r''^3}dr''-\int_{1}^{\infty}\frac{e^{-(r''+1)\frac{Dv}{2}}}{r''^3}dr''\right\}$$ **(37)**

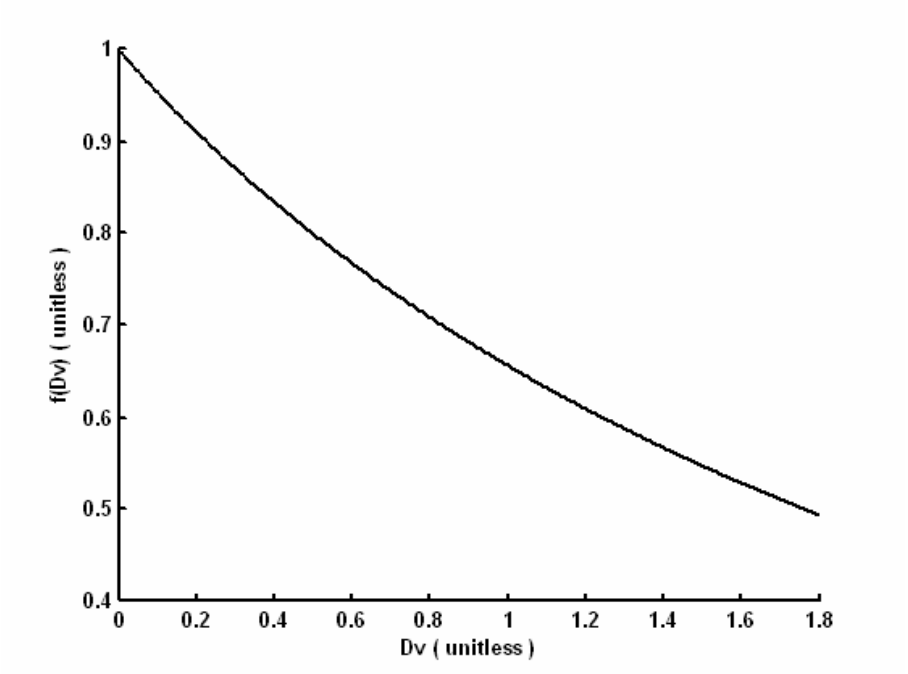

Figure 8. Perfusion correction factor. Although, it is a complicated function analytically, it has a simple appearance when plotted.

Then, maximum temperature rise can be written as the next:

$$\Delta T_{\max} = \frac{\sigma}{\rho_t}\left|E_z(R)l + \omega B_1 A e^{j\psi}\right|^2 \frac{f(Dv)}{2\alpha c_t} \tag{38}$$

From Eq. (21),

$$\Delta T_{max} = \frac{|I|^2}{8\pi^2}\frac{\sigma}{\left(\sigma^2+\omega^2\varepsilon^2\right)}\frac{1}{\alpha c_t \rho_t}\frac{1}{D^2} f(Dv) \tag{39}$$

That formulation illustrates the effect of induced current at the tip to the temperature increase in the tissue. Temperature rise can be limited by the induced current at the tip.

Finally, the safety index can be found as follows;

$$SI = \frac{\Delta T_{\max}}{SAR_{peak}} = \frac{\left|E_z(R)l + \omega B_1 A e^{j\psi}\right|^2}{\left|E_z(R_b)\right|^2}\frac{f(Dv)}{2\alpha c_t} \tag{40}$$

2.4. Modeling Fields inside the Body Coil

One of the main hardware components of an MRI scanner are RF coils. Their main function is to transmit the RF magnetic field B_1 homogeneously to the body in order to excite the spins. The spins are maintained in equilibrium by the static magnetic field B_0 before the RF magnetic field excites them to the plane perpendicular to B_0 field. Then, an MR signal is obtained. The reception of this MR signal is performed by RF coils as well.

However, the design of an RF coil with homogeneous transmission is a very challenging task and another research area. It is desirable to produce a high signal-to-noise ratio (SNR) in MRI systems to obtain a better spatial resolution in the images. SNR is defines as the B_1 field produced per unit coil current and tissue losses. This is succeeded with high static field intensity. As the intensity of B_0 field increases, the frequency of the B_1 field also increases. Considering the wavelength of the B_1 field, at higher frequencies the portion of the biological body to be imaged can be comparably large or even larger than the wavelength. Thus, this yields a stronger interaction between the biological tissues and the electromagnetic field. This interaction not only corrupt the B_1 field homogeneity; consequently causing low quality images, but also causes more power deposition in the body resulting safety problems for the MRI systems. Concerning the safety issues, the high frequency and increased B_1 field homogeneity introduces much intense electric field and accordingly eddy currents. These currents give rise to increased specific absorption rate (SAR) which is the primary source of temperature increase in the tissue [30].

Ever since they were introduced in 1985 [31], birdcage coils have been extensively used as a body coil in MR scanners due to their high RF field, B_1, homogeneity and high SNR over a large volume inside the coil. Homogeneity of RF field inside a birdcage coil is proportional to the number of excitations constructed at the corresponding legs of the coil. With birdcage coils, two types

of excitation are possible; linear excitation and quadratic excitation. Linear excitation gives rise to a linearly polarized B_1 field when it is fed at a single point while quadratic excitation produces a circularly polarized B_1 field when it is fed at two points perpendicular to each other with a phase difference of 90° [32]. Quadrature birdcage coils have more advantages than linear ones in terms of the excitation power with 50% reduction and SNR with $\sqrt{2}$ times amplification [23]. Therefore, quadrature birdcage coils are widely used in the current MRI systems.

The safety problem of electromagnetic interaction with the human body during MRI scans has been studied comprehensively for many years. Earlier works used an approximate model of human body, an infinitely long homogeneous cylindrical body [19, 23-25], and the resultant analytical solution of the problem showed that as the frequency of B_1 field increases, the homogeneity of B_1 field decrease while SAR in the object increases as well. With the advance of computer processor speed and electromagnetic simulators, it becomes possible to solve Maxwell's equations accurately on the two dimensional (2D) [32] and three dimensional (3D) [30, 33, 34] models of human body. Despite the fact that these numerical solutions provide a beneficial insight of the safety problem of MRI (especially at high frequencies between 64 MHz and 300 MHz) and validate the results of analytical solutions, they are expressed in complicated expressions, but make sense with their simulations.

Since the purpose in that study is to develop an analytical study to derive a simple and easy to use safety index formula, an analytical relationship between the transmitted electric field and RF magnetic field is needed. Because of this, we analytically calculated the RF magnetic field, B_1, over an approximate human body model, an infinitely long cylinder with homogeneous electrical properties, inside a quadrature birdcage coil. Since most of the MRI systems use circularly polarized quadrature birdcage body coil due to its high field

homogeneity, we developed this model for quadrature birdcage body coil to generate a homogeneous transverse RF magnetic field in the human subject.

In order to analyze the safety index of an active implant that is absolutely independent of the MRI system used, phase distribution of the transmitter must be carefully adjusted so that worst-case tip heating is guaranteed [35]. Thus, the quasistatic MRI fields for the analysis were assumed, so that the phase of the fields varies slowly on the implant that is small in comparison with the wavelength; therefore, constructive addition of fields at the tip was enabled for maximum heating. This phase distribution is even worse than the worst case heating distribution mentioned in [35]. As a result, plane waves can be used as a source of excitation. Then, assuming a homogeneous RF magnetic field, B_1, inside the body coil, the incident electric field on the implant with a slowly varying linear magnitude and worst-case phase distribution can be derived as a function of position.

For circularly polarized plane waves, at least two linearly polarized plane waves with a 90° phase difference are needed. As the simplest approximation for the birdcage coil, four plane waves were used considering the circular geometry of the coil with equal magnitudes and appropriate phases to achieve circular polarization. In fact, infinitely many excitations would be ideally more accurate for the modeling of a birdcage coil. Yet, for the ease of calculation, four plane waves were enough for the purpose.

As a background, it should be kept in mind the following constitutive relation;

$$B_1 = \mu H_1 \tag{41}$$

in which B_1 is the magnetic flux density and H_1 is the magnetic field intensity.

While the main magnetic field, B_0, is in the z-direction, the RF magnetic field, B_1, has only transverse components and they can be written as a sum of

the left and right hand circularly polarized rotating field components as in the Eq. (42).

$$\bar{H}_1 = \hat{a}_x H_x + \hat{a}_y H_y = \hat{a}_- H_- + \hat{a}_+ H_+ \quad \textbf{(42)}$$

where $\hat{a}_-$ is the left-hand sense (clockwise) rotation axis and $\hat{a}_+$ is the right-hand sense (counter-clockwise) rotation axis, which are defined as follows:

$$\hat{a}_- = \hat{a}_x + j\hat{a}_y \quad and \quad H_- = (H_x - jH_y)/2 \quad \textbf{(43)}$$

$$\hat{a}_+ = \hat{a}_x - j\hat{a}_y \quad and \quad H_+ = (H_x + jH_y)/2 \quad \textbf{(44)}$$

in which we can estimate the magnitude of magnetic field intensity, H_1, from the imaging parameters, i.e. flip angle, pulse sequence, TR.

As a rotating frame of reference, left-hand sense rotating frame was assumed because it is the only component that produces a torque on the magnetization of hydrogen spins at the larmor frequency, while the other component has no effect.

Consequently, the formulation was based on the mentioned assumptions and references for the construction of plane waves in Figure.

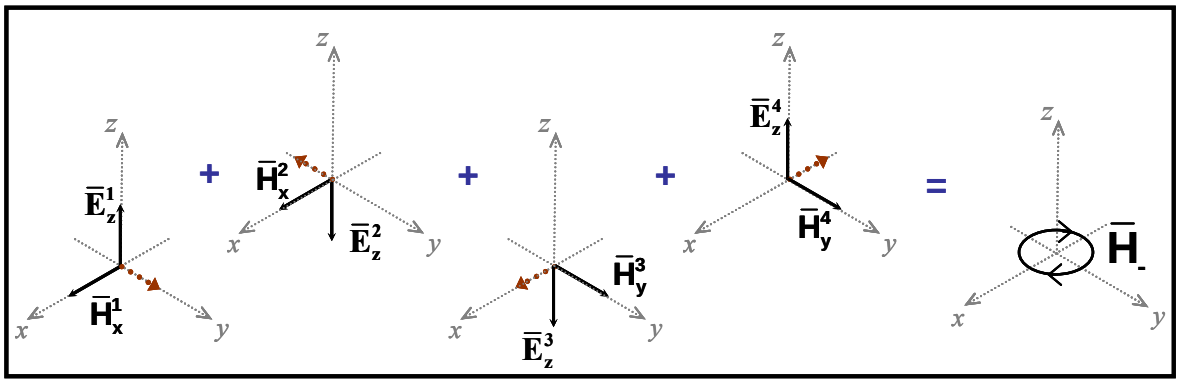

Figure 9. Representation of quadrature birdcage coil with plane waves.

We can write the wave equations of plane waves at the center of the body with the same amplitude considering their propagation directions as follows:

$$\bar{H}_x^1 = \hat{a}_x \frac{H_-}{2} e^{-jk_c y} \quad \textbf{(45)}$$

$$\bar{H}_x^2 = \hat{a}_x \frac{H_-}{2} e^{jk_c y} \quad \textbf{(46)}$$

$$\bar{H}_y^3 = j\,\hat{a}_y \frac{H_-}{2} e^{-jk_c x} \quad \textbf{(47)}$$

$$\bar{H}_y^4 = j\,\hat{a}_y \frac{H_-}{2} e^{jk_c x} \quad \textbf{(48)}$$

Then, the total magnetic field intensity gives the following:

$$\bar{H}_1 = H_- \left(\hat{a}_x \cos\left(k_c y\right) + j\hat{a}_y \cos\left(k_c x\right) \right) \quad \textbf{(49)}$$

where H_- is the magnetic field intensity, $\hat{a}_x$ and $\hat{a}_y$ are the unit vectors, x and y are the distance variables on the corresponding cartesian coordinates, and j is the complex number, $j = \sqrt{-1}$ a and k_c is the complex wavenumber. For circular polarization, $H_- = H_{10}(1-j)/2$. The complex wave number is calculated [36] as $k_c = \sqrt{\omega^2 \mu\varepsilon - j\omega\mu\sigma}$,in which ω is the angular frequency, and μ, ε and σ are respectively the magnetic permeability, electrical permittivity and conductivity of the tissue. Notice that for small k_c and distance from the center of the cylindrical human body, Eq. (49), gives the next:

$$\bar{H}_1 = H_-\left(\hat{a}_x + j\hat{a}_y \right) \quad \textbf{(50)}$$

that is consistent with the definition of left hand circularly polarized magnetic field intensity.

With that excitation scheme, left hand circularly polarized magnetic field was ensured only at the center of the body.

Next, from Maxwell's Ampere's law in time-harmonic form, that is $\nabla \times \bar{H} = (\sigma + j\omega\varepsilon)\bar{E}$, the following expression for the induced electric field on the longitudinal axis is obtained:

$$\bar{E}_z = \hat{a}_z \frac{H_- k_c}{(\sigma + j\omega\varepsilon)} \{\sin(k_c y) - j\sin(k_c x)\} \quad \textbf{(51)}$$

For small $k_c x$ and $k_c y$, the following approximation can be made; $\sin(k_c x) \approx k_c x$ and $\sin(k_c y) \approx k_c y$. This yields the following:

$$\bar{E}_z = -\hat{a}_z \mu H_- \omega(x + jy) \quad \textbf{(52)}$$

Eq. (52) can be written in cylindrical coordinates considering the geometry of the body inside the body coil. Then, the final form of the induced electric field was obtained in the body as a function of radial distance R (m) from the center of the human body and the cylindrical angular coordinate ϕ (rad) as follows:

$$E_z(R) = -\omega \mu H_- \mathrm{R}\, e^{j\phi} \quad \textbf{(53)}$$

It might be beneficial to express H_- in Eq. (43) in cylindrical coordinates for the purpose of comparison. While the unit vector with magnitude $\sqrt{2}$ is defined as in Eq. (54) , the left-hand rotating frame vector can be expressed as in Eq. (55).

$$\hat{a}_- = (\hat{a}_\rho + j\hat{a}_\phi) e^{j\phi} \quad \textbf{(54)}$$

$$H_- = (H_\rho - jH_\phi)/2 \quad \textbf{(55)}$$

Then, Eq. (53) is reduced to the following;

$$E_z(R) = -\omega \mu H_- \mathrm{R} \quad \textbf{(56)}$$

The same relationship between the incident electric field and the RF magnetic field can be obtained by solving the cylindrical wave expressions given in [37] for modes $m = 1$ and $n = 0$ for a large wavelength.

Using the relationship in Eq.(53), we can obtain more compact formulations for the induced current and SAR amplification at the tip, and safety index of active implantable medical devices.

2.4.1. Safety Index of Active Implants using Body Coil Field Model

The induced voltage between the tip and the metallic case can be written in terms of the induced electric field using Eq. (53) in Eq. (14).

$$V_{total} = \left(l + \frac{A}{R} e^{j\theta} \right) E_z(R) \tag{57}$$

in which $\theta = \pi + \psi - \phi = \beta - \phi + \pi/2$ as shown in Figure 10.

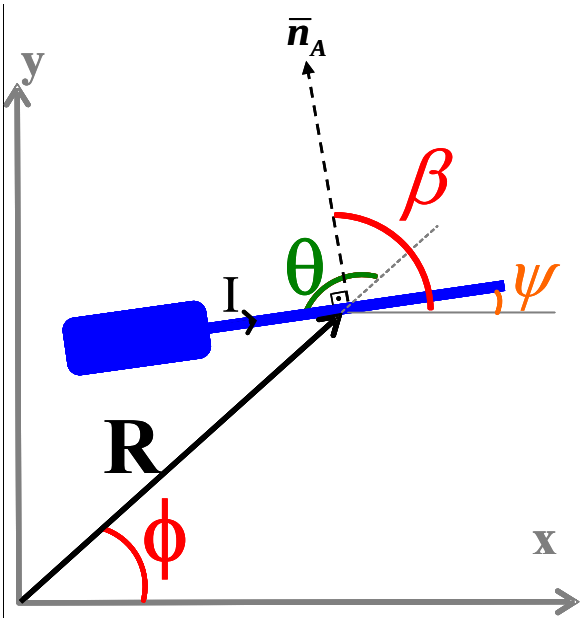

Figure 10. Axial view of the implant on the cylindrical human torso (see Figure 6 for a detailed description). θ is the angle that curvature of the implant makes with the radial axis connecting the center of the curvature with the center of the cylindrical object.

Yet, it is better to write induced voltage in terms of the maximum induced electric field in the body by taking advantage of Eq. (58) to avoid the misunderstanding that at the center it will be induced infinitely large.

$$E_z(R) = \frac{R}{R_b} E_z(R_b) \tag{58}$$

where R_b is the radius of the cylindrical body. Considering that induced electric field is a linear function of radial distance in the body, maximum electric field is induced at the periphery of the body. Then Eq. (57) is reduced to the following;

$$V_{total} = \left(Rl + Ae^{j\theta}\right)\frac{E_z(R_b)}{R_b} \tag{59}$$

Then the induced current at the tip in Eq. (21) was reduced to the next equation;

$$\mathrm{I} = 2\pi\left(\sigma + j\omega\varepsilon\right)\frac{D}{R_b}\left(Rl + Ae^{j\theta}\right)E_z(R_b) \tag{60}$$

Next, the amplified SAR at the tip becomes;

$$SAR'(r) = \frac{\sigma}{\rho_t}\,|\,E_z(R_b)\,|^2\,\left|Rl + Ae^{j\theta}\right|^2\left(\frac{D}{2R_b r^2}\right)^2 \tag{61}$$

Notice that it can be written in terms of the peak SAR without the implant in place as follows:

$$SAR'(r) = SAR_{peak}\left|Rl + Ae^{j\theta}\right|^2\left(\frac{D}{2R_b r^2}\right)^2 \tag{62}$$

Then maximum amplified power is the one obtained at the closest point to the tip that is $r = D/2$.

$$SAR'_{\max} = SAR_{\text{peak}}\left|Rl + Ae^{j\theta}\right|^2\left(\frac{2}{DR_b}\right)^2 \tag{63}$$

Thus, from the information given we can formulate SAR gain as follows;

$$SAR\,gain = \frac{SAR'_{\max}}{SAR_{\text{peak}}} = \left|Rl + Ae^{j\theta}\right|^2\left(\frac{2}{DR_b}\right)^2 \tag{64}$$

In other words, it can be defined as;

$$SAR\,gain = \frac{SAR'_{\max}}{SAR_{\text{peak}}} = \frac{|\,E(D/2)\,|^2}{|\,E_z(R_b)\,|^2} \tag{65}$$

Thus, SAR gain is the ratio of the amplified SAR at the tip of the implant, denoted as maximum SAR', to the maximum SAR in the body without the implant in place.

Consequently, using Eq. (62) temperature increase can be calculated as seen below:

$$\Delta T_{\max} = \frac{SAR_{\text{peak}}}{R_b^2}\left|Rl + Ae^{j\theta}\right|^2 \frac{1}{2\alpha c_t} f(Dv) \tag{66}$$

Finally, safety index can be defined in terms of the peak SAR in the body when there is no implant in the body as shown in the next line;

$$SI = \frac{\Delta T_{\max}}{SAR_{\text{peak}}} = \frac{1}{2\alpha c_t R_b^2}\left|Rl + Ae^{j\theta}\right|^2 f(Dv) \tag{67}$$

Chapter 3

Materials and Methods

3.1 Introduction

After developing an analytical solution of the RF heating of an AIMD during MRI exams and ending up with related formulas to identify the parameters of the problem, the simulations of the model was performed in a computer environment to debug the derived formulas and check their accuracy. Then, we tried to make a phantom to mimic a homogeneous cylindrical human torso in order to validate our quadrature birdcage model and measure the safety index.

3.2 MATLAB Simulations

Despite the fact that the derivations were simplified as much as possible, there left some integrals that could not be solved analytically. *Perfusion Correction Factor* is the one that is a combination of two complicated integrals. Therefore, we tried to analyze this part numerically by MATLAB 6.5 (Matworks Inc.).

Besides, the additional calculations for the evaluation of the formulas for comparing them with electromagnetic solver results were done in MATLAB. Also the data fit for the experimental data was done with MATLAB's curve fitting tool. The first order polynomial fit of the data was performed with linear least squares method.

3.3 Electromagnetic (EM) Simulations

In our simulations, a commercial method of moments solver software called FEKO (EM Software & Systems; Stellenbosch, South Africa) was used.

During the simulations the electrical conductivity and the relative electrical permittivity of the medium was respectively assigned as 0.2 S/m and 66. In spite of the fact that these values are not representative of the average values for human tissues [38], it was preferred to use these values due to the fact that they were very practical during the preparation of the experiment setup.

3.3.1 Simulation of Quadrature Birdcage Coil Model

In this part, four plane waves were used to obtain a left-hand circularly polarized RF magnetic field at the center of the cylindrical human torso for the excitation as proposed in the theory part. As a result, the RF magnetic field and the incident electric field at the radial points were simulated to verify the formula in Eq. (56). Later, these results were used in the following analytical calculations of the induced current to compare with the results obtained from the EM simulations.

3.3.2 Simulation of Induced Current at the Tip

In that part, a simplified version of an AIMD was placed inside the quadrature birdcage coil model and measured the induced current at the tip.

The case of the implant was simply assumed as a rectangular prism with dimensions of the 5cmx5cmx0.8cm for the ease of theoretical calculations. The tip was modeled as a sphere as it was assumed during the theoretical analysis. While the case and the spherical tip was defined as a PEC, the wire connecting them was insulated with 0.35mm Teflon ($\sigma = 0$, $\varepsilon_r = 2.3$, $\mu_r = 1$).

First, only the effect of the wire length, *l*, between the tip and the case was simulated by assuming there is no curvature as shown in Figure 11 and then in that configuration the effect of the radial distance of the implant to the center of the body was observed.

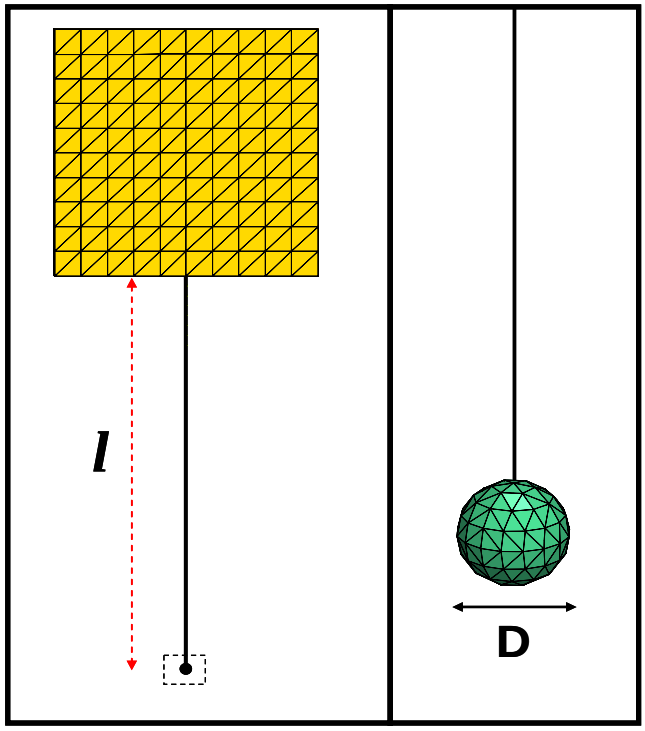

Figure 11. Left Panel: The simplified configuration of the implant without curvature of the lead in EM simulations. The implant was excited by quadrature birdcage coil model. **Right Panel:** The spherical tip of the implant is zoomed in.

Next, the effect of the curvature of the lead was simulated without any wire length between the case and the tip as shown in Figure 12. In that configuration, the effect of the area of the curvature was observed while the location of the curvature center was fixed, and for a constant area of the curvature, the effect of the loop center location was analyzed.

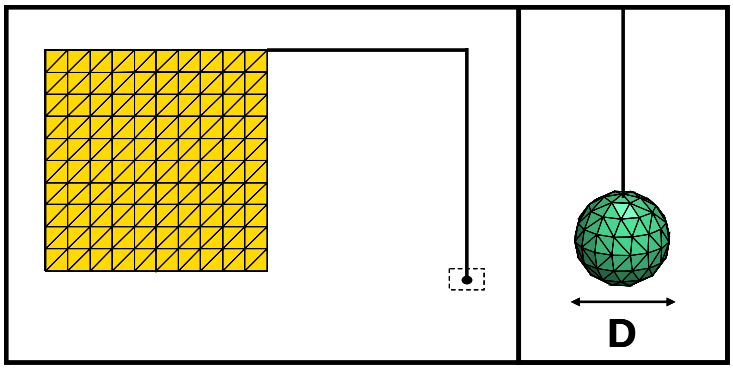

Figure 12. Left Panel: The simplified configuration of the implant with only loop in EM simulations. The implant was excited by quadrature birdcage coil model. **Right Panel:** The spherical tip of the implant is zoomed in.

3.3.3 Simulation of Gel Phantom

During the theoretical analysis, the human body was modeled as an infinitely long cylinder. Since in the experiments a cylindrical phantom container with a limited length can be used, it was critical to determine at which points the measurements should be taken so as to get valuable data from phantom experiments. Therefore, as a preparation for the gel experiments, the phantom inside the quadrature birdcage coil model was simulated as shown in Figure 13. The dimension of the phantom was the same as the one used in the experiments.

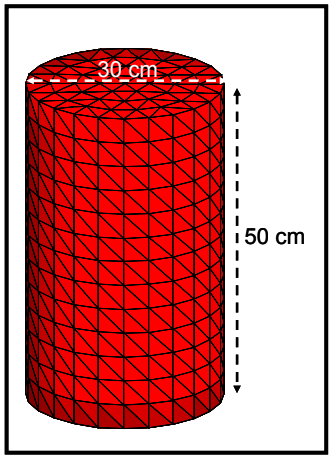

Figure 13. Simulation of phantom inside the quadratue birdcage coil model in the EM simulation.

3.4 Phantom Experiments

In order to perform phantom experiments, a cylindrical phantom container with 30 cm diameter and 50 cm length was constructed. Since the cylindrical phantom container has a very large volume, use of jello (fruit-flavored dessert made from gelatin powder) rather than polyacrylamide gel was preferred. This material is very cheap compared to polyacrylamide gel and commercially available in the stores. In spite of the fact that there are many companies producing jello, a brand called Dr. Oetker was used in the experiments. The main idea is to use a material that is viscous enough to prevent convection inside the phantom for the worst-case (perfusionless case) phantom that mimics the thermal and electrical properties of human tissue. The jello used in the experiment could provide enough viscosity when it was prepared using much more than the given recipe.

The gel phantom was constructed in a way that at the bottom, jello was poured until the required height (that will be understood in the simulation of gel phantom). After jello became viscous enough, NaCl solution was added on it as shown in Figure 15.

To provide electrical conductivity, a certain amount of sodium chloride (NaCl) was added to the jello. To decide how much NaCl was needed, the input impedance of a lossy transmission line was measured with the network analyzer (Model 8753D; Hewlett Packard, Palo Alto, CA). The lossy transmission line was imitated with a cylindrical parallel plate copper conductor inside which jello was poured to create a dielectric medium (for detailed explanation refer to [39]). To test the variability of the measurement, three setups that are totally the same were prepared. Since the more NaCl, the more difficult viscous jello to get, a small amount of NaCl was preferred to use. A 2.6 gr of NaCl was decided to be added to the gel made of 600 gr jello and 1lt of water. Consequently, an electrical conductivity of approximately 0.2 S/m and relative electrical

permittivity of approximately 66 were achieved as an average of the measurements done with these three setups shown in Table 1. In order to obtain the same electrical properties inside NaCl solution, 1.3 gr NaCl was added to the 1lt of water.

Table 1. The conductivity and electrical permittivity measurements of prepared gel.

	σ (S/m)	**ε_r**
S_1	0.1794	63
S_2	0.2018	72
S_3	0.1839	64
S_{mean}	0.1884	66.3

To compare the measured electrical properties with human data, dielectric properties of heart (for pacemakers), brain (for deep brain stimulators) and blood are given in Table 2. Notice that the measured dielectric properties of jello are lower than the human data for the specified tissues. It is possible to arrange them by adjusting the amount of NaCl in the jello. Yet, the disadvantage of using jello is that it becomes more difficult to make it viscous as the NaCl content in it increases. The main idea for the experiments is to know the dielectric properties of the jello so that the derived formulations can be checked.

Table 2. Dielectric properties of the human heart, brain and blood [38].

Tissue	**σ (S/m)**	**ε_r**
Heart	0.68	106.65
Brain	0.4	82.75
Blood	1.21	86.54

Using the thermal property measurement kit (KD2 Pro, Decagon Devices Inc.) the thermal properties of the jello was measured as follows; heat capacity c_t

= 3965 J/kg/ºC, thermal conductivity k = 0.543 W/m/ ºC, diffusivity α = 0.137 mm^2/sec. The measured values are in the range of human thermal properties. To show this, the thermal properties of the heart, brain and blood were obtained after a literature survey in Table 3. Notice that once heat capacity, thermal conductivity and mass density is known, the diffusivity can be calculated by $\alpha = k/(\rho_t c_t)$.

Table 3. Thermal properties of human heart, brain and blood.

Tissue	ρ_t (kg/m^3)	k (W/m/ºC)	c_t (J/kg/ºC)	Reference
Heart	1030 -1060	0.54 - 0.59	3700 - 3900	[40, 41]
Brain	1027.4 -1050	0.16 - 0.57	3600 - 3800	[40-44]
Blood	1055 - 1060	0.49 – 0.56	3600 - 3900	[40, 42-44]

In order to measure, the temperature increase inside the phantom, fiber optic temperature probes (Neoptix, Quebec, Canada) were used.

To validate the electric field distribution inside the cylindrical phantom without the implant is in place, a phantom experiment was conducted in a GE Signa MR scanner. The Fast SPGR pulse sequence was used with pulse repetition time TR = 6 msec with a transmit gain TG_0 = 125 for a flip angle of α_0 = 90° after an autoprescan. Transmit gain (TG) is not a generic parameter for all scanners, but it is used in a GE scanner. It determines the RF power emitted by the transmit coil and quantified in tenths of decibels (dB). TG must be adjusted for scanning of each object, since deposited SAR, which is proportional to the square of the flip angle, depends on the size of the object. Therefore, before each scan, an autoprescan must be performed to calibrate TG by determining the amount of the deposited power to produce a 90º flip angle [45]. After calibrating the TG of the scanner with an autoprescan, the transmit gain was increased manually to TG = 190 in order to observe a detectable temperature increase inside the gel. Otherwise, even the scan time (approximately 23 minutes) would not be enough to observe any temperature increase inside the gel, because there

was no implant inside the gel. Then, the corresponding flip angle was calculated as follows:

$$\alpha = \alpha_0 \cdot 10^{[(TG-TG_0)/200]} \quad \textbf{(68)}$$

From Eq.(68), the corresponding flip angle was calculated as $\alpha = 190.214^{\circ}$ which is equal to 1.1π radians. With that knowledge, H_{1rms} should be calculated. The applied RF magnetic field in the repetition time (TR) is defined as follows:

$$H_1(t) = H_1 \int_0^{TR} e(t) \quad \textbf{(69)}$$

in which H_1 and $e(\tau)$ are the amplitude and the envelope of the RF magnetic field. Then the flip angle can be calculated as in the next expression:

$$\alpha = \gamma \mu H_1(t) \quad \textbf{(70)}$$

where γ is the gyromagnetic ratio (2π 42.576 MHz/T) and μ is the magnetic permeability. Next, H_{1rms} can be calculated as follows:

$$H_{1_{rms}} = \frac{\alpha}{\gamma \mu \int_0^{TR} e(\tau) d\tau} \sqrt{\frac{1}{TR} \int_0^{TR} e^2(\tau) d\tau} \quad \textbf{(71)}$$

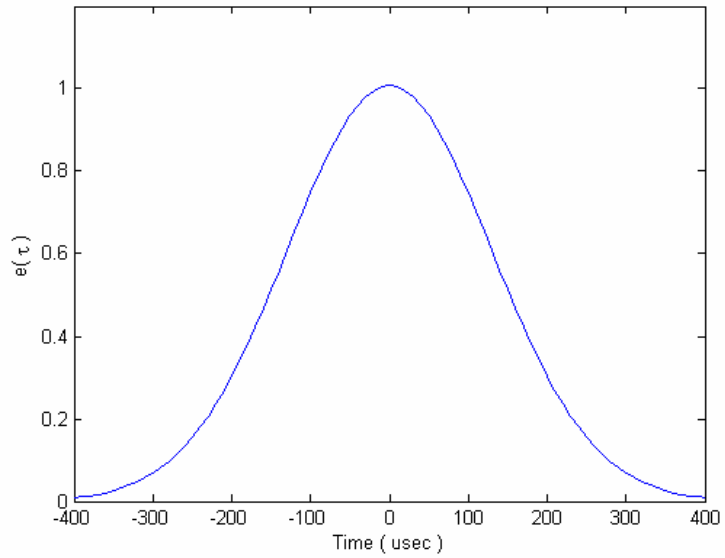

Figure 14. The envelope of the RF magnetic field.

The envelope of the RF magnetic field was measured with the oscilloscope as shown in Figure 14, so the required integrals in Eq.(71) in this way:

$$\int_0^{TR} e(\tau)d\tau = 325.6\times10^{-6} \quad \textbf{(72)}$$

$$\int_0^{TR} e^2(\tau)d\tau = 231.9\times10^{-6} \quad \textbf{(73)}$$

Then, the theoretical transmitted electric field was calculated using Eq.(56) and the resultant SAR was found using Eq. (1).

On the other hand, the consequent SAR obtained from the experiment can be calculated by calorimetry as follows:

$$SAR = c_t \frac{\Delta T}{\Delta t} \quad \textbf{(74)}$$

in which $\Delta T/\Delta t$ is the initial slope of the temperature rise obtained in the experiment.

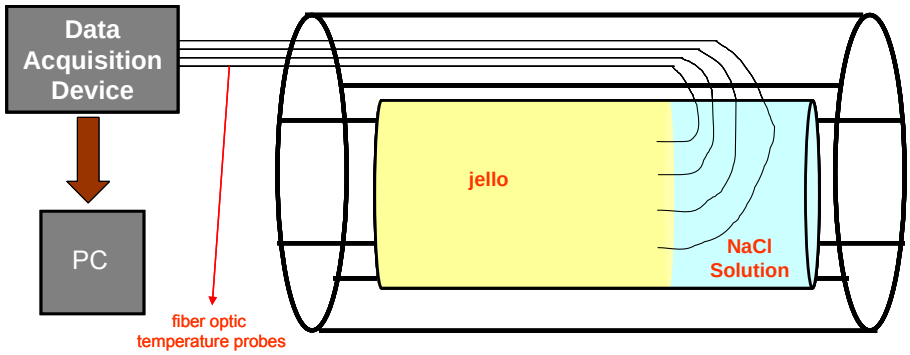

Figure 15. The experimental setup for the phantom experiment.

The probes were located as shown in Figure 16.The height of the gel was 24 cm inside the phantom container and the rest of it was filled with NaCl solution. The probes were 4 cm deeper from the surface of the gel. Thus, the measurements at the height of 20 cm were taken. Six experiments were

conducted to measure the temperature increase at the marked locations. The resultant SAR was calculated using Eq.(74). The theoretical SAR values were calculated using Eq. (1) with the known transmitted electric field distribution of the used MRI sequence using Eq.(71) and Eq. (53).

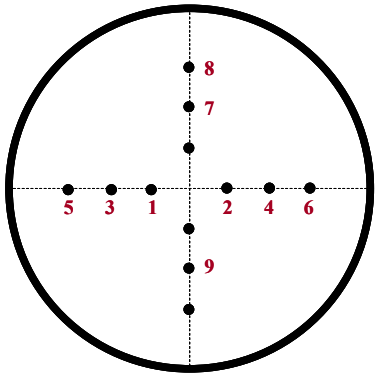

Figure 16. Axial view of the phantom container with probes inserted into the gel. The probes 1 and 2 are located 3 cm away from the center of the phantom. The probes 2, 4, 7, and 9 are placed 6 cm away while probes 5 and 6 are located 9 cm away from the center of the phantom.

Chapter 4

Results

4.1 Matlab Results

Even if *Perfusion Correction Factor* in Eq.(37) seems like a complicated function analytically, it is simply a decaying function of unitless quantity D*v* as shown in Figure 8. It is equal to 1 for the worst-case RF heating condition which is perfusionless case. All calculations can be done assuming that worst-case condition and then the results can be normalized with respect to the desired perfusion value if needed.

4.2 Simulation Results

4.2.1 Results of Quadrature Birdcage Coil Model

The simulation results obtained at 63.8 Hz is shown in Figure 17 for the RF magnetic field and Figure 18 for the RF electric field. It is seen that at that frequency, the RF magnetic field is totally uniform inside the quadrature birdcage coil at all data points with respect to the radial distance away from the center of the cylindrical human torso model.

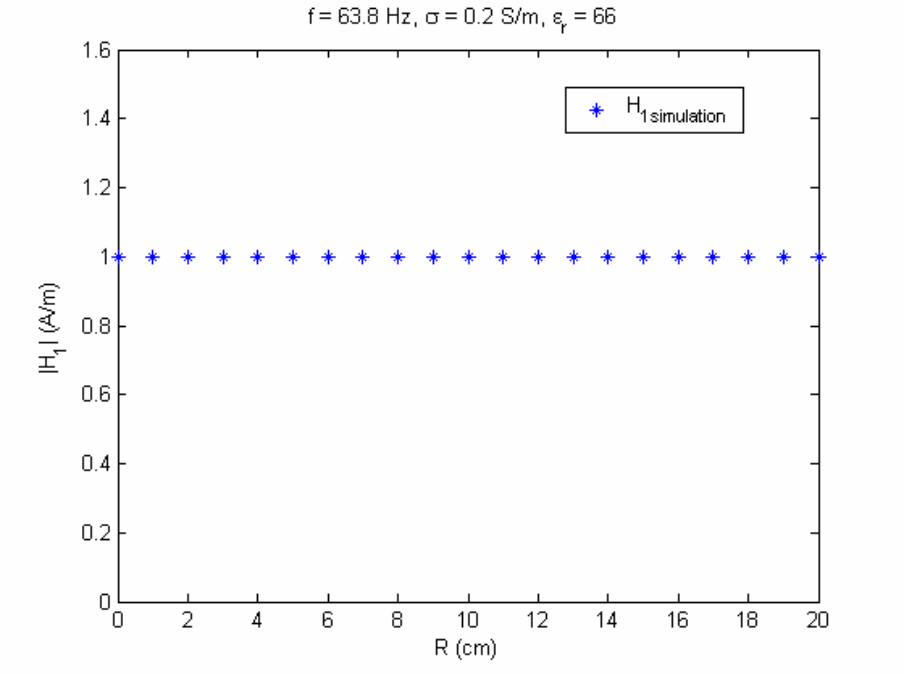

Figure 17. The RF magnetic field at 63.8 Hz observed from the quadrature birdcage coil model.

Yet, before using the magnetic field data for calculating the incident electric field inside the body it should be kept in mind that the magnetic field results of EM simulation should be normalized with $\sqrt{2}$. The reason for that is the rotating frame convention assumed at the beginning of the derivations. The convention accepted is different than the one used in EM simulation. In simulation, the magnitude of the rotating frame unit vector is equal to 1 as can be seen in Eq.(75) and consequently the RF magnetic field can be calculated as in Eq.(76). Whereas, the RF magnetic field in the derivations can be calculated as in Eq.(55) since the unit vector convention yields a vector with magnitude $\sqrt{2}$.

$$\hat{a}_{-}^{FEKO} = \left(\hat{a}_x + j\hat{a}_y\right)/\sqrt{2} \tag{75}$$

$$H_{-}^{FEKO} = (H_x - jH_y)/\sqrt{2} \tag{76}$$

As a result, since the quasistatic assumption was assumed at the beginning of the analysis, perfectly matching results with the EM simulation were obtained from the theoretical formulation.

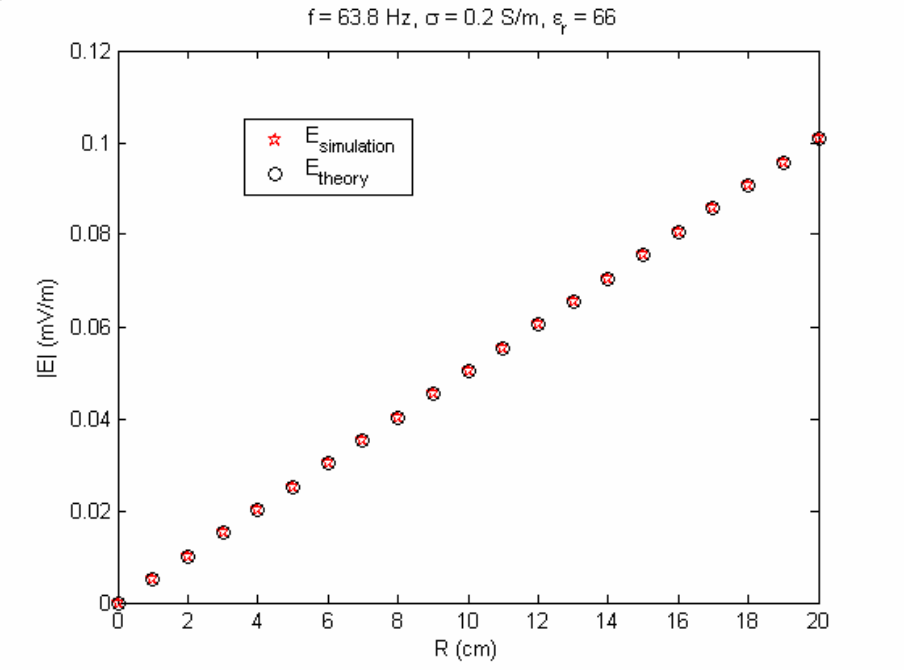

Figure 18. The transmitted RF electric field at 63.8 Hz observed from the quadrature birdcage coil model.

As much as the phases of the fields are concerned, it is seen in the EM simulation that the φ component of the magnetic field leads 90° the ρ component, while the phase of the magnetic field is equal to the one of ρ component for all radial distances from the center of the body. The phase of the transmitted electric field leads 180° the one of the RF magnetic field as expected from Eq. (56) again for all data points.

Considering the results obtained at 63.8 MHz, the plots of the RF magnetic field and the incident electric field are in that order shown in Figure 19 and Figure 20.

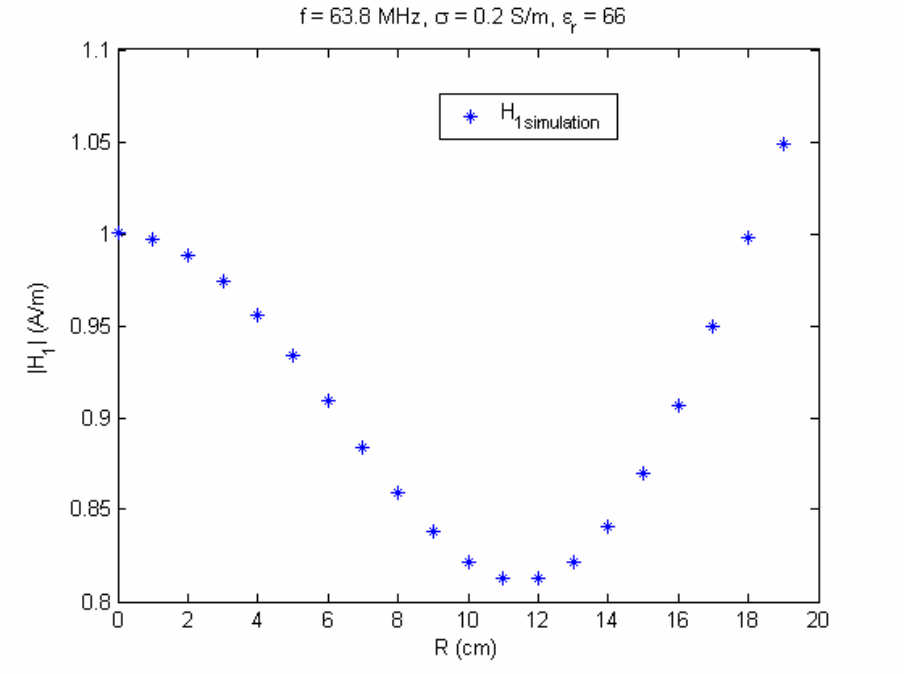

Figure 19. The RF magnetic field at 63.8 MHz observed from the quadrature birdcage coil model.

Contrary to the RF magnetic field obtained at 63.8 Hz, the RF magnetic field at 63.8 MHz is not uniform inside the body as shown in Figure 19 Therefore, in order to calculate the transmitted electric field inside the body only the magnetic field value obtained at the center of the body was used. Because, according to the quasistatic assumption, transmitted magnetic field should be uniform around the body and its value is the one at the center of the body due to the fact that the quadrature birdcage coil configuration was built-in at the center of the body. Therefore, the formulation of transmitted electric field of quadrature birdcage coil model in cylindrical coordinates can be oriented in Eq. (56) as follows:

$$E_z(R) = -\omega \mu H\_(R=0)\,\mathrm{R} \qquad \textbf{(77)}$$

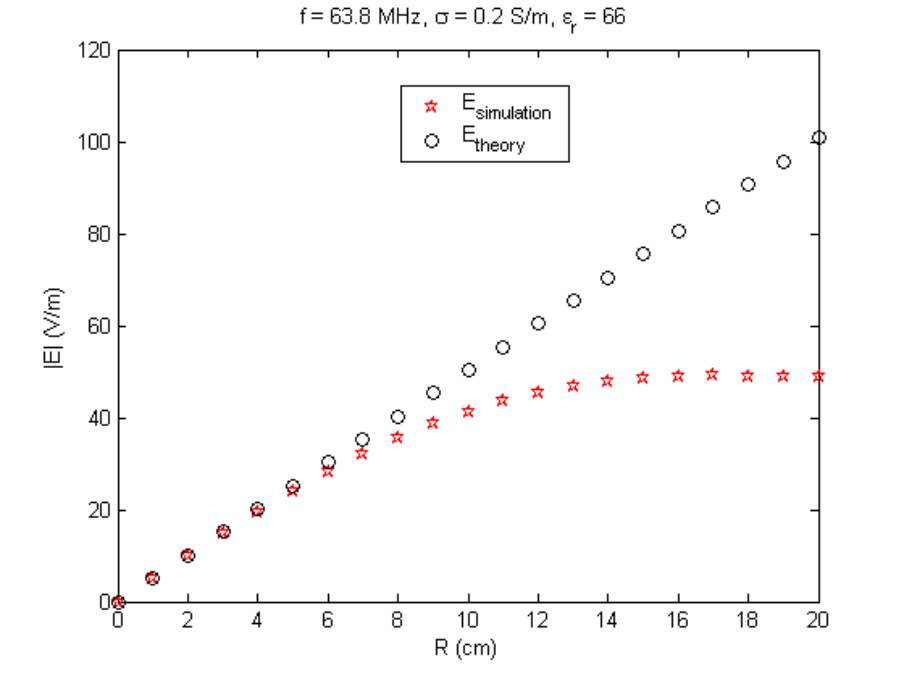

Figure 20. The transmitted RF electric field at 63.8 MHz observed from the quadrature birdcage coil model.

As a consequence, the transmitted electric field was obtained as shown in Figure 20. It is seen that, the theoretical formulation results closely match with the one in the EM simulation at the points close to the center of the body. Whereas, it keeps linearly increasing through the outer points of the body while the simulation results approaches to a steady magnitude.

Considering the phases of the fields, only the phase of the transmitted electric field at the center holds with respect to the referred magnetic field at the center.

4.2.2 Results of Induced Current at the Tip

The simulation results for the effect of the wire length between the case and the bare tip on the induced current at the tip are shown in Figure 21 and Figure 22 for different electromagnetic properties of the medium.

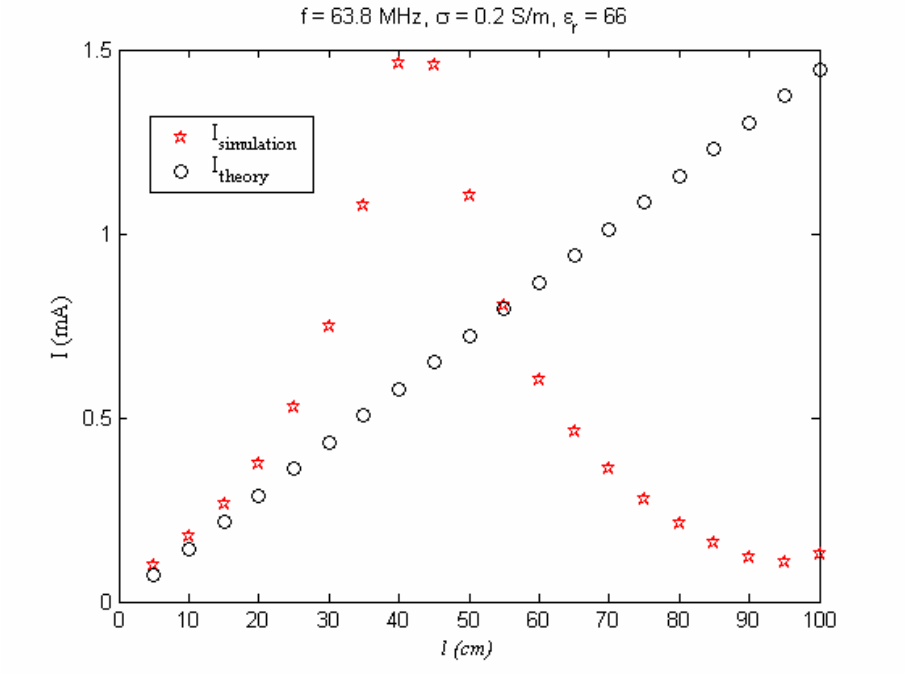

Figure 21. Induced current at 63.8 MHz as a function of wire length, *l*, between the case and the bare tip when the implant is located on R = 6 cm.

According to the plots, while the EM simulation results show resonance effect, the analytical solution linearly increases as a function of the wire length. When the wire length is smaller than the half wave length, the analytical solution closely matches with the EM simulation results. This is because of the quasistatic assumption made at the beginning of the analysis that the size of the implant including its lead was accepted smaller than the wavelength.

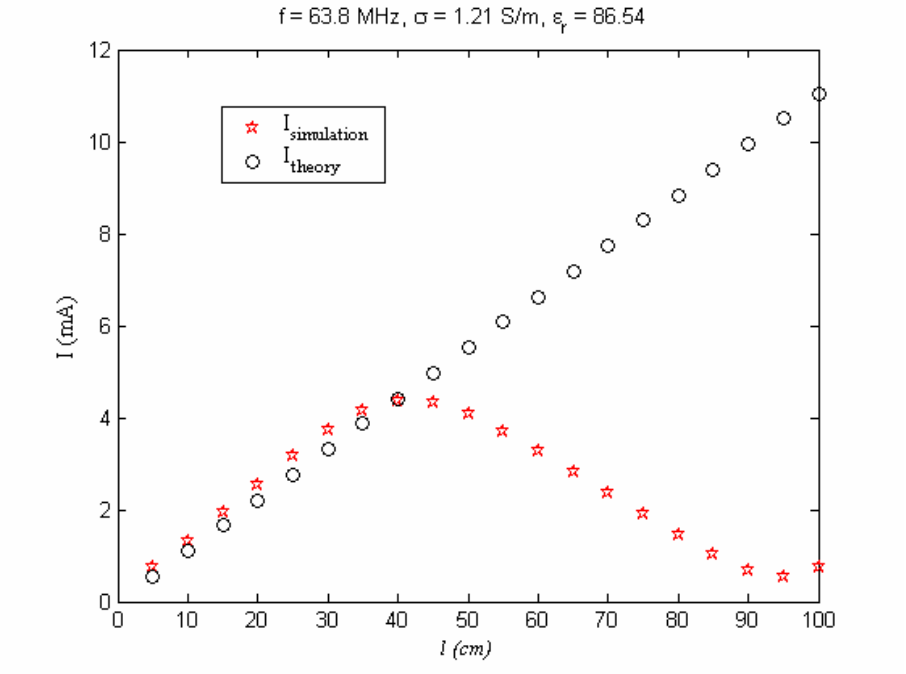

Figure 22. Induced current at 63.8 MHz as a function of wire length, *l*, between the case and the bare tip when the implant is located on R = 6 cm.

Recall that the wavelength in a lossy medium is calculated as the following:

$$\lambda = \frac{2\pi}{\omega\sqrt{\frac{\mu\varepsilon}{2}}\sqrt{1+\left(1+\frac{\sigma^2}{\omega^2\varepsilon^2}\right)^{1/2}}} \qquad \textbf{(78)}$$

This formula gives a wavelength of 53.63 cm for a medium with σ = 0.2 S/m and ε_r = 66. Thus, the half wavelength of this medium is around 26 cm. For another medium, that is blood, with σ = 1.21 S/m and ε_r = 86.54, it is given a wavelength of 31.87 cm with the half wavelength of approximately 15 cm. As it is shown in Figure 21 and 22, both results closely matches when the wire length is smaller than the half wavelength. It should be noted that in Figure 22, both results are very close to each other even when the wire length is longer than the

wavelength; this is most probably due to the damping of the system when it has higher electromagnetic properties.

Next, the effect of the implant position inside the cylindrical body was simulated in Figure 23 when the wire length is 10 cm that is smaller than the half wavelength. As can be observed from the plot, as the radial distance from the center increases, the observed current at the tip increases as well for both cases. Considering that RF magnetic field is constant at all radial points but the transmitted electric field increases linearly, the reason behind the rise in current is due to the coupling of the electric field with the straight wire with length *l*, but not the coupling with the transmitted magnetic field.

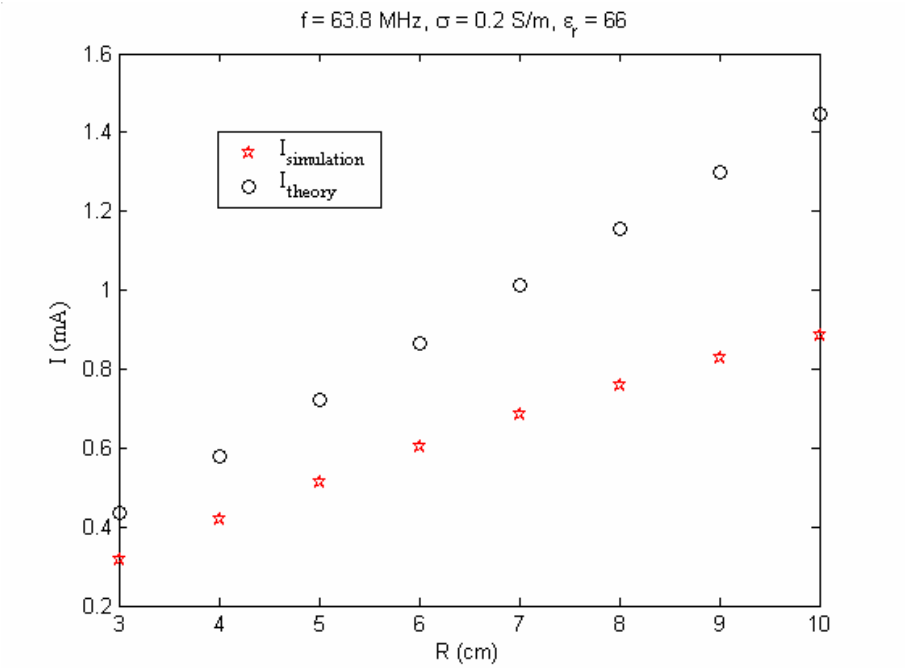

Figure 23. Induced current at 63.8 MHz as a function of R when the wire length, *l*, between the case and the bare tip is equal to 10cm.

Then, the induced current at the tip as a function of the diameter of the tip was simulated in Figure 24. According to Eq.(20), as the diameter of the tip

gets larger, the impedance of the tip gets smaller. Therefore, with the increasing diameter the induced current at the tip increases as well.

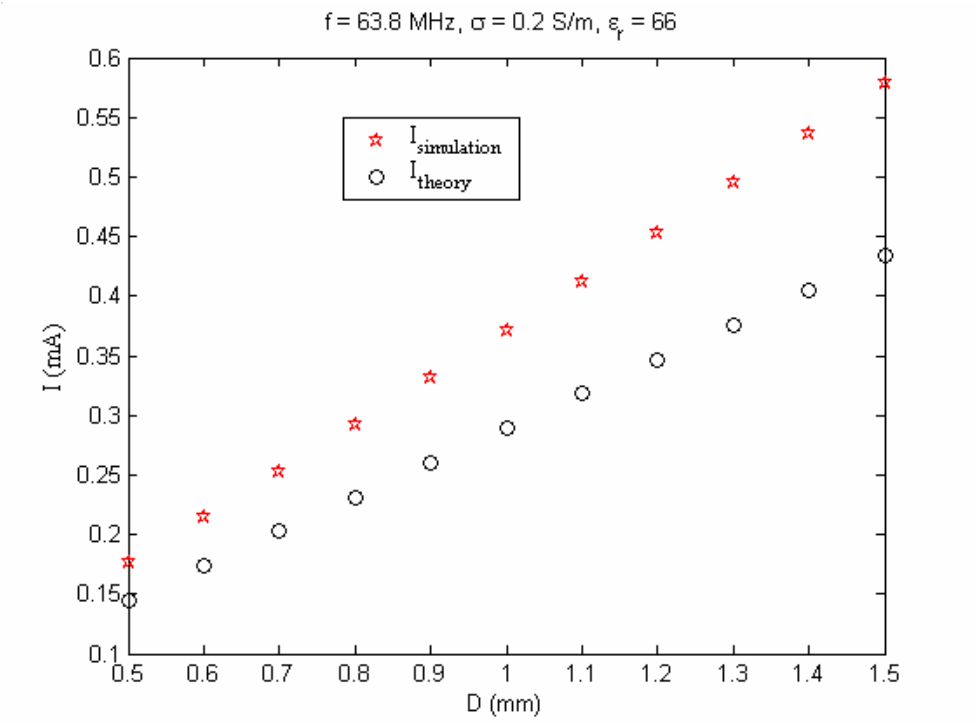

Figure 24. Induced current at 63.8 MHz as a function of the diameter of the tip when the wire length, *l*, is equal to 10 cm and the implant is located at R = 6 cm.

As shown in Figure 25, the induced current at the tip was simulated with respect to the conductivity of the medium. With the rising conductivity of the medium, the impedance of the tip to the medium around decreases depending on the Eq.(20). In this simulation, it is seen that how closely the EM simualtion and the theoretical results match closely.

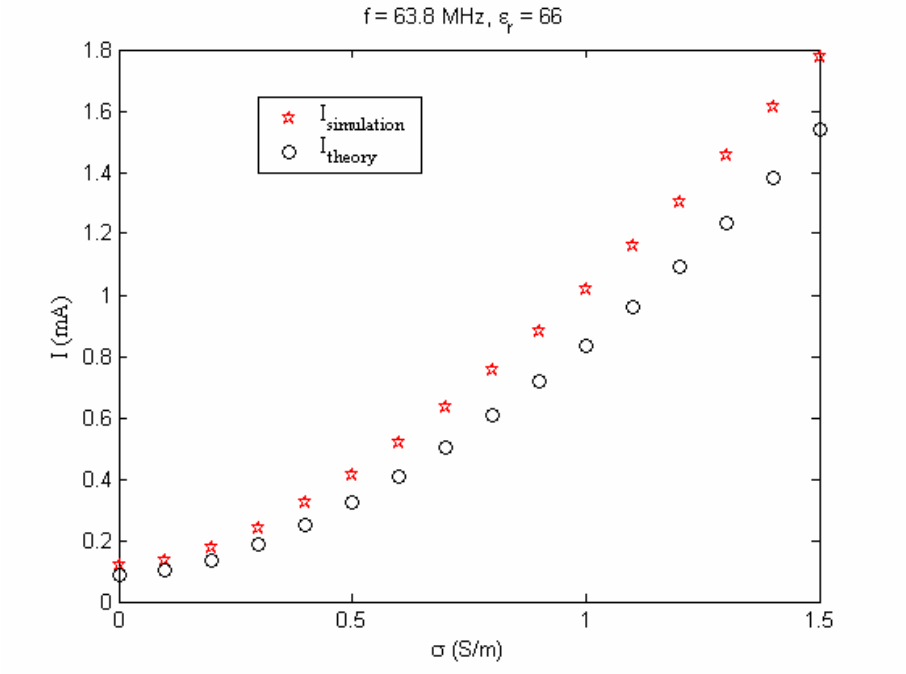

Figure 25. Induced current at 63.8 MHz as a function of the conductivity of the medium when the wire length, *l*, is equal to 10 cm and the implant is located at R = 6 cm.

As the other configuration, the general implant model was approximated as only the curvature of the lead when the wire length is zero. Then, the area of the curvature becomes independent of the wire length so that its effect for the current induction at the tip can be analyzed separately. It should be kept in mind that with that configuration the position of the implant is adjusted according to the center of the loop. First, the area of the curvature was kept constant and the implant was moved in radial direction. Then, the implant was placed at a fixed position, i.e. R = 6 cm, and the area of the lead curvature was changed.

First, in Figure 26 the implant with a constant lead curvature area was moved in the radial direction and the induced current at the tip was measured. Since the transmitted magnetic field assumed to be constant inside the body, it was expected to observe a constant current at the tip no matter the distance of the implant to the center of the body as in the theoretical result in Figure 26.

Contrary to this expectation, in EM simulation results the induced current raises as the distance to center increases. Considering the transmitted electric field distribution of EM simulation in Figure 20, the reason for that increase was thought to be the coupling of the transmitted electric field with the metallic case despite the fact that the wire length between the case and the tip was zero in the simulation. The same amount of current should have been induced to the tip for all R values as the one when R = 0, which is around 43 uA. However, if it is calculated in reverse order by substituting EM simulation data into the formula in Eq.(60), an additional wire length for all data points was observed despite there is no wire between the case and the tip in the simulation. This additional length was thought to be due to the effect of the metallic case height.

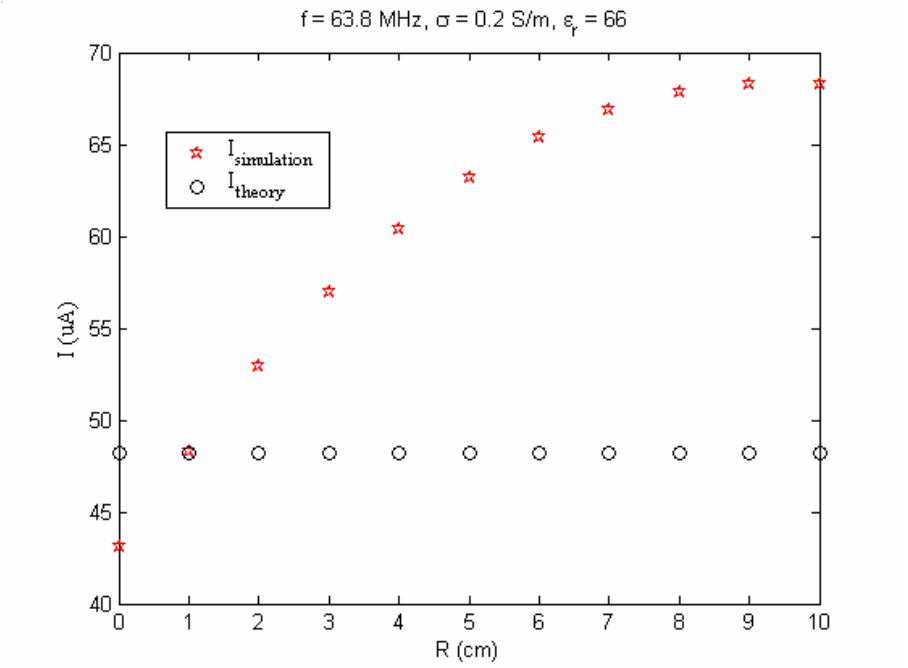

Figure 26. Induced current at 63.8 MHz as a function of R when the area, A, of the curvature is equal to 20 cm^2 when there is no wire between the case and the tip.

The same source of error was observed in Figure 27 as well when the area of the loop was changed without changing the location of the loop center.

When the area of the lead curvature was made wider, the induced current at the tip increases as expected since the coupling of the curvature with the magnetic field gets stronger. However, when it is calculated in the same way done for the previous plot, the same amount of error was observed.

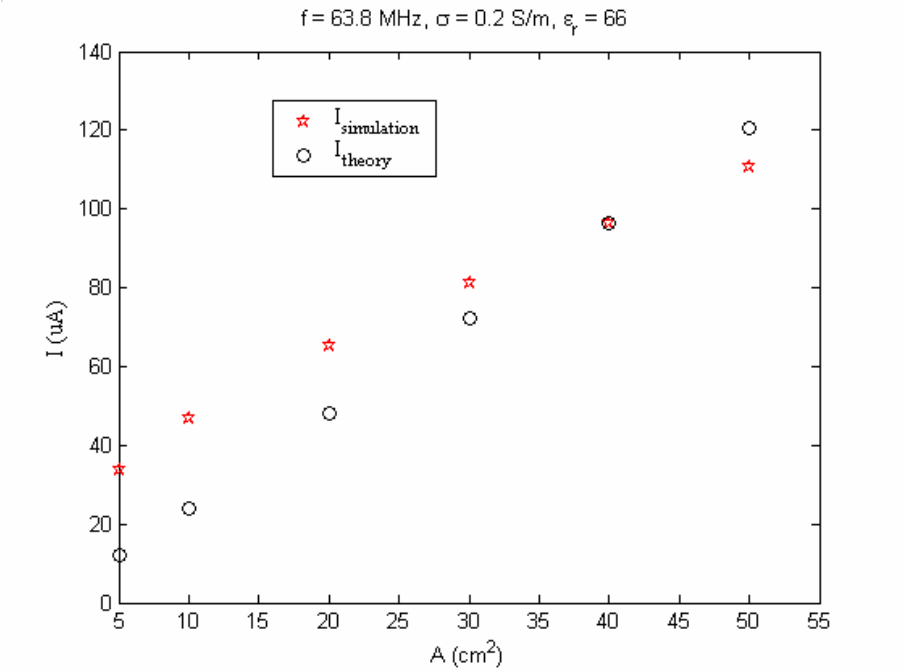

Figure 27. Induced current at 63.8 MHz as a function of area, A, of the curvature when there is no wire between the case and the tip. The center of the curvature is located at R = 6 cm.

In order to eliminate the effect of the metallic case height, the implant configuration was modified in a way that the metallic case was replaced with a wire connected to a sphere, which is the same as the one at the tip, and the area of the loop was conserved with additional wire with 5 cm length as shown in Figure 28. However, with that configuration the impedance of the tip was doubled while in the previous configuration the impedance of the case was negligibly small compared to the tip.

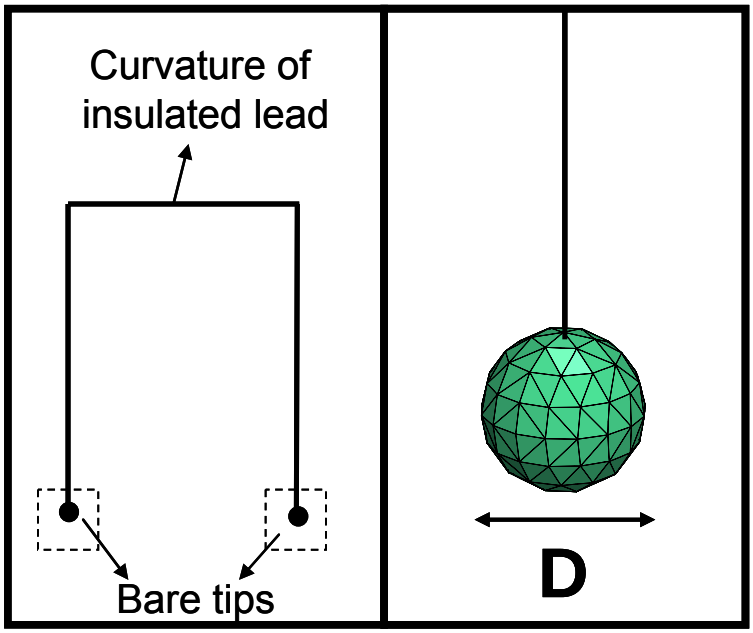

Figure 28. The modified version of implant configuration in Figur, configuration with only curvature of the wire when $l = 0$. There is a sphere at the each side of the lead. Quadrature birdcage coil model was used for the excitation.

With the simplified configuration, it seems in Figure 29 that the source of error can not be eliminated. The reason behind that is the quasistatic assumption assumed at the beginning of the analytical analysis in which the size of the implant was assumed to be significantly smaller than the wavelength; in other words the frequency of the system was assumed to be small. Therefore, we did the same simulation at an extreme case at 63.8 Hz to see the effect of the quasistatic assumption in Figure 30. As a result, a constant current induction at the tip independent of the radial position of the implant was observed.

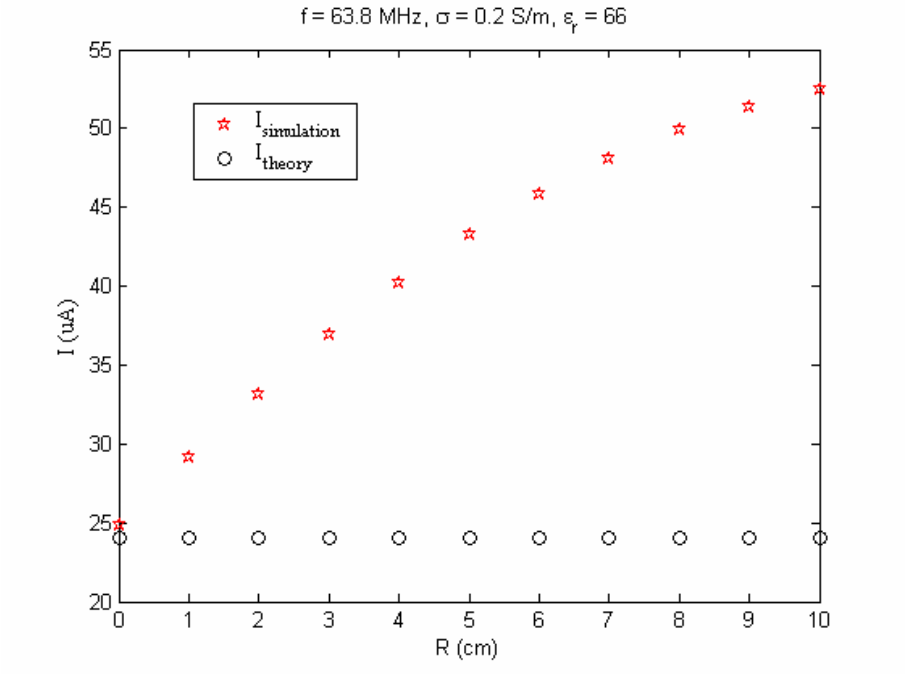

Figure 29. Induced current at 63.8 MHz as a function of R when the case was placed with a wire connected to a sphere, and the area, A, of the curvature is equal to 20 cm^2.

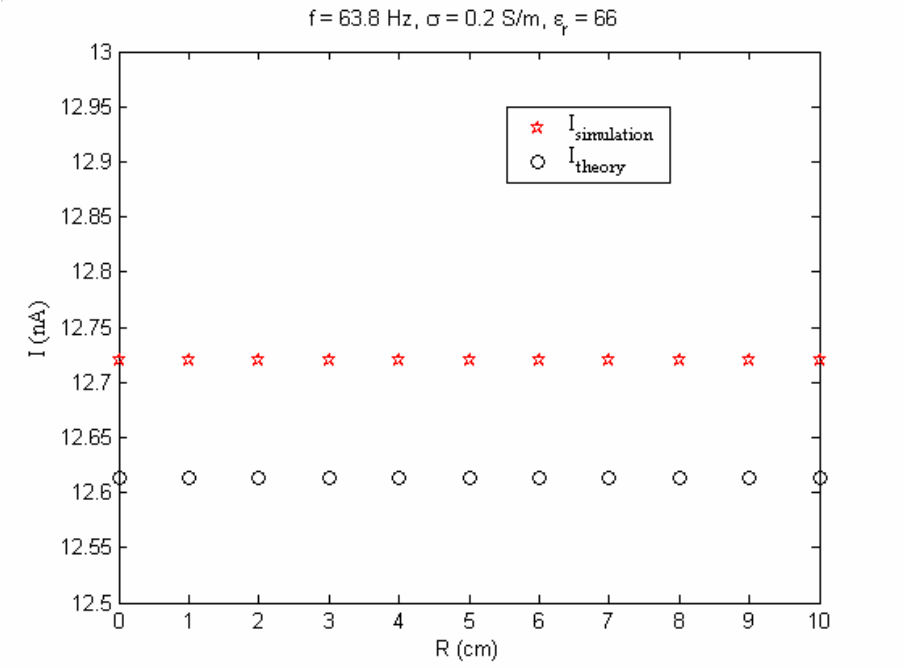

Figure 30. Induced current at 63.8 Hz as a function of R when the case was placed with a wire connected to a sphere, and the area, A, of the curvature is equal to 20 cm^2.

However, even if frequency of 63.8 Hz shows that under quasistatic fields the theoretical analysis matches well with the EM simualtion results; this does not give an intuition about error of the operating frequency, 63.8 MHz. Therefore, the simulation for other lower frequencies but in MHz order at critical data points was repeated. The obtained plots are shown in Figure 31 with the estimated maximum errors that are obtained at R = 10 cm were displayed in Table 4

Table 4. Estimated errors of induced current at the tip at different frequencies when the case was placed with a wire connected to a sphere, and the area, A, of the curvature is equal to 20 cm^2.

f (MHz)	I_{theory} (μA)	$I_{simulation}$ (μA) at R = 10 cm	Estimated Maximum Error (%)
63.8	24.07	52.51	118.12
10	5.12	8.59	67.82
5	3.55	4.44	24.9
1	1.58	1.61	1.99

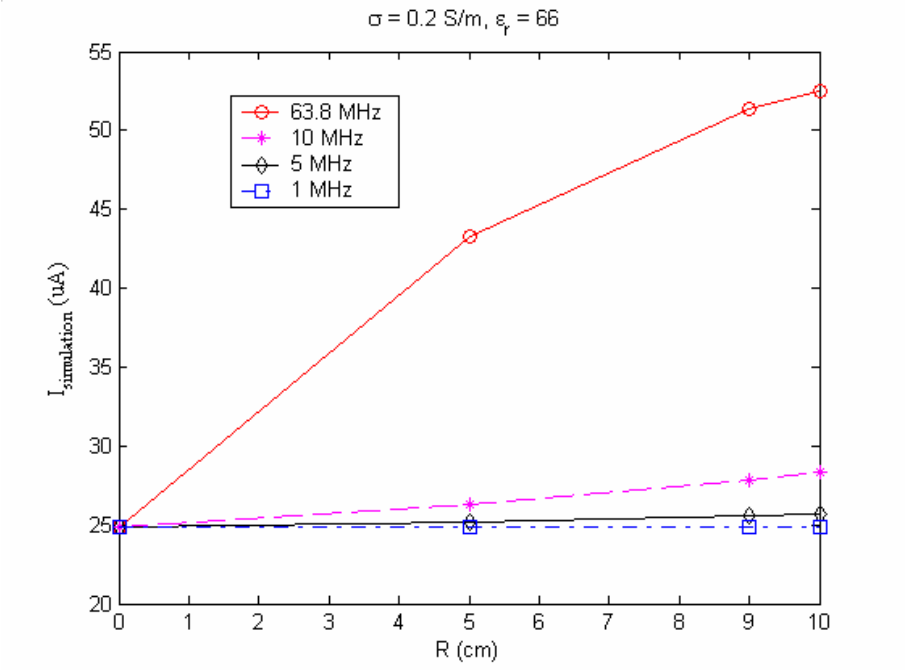

Figure 31. Induced current at different frequencies as a function of R when the case was placed with a wire connected to a sphere, and the area, A, of the curvature is equal to 20 cm^2. The results were normalized with respect to the 63.8 MHz data.

As shown in Table 4, at 63.8 MHz the estimated error was calculated as 118.12%, while at 10 MHz the estimated error was reduced by half. At 5 MHz and 1 MHz the estimated errors can be acceptable; therefore, these frequencies and lower ones can be in the quasistatic frequency range.

In Figure 32, the induced current as a function of area with the configuration of two spheres connected with a wire was plotted. This time the slopes of the both data match.

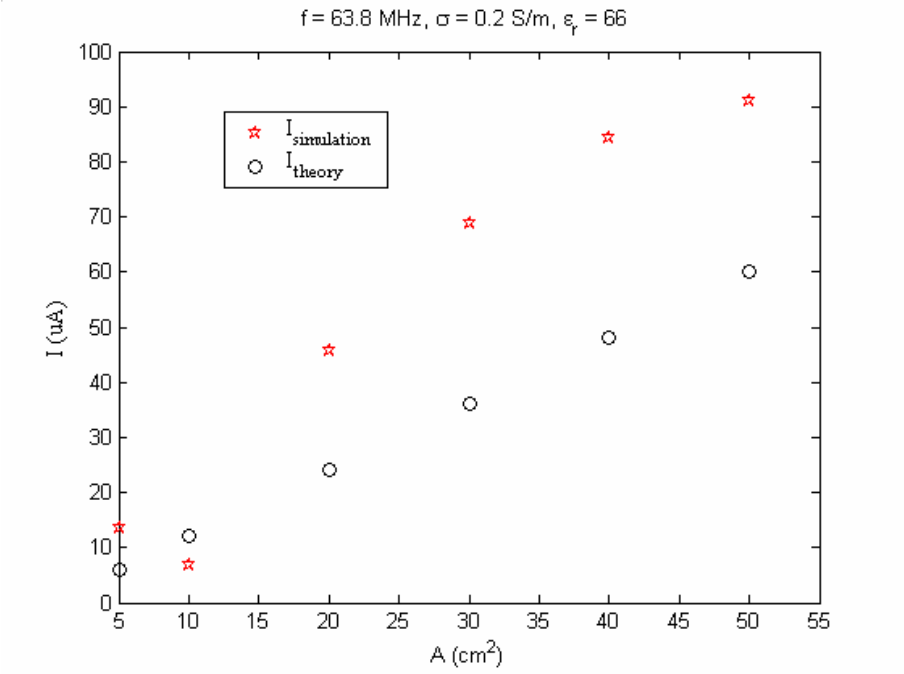

Figure 32. Induced current at 63.8 MHz as a function of area, A, of the curvature the case was placed with a wire connected to a sphere. The center of the curvature is located at R = 6 cm.

The most primitive configuration of an implant with the curved lead is a loop of wire of which one segment is loaded with the impedance of the tip as shown in Figure 33. In that configuration, the impedance of the spherical tip was calculated and added to the loop of wire. The simulation result is shown in

Figure 34. According to the EM simulation data with this configuration, the coupling of the loop with the magnetic field decreases as the loop gets further away in radial direction. This is because the magnetic field in the EM simulation decreases as a function of radial distance from the center of the body as shown in Figure 19. If the induced current data obtained at the center of the body in Figure 33 was considered (since we use the magnetic field value at the center of the body in the quadrature birdcage field model), the theoretical data calculated is very close to the EM simulation data as expected.

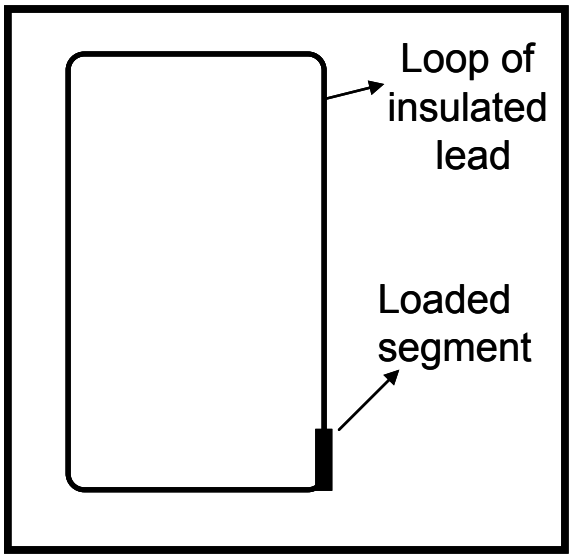

Figure 33. The most primitive version of implant configuration in Figure 12, configuration with a wire of loop that shown segment was loaded with the impedance of the tip. Quadrature birdcage coil model was used for the excitation.

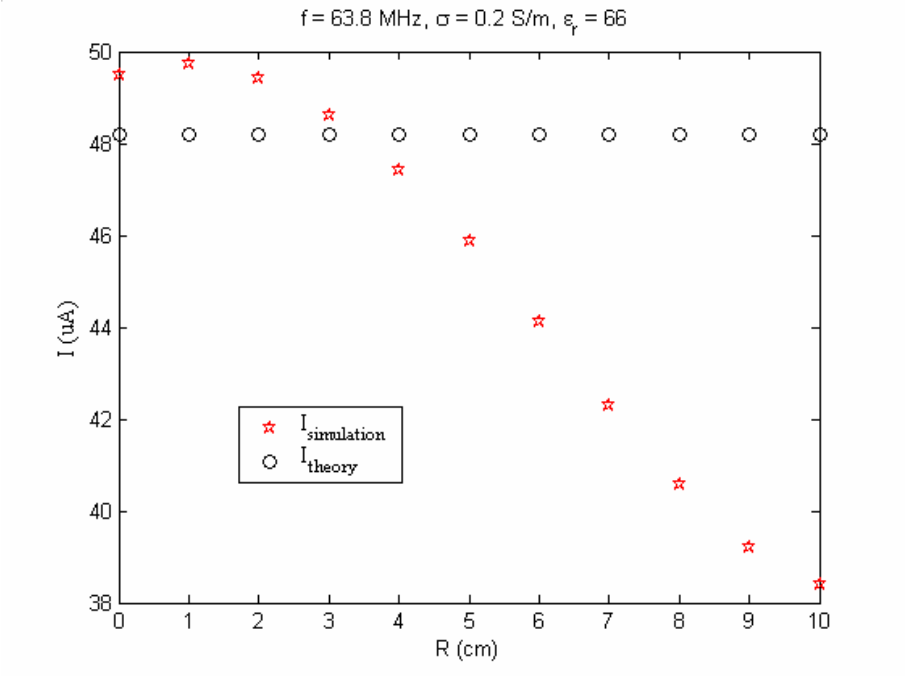

Figure 34. Induced current on a loop of wire whose one of the segments loaded with the impedance e of the tip as a function of R. the area of the loop is equal to 20 cm^2.

4.2.3 Results of Gel Phantom Simulation

The use of cylindrical phantom container with a limited length is the most important confliction of the real life with the theory. Therefore, before the experiment, the points where the eddy currents can be detected best should be determined. Since eddy current induction is directly related to the transmitted electric field, the electric field distribution inside the gel phantom gave the necessary insight for the experiment, i.e. where to place the probes inside the gel to obtain a reasonable data.

Besides, this simulation enabled to determine the accuracy of the quadrature birdcage coil model. Because, the quadrature birdcage coil model was developed by assuming an infinitely long cylindrical human model. It is important to estimate the amount of error in the transmitted electric field

distribution when the same excitation is used with a geometry that is limited in size.

As it is seen in Figure 35, if we place the fiber optic temperature probes very close to either the bottom or top ends, the electric field, consequently SAR, decreases as going away from the center contrary to it should increase. Therefore, it should be poured a gel with enough height to prevent probes from being very close to the bottom or top of the container.

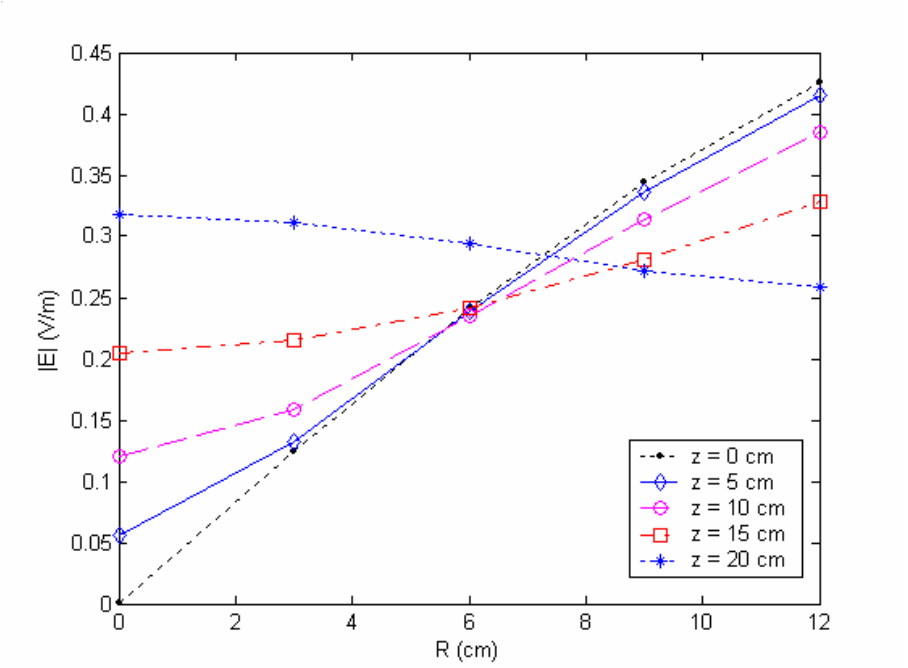

Figure 35. Transmitted electric field distribution inside a cylindrical gel phantom at the center, and the height of 5 cm, 10 cm, 15 cm and 20 cm.

For other heights, through the center of the phantom the intensity of fields increases, but it is stronger between 10 cm and 15 cm.

A gel that heights 24 cm was prepared, and the probes were placed at 4 cm depth from the top of the gel. Therefore, the simulation results for the

electric field distribution inside the gel phantom at z = 10 cm can give a useful insight about the deposited power in the gel in advance the phantom experiment is performed.

Table 5. The transmitted field results of gel phantom inside the quadrature birdcage coil model in the EM simulation. However, SAR is calculated by hand using Eq.(1)

R (cm)	|E| (V/m)	$\|H_-\|$ (F/m)	SAR (μW/kg)
0	0.056	0.0137	0.63
3	0.132	0.0134	3.48
6	0.239	0.0125	11.42
9	0.336	0.011	22.58

So as to calculate the corresponding transmitted electric field using Eq.(56), the RF magnetic field value at the center should be used but normalized with $\sqrt{2}$ as explained in section 3.3.1. That is $H_-(R = 0) / \sqrt{2} = 0.0097$ A/m. Then the resultant transmitted electric field and the SAR values are displayed in Table 6.

Table 6. The calculated transmitted field and resulted SAR values for the gel phantom inside the quadrature birdcage coil model.

R (cm)	|E| (V/m)	SAR (μW/kg)
0	0	0
3	0.147	4.32
6	0.294	17.29
9	0.441	38.9

As you seen in Table 7, the simulated SAR does not increase quadratically as a function of R while the theoretical SAR does. Besides, the percentage of the estimated error increases as going away from the center of the

body. That result is consistent with the transmitted electric field results shown in Figure 20.

Table 7. The estimated error between the EM simulation data and the theoretical data

R (cm)	$SAR_{simulation}$ (μW/kg)	SAR_{theory} (μW/kg)	Estimated Error (%)
0	0.63	0	-
3	3.48	4.32	19.44
6	11.42	17.29	33.95
9	22.58	38.9	41.95

4.3 Experiment Results

The theoretical SAR values calculated for the specified locations are shown in Table 8 using the transmitted electric field formula of quadrature birdcage coil model in Eq.(56) and SAR formula for rms electric field in Eq.(1) for comparison with the experimental results.

Table 8. The calculated theoretical SAR values

R (cm)	Theoretical SAR (W/kg)
3	1.77
6	7.08
9	15.94

One of the experimental data is shown in Figure 36 for experiment 2. After the linear fitting of the data between the start and end time of the experiment, the baseline SAR was calculated by calorimetry.

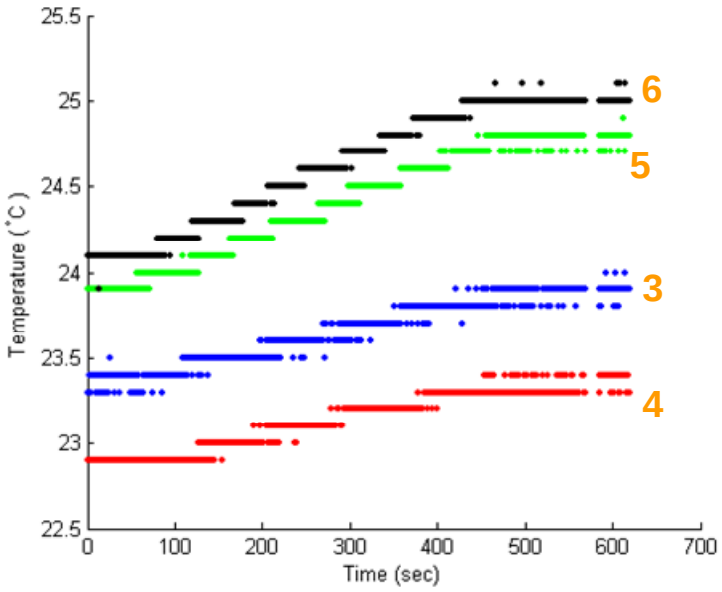

Figure 36. One of the typical experimental data. This is the data of the experiment 2 with probes 3, 4, 5 and 6.

As a result of the first experiment, the results displayed in Table 9 were obtained. Probes 1 and 2 should measure similar temperature values since they are located at equal distances from the center of the phantom while probes 5 and 6 should detect much more than them. Even if obtained data is reasonable considering the positions of probes with respect to each other, only probe 2 observes a good data considering the theoretical data.

Table 9. Results of experiment 1 with probes 1, 2, 5, and 6

Experiment 1 Probe No	Experimental SAR (W/kg)	Estimated Error (%)
1	2.98 - 3.42	40.51 - 48.28
2	1.6 - 1.8	1.84 - 11.02
5	7.51 - 7.65	108.37 - 112.23
6	8.23 - 8.42	89.42 - 93.72

In the second experiment, while probe 3 should detect similar results with probe 4, probe 5 should do with probe 6. Considering data of the first experiment, data of probes 3 and 4 is reasonable with respect to probes 1 and 2. Notice that probes 5 and 6 get similar values for both experiments.

Table 10. Results of experiment 2 with probes 3, 4, 5, and 6

Experiment 2 Probe No	Experimental SAR (W/kg)	Estimated Error (%)
3	4.31 - 4.57	55.09 - 64.17
4	4.23 - 4.43	59.83 - 67.58
5	7.41 - 7.61	109.47 - 115.27
6	8.53 - 8.75	82.28 - 86.9

In the third experiment, a quite good data was observed considering the analytical values in Table 8.

Table 11. Results of experiment 3 with probes 1, 2, 3, and 4

Experiment 3 Probe No	Experimental SAR (W/kg)	Estimated Error (%)
1	2.7 - 2.84	34.37 - 37.62
2	1.83 – 2.0	3.26 - 11.57
3	5.28 - 5.53	34.21 - 28.07
4	6.21 - 6.49	9.14 - 14.1

The experiments 4, 5 and 6 give also good results.

Common to all probes placed at 9cm away from the center of the phantom, i.e. probes 5, 6 and 8, the estimated percentage of error are much

larger than it can be accepted. The reason for that is the difference with the theory (developed for an infinitely long cylindrical human body model) and the experiment (done with a cylindrical phantom container with limited size).

Table 12. Results of experiment 4 with probes 2, 3, 4, and 6

Experiment 4 Probe No	Experimental SAR (W/kg)	Estimated Error (%)
2	2.47 - 2.9	28.17 - 38.91
3	4.45 - 4.57	54.84 - 59.04
4	4.59 - 4.71	50.5 - 54.22
6	9.05 - 9.29	71.57 - 76.23

Table 13. Results of experiment 5 with probes 4, 7, 8, and 9

Experiment 5 Probe No	Experimental SAR (W/kg)	Estimated Error (%)
4	4.46 - 4.63	52.88 - 58.65
7	4.03 - 4.16	70.24 - 75.97
8	8.36 - 8.58	85.86 - 90.66
9	4.5 - 4.64	52.64 - 57.23

Table 14. Results of experiment 6 with probes 3, 4, 7, and 8

Experiment 6 Probe No	Experimental SAR (W/kg)	Estimated Error (%)
3	4.72 - 4.88	45.19 - 50.03
4	4.18 - 4.31	64.45 - 69.64
7	4.07 - 4.19	68.9 - 74.23
8	9.17 - 9.41	69.37 - 73.9

Chapter 5

Discussion

In this thesis, the safety index of AIMDs, that is the maximum temperature increase at the tip of the implant as a result of unit applied SAR, has been analytically solved for known RF magnetic and transmitted electric field distribution. Throughout the analytical analysis, some simplifying assumptions had to be done to obtain a comprehensible and practical formulation that illustrates the effect of each parameter on the RF heating of AIMDs. Mentioning these assumptions once more is beneficial to discuss on their use during the design and limitations in the application of the safety index formula.

- This solution was derived under the quasistatic assumption. In other words, the size of the implant was assumed to be smaller than the half wavelength. Considering the implant configuration, length of the lead is the main component determining the size of the implant; therefore it can be concluded that this solution is valid for short leads. With short leads, it is meant to be leads shorter that 20 cm. Therefore, this analysis is valid for wires with length less than half wavelength. The safety index formulation derived is not suitable for most implants since the typical lead lengths are longer than 20 cm ranging 50-80 cm. The results obtained in this thesis are the first steps toward understanding longer lead lengths. We have started working on transmission line model in order to understand the current distribution on longer leads.

- The quasistatic assumption was helpful to reduce the number of variables contributing the RF heating of the AIMDs so that more effective parameters can be analyzed effectively.

- The operating frequency of safety index formulation is 63.8 MHz. The same RF heating model can be applied for higher field strengths, but the solution should be revised and tested at these frequencies. At 63.8 MHz, the homogeneity of fields was the main advantage and it was possible to take use of quasistatic assumption. At higher field strengths, the field homogeneity and wavelength decreases, therefore it is more complicated to derive the safety index of implants at higher frequencies.

- An alternative safety index formulation was proposed for an analytical model of the RF electric field transmitted by a quadrature birdcage coil. This solution presents a more compact formulation. The proposed quadrature birdcage coil model is the first model in the literature. For other body coil designs, the safety index formulation should be developed by relaying on the constraints of the body coil.

- The assumption of the bare tip as a spherical conductor while the insulated lead was assumed very thin enabled to use it as a point source during the Green's function averaging technique to find the temperature distribution in the tissue.

- During the analysis, body thermal and electrical properties were assumed to be constant around the tip. Because, local heating occurs in a small region of interest and away from any boundaries. This assumption made the use Green's function averaging technique possible during the analysis.

- In this thesis, the safety index formulation was derived for only an AIMD with a single lead. There are also AIMDs with multi-leads. For these implants, the safety index formulation should be modified considering the configuration of all leads in the human body.

The perfusion correction factor approaches 1 as perfusion and the lead diameter decrease. Note that, for typical values of the lumped perfusion parameter (less than 0.5 mm^{-1}) and the lead tip diameters (1 mm), this correction factor is between 0.5 and 1. Therefore, one can use f(Dv) as equal to 1 if a perfusion independent, worst case safety index value is desired.

On the other hand, the body thermal parameters used in safety index formulation, α and c_t can be found in literature and used in this equation. Phantom experiments needs to be carried out with care since phantom (gel) and body thermal parameters may not match.

The safety index formulation illustrates that the RF tip heating of an implant depends on the way the loop made and the position of the implant in the body. The angle of the loop with the radial axis has a significant effect on the RF heating of the tip. The worst angle is 0°, in that Rl and A terms add up and give rise to maximum heating. On the other hand, minimum heating occurs when this angle is 180° as shown in Figure 37. Note that this angle depends on how implant is placed in the body. The way the loop made also determines this angle because the direction of current changes depending on whether the lead is looped clockwise or counter-clockwise. With the changed current flow, the direction of loop normal changes, so the angle between the loop and the radial axis is altered as well.

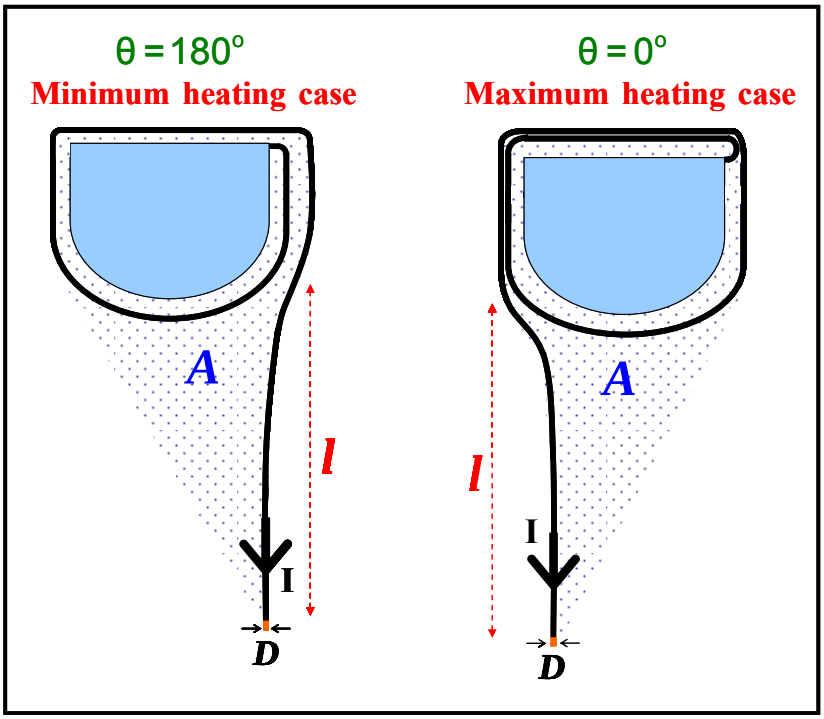

Figure 37. Two different configurations may result in significantly different heating at the tip. Right panel shows the maximum heating configuration.

For the sake of obtaining some numerical values, if the perfusion correction factor is ignored and a small area of the loop was assumed, and use the thermal parameters (α = 1.3x10-7 m^2/sec and c_t = 3662 J/kg/°C) measured, a very simple expression SI = 0.017 l^2 would be obtained where l is given in cm when the implant is located at a 6 cm away from the center of the body whose radius is 15 cm. In other words, while 1 cm lead would not cause any significant heating, a 20 cm lead heats up to approximately 7°C when it is exposed to 1 W/kg SAR.

The safety index estimates the maximum temperature increase when there is an active implant in the tissue per unit applied SAR without the implant in place. The safety index formulation ensures the RF safety of an implant by limiting the SAR of the applied RF field. This easy to understand formulation

enables to combine the MRI scanner estimated SAR that does not take into account of the existence of an implant with a contradictory situation scanning of a patient with an implant. This stress on the fact that scanner calculated SAR is an important parameter for the safety of implants.

Chapter 6

Conclusion and Future Work

To sum up, the RF heating of active implants during MRI scans was formulated with a simple formula such that it is very easy to foresee how much temperature rise can occur at the tip of the implant lead during MRI exam. By adjusting power level of pulse sequences, patient can be scanned safely.

First, the induced current and safety index formula was derived for active implants assuming a known RF electric and magnetic field distribution. Then, a quadrature birdcage coil model was developed for estimating the transmitted electric field distribution from a known RF magnetic field. The analytical solution of circular waves, simulation and experimental results showed that this model is a good analytical approximation of the incident electric field distribution inside an infinitely long cylindrical human model. Relying on that birdcage coil model, the induced current at the tip and safety index formula was modified. In order to understand the effects of wire length and the loop area on the induced current at the tip, the simulations of the induced current at the tip was done. Results of the simulations and analytical induced current formula showed that the analytical formulation is a good approximation of the RF heating phenomenon especially for wire lengths smaller than the half wavelength.

However, experimental verification of the safety index with gel phantom needs to be done to ensure the validity of the safety index formulation as a future work. As it is done in simulations, first loop of the implant can be neglected and only the safety index of a straight insulated wire with bare tip

connected to a metallic case can be measured. Then, the same can be done with only loop of wire without any wire length between the bare tip and the case.

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APPENDIX

Fourier Transform

The following Fourier Transform convention is used in our derivations;

$$F(v_x) = \int_{-\infty}^{\infty} f(x) e^{iv_x x} dx \quad \textbf{(79)}$$

$$f(x) = \frac{1}{2\pi} \int_{-\infty}^{\infty} F(v_x) e^{-iv_x x} dv_x \quad \textbf{(80)}$$

where $v_x = 2\pi k_x$, x is the distance in space domain and k_x is the distance in Fourier domain.

Depending on that convention, Fourier and inverse Fourier Transform of the spherically symmetric objects is calculated as follows (reference?);

$$F(q) = \int_{0}^{\infty} f(r) \frac{\sin(qr)}{qr} 4\pi r^2 dr \quad \textbf{(81)}$$

$$f(r) = \frac{1}{(2\pi)^3} \int_{0}^{\infty} F(q) \frac{\sin(qr)}{qr} 4\pi q^2 dq \quad \textbf{(82)}$$

where r and q are the radial distance away from the center of the sphere in space and Fourier domain respectively.

Convolution Property gives

$$f(r) * g(r) \overset{FT}{\leftrightarrow} F(q)G(q) \quad \textbf{(83)}$$

Special Integral Identities

We take advantage of some of the integral relationships from [46], which are listed below, in our calculations;

$$\int_{0}^{\infty} e^{-ax} \sin(mx) dx = \frac{m}{a^2 + m^2} \quad \text{for } a \geq 0 \quad \textbf{(84)}$$

$$\int_{0}^{\infty} \frac{\cos(mx)}{a^2 + x^2} dx = \frac{\pi}{2a} e^{-ma} \quad for \quad a > 0 \quad and \quad m \geq 0 \quad \textbf{(85)}$$

Reduction due to coronary blood flow of stent heating induced by the RF Magnetic Field during MRI

John Nyenhuis* and Nate Elder
Purdue University,
West Lafayette, Indiana USA
*Bemcalc, Inc. W. Lafayette, IN

Syed Hossainy
Abbott Vascular
Sunnyvale, CA USA

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July 7, 2015

Determination of temperature rise vs. length and in-vivo temperature rise for Wall stents

John Nyenhuis
Bemcalc, Inc.
824 North Chauncey Avenue
West Lafayette, Indiana 47906

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K152842/S1

Boston Scientific

Two Scimed Place
Maple Grove, MN 55311-1566
763.494.1700 Tel
www.bostonscientific.com

22nd October, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: **K152842—Traditional 510(k) Notification**
WALLSTENT™ RP Endoprosthesis Tracheobronchial
WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Sir or Madam:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 807 Subpart E, Boston Scientific Corporation (BSC) hereby submits the enclosed Traditional 510(k) Premarket Notification for the WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial Device.

This tracheobronchial self-expanding stent is a Class II device per 21 CFR 878.3720, Product Code JCT. Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial devices are self-expanding stents indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. The predicate device is the WALLSTENT Tracheobronchial Endoprosthesis, cleared via K992510 on November 18th, 1999. There have been no prior NSE determinations or prior submissions of any type for the subject device.

The proposed modification is to the Magnetic Resonance (MR) Safety section of the DFU, updating wording to align with current guidance recommendations for "MR Conditional". This labeling modification does not alter the indications for use or the fundamental scientific technology of the devices from that of the predicate device. As recommended in the FDA Guidance for Industry and FDA Staff, *Format for Traditional and Abbreviated 510(k)s,* August 12, 2005, the principal design and use factors of the device are tabulated below:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device ?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further information is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah Kucharski,

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
Fax: 763.494.2222
E-mail: carah.kucharski@bsci.com

Boston Scientific

Two Scimed Place
Maple Grove, MN 55311-1566
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22nd October, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: **K152842—RTA Hold Response to Traditional 510(k) Notification**
WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Ms. Levelle:

This amendment is in response to the Refuse To Accept (RTA) hold placed on K152842 on 15th October, 2015. Please see the enclosed response and associated attachments to satisfy the requirements for RTA hold.

Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further clarification is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah Kucharski

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
Fax: 763.494.2222
E-mail: carah.kucharski@bsci.com

Enclosures: Response, Amended 510(k) Summary, Amended Cover Letter, Relevent DFU Sections (for review purposes), Carton Prints

1. **A.2.b**

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a. **Response:**

(b)(4)

2. **A.8.a**

(b)(4)

a. **Response:**

(b)(4)

3. **B.11.c**

(b)(4)

a. **Response:**

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4. **C.14.b**

(b)(4)

a. **Response:**

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5. **D.15.a**
   - (b)(4)
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   - **Response:**
     (b)(4)

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- **Response:**
(b)(4)

- (b)(4)

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6. **D.15.b**

a. (b)(4)

a. **Response:**

(b)(4)

510k Summary

Per 21 CFR §807.92

Common or Usual Name	Self-Expanding Stent	
Trade Name(s)	Boston Scientific WALLSTENT™ RP Endoprosthesis Tracheobronchial and Boston Scientific WALLSTENT™ Endoprosthesis Tracheobronchial	
Product Code	JCT – Prosthesis, Tracheal, Expandable	
Classification of Device	The WALLSTENT Endoprosthesis Tracheobronchial device has been classified as Class II devices according to 21 CFR 878.3720 – Tracheal Prosthesis.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	**Owner /Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 3005099803
	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
Predicate Devices	WALLSTENT™ Tracheobronchial Endoprosthesis K992510 cleared November 18, 1999.	

Intended Use/ Indications for Use	The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
Description of Device	The WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial are comprised of two components: The implantable metallic stent and the UNISTEP Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89mm) guidewire.
Comparison of Required Technological Characteristics	The proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial is substantially equivalent to the existing Wallstent Endoprosthesis Tracheobronchial cleared by FDA under premarket notification K992510 (November 18, 1999). WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has the same intended use, scientific technology, design, sterilization method, and packaging as the applicable predicate device. The only difference is to the MR Safety labeling information within the Directions for Use. Bench testing in accordance with current FDA guidance supports a labeling as MR Conditional.
Summary of Non-Clinical Test Summary	Bench testing was performed in accordance with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11, 2014) to support labeling as MR Conditional. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALSLTENT Endoprosthesis Tracheobronchial (K992510).

Boston Scientific

Two Scimed Place
Maple Grove, MN 55311-1566
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22nd October, 2015

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: **K152842—Traditional 510(k) Notification**
WALLSTENT™ RP Endoprosthesis Tracheobronchial
WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Sir or Madam:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and in accordance with 21 CFR 807 Subpart E, Boston Scientific Corporation (BSC) hereby submits the enclosed Traditional 510(k) Premarket Notification for the WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial Device.

This tracheobronchial self-expanding stent is a Class II device per 21 CFR 878.3720, Product Code JCT. Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial devices are self-expanding stents indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. The predicate device is the WALLSTENT Tracheobronchial Endoprosthesis, cleared via K992510 on November 18th, 1999. There have been no prior NSE determinations or prior submissions of any type for the subject device.

The proposed modification is to the Magnetic Resonance (MR) Safety section of the DFU, updating wording to align with current guidance recommendations for "MR Conditional". This labeling modification does not alter the indications for use or the fundamental scientific technology of the devices from that of the predicate device. As recommended in the FDA Guidance for Industry and FDA Staff, *Format for Traditional and Abbreviated 510(k)s,* August 12, 2005, the principal design and use factors of the device are tabulated below:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 801 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device ?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further information is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah Kucharski,

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
Fax: 763.494.2222
E-mail: carah.kucharski@bsci.com

Boston Scientific

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRANSHEPATIC BILIARY

TRACHEOBRONCHIAL

TIPS

VENOUS

Self-Expanding Stent

Directions for Use **2**

DRAFT

This artwork is not ready for release until this note is removed. The Date-of-Issue will not be populated until this draft note is removed.

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Page 1 of 1

K152842/S002

Boston Scientific

Cardiology, Rhythm & Vascular
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Maple Grove, MN 55311-1566
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18 April 2016

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Amy Levelle

RE: **Additional Information Response to K152842/S001**
WALLSTENT™ RP Endoprosthesis Tracheobronchial
WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Ms. Levelle,

Boston Scientific Corporation (BSC) hereby submits responses to questions related to K152842/S001 for the WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial Device.

Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further information is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah J Kucharski

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
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Boston Scientific

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18 April 2016

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attn: Amy Levelle

RE: **Additional Information Response to K152842/S001**
WALLSTENT™ RP Endoprosthesis Tracheobronchial
WALLSTENT™ Endoprosthesis Tracheobronchial

Dear Ms. Levelle,

Boston Scientific Corporation (BSC) hereby submits responses to questions related to K152842/S001 for the WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial Device.

Two copies of this notification have been provided. In lieu of one of the paper copies, an electronic (eCopy) is also being provided on CD. The eCopy is an exact duplicate of the original paper submission.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 20.61(c), is not available for public disclosure. Boston Scientific hereby requests that the information designated as confidential in this submission be exempt from disclosure under exemption 4 of the Freedom of Information Act.

If further information is required, please contact me per the information below, or Melanie Raska at Melanie.raska@bsci.com or 763-494-2212.

Sincerely,

Carah J Kucharski

Carah Kucharski
Regulatory Affairs Specialist
Tel: 763.255.0738
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E-mail: carah.kucharski@bsci.com

K152842 Additional Information Responses

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a. (b)(4)

a. **BSC Response:** (b)(4)
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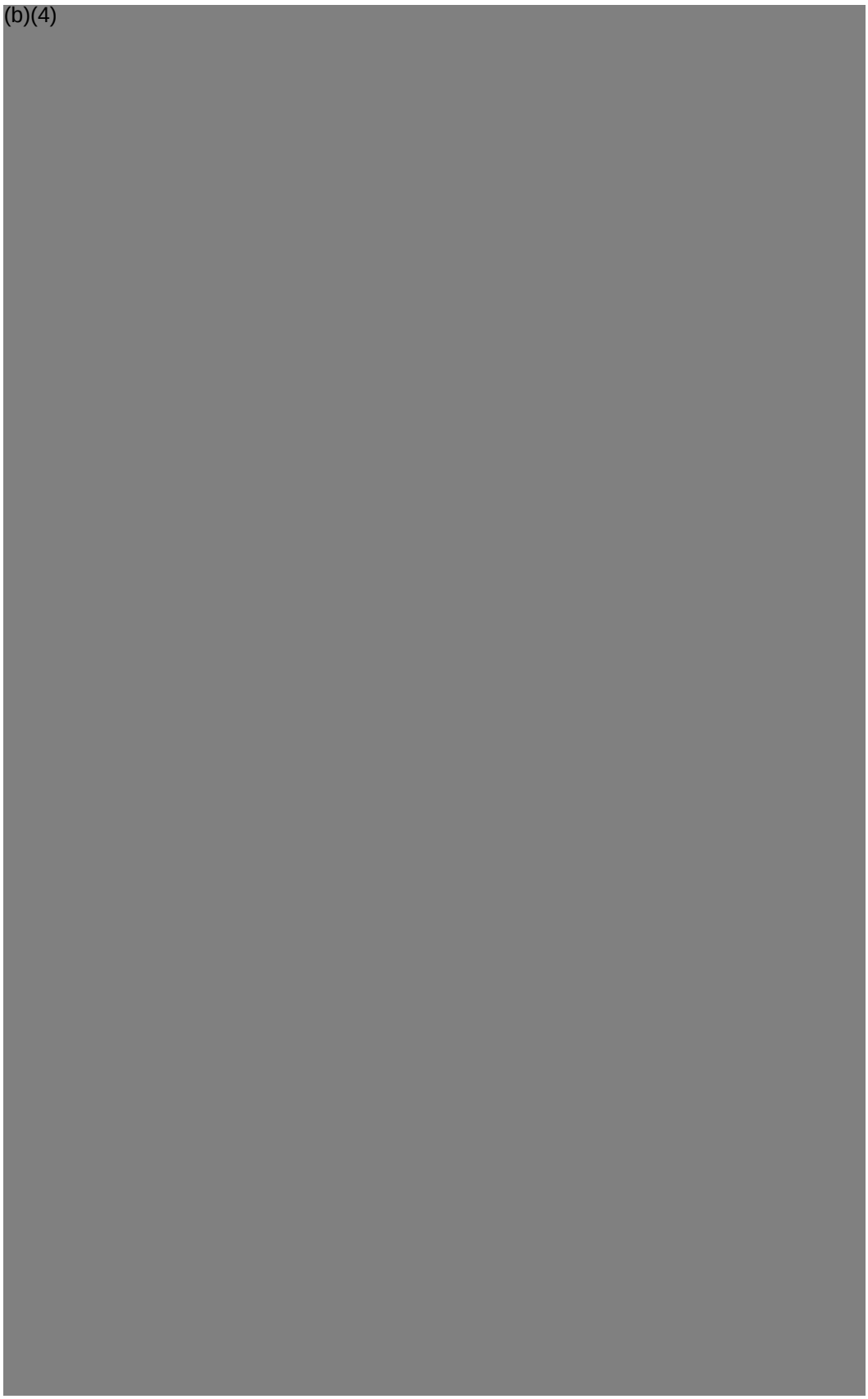

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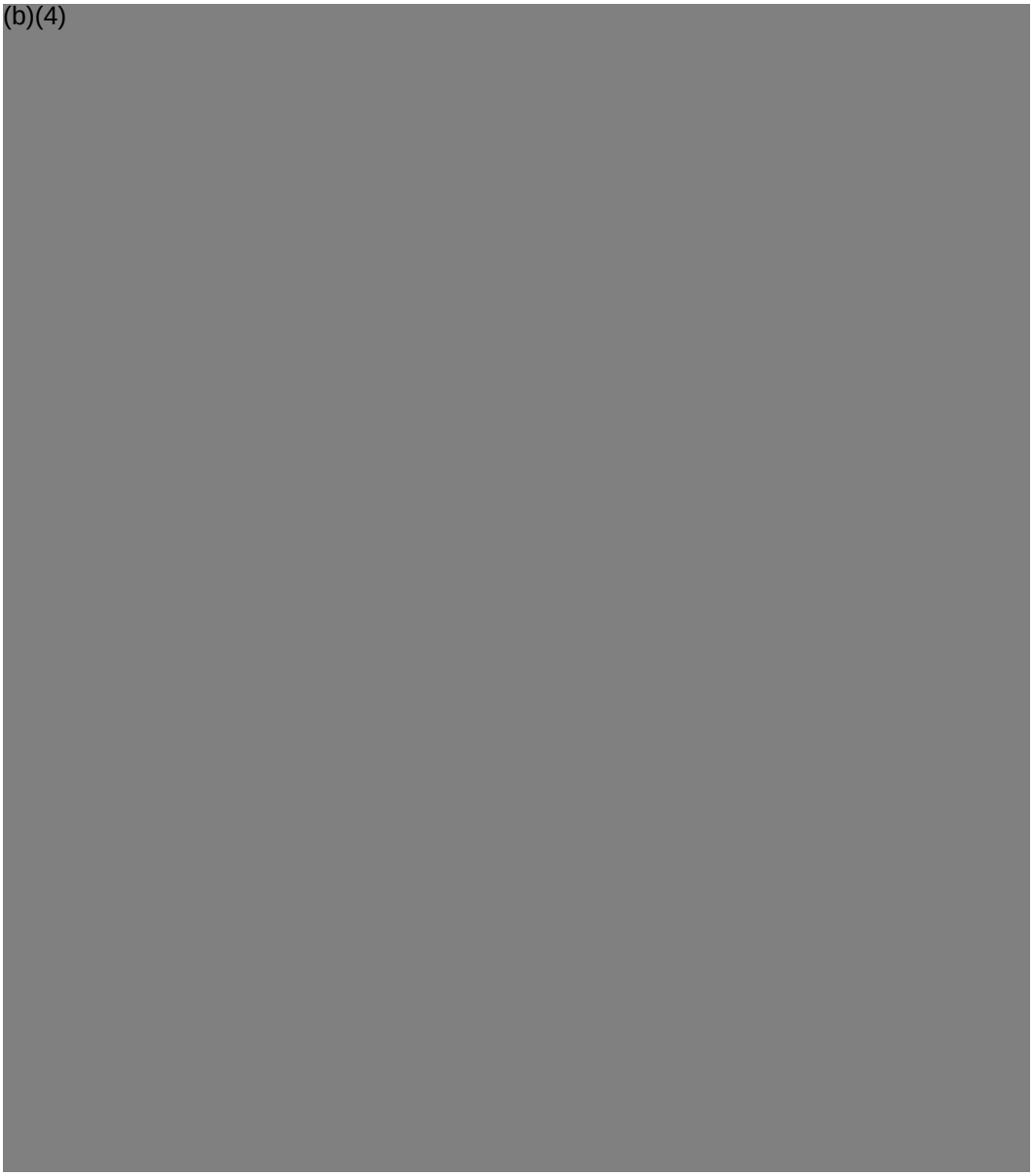

Table 1: Numerical Analysis of MDRs by Total Sales and On-Label Use

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b. (b)(4)

b. BSC Response: (b)(4)
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c. (b)(4)

c. BSC Response: (b)(4)

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2. (b)(4)

BSC Response: (b)(4)
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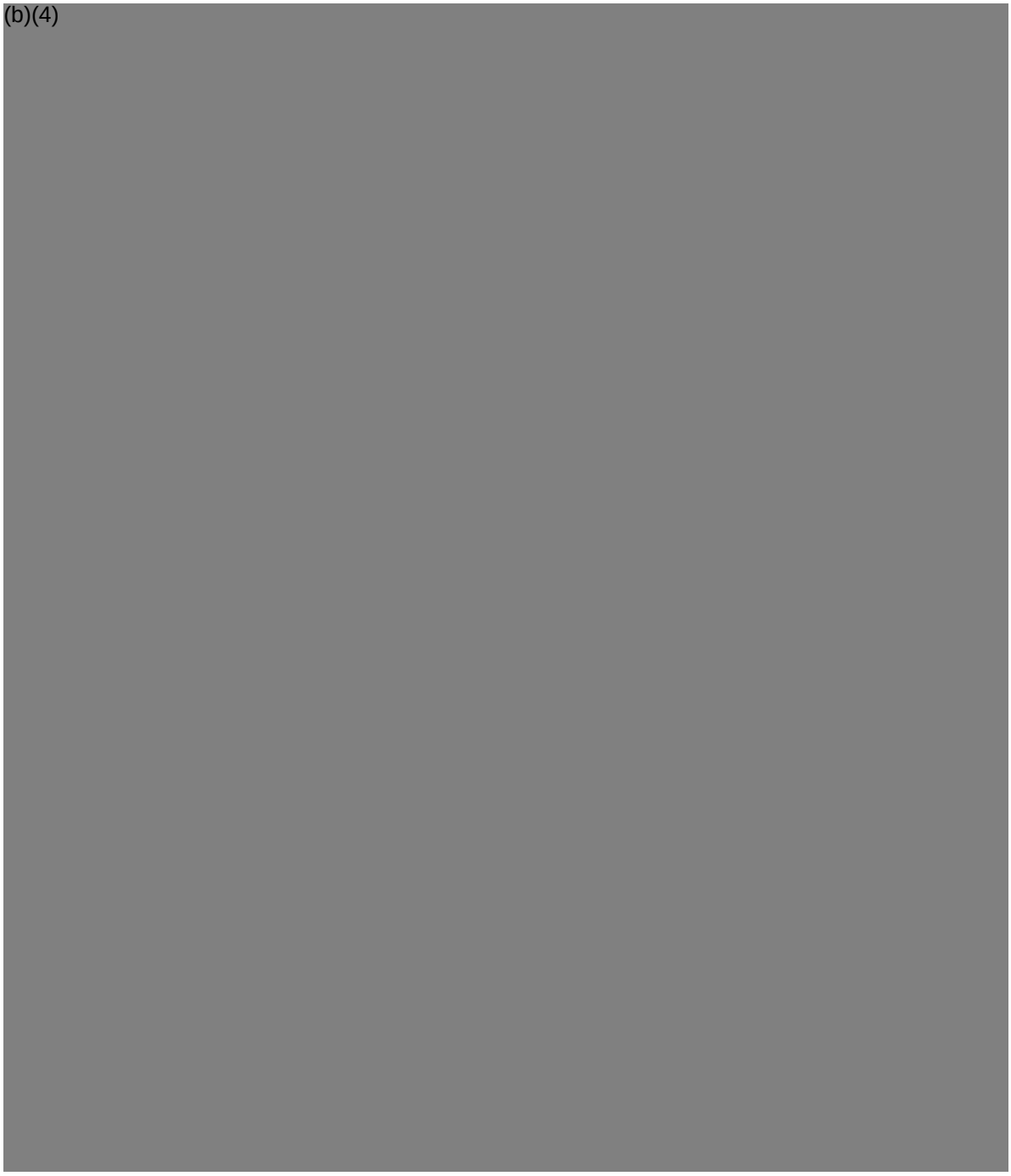

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3. (b)(4)

a. (b)(4)

BSC Response: (b)(4)
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b. (b)(4)

BSC Response: (b)(4)
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Additionally, comparative calorimetry tests and tensile testing were completed to further compare the two resins and confirm that device performance is not impacted by the change. Comparing the melting points from both the first and second sample heatings of Zeus Resin 13504 (Low-PFOA) to the average of the two lots of Zeus Resin 13504 (Zero-PFOA), the difference in the melting points was 0.97°C for the melting during the first heat and 0.49°C for the second heating. In both cases, this is less than a 1°C difference or less than a 0.3% difference in melting points. This suggests that the thermal history, the chemical identity, and the polymer structure for the polymer samples are equivalent.

Tensile tests were performed on Zeus Resin 13504 (Low-PFOA) and Zeus Resin 13504 (Zero-PFOA). The shape and important dimensions of the samples tested in tensile and elongation are listed in **Table 5**. **Table 6** displays the summarized results for various part numbers tested.

Table 5: Shape and Important Dimensions of Tensile and Elongation Samples

Zeus Part Numbers:	Low-PFOA	Zero-PFOA
42133	PTFE; Extruded Sub-Lite-Wall® Etch ID .069+/-.001 Wall.001+.001/-0 Natural Color Cut Length 58 +1 -.000	PTFE; Extruded Sub-Lite-Wall® Etch ID .069+/-.001 Wall.001+.001/-0 Natural Color Cut Length 58 +1 -.000
42849	PTFE; Extruded Sub-Lite-Wall® Etch ID .0665+/-.0005 Wall .0015+/-.0005 Natural Color Cut Length 55.118+/-.3937	PTFE; Extruded Sub-Lite-Wall® Etch ID .0665+/-.0005 Wall .0015+/-.0005 Natural Color Cut Length 55.118+/-.3937
44196	PTFE; Extruded Sub-Lite-Wall® Etch ID .068+/-.001 Wall .001+/-.0005 Natural Color Cut Length 50 +/-.500	PTFE; Extruded Sub-Lite-Wall® Etch ID .068+/-.001 Wall .001+/-.0005 Natural Color Cut Length 50 +/-.500
39938	PTFE; Extruded Special ID .062+.004/-0 OD .092+/-.002 Natural Color Cut Length 100 +/-.125 Annealed / Flare .110 +/- .020 Depth of Flare	PTFE; Extruded Special ID .062+.004/-0 OD .092+/-.002 Natural Color Cut Length 100 +/-.125 Annealed / Flare .110 +/- .020 Depth of Flare

Table 6: Summary of Tensile Test Results

Zeus Part Number	Metric	Zeus Resin 13504 (Low-PFOA) Tensile Strength (psi)	Zeus Resin 13504 (Zero-PFOA) Tensile Strength (psi)	Difference (%)
42133	Mean	22727.96	24899.79	10%
	Std Dev	1125.02	1097.68	
	$\mu + 2\sigma$	24978.01	27095.16	
	$\mu - 2\sigma$	20477.91	22704.42	
	Range	4500.10	4390.74	
	# Points	20	20	
42849	Mean	12422.88	14486.72	17%
	Std Dev	324.93	531.76	
	$\mu + 2\sigma$	13073.73	15550.24	
	$\mu - 2\sigma$	11773.02	13423.20	
	Range	1299.72	2127.04	
	# Points	20	20	
44196	Mean	15740.92	14793.27	-6%
	Std Dev	506.59	1607.08	
	$\mu + 2\sigma$	16754.10	18007.42	
	$\mu - 2\sigma$	14727.73	11579.12	
	Range	2026.37	6428.3	
	# Points	20	20	
39938	Mean	6927.27	7214.80	4%
	Std Dev	292.66	352.51	
	$\mu + 2\sigma$	7512.59	7919.81	
	$\mu - 2\sigma$	6341.95	6509.79	
	Range	1170.65	1410.02	
	# Points	20	20	

A graphical analysis (see **Figure 2**) was conducted on the raw data to determine whether there was a significant difference between the low and Zero-PFOA resins. Two of the part numbers (42133 and 42849) show tensile strengths that are slightly higher for Zero-PFOA resin. The tensile strengths of the other two part numbers are approximately equal.

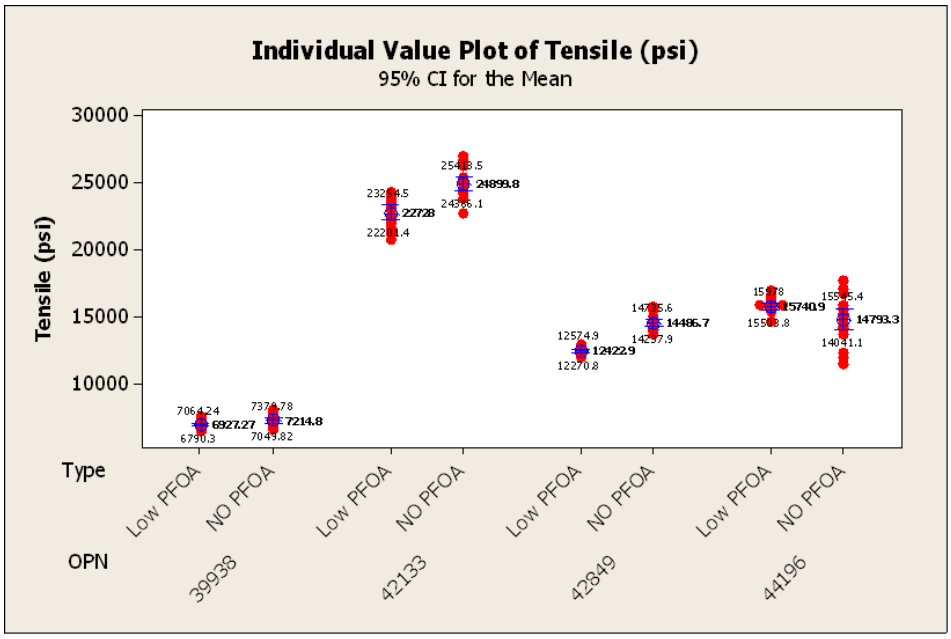

Figure 2: Individual Value Plot of Tensile Elongation Results

Tensile elongation tests were performed on Zeus Resin 13504 (Low-PFOA) and Zeus Resin 13504 (Zero-PFOA). **Table 7** shows the summarized results for various part numbers tested.

Table 7: Summary of Tensile Elongation Results

Zeus Part Number	Metric	Zeus Resin 13504 (Low-PFOA) Tensile Elongation (%)	Zeus Resin 13504 (Zero-PFOA) Tensile Elongation (%)	Difference (%)
42133	Mean	350.17	348.38	-1%
	Std Dev	30.73	22.89	
	μ + 2σ	411.64	394.16	
	μ - 2σ	288.70	302.60	
	Range	122.94	91.56	
	# Points	20	20	
42849	Mean	288.02	328.24	14%
	Std Dev	19.05	22.94	
	μ + 2σ	326.12	347.11	
	μ - 2σ	249.93	282.36	
	Range	76.19	91.75	
	# Points	20	20	
44196	Mean	382.45	347.02	-9%
	Std Dev	29.82	44.15	
	μ + 2σ	442.09	435.32	
	μ - 2σ	322.81	258.73	
	Range	119.28	176.59	
	# Points	20	20	
39938	Mean	477.43	488.49	2%
	Std Dev	81.52	91.00	

Zeus Part Number	Metric	Zeus Resin 13504 (Low-PFOA) Tensile Elongation (%)	Zeus Resin 13504 (Zero-PFOA) Tensile Elongation (%)	Difference (%)
	$\mu + 2\sigma$	640.47	670.49	
	$\mu - 2\sigma$	314.39	306.49	
	Range	326.08	364.00	
	# Points	20	20	

A graphical analysis (see **Figure 3**) was conducted on the raw data to determine whether there was a statistical significant difference between the low and Zero-PFOA resins. Two of the part numbers (42133 and 42849) show tensile elongations that are slightly higher for Zero-PFOA resin. The tensile elongations of the other two part numbers are approximately equal.

As illustrated in **Figure 3,** the elongations of two of the part numbers (39938 and 42133) are approximately the same. The other two part numbers show elongations that are slightly different; one slightly higher elongation for Zero-PFOA resin and the other slightly higher for the Low-PFOA resin. On the whole, there do not appear to be large differences in the mechanical properties between the Zero-PFOA resin and the Low-PFOA resin.

Subsequent to the initial Zeus tensile testing, Zeus provided a summary of ASTM D4895 Tensile and Elongation results from 18 months of Low-PFOA and Zero-PFOA resins. **Table 8** summarizes these results.

Table 8: Tensile and Elongation Results from Testing of 18 Months Production Material

	Zeus Low-PFOA PTFE Resin 13504	Zeus Zero-PFOA PTFE Resin 13504	Difference (%)
Tensile at Break (MPa)	30.6	32.4	5.9%
STD. DEV.	2.9	2.9	
Elongation at Break (%)	432	444	2.8%
STD. DEV.	44	35	

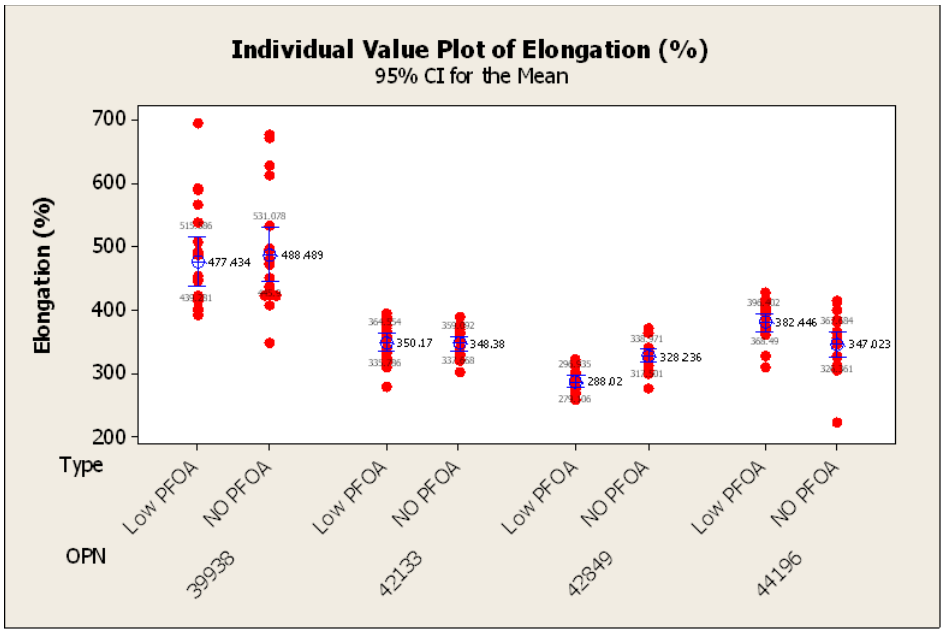

Figure 3: Individual Value Plot of Elongation results

All results support the conclusion that the removal of PFOA from the manufacturing process does not have an impact on the PTFE material supplied by Zeus. The material continues to be supplied as 100% PTFE with the same CAS number, 9002-84-0). Based on this, BSC Corporate Biocompatibility and Toxicology Services considers the two resins to be chemically equivalent. Therefore, this is not considered a material change, and because both the raw material and extruded components remain unchanged, so does device performance.

c. *You indicate that a change was made in your carton packaging and Tear-Tab Closure Strip. You indicate that applicable packaging verification; shelf life verification and sterilization evaluations were completed to demonstrate that packaging continues to meet specifications. It is unclear what impact these changes have on the sterility of your device. Additionally, you indicate the closure strip is not responsible for keeping the carton closed, and is used as a restocking aid only. It is unclear why shelf life and sterilization evaluations were necessary and why restocking is needed for your device, as this is a single use device. Please clarify why restocking is necessary and what impact these changes may have on sterility of your device.*

BSC Response: The tear-tab closure strip is a restocking aid placed on the outside of the carton, as shown in **Figure 4**. Design of the tear-tab closure strip is illustrated in **Figure 5**. The purpose of the closure strip is to serve as a restocking aid to determine whether or not a returned product has been opened and can be restocked in a BSC distribution center. If the closure strip has been opened (as shown in **Figure 4**), the product is not accepted for restocking. Sterilization and shelf life evaluations were completed on the closure strip performance only in order to confirm that the sterilization process and shelf life does not impact the adherence or performance of the closure strip. Because cartons which have been opened are

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4. (b)(4)

BSC Response: (b)(4)
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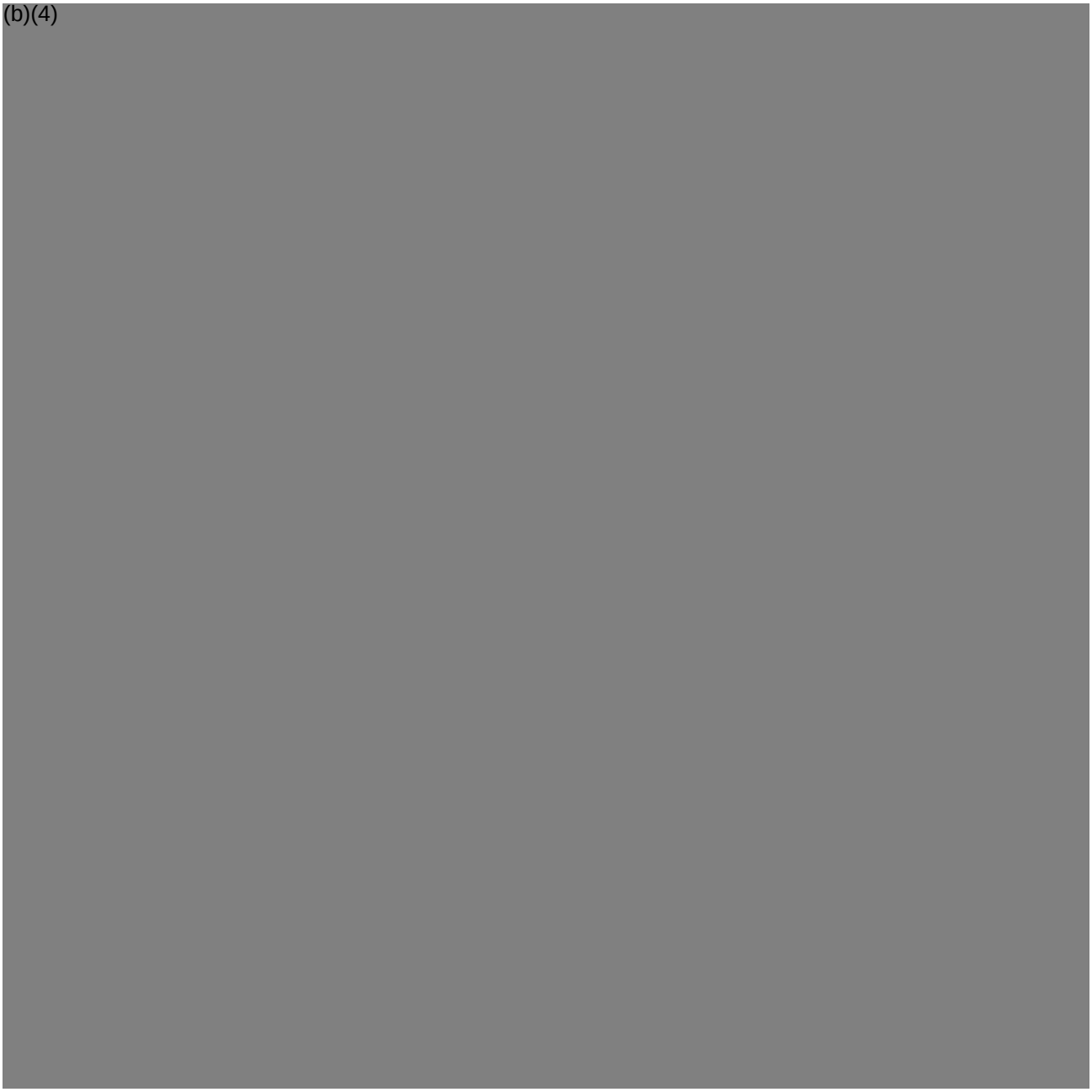

Table 11: Packaging Component Overview

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Labeled Carton	standard pre-printed symbols and information, common across multiple BSC products • Printed labels applied to closed carton contain product and batch-specific information and symbols • Spine label (contains sizing information, indications, and use-by dates • On short-pack configuration, main label is placed over three faces (front, bottom, and back) • Sizing chart label additionally placed on back • Labels are not removable from carton	See Image on Next Page

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Boston Scientific

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

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TIPS

VENOUS

Self-Expanding Stent

DRAFT

This artwork is not ready for release until this note is removed. The Date-of-Issue will not be populated until this draft note is removed.

91079000-01

2016-03

Attachment 2 –Question 2 Additional Information

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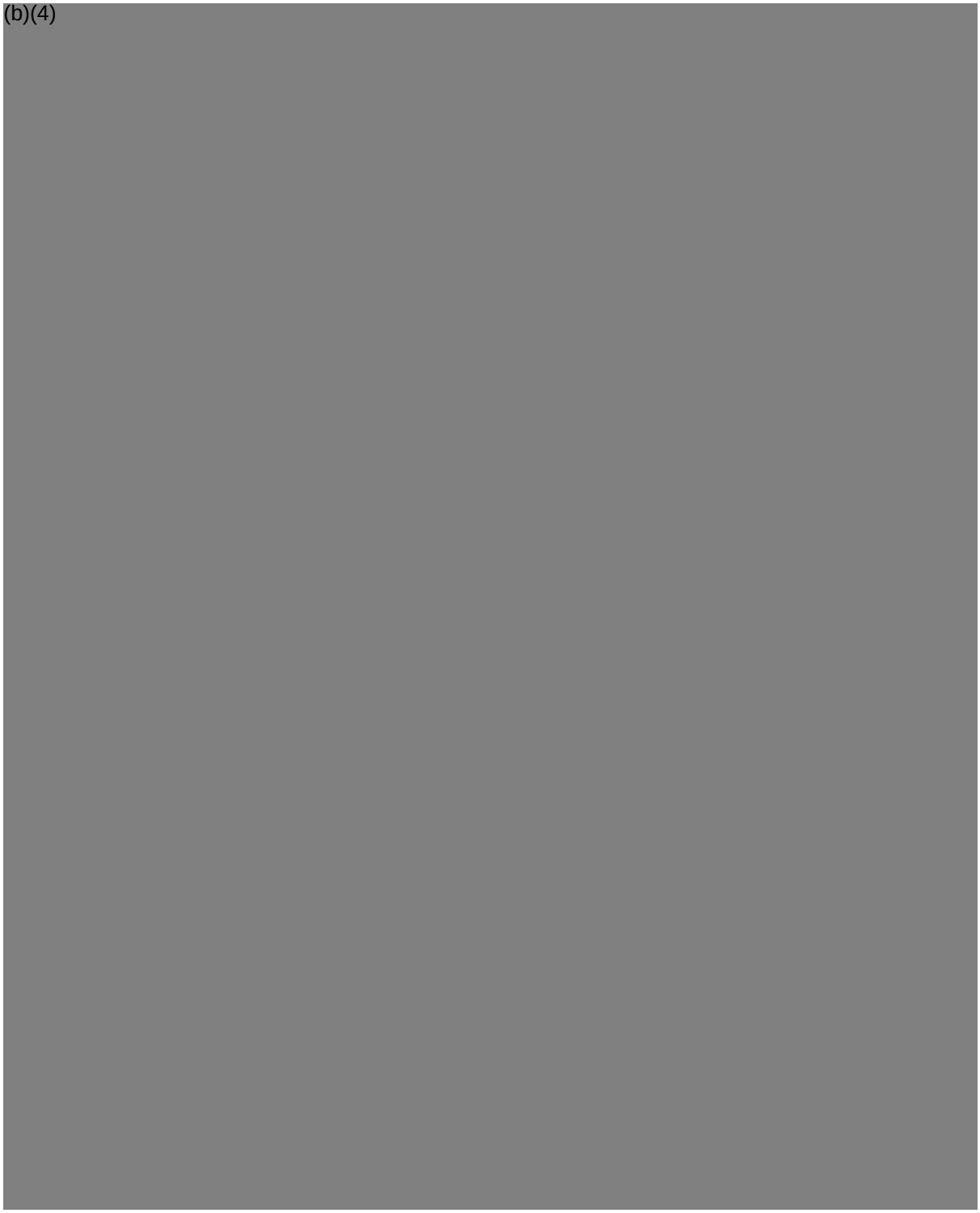

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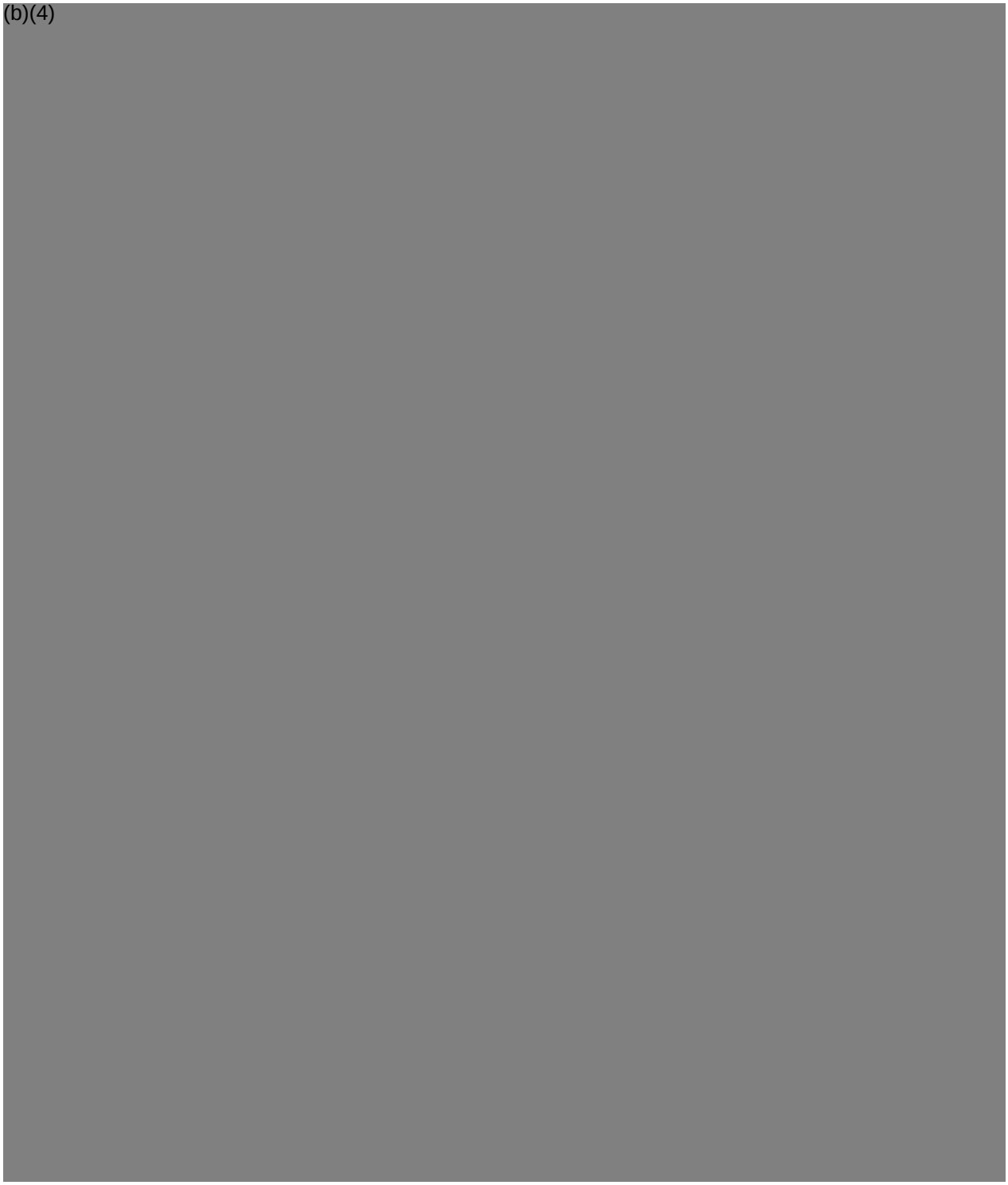

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(b)(4) **FINAL GLP REPORT:** (b)(4)

CLASS VI TEST – USP

Test Article
(b)(4)

(b)(4)

Final Report Date
April 15, 2011

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

(b)(4)

Sponsor
Zeus Industrial Products, Incorporated
620 Magnolia Street
Orangeburg, SC 29115

(b)(4) Test Data

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(b)(4) TEST PROTOCOL
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CLASS VI TEST – USP

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COMPLIANCE
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MANAGEMENT OF THE STUDY

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Orangeburg, SC 29115

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(b)(4) **FINAL GLP REPORT:** (b)(4)

L929 MEM ELUTION TEST – ISO

Test Article
(b)(4)

Author
(b)(4)

Final Report Date
March 28, 2011

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

Performing Laboratory
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Sponsor
Zeus Industrial Products, Incorporated
620 Magnolia Street
Orangeburg, SC 29115

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L929 MEM ELUTION TEST – ISO

(b)(4) PROTOCOL NUMBER: (b)(4)

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

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Sponsor
Zeus Industrial Products, Inc.
620 Magnolia Street
Orangeburg, SC 29115

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(b)(4) **FINAL GLP REPORT:** (b)(4)

HEMOLYSIS – RABBIT BLOOD – ISO INDIRECT CONTACT

Test Article
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(b)(4)

Final Report Date
March 30, 2011

COMPLIANCE
21 CFR, Part 58
Good Laboratory Practice for Non–Clinical Laboratory Studies

MANAGEMENT OF THE STUDY

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Orangeburg, SC 29115

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Document Number	(b)(4)
Project Name	(b)(4)
Project Number	(b)(4)
Author(s)	(b)(4)
Contributor(s)	

(Form 36086 Ver. AG – Follow Technical Report and Analytical Data / Report Content and Control (b)(4)

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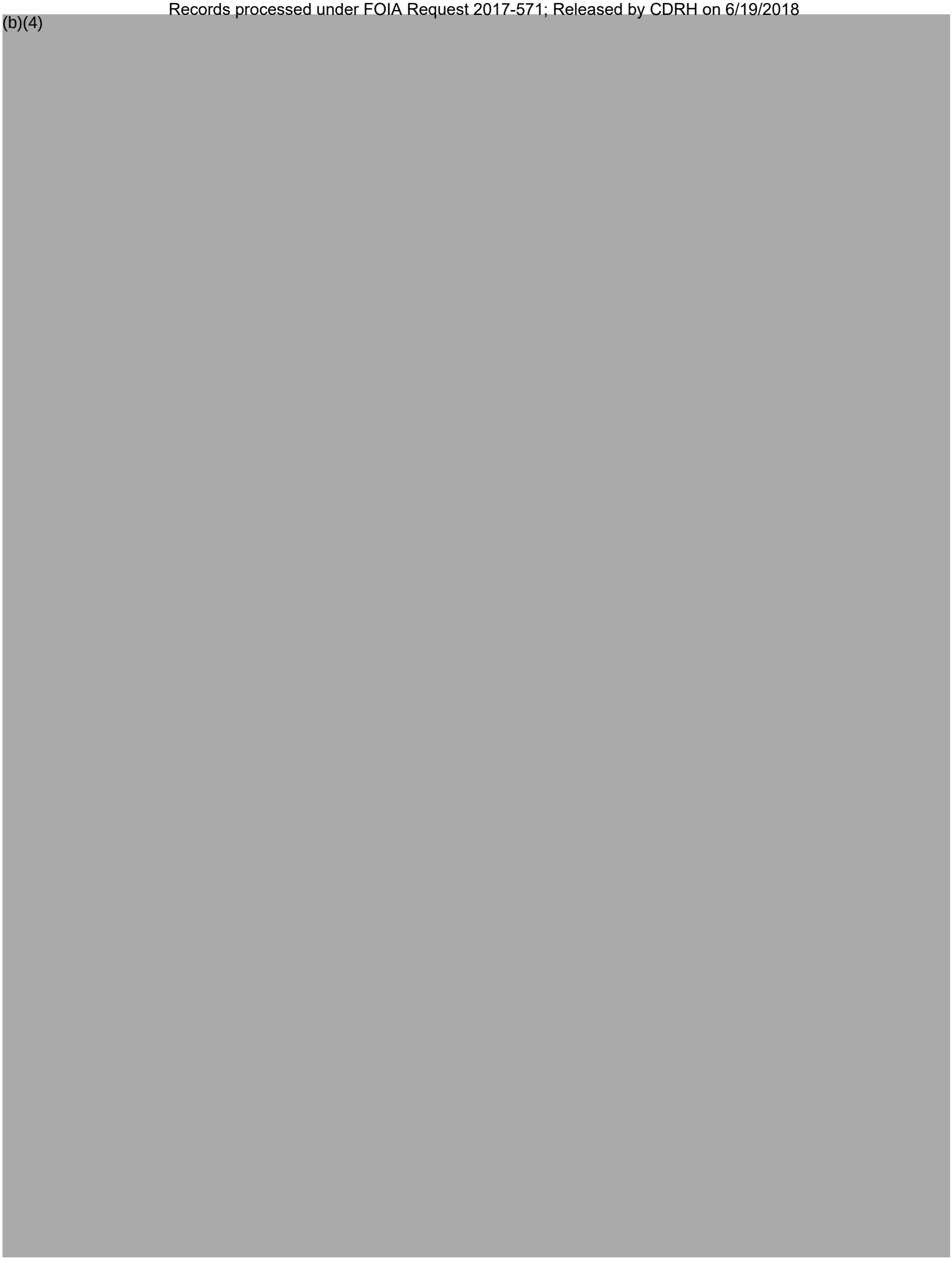

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March 14, 2011

Subject: (b)(4)

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Boston Scientific

5mm x 20mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

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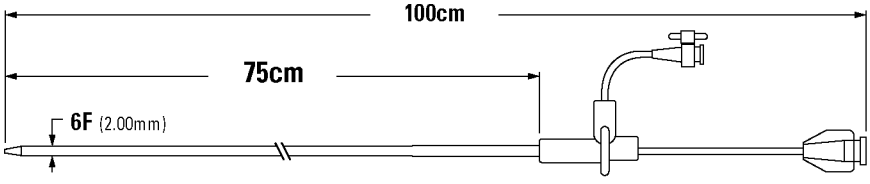

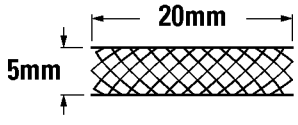

GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	26mm
3mm	30mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406112	LOT	12345678
REF Catalog No.	M001711000	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-01J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 75cm
GTIN 08714729406112
REF M001711000
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 75cm
GTIN 08714729406112
REF M001711000
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 75cm
GTIN 08714729406112
REF M001711000
LOT 12345678

(01)08714729406112(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

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STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-01J

Boston Scientific

5mm x 20mm 135cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

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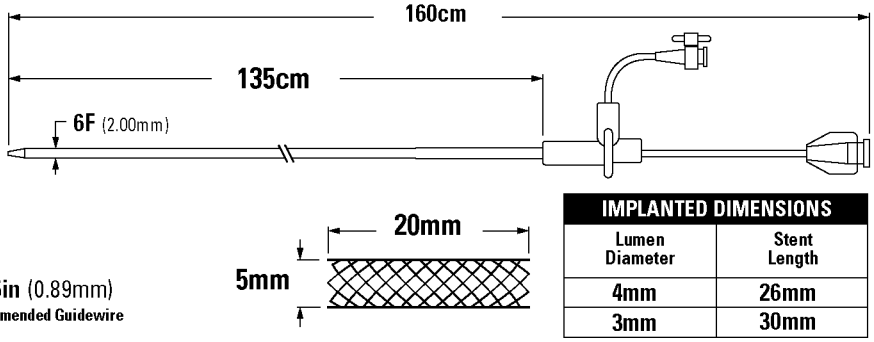

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	26mm
3mm	30mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406129	LOT	12345678
REF Catalog No.	M001711010	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-01J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 135cm
GTIN 08714729406129
REF M001711010
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 135cm
GTIN 08714729406129
REF M001711010
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 135cm
GTIN 08714729406129
REF M001711010
LOT 12345678

(01)08714729406129(17)101231(10)12345678 GS1

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Ballybrit Business Park
Galway, IRELAND

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STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-01J

Boston Scientific

5mm x 40mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

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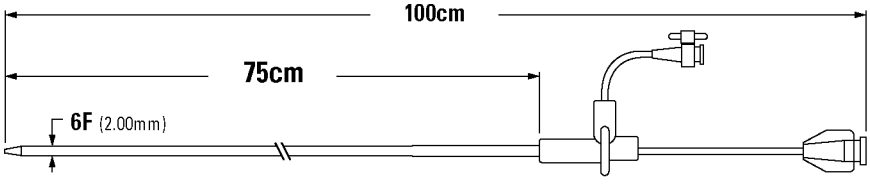

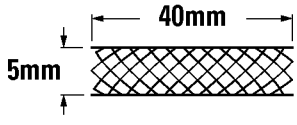

GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	54mm
3mm	63mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406136	LOT	12345678
REF Catalog No.	M001711020	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-02J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 75cm
GTIN 08714729406136
REF M001711020
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 75cm
GTIN 08714729406136
REF M001711020
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 75cm
GTIN 08714729406136
REF M001711020
LOT 12345678

(01)08714729406136(17)101231(10)12345678 GS1

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Galway, IRELAND

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STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-02J

Boston Scientific

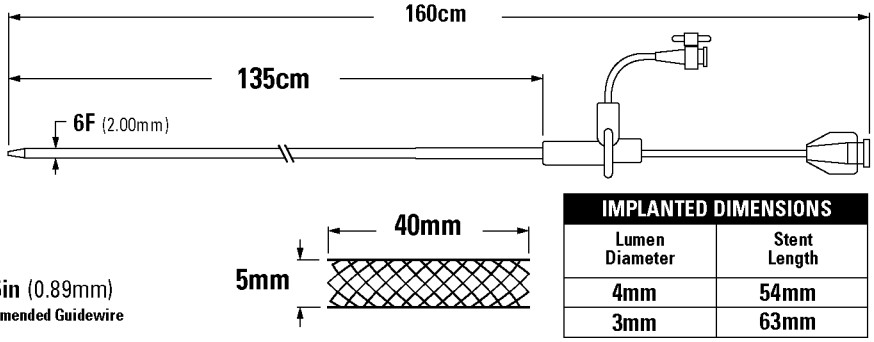
5mm x 40mm 135cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R 0.035in (0.89mm) Recommended Guidewire

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	54mm
3mm	63mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406143	LOT	12345678
REF Catalog No.	M001711030	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-02J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 135cm
GTIN 08714729406143
REF M001711030
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 135cm
GTIN 08714729406143
REF M001711030
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 135cm
GTIN 08714729406143
REF M001711030
LOT 12345678

(01)08714729406143(17)101231(10)12345678 GS1

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Ballybrit Business Park
Galway, IRELAND

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STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-02J

Boston Scientific

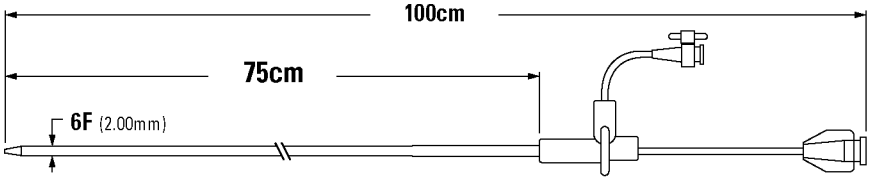
5mm x 55mm 75cm

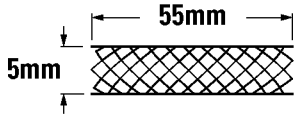
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	78mm
3mm	89mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406150	LOT	12345678
REF Catalog No.	M001711040	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-03J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 75cm
GTIN 08714729406150
REF M001711040
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 75cm
GTIN 08714729406150
REF M001711040
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 75cm
GTIN 08714729406150
REF M001711040
LOT 12345678

(01)08714729406150(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-03J

Boston Scientific

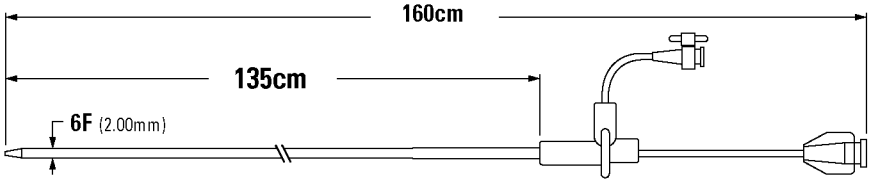
5mm x 55mm 135cm

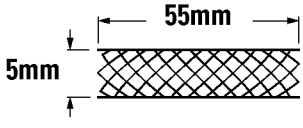
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	78mm
3mm	89mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406167	LOT	12345678
REF Catalog No.	M001711050	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-03J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 135cm
GTIN 08714729406167
REF M001711050
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 135cm
GTIN 08714729406167
REF M001711050
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 135cm
GTIN 08714729406167
REF M001711050
LOT 12345678

(01)08714729406167(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-03J

Boston Scientific

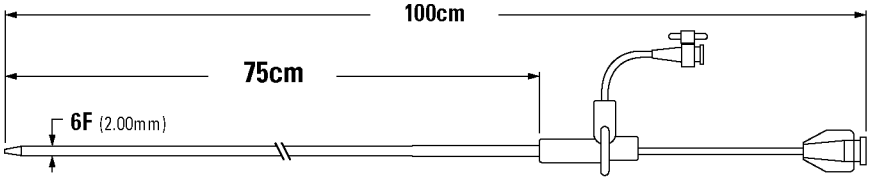
5mm x 80mm 75cm

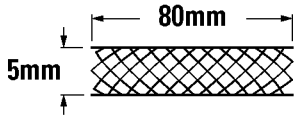
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	116mm
3mm	134mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406174	LOT	12345678
REF Catalog No.	M001711060	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-04J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 75cm
GTIN 08714729406174
REF M001711060
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 75cm
GTIN 08714729406174
REF M001711060
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 75cm
GTIN 08714729406174
REF M001711060
LOT 12345678

(01)08714729406174(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-04J

Boston Scientific

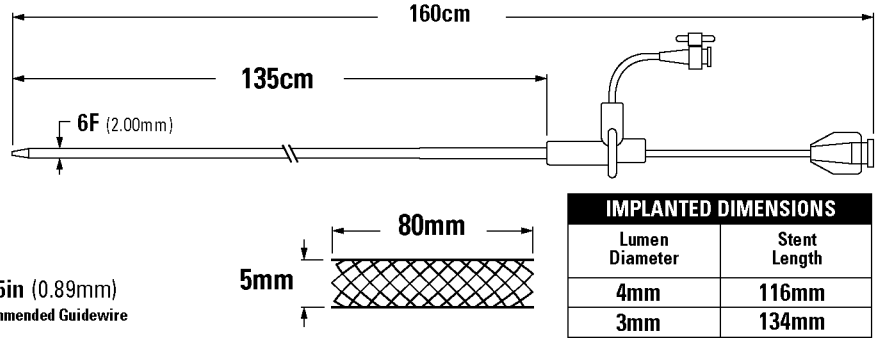
5mm x 80mm 135cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R 0.035in (0.89mm) Recommended Guidewire

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	116mm
3mm	134mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406181	LOT	12345678
REF Catalog No.	M001711070	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-04J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 135cm
GTIN 08714729406181
REF M001711070
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 135cm
GTIN 08714729406181
REF M001711070
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 135cm
GTIN 08714729406181
REF M001711070
LOT 12345678

(01)08714729406181(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-04J

Boston Scientific

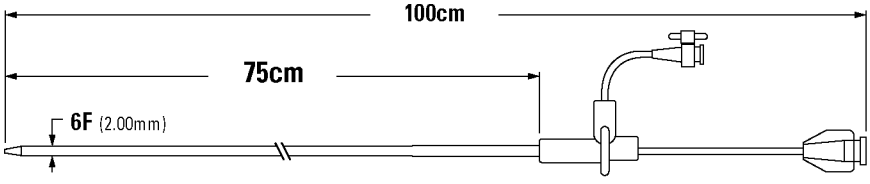
6mm x 20mm 75cm

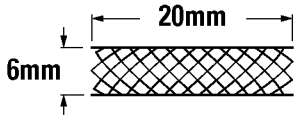
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	25mm
4mm	29mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406198	LOT	12345678
REF Catalog No.	M001711080	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-05J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 75cm
GTIN 08714729406198
REF M001711080
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 75cm
GTIN 08714729406198
REF M001711080
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 75cm
GTIN 08714729406198
REF M001711080
LOT 12345678

(01)08714729406198(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-05J

Boston Scientific

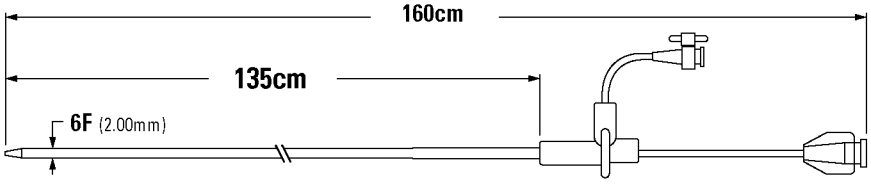
6mm x 20mm 135cm

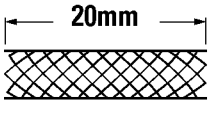
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	25mm
4mm	29mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406204	LOT	12345678
REF Catalog No.	M001711090	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-05J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 135cm
GTIN 08714729406204
REF M001711090
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 135cm
GTIN 08714729406204
REF M001711090
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 135cm
GTIN 08714729406204
REF M001711090
LOT 12345678

(01)08714729406204(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322700-05J

Boston Scientific

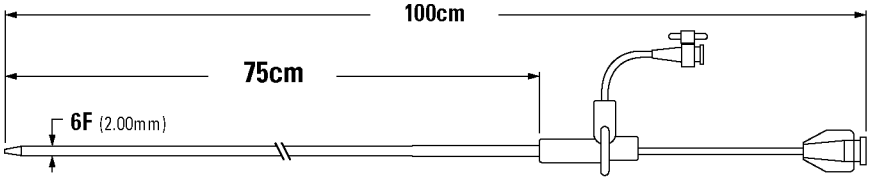
6mm x 45mm 75cm

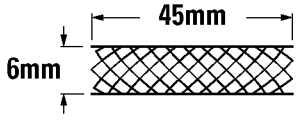
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	52mm
4mm	60mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406211	LOT	12345678
REF Catalog No.	M001711100	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-06J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 75cm
GTIN 08714729406211
REF M001711100
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 75cm
GTIN 08714729406211
REF M001711100
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 75cm
GTIN 08714729406211
REF M001711100
LOT 12345678

(01)08714729406211(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-06J

Boston Scientific

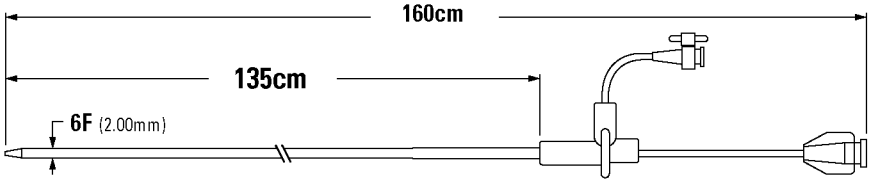
6mm x 45mm 135cm

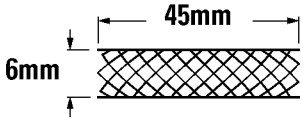
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	52mm
4mm	60mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406228	LOT	12345678
REF Catalog No.	M001711110	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-06J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 135cm
GTIN 08714729406228
REF M001711110
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 135cm
GTIN 08714729406228
REF M001711110
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 135cm
GTIN 08714729406228
REF M001711110
LOT 12345678

(01)08714729406228(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-06J

Boston Scientific

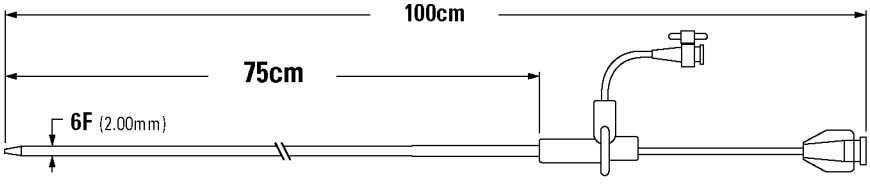
6mm x 60mm 75cm

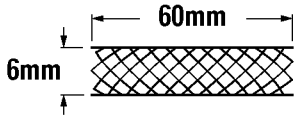
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	74mm
4mm	85mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406235	LOT	12345678
REF Catalog No.	M001711120	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-07J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 75cm
GTIN 08714729406235
REF M001711120
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 75cm
GTIN 08714729406235
REF M001711120
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 75cm
GTIN 08714729406235
REF M001711120
LOT 12345678

(01)08714729406235(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-07J

Boston Scientific

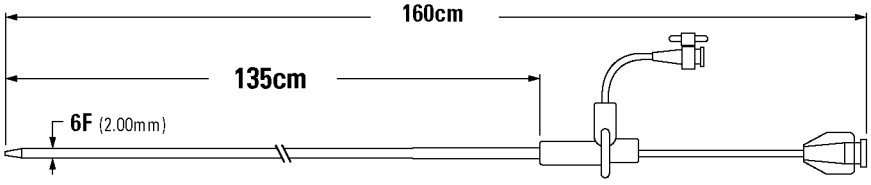
6mm x 60mm 135cm

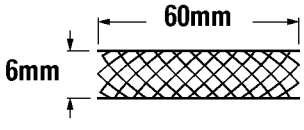
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	74mm
4mm	85mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406242	LOT	12345678
REF Catalog No.	M001711130	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-07J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 135cm
GTIN 08714729406242
REF M001711130
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 135cm
GTIN 08714729406242
REF M001711130
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 135cm
GTIN 08714729406242
REF M001711130
LOT 12345678

(01)08714729406242(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-07J

Boston Scientific

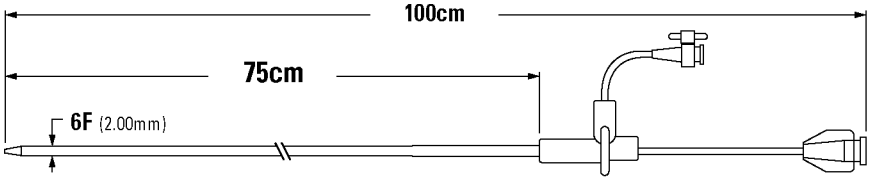
6mm x 90mm 75cm

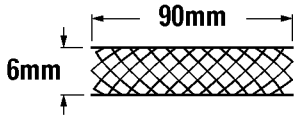
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	111mm
4mm	128mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406259	LOT	12345678
REF Catalog No.	M001711140	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-08J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 75cm
GTIN 08714729406259
REF M001711140
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 75cm
GTIN 08714729406259
REF M001711140
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 75cm
GTIN 08714729406259
REF M001711140
LOT 12345678

(01)08714729406259(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-08J

Boston Scientific

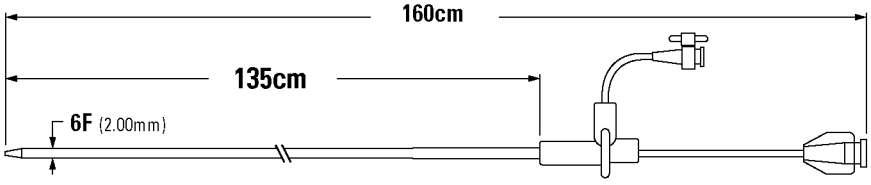
6mm x 90mm 135cm

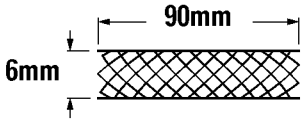
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	111mm
4mm	128mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406266	LOT	12345678
REF Catalog No.	M001711150	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-08J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 135cm
GTIN 08714729406266
REF M001711150
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 135cm
GTIN 08714729406266
REF M001711150
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 135cm
GTIN 08714729406266
REF M001711150
LOT 12345678

(01)08714729406266(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-08J

Boston Scientific

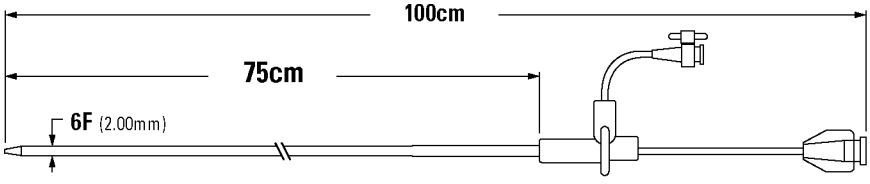
7mm x 20mm 75cm

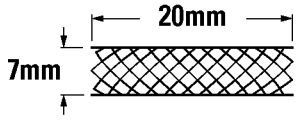
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	25mm
5mm	28mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406273	LOT	12345678
REF Catalog No.	M001711160	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-09J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 75cm
GTIN 08714729406273
REF M001711160
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 75cm
GTIN 08714729406273
REF M001711160
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 75cm
GTIN 08714729406273
REF M001711160
LOT 12345678

(01)08714729406273(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-09J

Boston Scientific

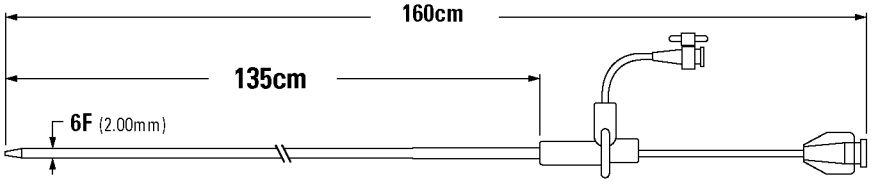
7mm x 20mm 135cm

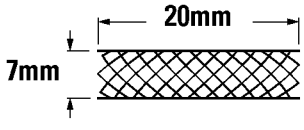
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	25mm
5mm	28mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406280	LOT	12345678
REF Catalog No.	M001711170	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-09J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 135cm
GTIN 08714729406280
REF M001711170
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 135cm
GTIN 08714729406280
REF M001711170
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 135cm
GTIN 08714729406280
REF M001711170
LOT 12345678

(01)08714729406280(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-09J

Boston Scientific

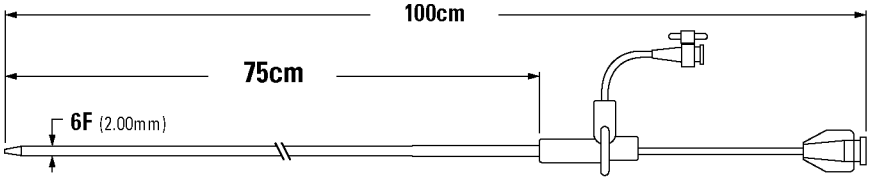
7mm x 40mm 75cm

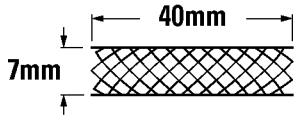
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	50mm
5mm	57mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406297	LOT	12345678
REF Catalog No.	M001711180	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-10J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 75cm
GTIN 08714729406297
REF M001711180
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 75cm
GTIN 08714729406297
REF M001711180
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 75cm
GTIN 08714729406297
REF M001711180
LOT 12345678

(01)08714729406297(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-10J

Boston Scientific

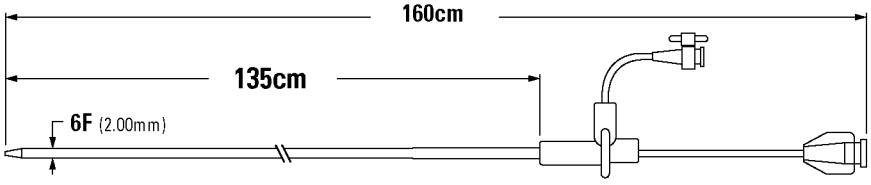
7mm x 40mm 135cm

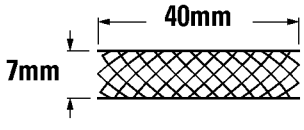
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	50mm
5mm	57mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406303	LOT	12345678
REF Catalog No.	M001711190	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-10J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 135cm
GTIN 08714729406303
REF M001711190
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 135cm
GTIN 08714729406303
REF M001711190
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 135cm
GTIN 08714729406303
REF M001711190
LOT 12345678

(01)08714729406303(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-10J

Boston Scientific

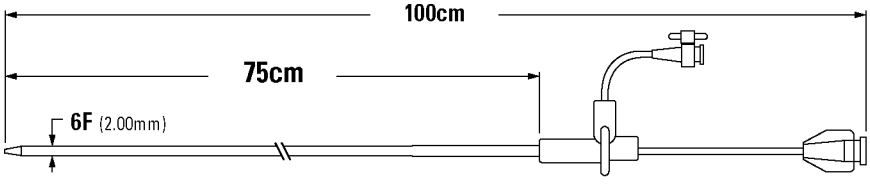
7mm x 60mm 75cm

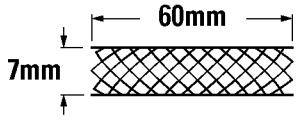
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	72mm
5mm	82mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406310	LOT	12345678
REF Catalog No.	M001711200	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-11J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 75cm
GTIN 08714729406310
REF M001711200
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 75cm
GTIN 08714729406310
REF M001711200
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 75cm
GTIN 08714729406310
REF M001711200
LOT 12345678

(01)08714729406310(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-11J

Boston Scientific

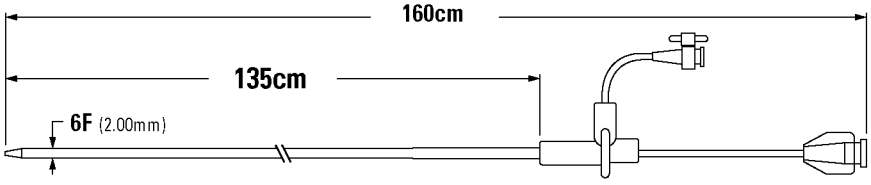
7mm x 60mm 135cm

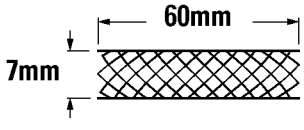
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	72mm
5mm	82mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406327	LOT	12345678
REF Catalog No.	M001711210	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-11J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 135cm
GTIN 08714729406327
REF M001711210
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 135cm
GTIN 08714729406327
REF M001711210
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 135cm
GTIN 08714729406327
REF M001711210
LOT 12345678

(01)08714729406327(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-11J

Boston Scientific

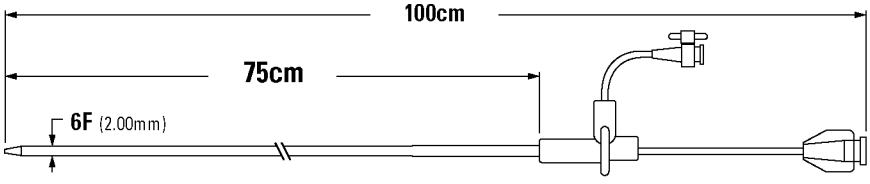
7mm x 90mm 75cm

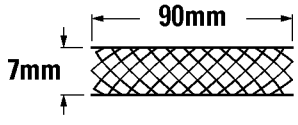
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	108mm
5mm	123mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406334	LOT	12345678
REF Catalog No.	M001711220	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322698-12J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 75cm
GTIN 08714729406334
REF M001711220
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 75cm
GTIN 08714729406334
REF M001711220
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 75cm
GTIN 08714729406334
REF M001711220
LOT 12345678

(01)08714729406334(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322698-12J

Boston Scientific

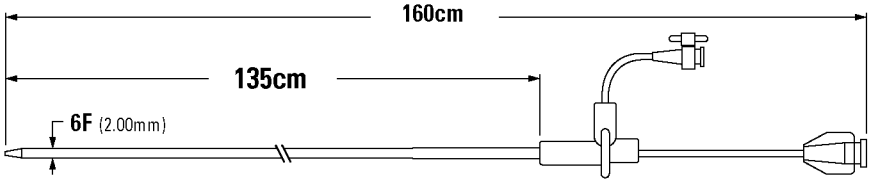
7mm x 90mm 135cm

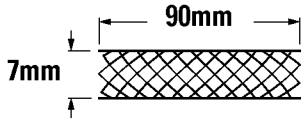
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	108mm
5mm	123mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406341	LOT	12345678
REF Catalog No.	M001711230	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-12J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 135cm
GTIN 08714729406341
REF M001711230
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 135cm
GTIN 08714729406341
REF M001711230
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 135cm
GTIN 08714729406341
REF M001711230
LOT 12345678

(01)08714729406341(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-12J

Boston Scientific

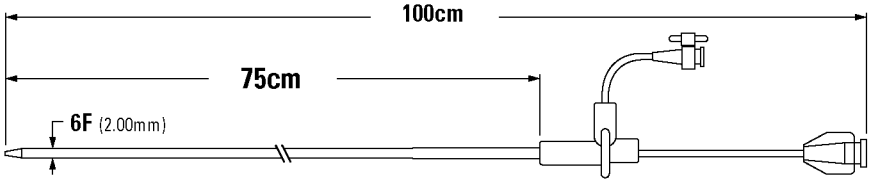
8mm x 20mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

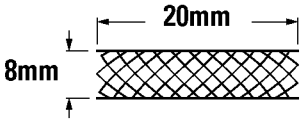
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	29mm
6mm	36mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406358	LOT	12345678
REF Catalog No.	M001711240	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322708-01H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

(01)08714729406358(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322708-01H

Boston Scientific

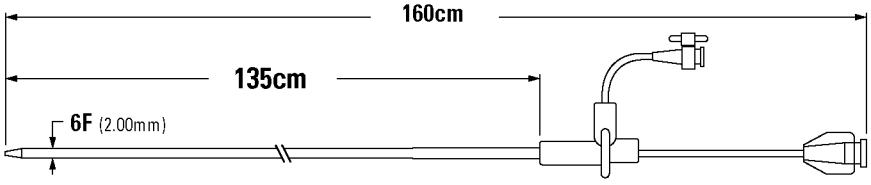
8mm x 20mm 135cm

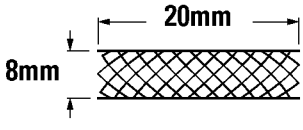
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	29mm
6mm	36mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406365	LOT	12345678
REF Catalog No.	M001711250	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-13J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 135cm
GTIN 08714729406365
REF M001711250
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 135cm
GTIN 08714729406365
REF M001711250
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 135cm
GTIN 08714729406365
REF M001711250
LOT 12345678

(01)08714729406365(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-13J

Boston Scientific

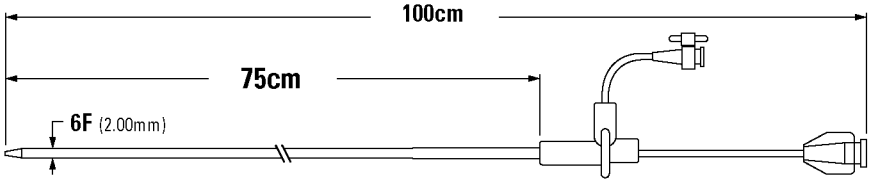
8mm x 40mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

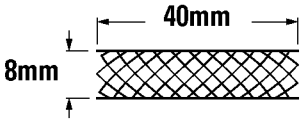
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	49mm
6mm	56mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406372	LOT	12345678
REF Catalog No.	M001711260	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322708-02H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 75cm
GTIN 08714729406372
REF M001711260
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 75cm
GTIN 08714729406372
REF M001711260
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 75cm
GTIN 08714729406372
REF M001711260
LOT 12345678

(01)08714729406372(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322708-02H

Boston Scientific

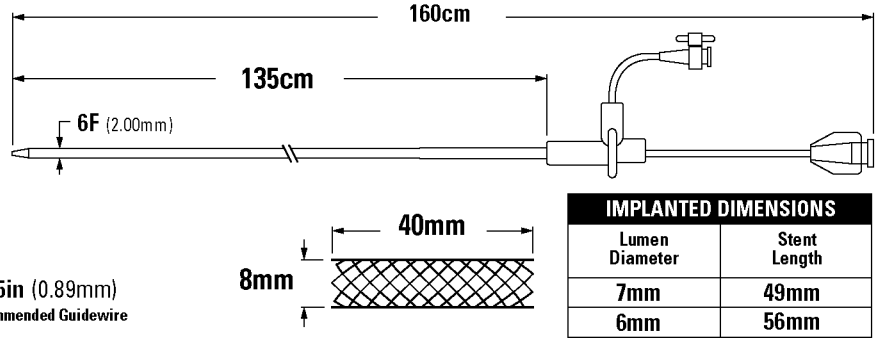
8mm x 40mm 135cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW 0.035in (0.89mm) Recommended Guidewire

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	49mm
6mm	56mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406389	LOT	12345678
REF Catalog No.	M001711270	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-14J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 135cm
GTIN 08714729406389
REF M001711270
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 135cm
GTIN 08714729406389
REF M001711270
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 135cm
GTIN 08714729406389
REF M001711270
LOT 12345678

(01)08714729406389(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-14J

Boston Scientific

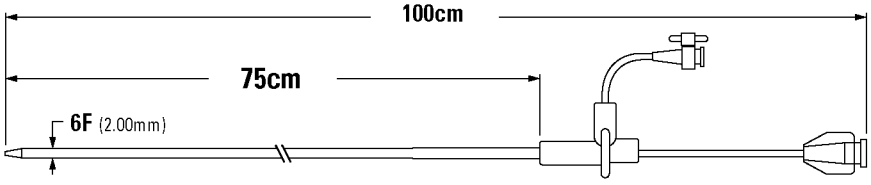
8mm x 60mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

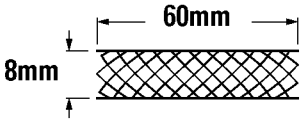
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	70mm
6mm	79mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406396	LOT	12345678
REF Catalog No.	M001711280	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322708-03H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 75cm
GTIN 08714729406396
REF M001711280
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 75cm
GTIN 08714729406396
REF M001711280
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 75cm
GTIN 08714729406396
REF M001711280
LOT 12345678

(01)08714729406396(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322708-03H

Boston Scientific

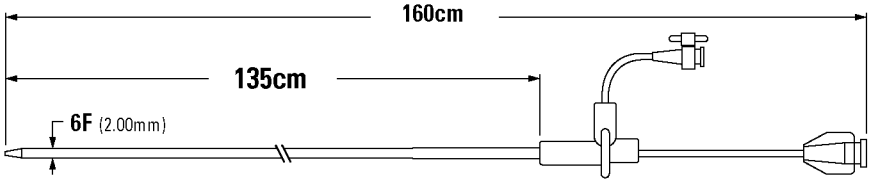
8mm x 60mm 135cm

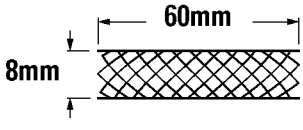
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	70mm
6mm	79mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406402	LOT	12345678
REF Catalog No.	M001711290	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-15J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 135cm
GTIN 08714729406402
REF M001711290
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 135cm
GTIN 08714729406402
REF M001711290
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 135cm
GTIN 08714729406402
REF M001711290
LOT 12345678

(01)08714729406402(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-15J

Boston Scientific

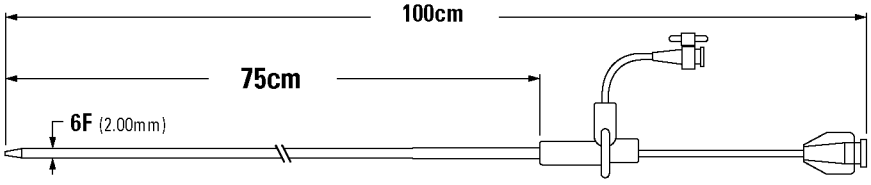
8mm x 80mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

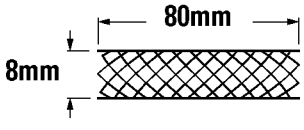
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	105mm
6mm	119mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406419	LOT	12345678
REF Catalog No.	M001711300	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322708-04H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 75cm
GTIN 08714729406419
REF M001711300
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 75cm
GTIN 08714729406419
REF M001711300
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 75cm
GTIN 08714729406419
REF M001711300
LOT 12345678

(01)08714729406419(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322708-04H

Boston Scientific

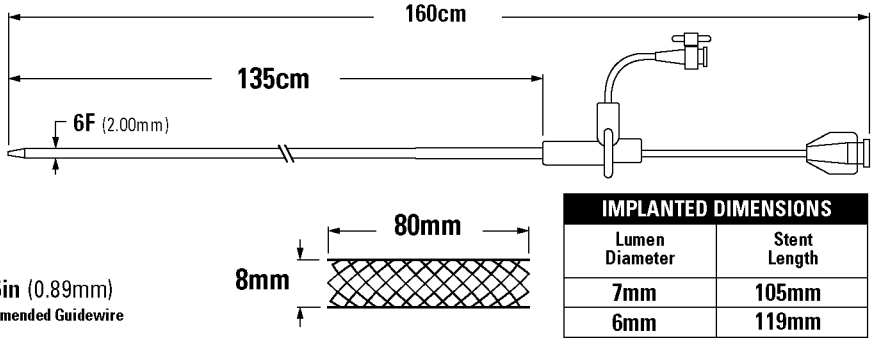
8mm x 80mm 135cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R 0.035in (0.89mm) Recommended Guidewire

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	105mm
6mm	119mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406426	LOT	12345678
REF Catalog No.	M001711310	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-16J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 135cm
GTIN 08714729406426
REF M001711310
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 135cm
GTIN 08714729406426
REF M001711310
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 135cm
GTIN 08714729406426
REF M001711310
LOT 12345678

(01)08714729406426(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-16J

Boston Scientific

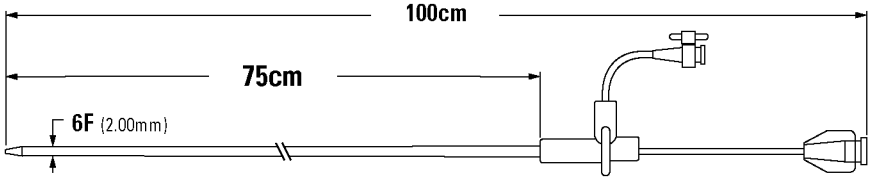
10mm x 20mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

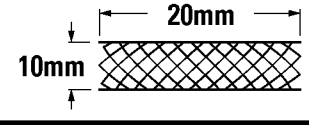
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **6F** (2.00mm) Recommended Introducer Sheath



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	27mm
8mm	33mm

GTIN	08714729406433	LOT	12345678
REF Catalog No.	M001711320	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322708-05H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 75cm
GTIN 08714729406433
REF M001711320
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 75cm
GTIN 08714729406433
REF M001711320
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 75cm
GTIN 08714729406433
REF M001711320
LOT 12345678

(01)08714729406433(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322708-05H

Boston Scientific

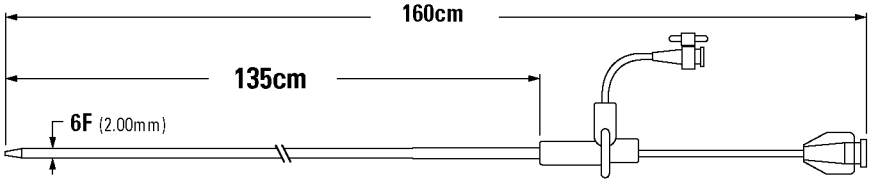
10mm x 20mm 135cm

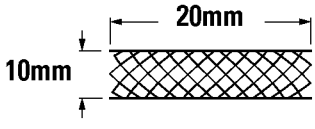
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	27mm
8mm	33mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406440	LOT	12345678
REF Catalog No.	M001711330	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-17J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 135cm
GTIN 08714729406440
REF M001711330
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 135cm
GTIN 08714729406440
REF M001711330
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 135cm
GTIN 08714729406440
REF M001711330
LOT 12345678

(01)08714729406440(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322700-17J

Boston Scientific

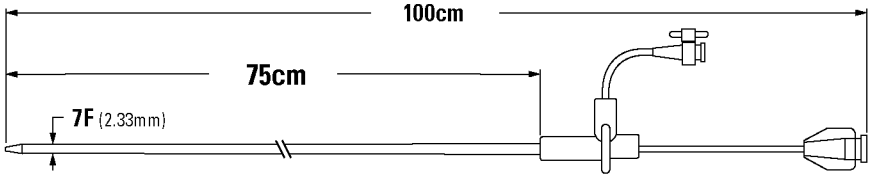
10mm x 42mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS

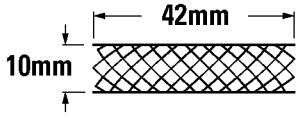
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **7F** (2.33mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	48mm
8mm	54mm

GTIN	**08714729406457**	LOT	**12345678**
REF Catalog No.	**M001711340**	Use By	**2010-12-31**

90320208-01

Internal BSC Bar Code

L322710-01H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 75cm
GTIN 08714729406457
REF M001711340
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 75cm
GTIN 08714729406457
REF M001711340
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 75cm
GTIN 08714729406457
REF M001711340
LOT 12345678

(01)08714729406457(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322710-01H

Boston Scientific

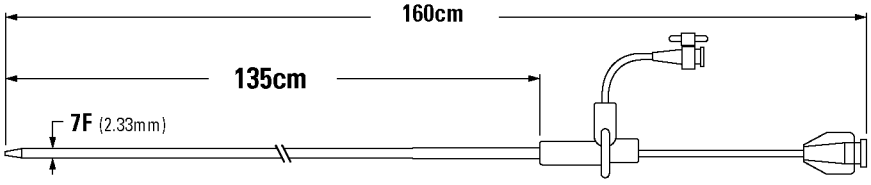
10mm x 42mm 135cm

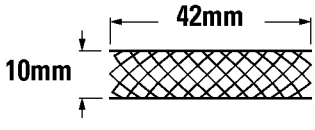
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	48mm
8mm	54mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406464	LOT	12345678
REF Catalog No.	M001711350	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-18J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 135cm
GTIN 08714729406464
REF M001711350
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 135cm
GTIN 08714729406464
REF M001711350
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 135cm
GTIN 08714729406464
REF M001711350
LOT 12345678

(01)08714729406464(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-18J

Boston Scientific

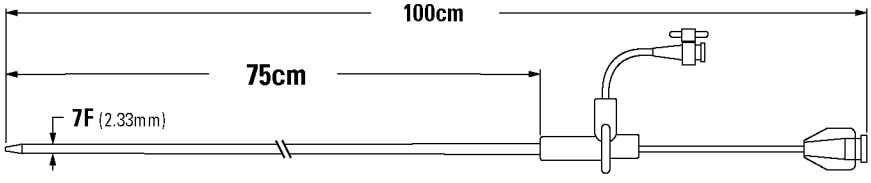
10mm x 68mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS

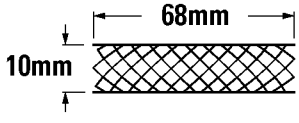
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **7F** (2.33mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	69mm
8mm	77mm

GTIN	08714729406471	LOT	12345678
REF Catalog No.	M001711360	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322710-02H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 75cm
GTIN 08714729406471
REF M001711360
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 75cm
GTIN 08714729406471
REF M001711360
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 75cm
GTIN 08714729406471
REF M001711360
LOT 12345678

(01)08714729406471(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322710-02H

Boston Scientific

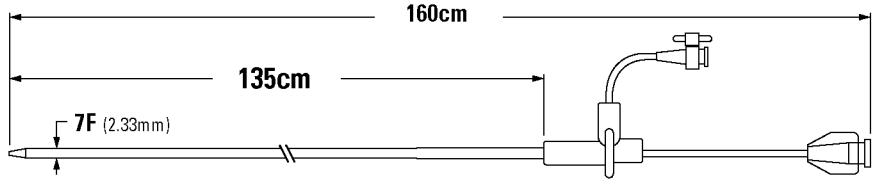
10mm x 68mm 135cm

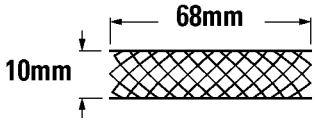
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	69mm
8mm	77mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406488	LOT	12345678
REF Catalog No.	M001711370	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322700-19J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 135cm
GTIN 08714729406488
REF M001711370
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 135cm
GTIN 08714729406488
REF M001711370
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 135cm
GTIN 08714729406488
REF M001711370
LOT 12345678

(01)08714729406488(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-19J

Boston Scientific

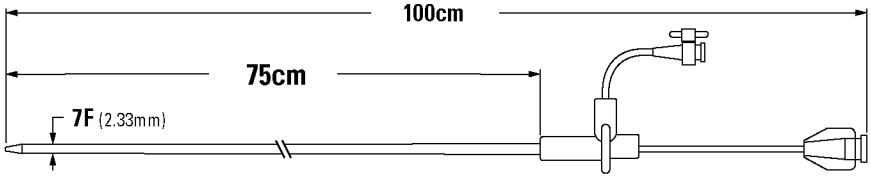
10mm x 94mm 75cm

WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS

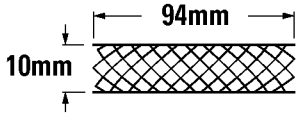
Self-Expanding Stent, Stent Auto-expansível

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **7F** (2.33mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	103mm
8mm	115mm

GTIN	08714729406495	LOT	12345678
REF Catalog No.	M001711380	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322710-03H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 75cm
GTIN 08714729406495
REF M001711380
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 75cm
GTIN 08714729406495
REF M001711380
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 75cm
GTIN 08714729406495
REF M001711380
LOT 12345678

(01)08714729406495(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322710-03H

Boston Scientific

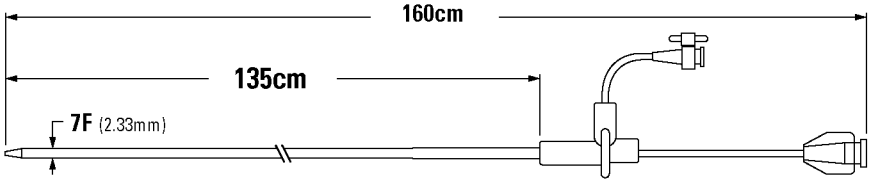
10mm x 94mm 135cm

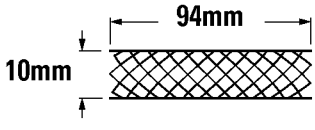
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	103mm
8mm	115mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406501	LOT	12345678
REF Catalog No.	M001711390	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322700-20J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 135cm
GTIN 08714729406501
REF M001711390
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 135cm
GTIN 08714729406501
REF M001711390
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 135cm
GTIN 08714729406501
REF M001711390
LOT 12345678

(01)08714729406501(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322700-20J

Boston Scientific

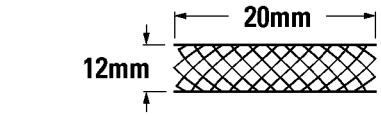
12mm x20mm 75cm

WALLSTENT® Endoprosthesis

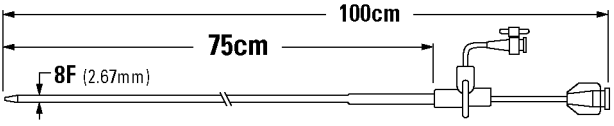
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	26mm
10mm	31mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **9F** (3.00mm) Recommended Introducer Sheath

GTIN 08714729203940

REF Catalog No. H965402100

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-01G

(01)08714729203940(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322690-01G

Boston Scientific

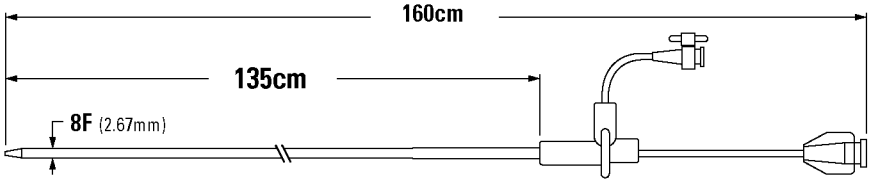
12mm x 20mm 135cm

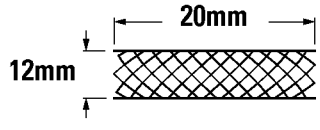
WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	26mm
10mm	31mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204398	LOT	12345678
REF Catalog No.	H965412000	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322692-01H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 135cm
GTIN 08714729204398
REF H965412000
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 135cm
GTIN 08714729204398
REF H965412000
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 135cm
GTIN 08714729204398
REF H965412000
LOT 12345678

(01)08714729204398(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322692-01H

Boston Scientific

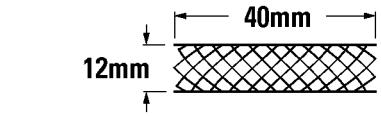
12mm x40mm 75cm

WALLSTENT® Endoprosthesis

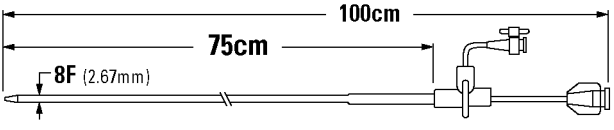
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	47mm
10mm	51mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **9F** (3.00mm) Recommended Introducer Sheath

GTIN 08714729203957

REF Catalog No. H965402110

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 75cm
GTIN 08714729203957
REF H965402110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 75cm
GTIN 08714729203957
REF H965402110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 75cm
GTIN 08714729203957
REF H965402110
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-02G

(01)08714729203957(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322690-02G

Boston Scientific

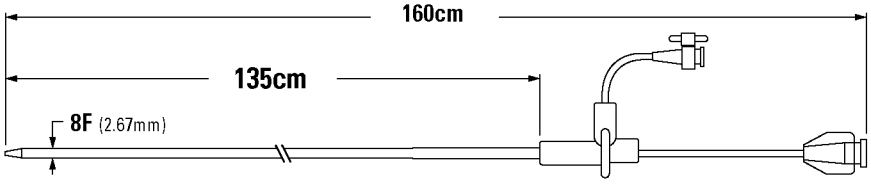
12mm x 40mm 135cm

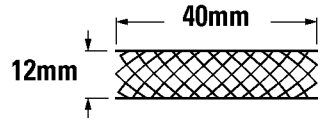
WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	47mm
10mm	51mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204404	LOT	12345678
REF Catalog No.	H965412010	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322692-02H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 135cm
GTIN 08714729204404
REF H965412010
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 135cm
GTIN 08714729204404
REF H965412010
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 135cm
GTIN 08714729204404
REF H965412010
LOT 12345678

(01)08714729204404(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322692-02H

Boston Scientific

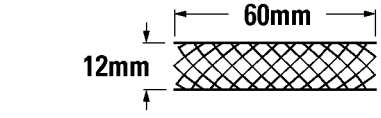
12mm x60mm 75cm

WALLSTENT® Endoprosthesis

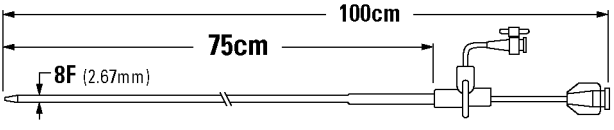
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	66mm
10mm	73mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **9F** (3.00mm) Recommended Introducer Sheath

GTIN 08714729203964

REF Catalog No. H965402120

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 75cm
GTIN 08714729203964
REF H965402120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 75cm
GTIN 08714729203964
REF H965402120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 75cm
GTIN 08714729203964
REF H965402120
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-03G

(01)08714729203964(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

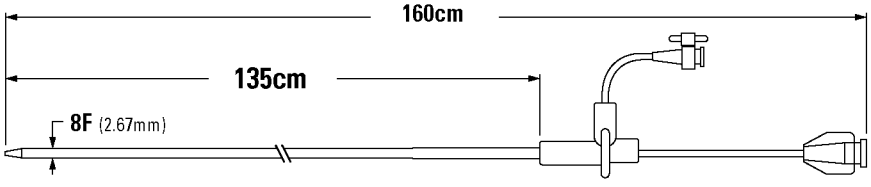
12mm x 60mm 135cm

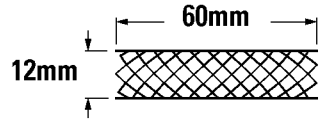
WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	66mm
10mm	73mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204411	LOT	12345678
REF Catalog No.	H965412020	Use By	2010-12-31

90320208-01

Internal BSC Bar Code
L322692-03H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 135cm
GTIN 08714729204411
REF H965412020
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 135cm
GTIN 08714729204411
REF H965412020
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 135cm
GTIN 08714729204411
REF H965412020
LOT 12345678

(01)08714729204411(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322692-03H

Boston Scientific

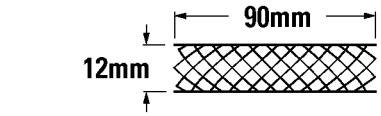
12mm x90mm 75cm

WALLSTENT® Endoprosthesis

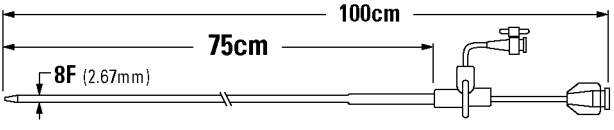
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	100mm
10mm	110mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **9F** (3.00mm) Recommended Introducer Sheath

GTIN 08714729203971

REF Catalog No. H965402130

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 75cm
GTIN 08714729203971
REF H965402130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 75cm
GTIN 08714729203971
REF H965402130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 75cm
GTIN 08714729203971
REF H965402130
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-04G

(01)08714729203971(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322690-04G

Boston Scientific

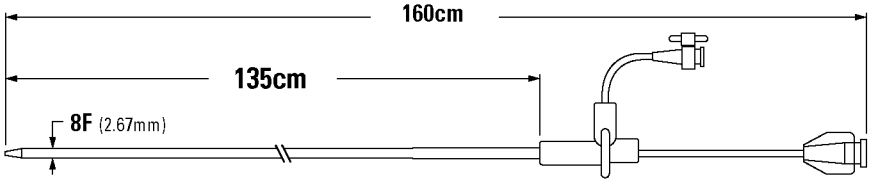
12mm x 90mm 135cm

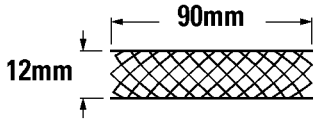
WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)





GW R **0.035in** (0.89mm) **Recommended Guidewire**

IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	100mm
10mm	110mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204428	LOT	12345678
REF Catalog No.	H965412030	Use By	2010-12-31

90320208-01

Internal BSC Bar Code

L322692-04H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 135cm
GTIN 08714729204428
REF H965412030
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 135cm
GTIN 08714729204428
REF H965412030
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 135cm
GTIN 08714729204428
REF H965412030
LOT 12345678

(01)08714729204428(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322692-04H

Boston Scientific

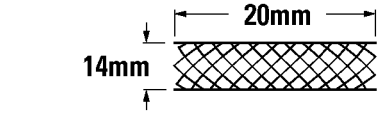
14mm x20mm 75cm

WALLSTENT® Endoprosthesis

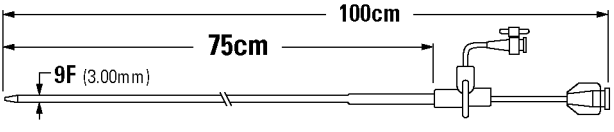
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	27mm
12mm	33mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729203988

REF Catalog No. H965403100

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 20mm 75cm
GTIN 08714729203988
REF H965403100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 20mm 75cm
GTIN 08714729203988
REF H965403100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 20mm 75cm
GTIN 08714729203988
REF H965403100
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-05G

(01)08714729203988(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

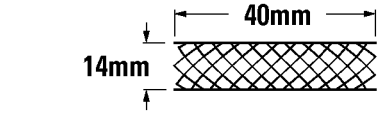
14mm x40mm 75cm

WALLSTENT® Endoprosthesis

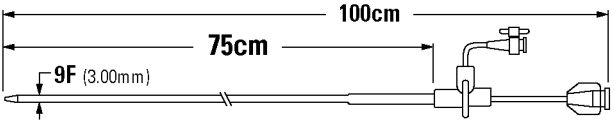
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	46mm
12mm	50mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729203995

REF Catalog No. H965403110

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 40mm 75cm
GTIN 08714729203995
REF H965403110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 40mm 75cm
GTIN 08714729203995
REF H965403110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 40mm 75cm
GTIN 08714729203995
REF H965403110
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-06G

(01)08714729203995(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

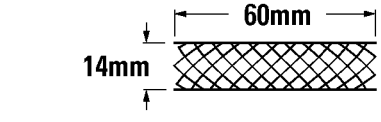
14mm x60mm 75cm

WALLSTENT® Endoprosthesis

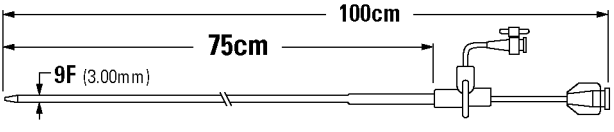
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	65mm
12mm	72mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729204008

REF Catalog No. H965403120

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 60mm 75cm
GTIN 08714729204008
REF H965403120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 60mm 75cm
GTIN 08714729204008
REF H965403120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 60mm 75cm
GTIN 08714729204008
REF H965403120
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-07G

(01)08714729204008(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

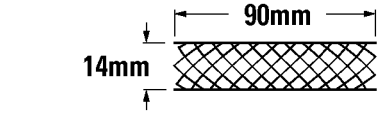
14mm x90mm 75cm

WALLSTENT® Endoprosthesis

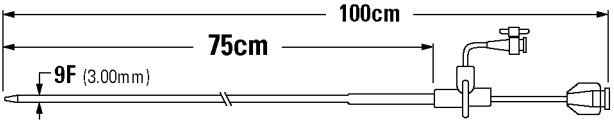
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	98mm
12mm	107mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729204015

REF Catalog No. H965403130

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 90mm 75cm
GTIN 08714729204015
REF H965403130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 90mm 75cm
GTIN 08714729204015
REF H965403130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 90mm 75cm
GTIN 08714729204015
REF H965403130
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-08G

(01)08714729204015(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

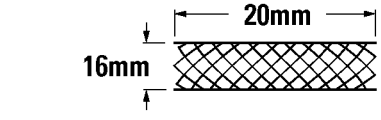
16mm x20mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
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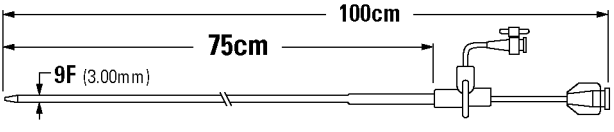
14mm	28mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729204022

REF Catalog No. H965403300

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 20mm 75cm
GTIN 08714729204022
REF H965403300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 20mm 75cm
GTIN 08714729204022
REF H965403300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 20mm 75cm
GTIN 08714729204022
REF H965403300
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-09G

(01)08714729204022(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

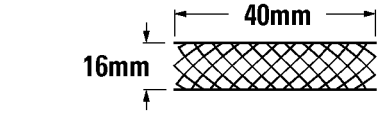
16mm x40mm 75cm

WALLSTENT® Endoprosthesis

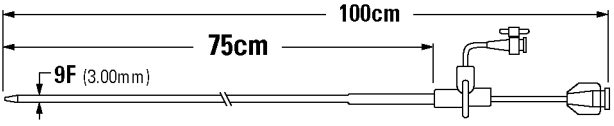
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	45mm
14mm	49mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729204039

REF Catalog No. H965403310

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 40mm 75cm
GTIN 08714729204039
REF H965403310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 40mm 75cm
GTIN 08714729204039
REF H965403310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 40mm 75cm
GTIN 08714729204039
REF H965403310
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-10G

(01)08714729204039(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

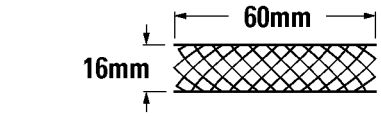
16mm x60mm 75cm

WALLSTENT® Endoprosthesis

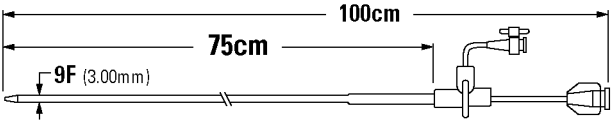
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	64mm
14mm	70mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729204046

REF Catalog No. H965403320

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 60mm 75cm
GTIN 08714729204046
REF H965403320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 60mm 75cm
GTIN 08714729204046
REF H965403320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 60mm 75cm
GTIN 08714729204046
REF H965403320
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-11G

(01)08714729204046(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322690-11G

Boston Scientific

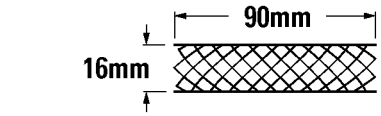
16mm x90mm 75cm

WALLSTENT® Endoprosthesis

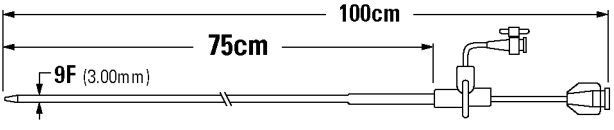
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	97mm
14mm	105mm



GW R **0.035in** (0.89mm) Recommended Guidewire

IS R **10F** (3.33mm) Recommended Introducer Sheath

GTIN 08714729204053

REF Catalog No. H965403330

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 90mm 75cm
GTIN 08714729204053
REF H965403330
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 90mm 75cm
GTIN 08714729204053
REF H965403330
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 90mm 75cm
GTIN 08714729204053
REF H965403330
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-12G

(01)08714729204053(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322690-12G

Boston Scientific

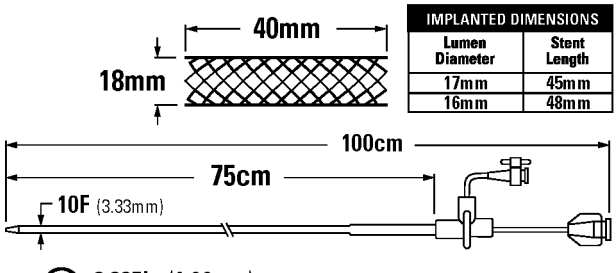
18mm x40mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
17mm	45mm
16mm	48mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204060

REF **Catalog No.** H965404110

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 40mm 75cm
GTIN 08714729204060
REF H965404110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 40mm 75cm
GTIN 08714729204060
REF H965404110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 40mm 75cm
GTIN 08714729204060
REF H965404110
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-13G

(01)08714729204060(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

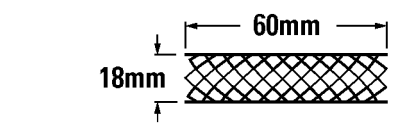
18mm x60mm 75cm

WALLSTENT® Endoprosthesis

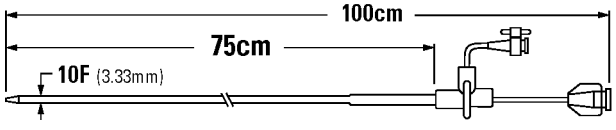
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
17mm	64mm
16mm	69mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204077

REF Catalog No. H965404120

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 60mm 75cm
GTIN 08714729204077
REF H965404120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 60mm 75cm
GTIN 08714729204077
REF H965404120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 60mm 75cm
GTIN 08714729204077
REF H965404120
LOT 12345678

90478733-01

Internal BSC Bar Code L322690-14G

(01)08714729204077(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322690-14G

Boston Scientific

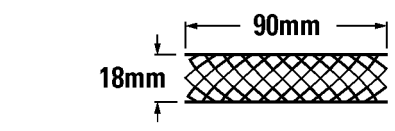
18mm x90mm 75cm

WALLSTENT® Endoprosthesis

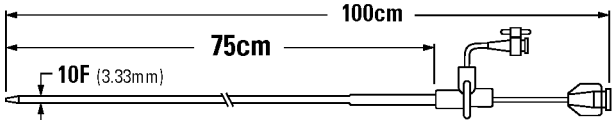
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
17mm	95mm
16mm	103mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204084

REF **Catalog No.** H965404130

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 90mm 75cm
GTIN 08714729204084
REF H965404130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 90mm 75cm
GTIN 08714729204084
REF H965404130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 90mm 75cm
GTIN 08714729204084
REF H965404130
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-15G

(01)08714729204084(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

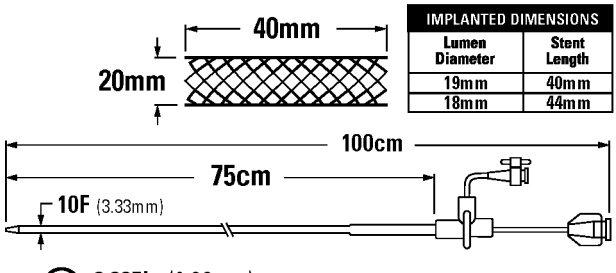
20mm x40mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
19mm	40mm
18mm	44mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204091

REF Catalog No. H965404300

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 40mm 75cm
GTIN 08714729204091
REF H965404300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 40mm 75cm
GTIN 08714729204091
REF H965404300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 40mm 75cm
GTIN 08714729204091
REF H965404300
LOT 12345678

90478733-01

Internal BSC Bar Code L322690-16G

(01)08714729204091(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322690-16G

Boston Scientific

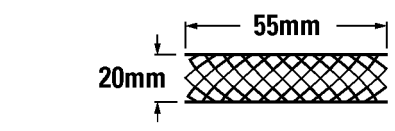
20mm x55mm 75cm

WALLSTENT® Endoprosthesis

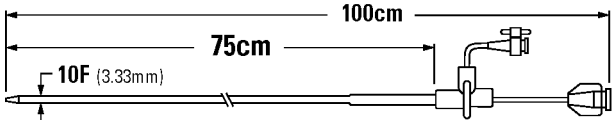
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
19mm	57mm
18mm	63mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204107

REF Catalog No. H965404310

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 55mm 75cm
GTIN 08714729204107
REF H965404310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 55mm 75cm
GTIN 08714729204107
REF H965404310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 55mm 75cm
GTIN 08714729204107
REF H965404310
LOT 12345678

90478733-01

Internal BSC Bar Code L322690-17G

(01)08714729204107(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322690-17G

Boston Scientific

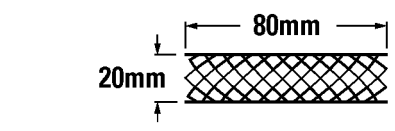
20mm x80mm 75cm

WALLSTENT® Endoprosthesis

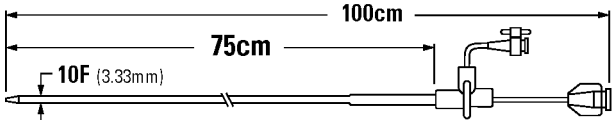
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
19mm	86mm
18mm	94mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204114

REF Catalog No. H965404320

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 80mm 75cm
GTIN 08714729204114
REF H965404320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 80mm 75cm
GTIN 08714729204114
REF H965404320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 80mm 75cm
GTIN 08714729204114
REF H965404320
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-18G

(01)08714729204114(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322690-18G

Boston Scientific

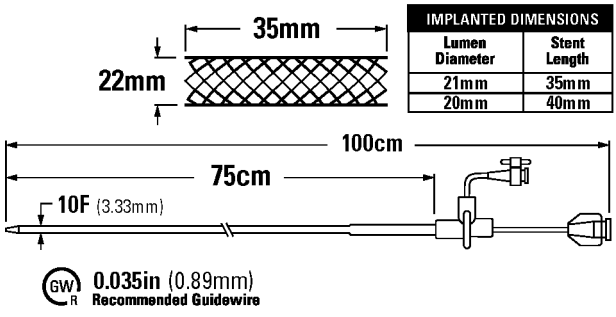
22mm x35mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
21mm	35mm
20mm	40mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204121

REF Catalog No. H965404500

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 35mm 75cm
GTIN 08714729204121
REF H965404500
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 35mm 75cm
GTIN 08714729204121
REF H965404500
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 35mm 75cm
GTIN 08714729204121
REF H965404500
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-19G

(01)08714729204121(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322690-19G

Boston Scientific

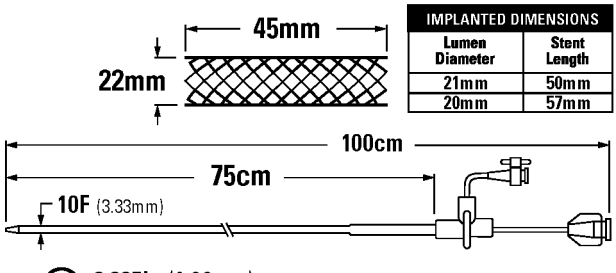
22mm x45mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
21mm	50mm
20mm	57mm

GW R **0.035in** (0.89mm)
Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204138

REF Catalog No. H965404510

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 45mm 75cm
GTIN 08714729204138
REF H965404510
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 45mm 75cm
GTIN 08714729204138
REF H965404510
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 45mm 75cm
GTIN 08714729204138
REF H965404510
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-20G

(01)08714729204138(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Boston Scientific

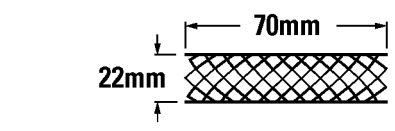
22mm x70mm 75cm

WALLSTENT® Endoprosthesis

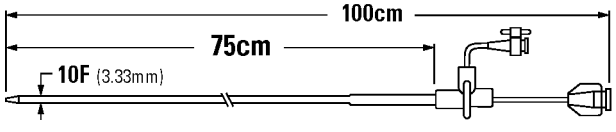
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
21mm	75mm
20mm	85mm



GW R **0.035in** (0.89mm)
Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204145

REF **Catalog No.** H965404520

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 70mm 75cm
GTIN 08714729204145
REF H965404520
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 70mm 75cm
GTIN 08714729204145
REF H965404520
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 70mm 75cm
GTIN 08714729204145
REF H965404520
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-21G

(01)08714729204145(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

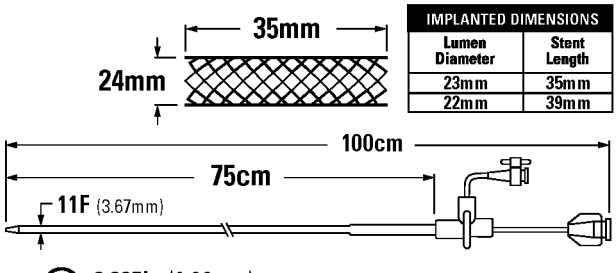
24mm x35mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
23mm	35mm
22mm	39mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204152

REF Catalog No. H965405100

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 35mm 75cm
GTIN 08714729204152
REF H965405100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 35mm 75cm
GTIN 08714729204152
REF H965405100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 35mm 75cm
GTIN 08714729204152
REF H965405100
LOT 12345678

90478733-01

Internal BSC Bar Code L322690-22G

(01)08714729204152(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322690-22G

Boston Scientific

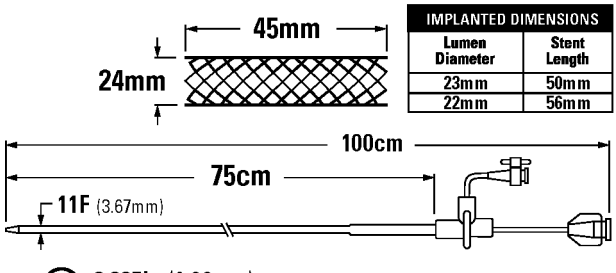
24mm x45mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
23mm	50mm
22mm	56mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204169

REF **Catalog No.** H965405110

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 45mm 75cm
GTIN 08714729204169
REF H965405110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 45mm 75cm
GTIN 08714729204169
REF H965405110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 45mm 75cm
GTIN 08714729204169
REF H965405110
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-23G

(01)08714729204169(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Boston Scientific

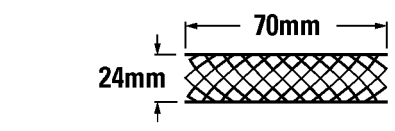
24mm x70mm 75cm

WALLSTENT® Endoprosthesis

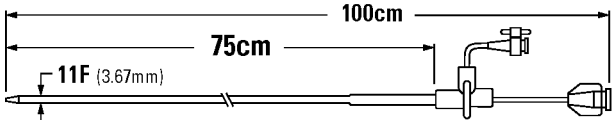
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
23mm	75mm
22mm	84mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204176

REF **Catalog No.** H965405120

Use By 2010-12-31

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 70mm 75cm
GTIN 08714729204176
REF H965405120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 70mm 75cm
GTIN 08714729204176
REF H965405120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 70mm 75cm
GTIN 08714729204176
REF H965405120
LOT 12345678

90478733-01

Internal BSC Bar Code

L322690-24G

(01)08714729204176(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322690-24G

Boston Scientific

℞ ONLY

For single use only. Do not reuse.

Do Not Resterilize

Consult instructions for use.

Do not use if package is damaged.

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

90968444-01

Boston Scientific
(Master Brand Template 90218088AE)
Pouch, MB
10 x 24.19
90968444-01A
Page 1 of 1

Records processed under FOIA Request 2017-571; Released by CDRH on 6/19/2018

Boston Scientific

℞ ONLY

For single use only.
Do not reuse.

Do Not
Resterilize

Consult instructions
for use.

Do not use if package
is damaged.

EC REP EU Authorized
Representative

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Legal
Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

90993327-01

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Boston Scientific
(Master Brand Template 90218088AE)
Pouch, MB
4.00 x 54.04
90993327-01A

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

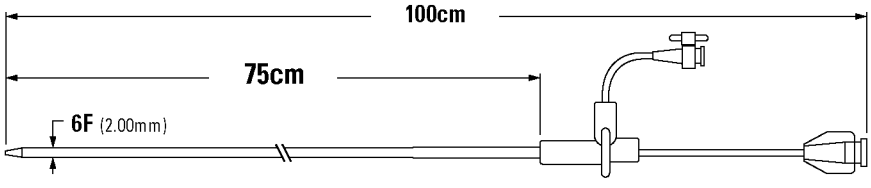
WALLSTENT™ RP Endoprosthesis

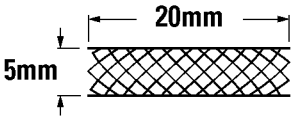
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x20mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	26mm
3mm	30mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406112	LOT	12345678
REF Catalog No.	M001711000	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 20 mm 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 20 mm 75 cm

90499465-01

Internal BSC Bar Code

L322697-01J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 75cm
GTIN 08714729406112
REF M001711000
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 75cm
GTIN 08714729406112
REF M001711000
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 75cm
GTIN 08714729406112
REF M001711000
LOT 12345678

(01)08714729406112(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 20 mm 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-01J

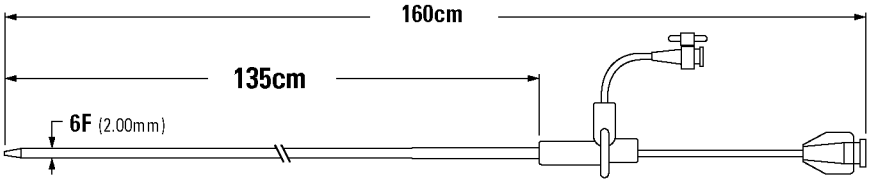
WALLSTENT™ RP Endoprosthesis

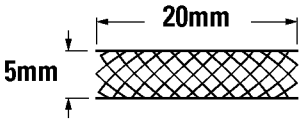
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x 20mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	26mm
3mm	30mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406129	LOT	12345678
REF Catalog No.	M001711010	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 20 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 20 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-01J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 135cm
GTIN 08714729406129
REF M001711010
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 135cm
GTIN 08714729406129
REF M001711010
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 20mm 135cm
GTIN 08714729406129
REF M001711010
LOT 12345678

(01)08714729406129(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 20 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-01J

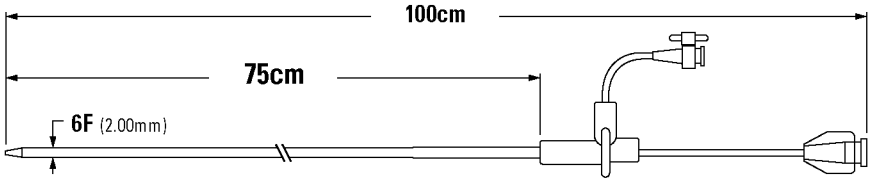
WALLSTENT™ RP Endoprosthesis

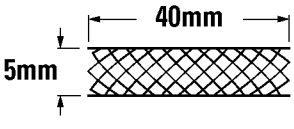
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x40mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	54mm
3mm	63mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406136	LOT	12345678
REF Catalog No.	M001711020	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 40 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 40 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-02J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 75cm
GTIN 08714729406136
REF M001711020
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 75cm
GTIN 08714729406136
REF M001711020
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 75cm
GTIN 08714729406136
REF M001711020
LOT 12345678

(01)08714729406136(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 40 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-02J

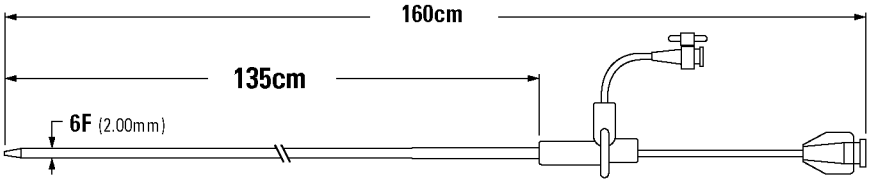
WALLSTENT™ RP Endoprosthesis

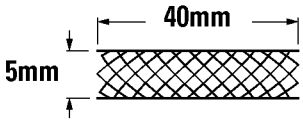
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x40mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	54mm
3mm	63mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406143	LOT	12345678
REF Catalog No.	M001711030	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 40 mm 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 40 mm 135 cm

90499465-01

Internal BSC Bar Code

L322699-02J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 135cm
GTIN 08714729406143
REF M001711030
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 135cm
GTIN 08714729406143
REF M001711030
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 40mm 135cm
GTIN 08714729406143
REF M001711030
LOT 12345678

(01)08714729406143(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 40 mm 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-02J

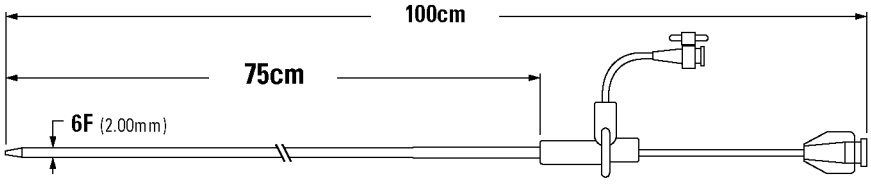
WALLSTENT™ RP Endoprosthesis

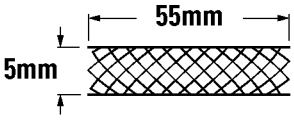
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x 55mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	78mm
3mm	89mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406150	LOT	12345678
REF Catalog No.	M001711040	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 5 mm | 55 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 55 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-03J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 75cm
GTIN 08714729406150
REF M001711040
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 75cm
GTIN 08714729406150
REF M001711040
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 75cm
GTIN 08714729406150
REF M001711040
LOT 12345678

(01)08714729406150(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 55 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-03J

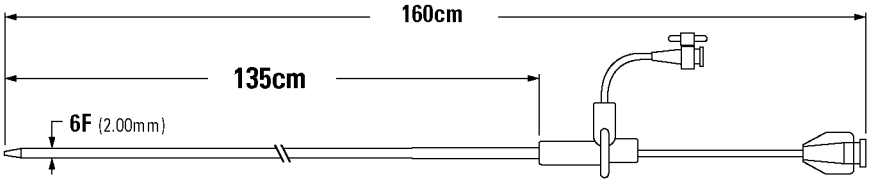
WALLSTENT™ RP Endoprosthesis

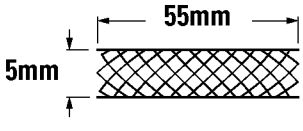
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x 55mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	78mm
3mm	89mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406167	LOT	12345678
REF Catalog No.	M001711050	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 55 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 55 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-03J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 135cm
GTIN 08714729406167
REF M001711050
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 135cm
GTIN 08714729406167
REF M001711050
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 55mm 135cm
GTIN 08714729406167
REF M001711050
LOT 12345678

(01)08714729406167(17)101231(10)12345678 GS1

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Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm | 55 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-03J

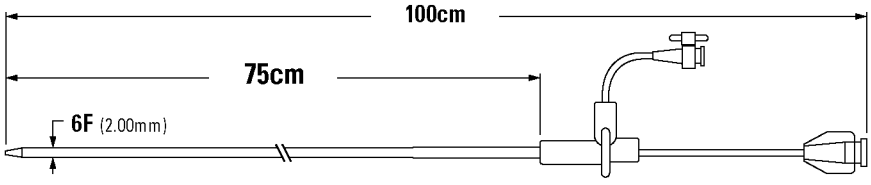
WALLSTENT™ RP Endoprosthesis

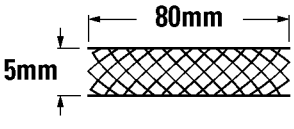
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x80mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	116mm
3mm	134mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406174	LOT	12345678
REF Catalog No.	M001711060	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 5 mm | 80 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 5 mm | 80 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-04J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 75cm
GTIN 08714729406174
REF M001711060
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 75cm
GTIN 08714729406174
REF M001711060
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 75cm
GTIN 08714729406174
REF M001711060
LOT 12345678

(01)08714729406174(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 5 mm | 80 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-04J

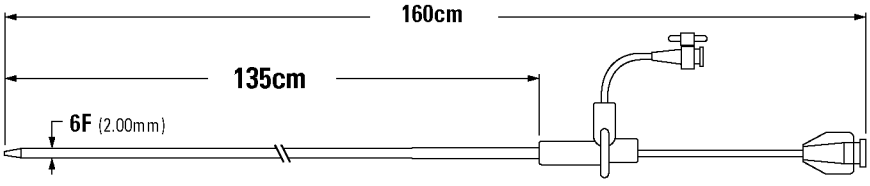
WALLSTENT™ RP Endoprosthesis

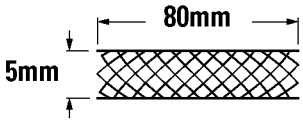
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

5mm x 80mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
4mm	116mm
3mm	134mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406181	LOT	12345678
REF Catalog No.	M001711070	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 80 mm 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 80 mm 135 cm

90499465-01

Internal BSC Bar Code

L322699-04J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 135cm
GTIN 08714729406181
REF M001711070
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 135cm
GTIN 08714729406181
REF M001711070
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
5mm x 80mm 135cm
GTIN 08714729406181
REF M001711070
LOT 12345678

(01)08714729406181(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 5 mm 80 mm 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-04J

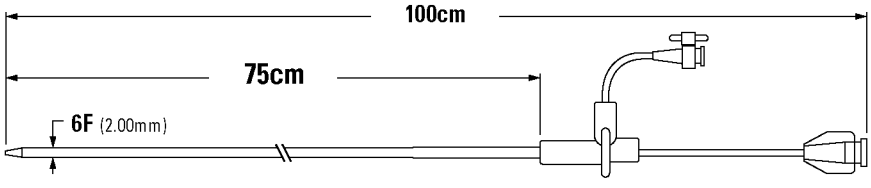
WALLSTENT™ RP Endoprosthesis

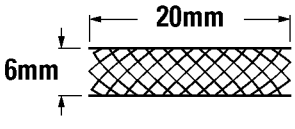
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x20mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	25mm
4mm	29mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406198	LOT	12345678
REF Catalog No.	M001711080	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 20 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 20 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-05J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 75cm
GTIN 08714729406198
REF M001711080
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 75cm
GTIN 08714729406198
REF M001711080
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 75cm
GTIN 08714729406198
REF M001711080
LOT 12345678

(01)08714729406198(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 20 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-05J

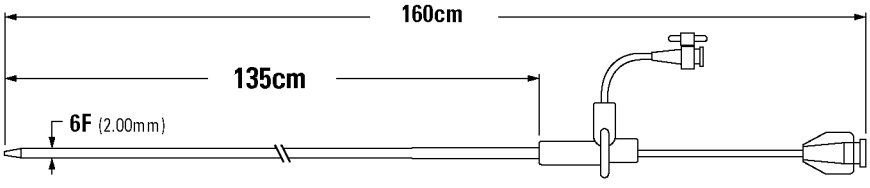
WALLSTENT™ RP Endoprosthesis

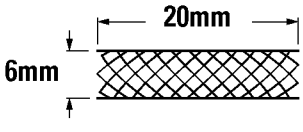
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x20mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	25mm
4mm	29mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406204	LOT	12345678
REF Catalog No.	M001711090	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm 20 mm 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm 20 mm 135 cm

90499465-01

Internal BSC Bar Code

L322699-05J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 135cm
GTIN 08714729406204
REF M001711090
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 135cm
GTIN 08714729406204
REF M001711090
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 20mm 135cm
GTIN 08714729406204
REF M001711090
LOT 12345678

(01)08714729406204(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm 20 mm 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-05J

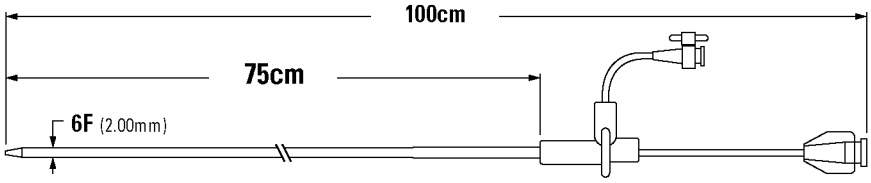
WALLSTENT™ RP Endoprosthesis

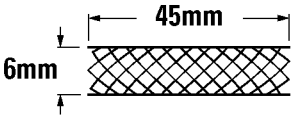
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x45mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	52mm
4mm	60mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406211	LOT	12345678
REF Catalog No.	M001711100	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 45 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 45 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-06J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 75cm
GTIN 08714729406211
REF M001711100
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 75cm
GTIN 08714729406211
REF M001711100
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 75cm
GTIN 08714729406211
REF M001711100
LOT 12345678

(01)08714729406211(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 45 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-06J

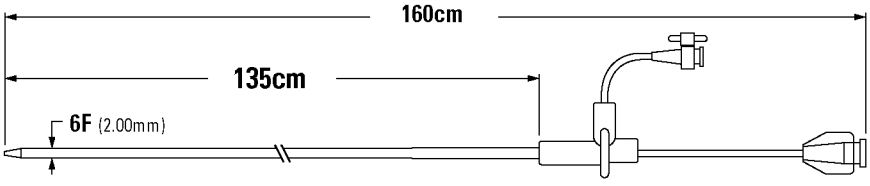
WALLSTENT™ RP Endoprosthesis

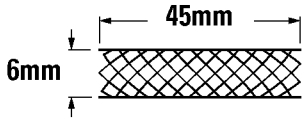
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x45mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	52mm
4mm	60mm

GW 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406228	LOT	12345678
REF Catalog No.	M001711110	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 45 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 45 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-06J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 135cm
GTIN 08714729406228
REF M001711110
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 135cm
GTIN 08714729406228
REF M001711110
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 45mm 135cm
GTIN 08714729406228
REF M001711110
LOT 12345678

(01)08714729406228(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 45 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-06J

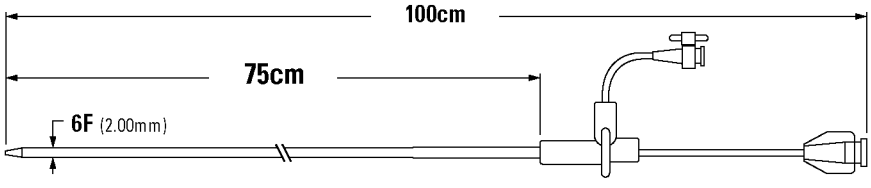
WALLSTENT™ RP Endoprosthesis

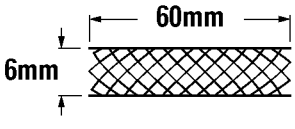
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x60mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	74mm
4mm	85mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406235	LOT	12345678
REF Catalog No.	M001711120	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 6 mm | 60 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 6 mm | 60 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-07J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 75cm
GTIN 08714729406235
REF M001711120
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 75cm
GTIN 08714729406235
REF M001711120
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 75cm
GTIN 08714729406235
REF M001711120
LOT 12345678

(01)08714729406235(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 6 mm | 60 mm | 75 cm GS1 2010-12-31

Label Specification Part Number:L322697-07J

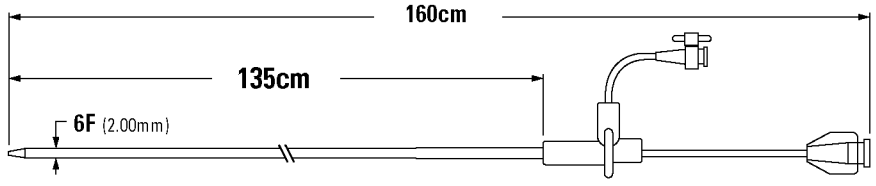
WALLSTENT™ RP Endoprosthesis

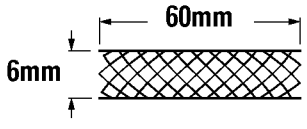
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x 60mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	74mm
4mm	85mm

GW 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406242	LOT	12345678
REF Catalog No.	M001711130	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 60 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 60 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-07J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 135cm
GTIN 08714729406242
REF M001711130
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 135cm
GTIN 08714729406242
REF M001711130
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 60mm 135cm
GTIN 08714729406242
REF M001711130
LOT 12345678

(01)08714729406242(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 60 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-07J

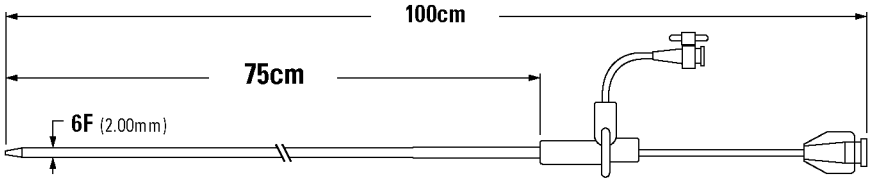
WALLSTENT™ RP Endoprosthesis

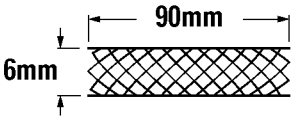
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x90mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	111mm
4mm	128mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406259	LOT	12345678
REF Catalog No.	M001711140	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 90 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 90 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-08J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 75cm
GTIN 08714729406259
REF M001711140
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 75cm
GTIN 08714729406259
REF M001711140
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 75cm
GTIN 08714729406259
REF M001711140
LOT 12345678

(01)08714729406259(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 90 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-08J

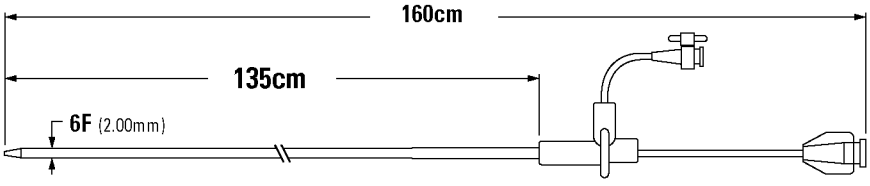
WALLSTENT™ RP Endoprosthesis

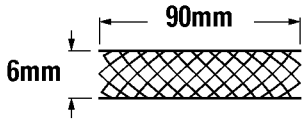
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

6mm x 90mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
5mm	111mm
4mm	128mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406266	LOT	12345678
REF Catalog No.	M001711150	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 90 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 90 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-08J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 135cm
GTIN 08714729406266
REF M001711150
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 135cm
GTIN 08714729406266
REF M001711150
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
6mm x 90mm 135cm
GTIN 08714729406266
REF M001711150
LOT 12345678

(01)08714729406266(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 6 mm | 90 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-08J

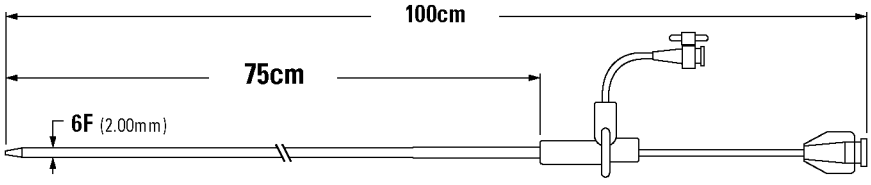
WALLSTENT™ RP Endoprosthesis

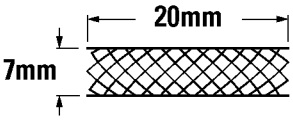
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x20mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	25mm
5mm	28mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406273	LOT	12345678
REF Catalog No.	M001711160	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm 20 mm 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm 20 mm 75 cm

90499465-01

Internal BSC Bar Code

L322697-09J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 75cm
GTIN 08714729406273
REF M001711160
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 75cm
GTIN 08714729406273
REF M001711160
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 75cm

GTIN 08714729406273
REF M001711160
LOT 12345678

(01)08714729406273(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm 20 mm 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-09J

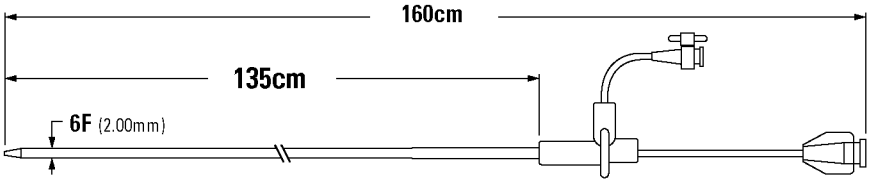
WALLSTENT™ RP Endoprosthesis

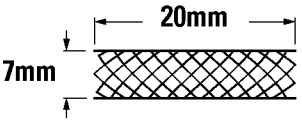
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x 20mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	25mm
5mm	28mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406280	LOT	12345678
REF Catalog No.	M001711170	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 20 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 20 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-09J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 135cm
GTIN 08714729406280
REF M001711170
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 135cm
GTIN 08714729406280
REF M001711170
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 20mm 135cm
GTIN 08714729406280
REF M001711170
LOT 12345678

(01)08714729406280(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 20 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-09J

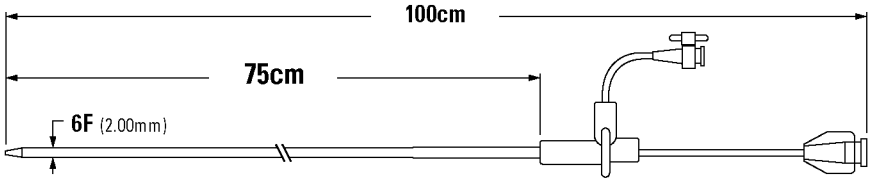
WALLSTENT™ RP Endoprosthesis

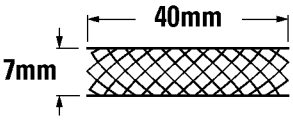
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x40mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	50mm
5mm	57mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406297	LOT	12345678
REF Catalog No.	M001711180	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 40 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 40 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-10J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 75cm
GTIN 08714729406297
REF M001711180
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 75cm
GTIN 08714729406297
REF M001711180
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 75cm
GTIN 08714729406297
REF M001711180
LOT 12345678

(01)08714729406297(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 40 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-10J

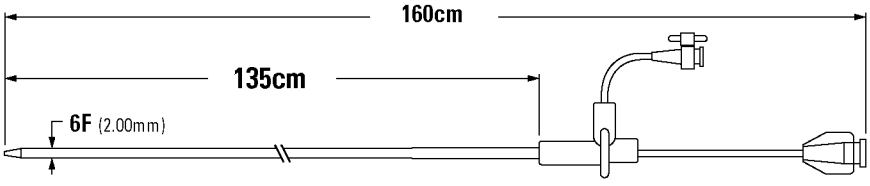
WALLSTENT™ RP Endoprosthesis

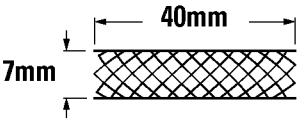
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x40mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	50mm
5mm	57mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406303	LOT	12345678
REF Catalog No.	M001711190	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 40 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 40 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-10J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 135cm
GTIN 08714729406303
REF M001711190
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 135cm
GTIN 08714729406303
REF M001711190
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 40mm 135cm
GTIN 08714729406303
REF M001711190
LOT 12345678

(01)08714729406303(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 40 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-10J

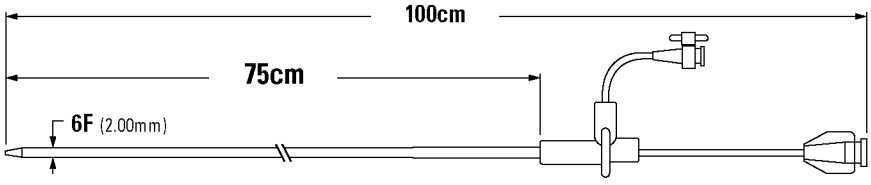
WALLSTENT™ RP Endoprosthesis

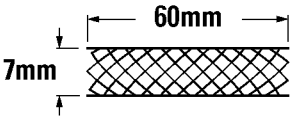
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x60mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	72mm
5mm	82mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406310	LOT	12345678
REF Catalog No.	M001711200	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 60 mm | 75 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 60 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322697-11J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 75cm
GTIN 08714729406310
REF M001711200
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 75cm
GTIN 08714729406310
REF M001711200
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 75cm
GTIN 08714729406310
REF M001711200
LOT 12345678

(01)08714729406310(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 60 mm | 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-11J

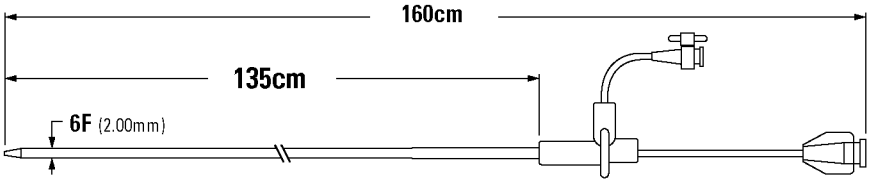
WALLSTENT™ RP Endoprosthesis

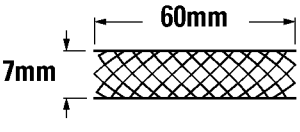
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x60mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	72mm
5mm	82mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406327	LOT	12345678
REF Catalog No.	M001711210	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 60 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 60 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-11J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 135cm
GTIN 08714729406327
REF M001711210
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 135cm
GTIN 08714729406327
REF M001711210
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 60mm 135cm
GTIN 08714729406327
REF M001711210
LOT 12345678

(01)08714729406327(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm | 60 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-11J

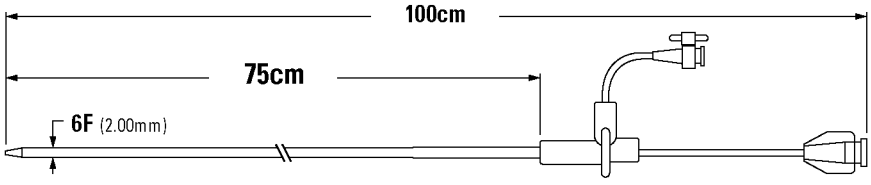
WALLSTENT™ RP Endoprosthesis

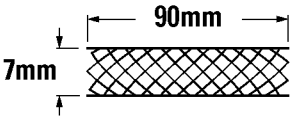
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x 90mm 75cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	108mm
5mm	123mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406334	LOT	12345678
REF Catalog No.	M001711220	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL **7 mm** **90 mm** **75 cm** GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm 90 mm 75 cm

90499465-01

Internal BSC Bar Code

L322697-12J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 75cm
GTIN 08714729406334
REF M001711220
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 75cm
GTIN 08714729406334
REF M001711220
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 75cm
GTIN 08714729406334
REF M001711220
LOT 12345678

(01)08714729406334(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 7 mm 90 mm 75 cm GS1 2010-12-31

Label Specification Part Number: L322697-12J

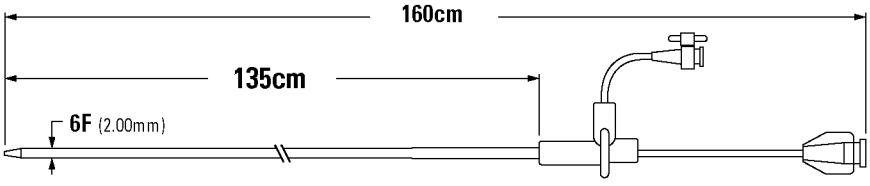
WALLSTENT™ RP Endoprosthesis

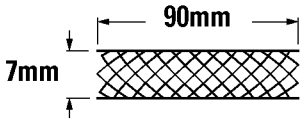
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

7mm x 90mm 135cm

Contents **(1)**





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
6mm	108mm
5mm	123mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	**08714729406341**	LOT	**12345678**
REF Catalog No.	**M001711230**	Use By	**2010-12-31**

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** **7 mm** **90 mm** **135 cm** GS1 **2010-12-31**

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** 7 mm 90 mm 135 cm

90499465-01

Internal BSC Bar Code

L322699-12J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 135cm
GTIN 08714729406341
REF M001711230
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 135cm
GTIN 08714729406341
REF M001711230
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
7mm x 90mm 135cm
GTIN 08714729406341
REF M001711230
LOT 12345678

(01)08714729406341(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis **TRACHEOBRONCHIAL** **7 mm** **90 mm** **135 cm** GS1 **2010-12-31**

Label Specification Part Number: L322699-12J

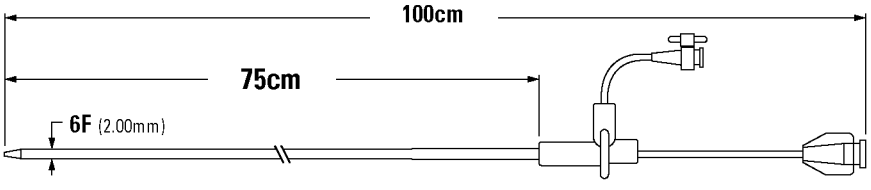
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

Self-Expanding Stent, Stent Auto-expansível

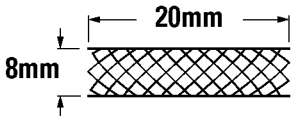
8mm x20mm 75cm

Contents **(1)**



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	29mm
6mm	36mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406358	LOT	12345678
REF Catalog No.	M001711240	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 20 mm | 75 cm
GS1
2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY 8 mm 20 mm 75 cm

90499465-01

Internal BSC Bar Code
L322707-01H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 75cm
GTIN 08714729406358
REF M001711240
LOT 12345678

(01)08714729406358(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 20 mm | 75 cm
GS1
2010-12-31

Label Specification Part Number:L322707-01H

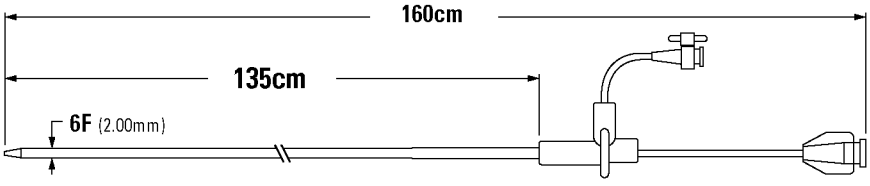
WALLSTENT™ RP Endoprosthesis

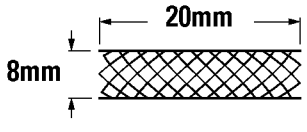
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

8mm x20mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	29mm
6mm	36mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406365	LOT	12345678
REF Catalog No.	M001711250	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 20 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 20 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-13J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 135cm
GTIN 08714729406365
REF M001711250
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 135cm
GTIN 08714729406365
REF M001711250
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 20mm 135cm
GTIN 08714729406365
REF M001711250
LOT 12345678

(01)08714729406365(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 20 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-13J

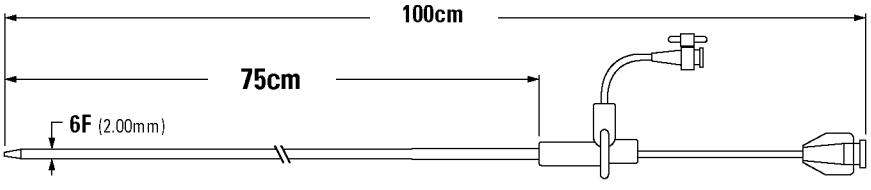
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

Self-Expanding Stent, Stent Auto-expansível

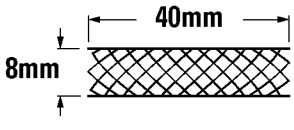
8mm x40mm 75cm

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	49mm
6mm	56mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406372	LOT	12345678
REF Catalog No.	M001711260	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 40 mm | 75 cm
GS1
2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY 8 mm 40 mm 75 cm

90499465-01

Internal BSC Bar Code

L322707-02H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 75cm
GTIN 08714729406372
REF M001711260
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 75cm
GTIN 08714729406372
REF M001711260
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 75cm
GTIN 08714729406372
REF M001711260
LOT 12345678

(01)08714729406372(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 40 mm | 75 cm
GS1
2010-12-31

Label Specification Part Number:L322707-02H

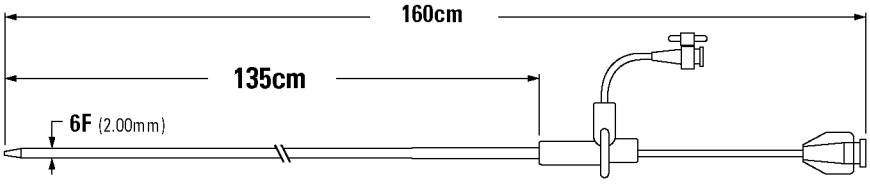
WALLSTENT™ RP Endoprosthesis

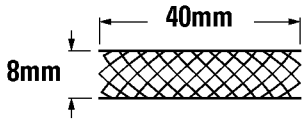
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

8mm x40mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	49mm
6mm	56mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406389	LOT	12345678
REF Catalog No.	M001711270	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 40 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 40 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-14J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 135cm
GTIN 08714729406389
REF M001711270
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 135cm
GTIN 08714729406389
REF M001711270
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 40mm 135cm
GTIN 08714729406389
REF M001711270
LOT 12345678

(01)08714729406389(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 40 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-14J

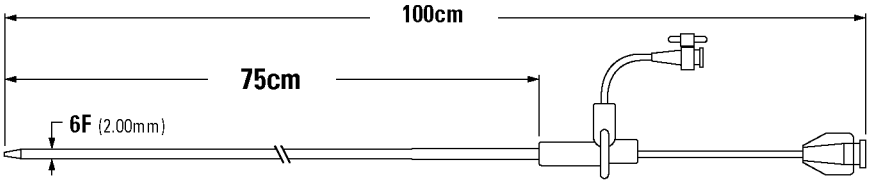
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

Self-Expanding Stent, Stent Auto-expansível

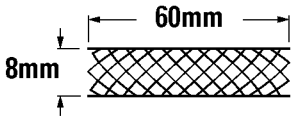
8mm x60mm 75cm

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	70mm
6mm	79mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406396	LOT	12345678
REF Catalog No.	M001711280	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 60 mm | 75 cm
GS1
2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY 8 mm | 60 mm | 75 cm

90499465-01

Internal BSC Bar Code

L322707-03H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 75cm
GTIN 08714729406396
REF M001711280
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 75cm
GTIN 08714729406396
REF M001711280
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 75cm
GTIN 08714729406396
REF M001711280
LOT 12345678

(01)08714729406396(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 60 mm | 75 cm
GS1
2010-12-31

Label Specification Part Number:L322707-03H

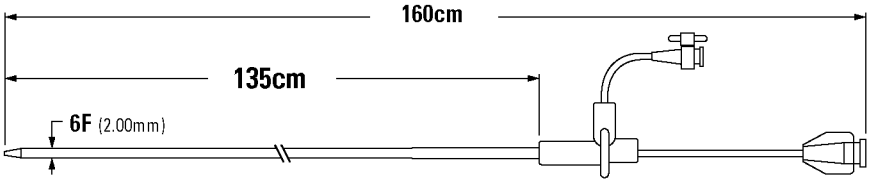
WALLSTENT™ RP Endoprosthesis

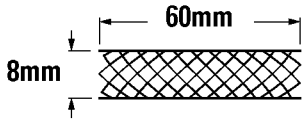
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

8mm x60mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	70mm
6mm	79mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406402	LOT	12345678
REF Catalog No.	M001711290	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 60 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 60 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-15J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 135cm
GTIN 08714729406402
REF M001711290
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 135cm
GTIN 08714729406402
REF M001711290
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 60mm 135cm
GTIN 08714729406402
REF M001711290
LOT 12345678

(01)08714729406402(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 60 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-15J

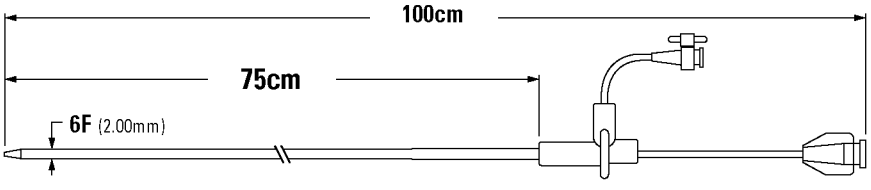
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY

Self-Expanding Stent, Stent Auto-expansível

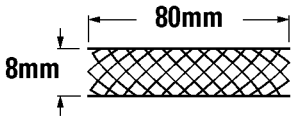
8mm x80mm 75cm

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	105mm
6mm	119mm

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406419	LOT	12345678
REF Catalog No.	M001711300	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 80 mm | 75 cm
GS1
2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY 8 mm 80 mm 75 cm

90499465-01

Internal BSC Bar Code
L322707-04H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 75cm
GTIN 08714729406419
REF M001711300
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 75cm
GTIN 08714729406419
REF M001711300
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 75cm
GTIN 08714729406419
REF M001711300
LOT 12345678

(01)08714729406419(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY
8 mm | 80 mm | 75 cm
GS1
2010-12-31

Label Specification Part Number:L322707-04H

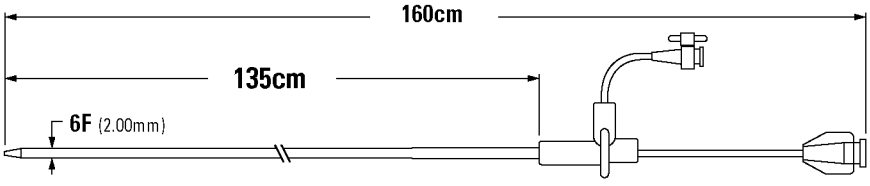
WALLSTENT™ RP Endoprosthesis

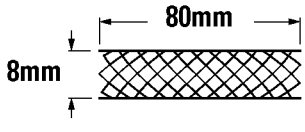
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

8mm x80mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
7mm	105mm
6mm	119mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406426	LOT	12345678
REF Catalog No.	M001711310	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 80 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 80 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-16J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 135cm
GTIN 08714729406426
REF M001711310
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 135cm
GTIN 08714729406426
REF M001711310
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
8mm x 80mm 135cm
GTIN 08714729406426
REF M001711310
LOT 12345678

(01)08714729406426(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 8 mm | 80 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-16J

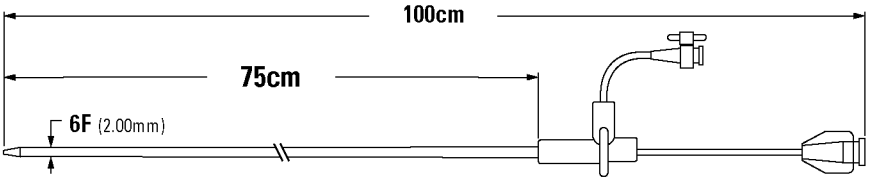
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

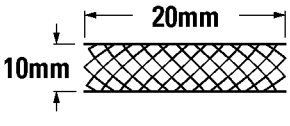
10mm x20mm 75cm

Contents **(1)**



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **6F** (2.00mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	27mm
8mm	33mm

GTIN	08714729406433	LOT	12345678
REF Catalog No.	M001711320	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS
10 mm | 20 mm | 75 cm
GS1
2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS
10 mm | 20 mm | 75 cm

90499465-01

Internal BSC Bar Code
L322707-05H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 75cm
GTIN 08714729406433
REF M001711320
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 75cm
GTIN 08714729406433
REF M001711320
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 75cm
GTIN 08714729406433
REF M001711320
LOT 12345678

(01)08714729406433(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS
10 mm | 20 mm | 75 cm
GS1
2010-12-31

Label Specification Part Number:L322707-05H

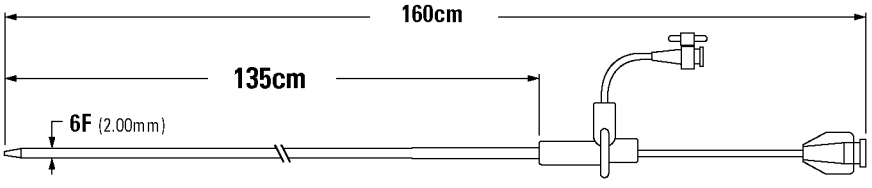
WALLSTENT™ RP Endoprosthesis

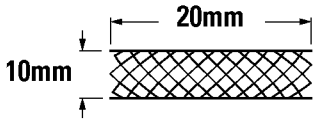
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

10mm x20mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	27mm
8mm	33mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406440	LOT	12345678
REF Catalog No.	M001711330	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 20 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 20 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-17J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 135cm
GTIN 08714729406440
REF M001711330
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 135cm
GTIN 08714729406440
REF M001711330
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 20mm 135cm
GTIN 08714729406440
REF M001711330
LOT 12345678

(01)08714729406440(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 20 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-17J

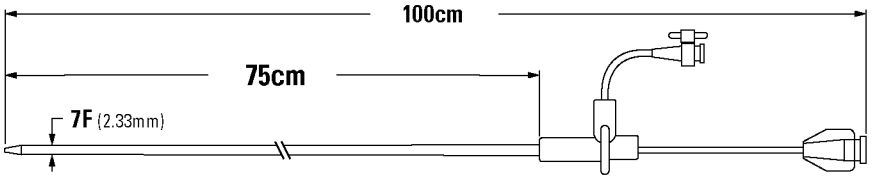
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

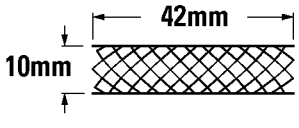
10mm x42mm 75cm

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **7F** (2.33mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	48mm
8mm	54mm

GTIN	08714729406457	LOT	12345678
REF Catalog No.	M001711340	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS
10 mm | 42 mm | 75 cm | GS1 | 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS 10 mm 42 mm 75 cm

90499465-01

Internal BSC Bar Code
L322709-01H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 75cm
GTIN 08714729406457
REF M001711340
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 75cm
GTIN 08714729406457
REF M001711340
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 75cm
GTIN 08714729406457
REF M001711340
LOT 12345678

(01)08714729406457(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS
10 mm | 42 mm | 75 cm | GS1 | 2010-12-31

Label Specification Part Number:L322709-01H

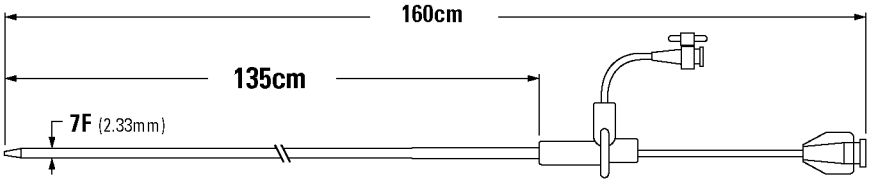
WALLSTENT™ RP Endoprosthesis

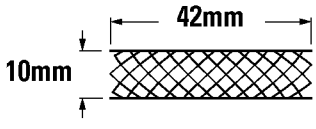
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

10mm x42mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	48mm
8mm	54mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406464	LOT	12345678
REF Catalog No.	M001711350	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 42 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 42 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-18J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 135cm
GTIN 08714729406464
REF M001711350
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 135cm
GTIN 08714729406464
REF M001711350
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 42mm 135cm
GTIN 08714729406464
REF M001711350
LOT 12345678

(01)08714729406464(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 42 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-18J

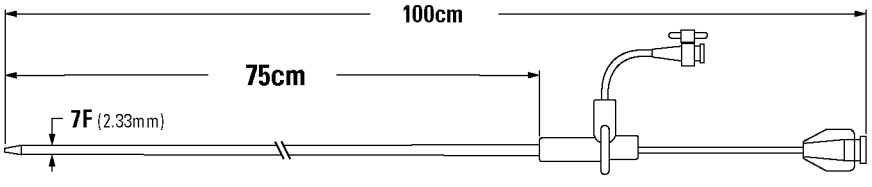
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

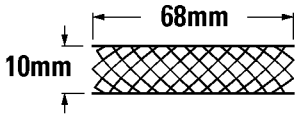
10mm x68mm 75cm

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **7F** (2.33mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	69mm
8mm	77mm

GTIN	08714729406471	LOT	12345678
REF Catalog No.	M001711360	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS
10 mm | 68 mm | 75 cm | GS1 | 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS 10 mm 68 mm 75 cm

90499465-01

Internal BSC Bar Code
L322709-02H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 75cm
GTIN 08714729406471
REF M001711360
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 75cm
GTIN 08714729406471
REF M001711360
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 75cm
GTIN 08714729406471
REF M001711360
LOT 12345678

(01)08714729406471(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS
10 mm | 68 mm | 75 cm | GS1 | 2010-12-31

Label Specification Part Number:L322709-02H

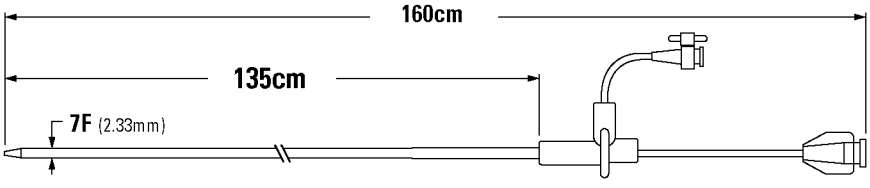
WALLSTENT™ RP Endoprosthesis

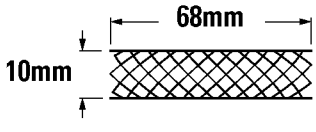
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

10mm x68mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	69mm
8mm	77mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406488	LOT	12345678
REF Catalog No.	M001711370	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 68 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 68 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-19J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 135cm
GTIN 08714729406488
REF M001711370
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 135cm
GTIN 08714729406488
REF M001711370
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 68mm 135cm
GTIN 08714729406488
REF M001711370
LOT 12345678

(01)08714729406488(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 68 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-19J

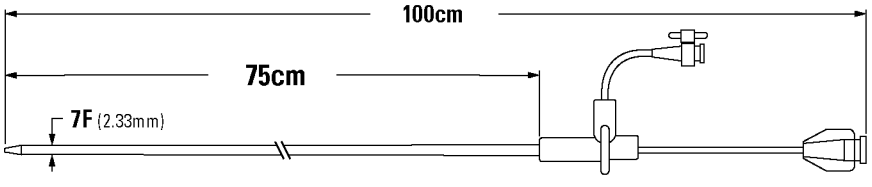
WALLSTENT™ RP Endoprosthesis

TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

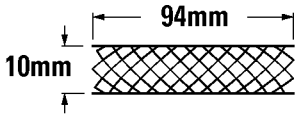
10mm x94mm 75cm

Contents (1)



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **7F** (2.33mm) **Recommended Introducer Sheath**



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	103mm
8mm	115mm

GTIN	08714729406495	LOT	12345678
REF Catalog No.	M001711380	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS
10 mm | 94 mm | 75 cm | GS1 | 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS 10 mm 94 mm 75 cm

90499465-01

Internal BSC Bar Code
L322709-03H

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 75cm
GTIN 08714729406495
REF M001711380
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 75cm
GTIN 08714729406495
REF M001711380
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 75cm
GTIN 08714729406495
REF M001711380
LOT 12345678

(01)08714729406495(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

WALLSTENT™ RP Endoprosthesis
TRACHEOBRONCHIAL - TIPS - TRANSHEPATIC BILIARY - VENOUS
10 mm | 94 mm | 75 cm | GS1 | 2010-12-31

Label Specification Part Number:L322709-03H

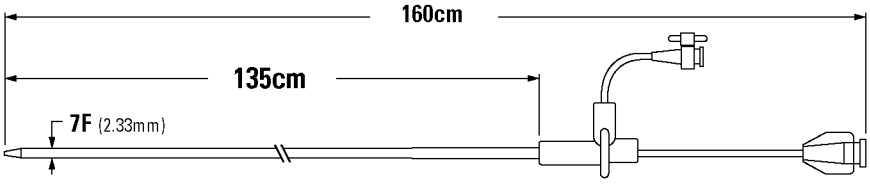
WALLSTENT™ RP Endoprosthesis

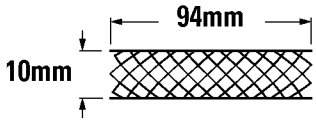
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

10mm x94mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
9mm	103mm
8mm	115mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729406501	LOT	12345678
REF Catalog No.	M001711390	Use By	2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 94 mm | 135 cm GS1 2010-12-31

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 94 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322699-20J

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 135cm
GTIN 08714729406501
REF M001711390
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 135cm
GTIN 08714729406501
REF M001711390
LOT 12345678

Boston Scientific
WALLSTENT™ RP Endoprosthesis
10mm x 94mm 135cm
GTIN 08714729406501
REF M001711390
LOT 12345678

(01)08714729406501(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT™ RP Endoprosthesis TRACHEOBRONCHIAL 10 mm | 94 mm | 135 cm GS1 2010-12-31

Label Specification Part Number: L322699-20J

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

GS1

12 mm | 20 mm | 75 cm

2010-12-31

Boston Scientific

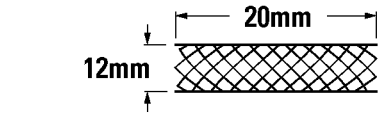
12mm x20mm 75cm

WALLSTENT® Endoprosthesis

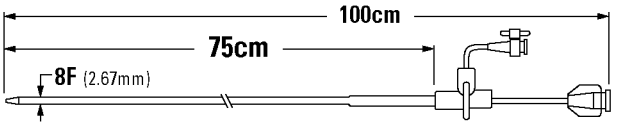
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	26mm
10mm	31mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **9F** (3.00mm) **Recommended Introducer Sheath**

GTIN **08714729203940**

REF **Catalog No.** **H965402100**

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 75cm
GTIN 08714729203940
REF H965402100
LOT 12345678

(01)08714729203940(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-01H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-01H

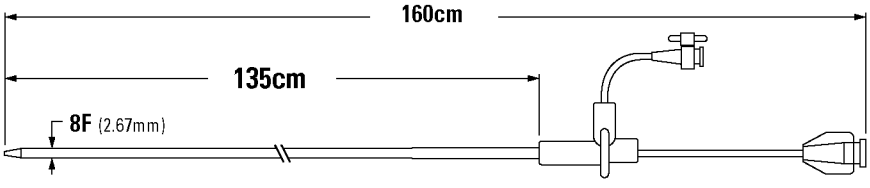
WALLSTENT® Endoprosthesis

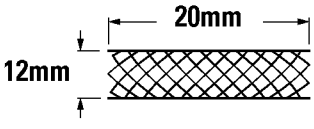
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

12mm x20mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	26mm
10mm	31mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204398	LOT	12345678
REF Catalog No.	H965412000	Use By	2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 20 mm | 135 cm GS1 2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 20 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322691-01H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 135cm
GTIN 08714729204398
REF H965412000
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 135cm
GTIN 08714729204398
REF H965412000
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 20mm 135cm
GTIN 08714729204398
REF H965412000
LOT 12345678

(01)08714729204398(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 20 mm | 135 cm GS1 2010-12-31

Label Specification Part Number:L322691-01H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

GS1

12 mm | 40 mm | 75 cm

2010-12-31

Boston Scientific

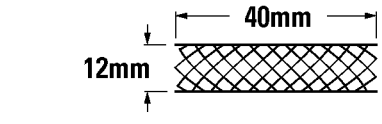
12mm x40mm 75cm

WALLSTENT® Endoprosthesis

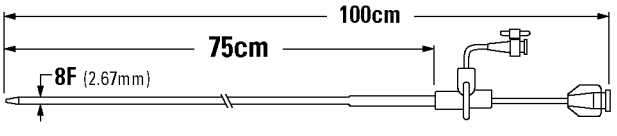
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	47mm
10mm	51mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **9F** (3.00mm) **Recommended Introducer Sheath**

GTIN **08714729203957**

REF **Catalog No.** **H965402110**

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 75cm
GTIN 08714729203957
REF H965402110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 75cm
GTIN 08714729203957
REF H965402110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 75cm
GTIN 08714729203957
REF H965402110
LOT 12345678

(01)08714729203957(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-02H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-02H

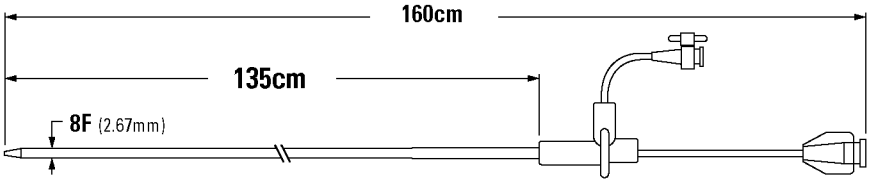
WALLSTENT® Endoprosthesis

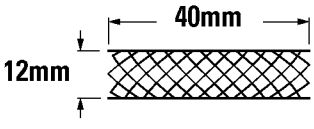
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

12mm x40mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	47mm
10mm	51mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204404	LOT	12345678
REF Catalog No.	H965412010	Use By	2010-12-31

WALLSTENT® Endoprosthesis
TRACHEOBRONCHIAL
12 mm | 40 mm | 135 cm
GS1
2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 40 mm | 135 cm

90499465-01

Internal BSC Bar Code
L322691-02H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 135cm
GTIN 08714729204404
REF H965412010
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 135cm
GTIN 08714729204404
REF H965412010
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 40mm 135cm
GTIN 08714729204404
REF H965412010
LOT 12345678

(01)08714729204404(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis
TRACHEOBRONCHIAL
12 mm | 40 mm | 135 cm
GS1
2010-12-31

Label Specification Part Number: L322691-02H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

GS1

12 mm | 60 mm | 75 cm

2010-12-31

Boston Scientific

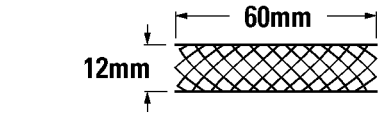
12mm x60mm 75cm

WALLSTENT® Endoprosthesis

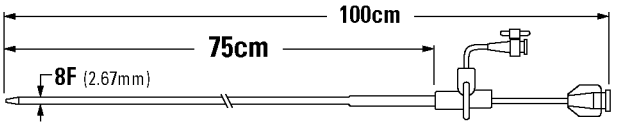
TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	66mm
10mm	73mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **9F** (3.00mm) **Recommended Introducer Sheath**

GTIN **08714729203964**

REF **Catalog No.** **H965402120**

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 75cm
GTIN 08714729203964
REF H965402120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 75cm
GTIN 08714729203964
REF H965402120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 75cm
GTIN 08714729203964
REF H965402120
LOT 12345678

(01)08714729203964(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-03H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-03H

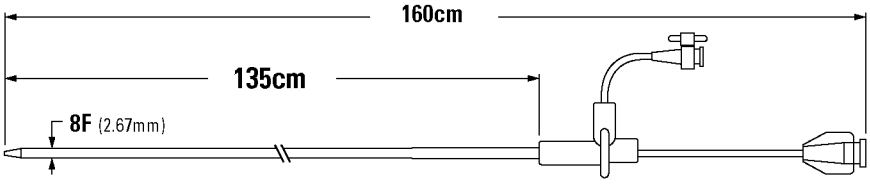
WALLSTENT® Endoprosthesis

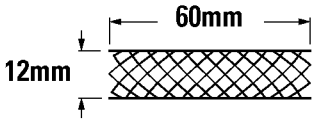
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

12mm x60mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	66mm
10mm	73mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204411	LOT	12345678
REF Catalog No.	H965412020	Use By	2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 60 mm | 135 cm GS1 2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 60 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322691-03H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 135cm
GTIN 08714729204411
REF H965412020
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 135cm
GTIN 08714729204411
REF H965412020
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 60mm 135cm
GTIN 08714729204411
REF H965412020
LOT 12345678

(01)08714729204411(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 60 mm | 135 cm GS1 2010-12-31

Label Specification Part Number:L322691-03H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

GS1

12 mm | 90 mm | 75 cm

2010-12-31

Boston Scientific

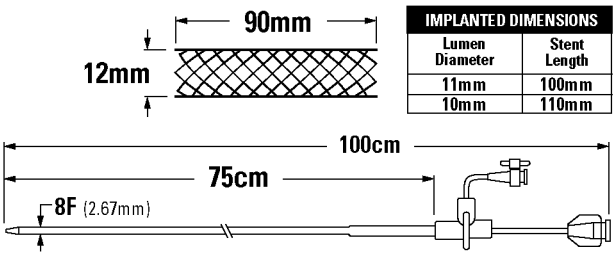
12mm x 90mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - TRANSHEPATIC BILIARY - TIPS - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	100mm
10mm	110mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **9F** (3.00mm) **Recommended Introducer Sheath**

GTIN **08714729203971**

REF **Catalog No.** **H965402130**

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 75cm
GTIN 08714729203971
REF H965402130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 75cm
GTIN 08714729203971
REF H965402130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 75cm
GTIN 08714729203971
REF H965402130
LOT 12345678

(01)08714729203971(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-04H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-04H

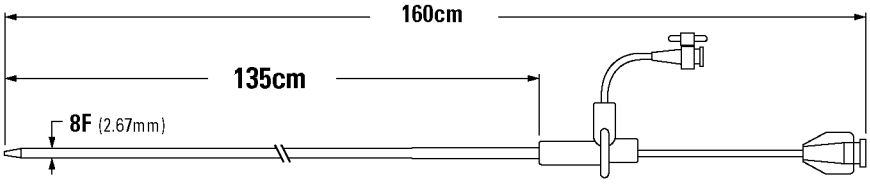
WALLSTENT® Endoprosthesis

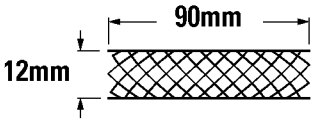
TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

12mm x90mm 135cm

Contents (1)





IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
11mm	100mm
10mm	110mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN	08714729204428	LOT	12345678
REF Catalog No.	H965412030	Use By	2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 90 mm | 135 cm GS1 2010-12-31

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 90 mm | 135 cm

90499465-01

Internal BSC Bar Code

L322691-04H

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 135cm
GTIN 08714729204428
REF H965412030
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 135cm
GTIN 08714729204428
REF H965412030
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
12mm x 90mm 135cm
GTIN 08714729204428
REF H965412030
LOT 12345678

(01)08714729204428(17)101231(10)12345678 GS1

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis TRACHEOBRONCHIAL 12 mm | 90 mm | 135 cm GS1 2010-12-31

Label Specification Part Number:L322691-04H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1 | 14 mm | 20 mm | 75 cm | 2010-12-31

Boston Scientific

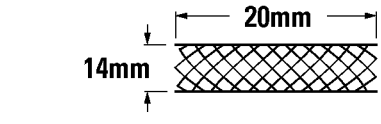
14mm x20mm 75cm

WALLSTENT® Endoprosthesis

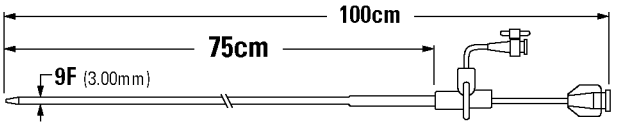
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	27mm
12mm	33mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN **08714729203988**

REF **Catalog No.** **H965403100**

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 20mm 75cm
GTIN 08714729203988
REF H965403100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 20mm 75cm
GTIN 08714729203988
REF H965403100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 20mm 75cm
GTIN 08714729203988
REF H965403100
LOT 12345678

(01)08714729203988(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-05H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-05H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1

14 mm | 40 mm | 75 cm

2010-12-31

Boston Scientific

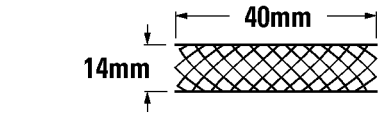
14mm x40mm 75cm

WALLSTENT® Endoprosthesis

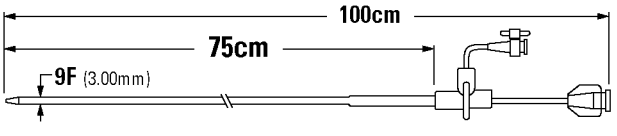
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	46mm
12mm	50mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN 08714729203995

REF **Catalog No.** H965403110

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 40mm 75cm
GTIN 08714729203995
REF H965403110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 40mm 75cm
GTIN 08714729203995
REF H965403110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 40mm 75cm
GTIN 08714729203995
REF H965403110
LOT 12345678

(01)08714729203995(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-06H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-06H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1

14 mm | 60 mm | 75 cm

2010-12-31

Boston Scientific

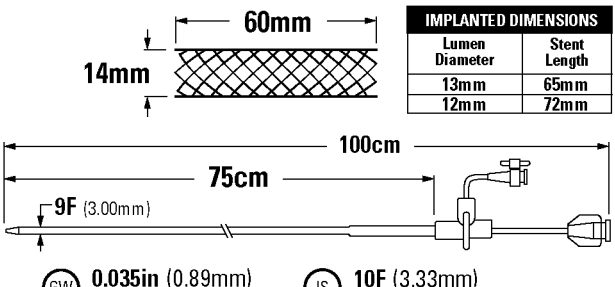
14mm x60mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	65mm
12mm	72mm

GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN 08714729204008

REF **Catalog No.** H965403120

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 60mm 75cm
GTIN 08714729204008
REF H965403120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 60mm 75cm
GTIN 08714729204008
REF H965403120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 60mm 75cm
GTIN 08714729204008
REF H965403120
LOT 12345678

(01)08714729204008(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-07H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-07H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1

14 mm | 90 mm | 75 cm

2010-12-31

Boston Scientific

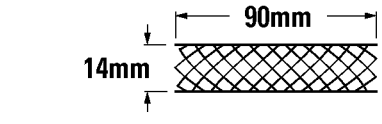
14mm x90mm 75cm

WALLSTENT® Endoprosthesis

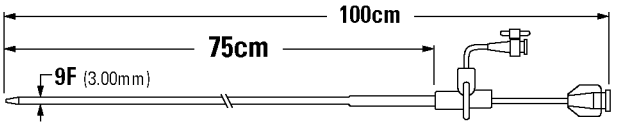
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
13mm	98mm
12mm	107mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN **08714729204015**

REF **Catalog No.** **H965403130**

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 90mm 75cm
GTIN 08714729204015
REF H965403130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 90mm 75cm
GTIN 08714729204015
REF H965403130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
14mm x 90mm 75cm
GTIN 08714729204015
REF H965403130
LOT 12345678

(01)08714729204015(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-08H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-08H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1

16 mm | 20 mm | 75 cm

2010-12-31

Boston Scientific

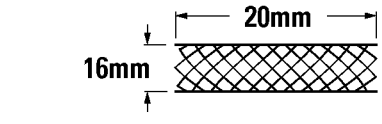
16mm x20mm 75cm

WALLSTENT® Endoprosthesis

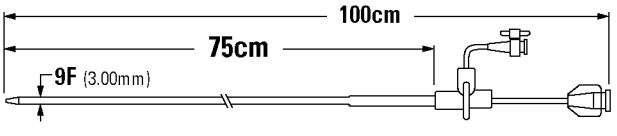
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	23mm
14mm	28mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN **08714729204022**

REF **Catalog No.** **H965403300**

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 20mm 75cm
GTIN 08714729204022
REF H965403300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 20mm 75cm
GTIN 08714729204022
REF H965403300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 20mm 75cm
GTIN 08714729204022
REF H965403300
LOT 12345678

(01)08714729204022(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-09H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-09H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1

16 mm | 40 mm | 75 cm

2010-12-31

Boston Scientific

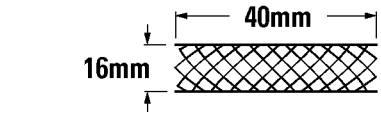
16mm x40mm 75cm

WALLSTENT® Endoprosthesis

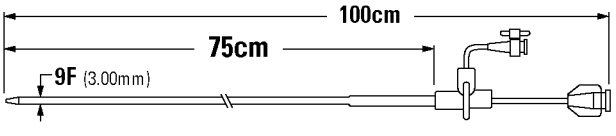
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	45mm
14mm	49mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN 08714729204039

REF **Catalog No.** H965403310

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 40mm 75cm
GTIN 08714729204039
REF H965403310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 40mm 75cm
GTIN 08714729204039
REF H965403310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 40mm 75cm
GTIN 08714729204039
REF H965403310
LOT 12345678

(01)08714729204039(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-10H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-10H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1 | 16 mm | 60 mm | 75 cm | 2010-12-31

Boston Scientific

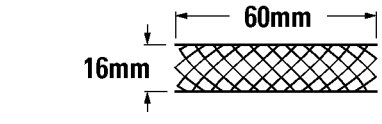
16mm x60mm 75cm

WALLSTENT® Endoprosthesis

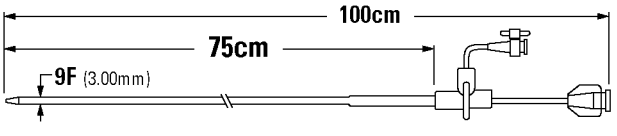
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	64mm
14mm	70mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN 08714729204046

REF **Catalog No.** H965403320

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 60mm 75cm
GTIN 08714729204046
REF H965403320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 60mm 75cm
GTIN 08714729204046
REF H965403320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 60mm 75cm
GTIN 08714729204046
REF H965403320
LOT 12345678

(01)08714729204046(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-11H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-11H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL - VENOUS

GS1

16 mm | 90 mm | 75 cm

2010-12-31

Boston Scientific

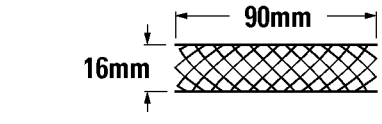
16mm x90mm 75cm

WALLSTENT® Endoprosthesis

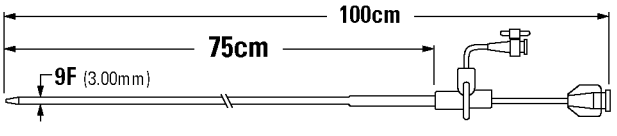
TRACHEOBRONCHIAL - VENOUS

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
15mm	97mm
14mm	105mm



GW R **0.035in** (0.89mm) **Recommended Guidewire**

IS R **10F** (3.33mm) **Recommended Introducer Sheath**

GTIN **08714729204053**

REF **Catalog No.** **H965403330**

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 90mm 75cm
GTIN 08714729204053
REF H965403330
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 90mm 75cm
GTIN 08714729204053
REF H965403330
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
16mm x 90mm 75cm
GTIN 08714729204053
REF H965403330
LOT 12345678

(01)08714729204053(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-12H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT **12345678** Use By **2010-12-31**

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number: L322689-12H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

18 mm | 40 mm | 75 cm

2010-12-31

Boston Scientific

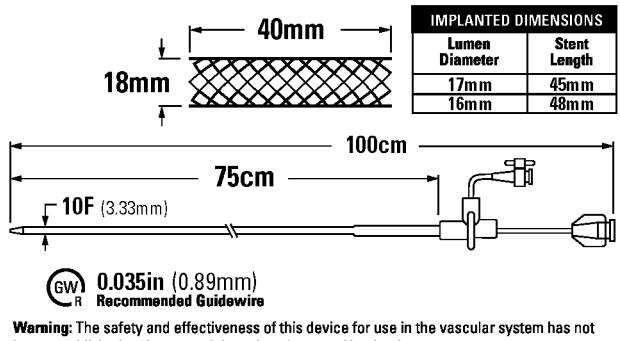
18mm x40mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
17mm	45mm
16mm	48mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204060

REF Catalog No. H965404110

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 40mm 75cm
GTIN 08714729204060
REF H965404110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 40mm 75cm
GTIN 08714729204060
REF H965404110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 40mm 75cm
GTIN 08714729204060
REF H965404110
LOT 12345678

(01)08714729204060(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-13H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-13H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

18 mm 60 mm 75 cm

2010-12-31

Boston Scientific

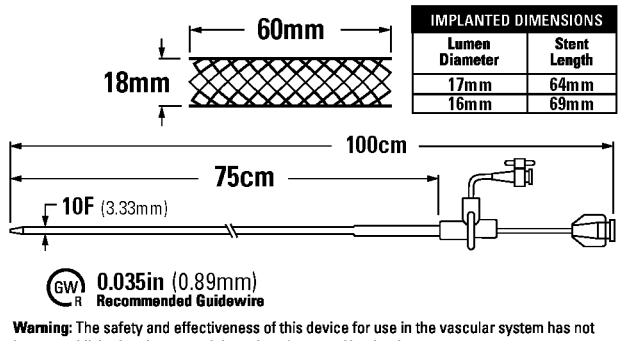
18mm x60mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
17mm	64mm
16mm	69mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204077

REF Catalog No. H965404120

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 60mm 75cm
GTIN 08714729204077
REF H965404120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 60mm 75cm
GTIN 08714729204077
REF H965404120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 60mm 75cm
GTIN 08714729204077
REF H965404120
LOT 12345678

(01)08714729204077(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-14H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

18 mm 90 mm 75 cm

GS1

2010-12-31

Boston Scientific

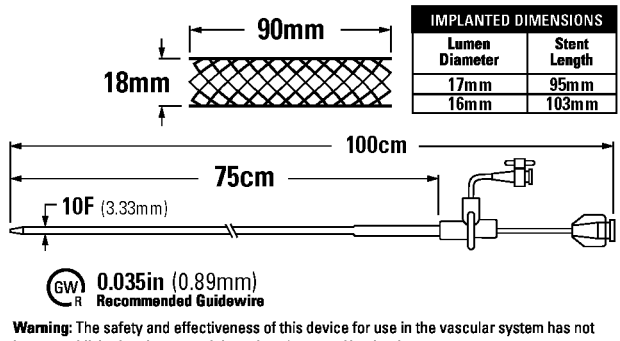
18mm x 90mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
17mm	95mm
16mm	103mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204084

REF Catalog No. H965404130

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 90mm 75cm
GTIN 08714729204084
REF H965404130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 90mm 75cm
GTIN 08714729204084
REF H965404130
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
18mm x 90mm 75cm
GTIN 08714729204084
REF H965404130
LOT 12345678

(01)08714729204084(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-15H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-15H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

20 mm 40 mm 75 cm

2010-12-31

Boston Scientific

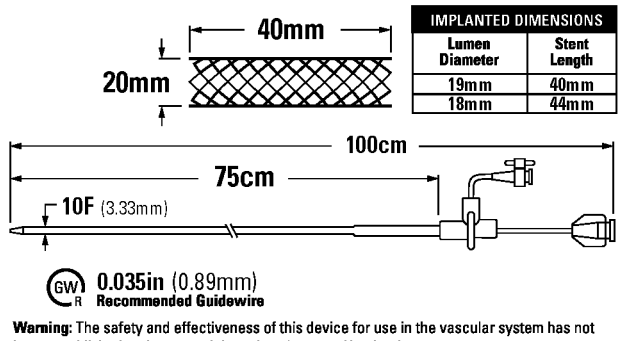
20mm x40mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
19mm	40mm
18mm	44mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204091

REF Catalog No. H965404300

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 40mm 75cm
GTIN 08714729204091
REF H965404300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 40mm 75cm
GTIN 08714729204091
REF H965404300
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 40mm 75cm
GTIN 08714729204091
REF H965404300
LOT 12345678

(01)08714729204091(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-16H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-16H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

20 mm 55 mm 75 cm

2010-12-31

Boston Scientific

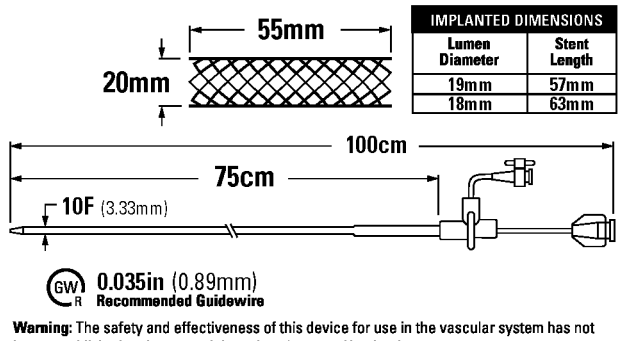
20mm x55mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
19mm	57mm
18mm	63mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204107

REF Catalog No. H965404310

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 55mm 75cm
GTIN 08714729204107
REF H965404310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 55mm 75cm
GTIN 08714729204107
REF H965404310
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 55mm 75cm
GTIN 08714729204107
REF H965404310
LOT 12345678

(01)08714729204107(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-17H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

20 mm **80 mm** 75 cm

2010-12-31

Boston Scientific

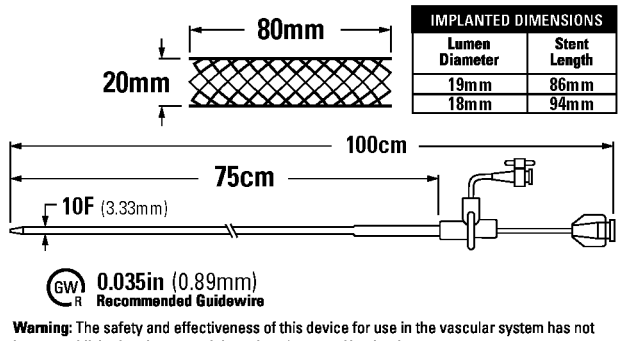
20mm x80mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
19mm	86mm
18mm	94mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204114

REF Catalog No. H965404320

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 80mm 75cm
GTIN 08714729204114
REF H965404320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 80mm 75cm
GTIN 08714729204114
REF H965404320
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
20mm x 80mm 75cm
GTIN 08714729204114
REF H965404320
LOT 12345678

(01)08714729204114(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-18H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

22 mm | 35 mm | 75 cm

2010-12-31

Boston Scientific

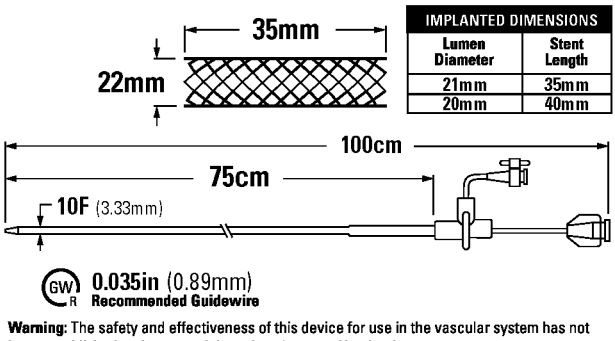
22mm x 35mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
21mm	35mm
20mm	40mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204121

REF Catalog No. H965404500

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 35mm 75cm
GTIN 08714729204121
REF H965404500
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 35mm 75cm
GTIN 08714729204121
REF H965404500
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 35mm 75cm
GTIN 08714729204121
REF H965404500
LOT 12345678

(01)08714729204121(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-19H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-19H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

22 mm | 45 mm | 75 cm

2010-12-31

Boston Scientific

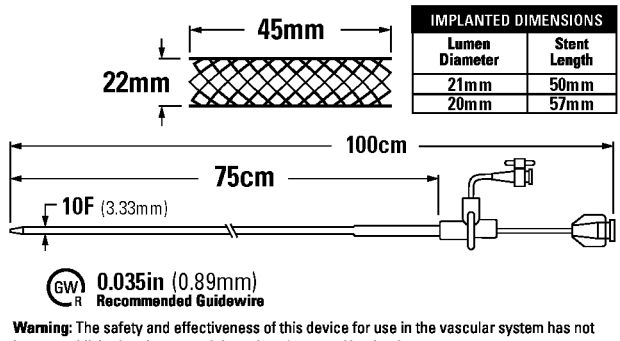
22mm x45mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
21mm	50mm
20mm	57mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204138

REF Catalog No. H965404510

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 45mm 75cm
GTIN 08714729204138
REF H965404510
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 45mm 75cm
GTIN 08714729204138
REF H965404510
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 45mm 75cm
GTIN 08714729204138
REF H965404510
LOT 12345678

(01)08714729204138(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-20H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-20H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

22 mm | 70 mm | 75 cm

2010-12-31

Boston Scientific

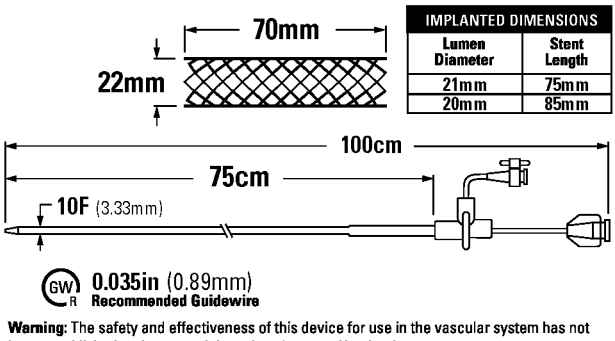
22mm x 70mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
21mm	75mm
20mm	85mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204145

REF Catalog No. H965404520

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 70mm 75cm
GTIN 08714729204145
REF H965404520
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 70mm 75cm
GTIN 08714729204145
REF H965404520
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
22mm x 70mm 75cm
GTIN 08714729204145
REF H965404520
LOT 12345678

(01)08714729204145(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-21H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-21H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

24 mm | 35 mm | 75 cm

GS1

2010-12-31

Boston Scientific

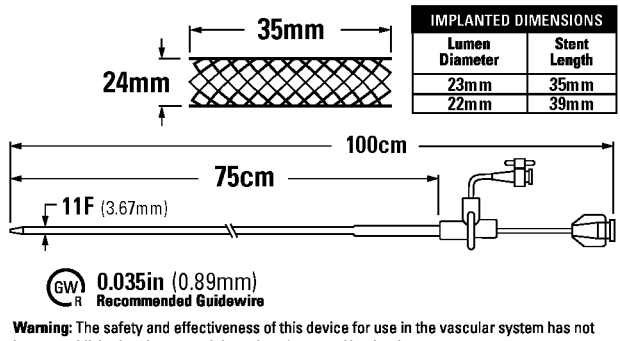
24mm x35mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
23mm	35mm
22mm	39mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204152

REF Catalog No. H965405100

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 35mm 75cm
GTIN 08714729204152
REF H965405100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 35mm 75cm
GTIN 08714729204152
REF H965405100
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 35mm 75cm
GTIN 08714729204152
REF H965405100
LOT 12345678

(01)08714729204152(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-22H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-22H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

24 mm | 45 mm | 75 cm

2010-12-31

Boston Scientific

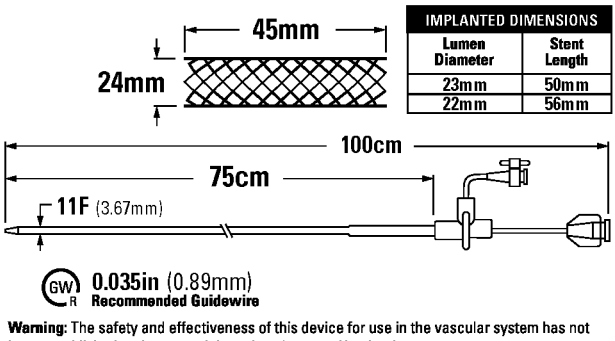
24mm x 45mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
23mm	50mm
22mm	56mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204169

REF Catalog No. H965405110

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 45mm 75cm
GTIN 08714729204169
REF H965405110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 45mm 75cm
GTIN 08714729204169
REF H965405110
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 45mm 75cm
GTIN 08714729204169
REF H965405110
LOT 12345678

(01)08714729204169(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-23H

Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-23H

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

GS1

24 mm | 70 mm | 75 cm

2010-12-31

Boston Scientific

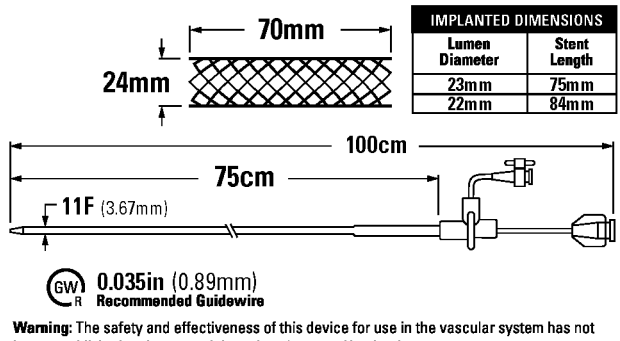
24mm x 70mm 75cm

WALLSTENT® Endoprosthesis

TRACHEOBRONCHIAL

Self-Expanding Stent, Stent Auto-expansível

Contents (1)



IMPLANTED DIMENSIONS	
Lumen Diameter	Stent Length
23mm	75mm
22mm	84mm

GW R 0.035in (0.89mm) Recommended Guidewire

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

GTIN 08714729204176

REF Catalog No. H965405120

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 70mm 75cm
GTIN 08714729204176
REF H965405120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 70mm 75cm
GTIN 08714729204176
REF H965405120
LOT 12345678

Boston Scientific
WALLSTENT® Endoprosthesis
24mm x 70mm 75cm
GTIN 08714729204176
REF H965405120
LOT 12345678

(01)08714729204176(17)101231(10)12345678 GS1

90478732-01

Internal BSC Bar Code

L322689-24H

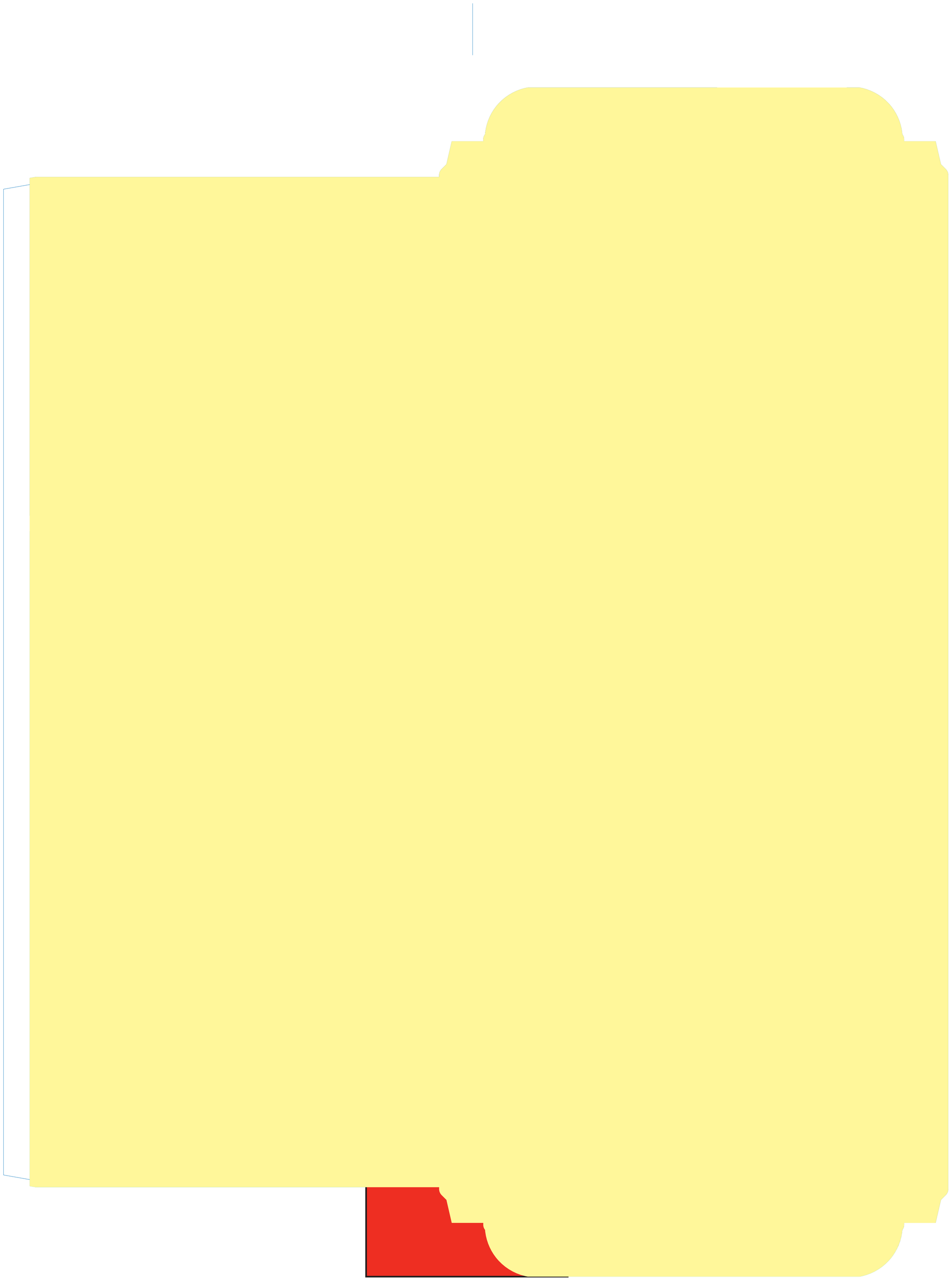
Made in IRELAND
Ballybrit Business Park
Galway, IRELAND

LOT 12345678 Use By 2010-12-31

This product may be protected by one or more patents. Patent information can be obtained at http://www.bostonscientific.com/patents

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number: L322689-24H



Boston Scientific
(Master Brand Template 90218086AF)
Carton, MB
7.87 x .88 x 19.25
90965525-02A

Boston Scientific
(Master Brand Template 90218087AF)
Carton, MB
4.5 x .75 x 51.02
90965521-01A
Page 1 of 1

Hi Ms. Marrone and Ms. Levelle,

I just wanted to follow up via email after April's call to me this afternoon, in order to get written documentation of the DFU strategy. To confirm, both submissions, K152842 and K152853, need proposed Directions for Use that only incorporate proposed labeling for the applicable indication, and not the other Class II indication. Here is what I have for notes:

* Boston Scientific will submit proposed Directions for Use with only proposed MR wording for the applicable indication to each reviewer (via email)

o The proposed DFU for each indication will still include cumulative changes (noted within each submission) for both indication, as this is the currently released DFU.

o The proposed DFU for each indication will include approved wording from the two PMA supplements, P980033/S043 and P930031/S054 in their respective sections

* Upon clearance of both 510(k)'s, Boston Scientific will implement a single, combined DFU, using approved wording for each respective Indication. The DFU update will not be implemented for the DFU until both 510(k)'s are cleared, so the only implemented DFU update will include cleared wording for both indications.

* April indicated that she needed an updated DFU (for K152853, Transhepatic Biliary) by next Friday, October 30th, to complete her RTA review before the RTA deadline. I noted that getting blacklines would likely not be possible for this, as the artwork turnaround is our limiting factor. I did confirm that I would send redlines (of the currently released DFU) by the morning of October 30th, and Blacklines as soon as they are ready (My engineer anticipates having them by November 6th).

o Ms. Levelle, I should be able to have both red and blacklines available for you (K152842, Tracheobronchial) by November 6th, which should be in time to complete your RTA review by the deadline (the RTA response was mailed yesterday, if you haven't received it yet). If not, I will have redlines at minimum by November 6th, and blacklines by November 15th at the latest.

If it is possible, could you confirm that the strategy above is acceptable? If you have any questions, please don't hesitate to call or email me. I look forward to working with both of you during the review of these 510(k)s.

Thank you,

Carah

Carah Kucharski
Reg Affairs Specialist
Boston Scientific
Regulatory Affairs
Carah.Kucharski@bsci.com<mailto:Carah.Kucharski@bsci.com>
763-255-0738
Maple Grove, MN
www.bostonscientific.com

[Boston Scientific - Advancing science for life (tm)]

Good morning Ms. Levelle,

Attached is the amended labeling for K152842, Wallstent RP Endoprosthesis Tracheobronchial and Wallstent Endoprosthesis Tracheobronchial as discussed several weeks ago. The redlines in this DFU include the approved wording for the class III indications (because we are planning on implementing all approved/cleared wording together), which is what the Tracheobronchial wording was based on, but does not include the proposed changes for K152853, which is the Biliary DFU under review by April Marrone. Please let me know if you have any questions.

Thank you,
Carah
Carah Kucharski
Reg Affairs Specialist.
Boston Scientific
Regulatory Affairs
Carah.Kucharski@bsci.com<mailto:Carah.Kucharski@bsci.com>
763-255-0738
Maple Grove, MN
www.bostonscientific.com<http://www.bostonscientific.com>

[Boston Scientific - Advancing science for life (tm)]

From: Amy Levelle [mailto:amy.levelle@fda.hhs.gov]
Sent: Thursday, November 05, 2015 11:23 PM
To: Kucharski, Carah
Cc: Amy Levelle
Subject: K152842/S001 was Accepted

November 6, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K152842/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Amy Levelle.

*** This is a system-generated email notification ***

Good morning Ms. Levelle,

Attached is the amended labeling for K152842, Wallstent RP Endoprosthesis Tracheobronchial and Wallstent Endoprosthesis Tracheobronchial as discussed several weeks ago. The redlines in this DFU include the approved wording for the class III indications (because we are planning on implementing all approved/cleared wording together), which is what the Tracheobronchial wording was based on, but does not include the proposed changes for K152853, which is the Biliary DFU under review by April Marrone. Please let me know if you have any questions.

Thank you,
Carah

Carah Kucharski
Reg Affairs Specialist.
Boston Scientific
Regulatory Affairs
Carah.Kucharski@bsci.com
763-255-0738
Maple Grove, MN
www.bostonscientific.com

Boston Scientific - Advancing

From: Amy Levelle [mailto:amy.levelle@fda.hhs.gov]
Sent: Thursday, November 05, 2015 11:23 PM
To: Kucharski, Carah
Cc: Amy Levelle
Subject: K152842/S001 was Accepted

November 6, 2015

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K152842/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Amy Levelle.

*** This is a system-generated email notification ***

Hi Ms. Levelle,

I have been working on BSC's responses to the Additional Information request for K151482/S001 for Wallstent RP Endoprosthesis and Wallstent Endoprosthesis Tracheobronchial, placed on hold on December 23rd, 2015. I am wondering if it would be possible to schedule a short call with you sometime early next week to walk through our proposed responses and provide any needed clarifications. We are available next week Monday-Wednesday, March 28th-30th. If this is possible, I can provide a draft copy of the responses and a call-in number prior to the call. If you have any questions, please do not hesitate to ask.

Regards,
Carah

From: Amy Levelle [mailto:amy.levelle@fda.hhs.gov]
Sent: Tuesday, December 22, 2015 4:47 PM
To: Kucharski, Carah
Cc: Amy Levelle
Subject: K152842/S001 is on Hold Pending Your Response

December 22, 2015

We have reviewed your submission K152842/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K152842/S001 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is June 19, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a

Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Amy Levelle, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

Hi Ms. Levelle,

I have been working on BSC's responses to the Additional Information request for K151482/S001 for Wallstent RP Endoprosthesis and Wallstent Endoprosthesis Tracheobronchial, placed on hold on December 23rd, 2015. I am wondering if it would be possible to schedule a short call with you sometime early next week to walk through our proposed responses and provide any needed clarifications. We are available next week Monday-Wednesday, March 28th-30th. If this is possible, I can provide a draft copy of the responses and a call-in number prior to the call. If you have any questions, please do not hesitate to ask.

Regards,
Carah

From: Amy Levelle [mailto:amy.levelle@fda.hhs.gov]
Sent: Tuesday, December 22, 2015 4:47 PM
To: Kucharski, Carah
Cc: Amy Levelle
Subject: K152842/S001 is on Hold Pending Your Response

December 22, 2015

We have reviewed your submission K152842/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K152842/S001 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf
for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is June 19, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Amy Levelle, the lead reviewer assigned to your submission.

*** This is a system-generated email notification ***

Boston Scientific

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRANSHEPATIC BILIARY

TRACHEOBRONCHIAL

TIPS

VENOUS

Self-Expanding Stent

Directions for Use **2**

DRAFT

This artwork is not ready for release until this note is removed. The Date-of-Issue will not be populated until this draft note is removed.

Regulatory Submission

91079000-01

2015-11

Boston Scientific (Master Brand DFUTemplate 3in x 9in Global, 90106040AP), DFU, MB, WALLSTENT ENDO, EN/PT 91079000-01A_pretrans

CV01

Black (K) ΔE ≤5.0

TABLE OF CONTENTS

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

Self-Expanding Stent

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus delivery system (reference Figure A). The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5 mm–12 mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89 mm) guidewire.

User Information

This system is intended for use by physicians who have received appropriate training.

Contents

One (1) WALLSTENT RP Endoprosthesis

Or

One (1) WALLSTENT Endoprosthesis

WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis with UNISTEP™ Plus Delivery System

Table 1. Size and Indication Information

UPN	Order Number	Stent Diameter Compatibility	Stent Length	Sheath Diameter	Effective Length	Total	Indications
		mm	mm	F(mm)	cm	cm	
M001711000	71-100	5	20	6 (2.0)	75	100	1
M001711010	71-101	5	20	6 (2.0)	135	160	1
M001711020	71-102	5	40	6 (2.0)	75	100	1
M001711030	71-103	5	40	6 (2.0)	135	160	1
M001711040	71-104	5	55	6 (2.0)	75	100	1
M001711050	71-105	5	55	6 (2.0)	135	160	1
M001711060	71-106	5	80	6 (2.0)	75	100	1
M001711070	71-107	5	80	6 (2.0)	135	160	1
M001711080	71-108	6	20	6 (2.0)	75	100	1
M001711090	71-109	6	20	6 (2.0)	135	160	1
M001711100	71-110	6	45	6 (2.0)	75	100	1
M001711110	71-111	6	45	6 (2.0)	135	160	1
M001711120	71-112	6	60	6 (2.0)	75	100	1
M001711130	71-113	6	60	6 (2.0)	135	160	1
M001711140	71-114	6	90	6 (2.0)	75	100	1
M001711150	71-115	6	90	6 (2.0)	135	160	1
M001711160	71-116	7	20	6 (2.0)	75	100	1
M001711170	71-117	7	20	6 (2.0)	135	160	1
M001711180	71-118	7	40	6 (2.0)	75	100	1
M001711190	71-119	7	40	6 (2.0)	135	160	1
M001711200	71-120	7	60	6 (2.0)	75	100	1
M001711210	71-121	7	60	6 (2.0)	135	160	1
M001711220	71-122	7	90	6 (2.0)	75	100	1
M001711230	71-123	7	90	6 (2.0)	135	160	1
M001711240	71-124	8	20	6 (2.0)	75	100	1, 3
M001711250	71-125	8	20	6 (2.0)	135	160	1
M001711260	71-126	8	40	6 (2.0)	75	100	1, 3
M001711270	71-127	8	40	6 (2.0)	135	160	1
M001711280	71-128	8	60	6 (2.0)	75	100	1, 3
M001711290	71-129	8	60	6 (2.0)	135	160	1
M001711300	71-130	8	80	6 (2.0)	75	100	1, 3
M001711310	71-131	8	80	6 (2.0)	135	160	1
M001711320	71-132	10	20	6 (2.0)	75	100	1, 3, 4
M001711330	71-133	10	20	6 (2.0)	135	160	1
M001711340	71-134	10	42	7 (2.3)	75	100	1, 2, 3, 4
M001711350	71-135	10	42	7 (2.3)	135	160	1
M001711360	71-136	10	68	7 (2.3)	75	100	1, 2, 3, 4
M001711370	71-137	10	68	7 (2.3)	135	160	1
M001711380	71-138	10	94	7 (2.3)	75	100	1, 2, 3, 4
M001711390	71-139	10	94	7 (2.3)	135	160	1
H965402100	40210	12	20	9 (3.0)	75	100	1, 3, 4
H965412000	41200	12	20	9 (3.0)	135	160	1
H965402110	40211	12	40	9 (3.0)	75	100	1, 2, 3, 4
H965412010	41201	12	40	9 (3.0)	135	160	1
H965402120	40212	12	60	9 (3.0)	75	100	1, 2, 3, 4
H965412020	41202	12	60	9 (3.0)	135	160	1
H965402130	40213	12	90	9 (3.0)	75	100	1, 2, 3, 4
H965412030	41203	12	90	9 (3.0)	135	160	1
H965403100	40310	14	20	10 (3.3)	75	100	1, 4
H965403110	40311	14	40	10 (3.3)	75	100	1, 4
H965403120	40312	14	60	10 (3.3)	75	100	1, 4
H965403130	40313	14	90	10 (3.3)	75	100	1, 4
H965403300	40330	16	20	10 (3.3)	75	100	1, 4
H965403310	40331	16	40	10 (3.3)	75	100	1, 4
H965403320	40332	16	60	10 (3.3)	75	100	1, 4
H965403330	40333	16	90	10 (3.3)	75	100	1, 4
H965404110	40411	16	40	11 (3.7)	75	100	1
H965404120	40412	16	60	11 (3.7)	75	100	1
H965404130	40413	16	90	11 (3.7)	75	100	1
H965404300	40430	20	40	11 (3.7)	75	100	1
H965404310	40431	20	55	11 (3.7)	75	100	1
H965404320	40432	20	80	11 (3.7)	75	100	1
H965404500	40450	22	35	11 (3.7)	75	100	1
H965404510	40451	22	45	11 (3.7)	75	100	1
H965404520	40452	22	70	11 (3.7)	75	100	1
H965405100	40510	24	35	12 (4.0)	75	100	1
H965405110	40511	24	45	12 (4.0)	75	100	1
H965405120	40512	24	70	12 (4.0)	75	100	1

Indication Key
1 Tracheobronchial
2 Transjugular Intrahepatic Portosystemic Shunt (TIPS)
3 Transhepatic Biliary
4 Venous

Table 2 Sizing Chart

Fully Open Dimension (As labelled on box)	Approximate Implanted Stent Length					Delivery System
Diameter x Length	Nominal Lumen Diameter	Stent Length	Nominal Lumen Diameter	Stent Length	Nominal Lumen Diameter	Catheter Size
mm	mm	mm	mm	mm	mm	F (mm)
5 x 20 5 x 40 5 x 55 5 x 60	4.0	26 54 78 116	3.0	30 63 89 134	2.0	33 68 97 145	6 (2.00)
6 x 20 6 x 45 6 x 60 6 x 90	5.0	25 52 74 111	4.0	29 60 85 128	3.0	32 65 93 139	6 (2.00)
7 x 20 7 x 40 7 x 60 7 x 90	6.0	25 50 72 108	5.0	28 57 82 123	4.0	30 63 90 134	6 (2.00)
8 x 20 8 x 40 8 x 60 8 x 80	7.0	29 49 70 105	6.0	35 56 79 119	5.0	41 61 86 130	6 (2.00)
10 x 20	9.0	27	8.0	33	7.0	38	6 (2.00)
10 x 42 10 x 68 10 x 94	9.0	48 69 103	8.0	54 77 115	7.0	58 83 124	7 (2.33)
12 x 20 12 x 40 12 x 60 12 x 90	11.0	26 47 66 100	10.0	31 51 73 110	9.0	36 55 79 119	8 (2.67)
14 x 20 14 x 40 14 x 60 14 x 90	13.0	27 48 65 98	12.0	33 50 72 107	11.0	38 54 77 115	9 (3.00)
16 x 20 16 x 40 16 x 60 16 x 90	15.0	23 45 64 97	14.0	28 49 70 105	13.0	32 52 75 112	9 (3.00)
18 x 40 18 x 60 18 x 90	17.0	45 64 95	16.0	49 69 103	15.0	51 73 110	10 (3.33)
20 x 40 20 x 55 20 x 80	19.0	40 57 86	18.0	44 63 94	17.0	47 68 102	10 (3.33)
22 x 35 22 x 45 22 x 70	21.0	35 50 75	20.0	40 57 85	19.0	44 62 93	10 (3.33)
24 x 35 24 x 45 24 x 70	23.0	35 50 75	22.0	39 56 84	21.0	43 61 92	11 (3.67)

INDICATION: Tracheobronchial: 5-24 mm stents
Transhepatic Biliary: 8-12 mm stents
Vascus: 10-15 mm stents
TIPS: 10-12 mm stents

Boston Scientific (Master Brand DFU Template 3in x 9in Global, 90106040AP), DFU, MB, WALLSTENT ENDO, EN/PT 91079000-01A_pretrans

Black (K) AE 5.0

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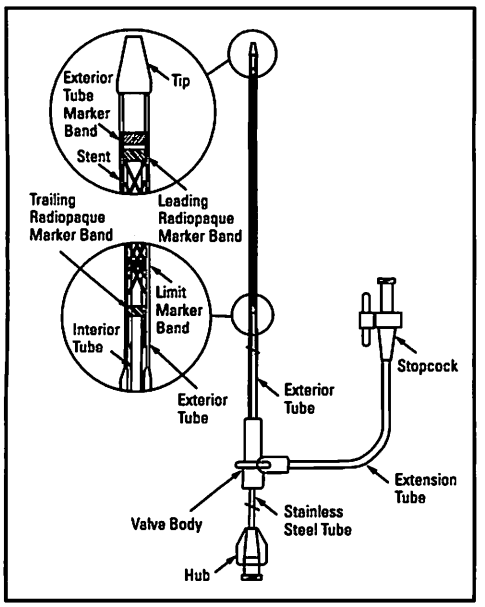

Figure A. UNISTEP™ Plus Delivery System

PRINCIPLE OF OPERATION

The exterior tube is easily retracted by immobilizing the stainless steel tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the stent from constrainment. A single operator can thus control deployment and implant the stent.

The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. (The stent deployment threshold or point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band (Figure A)). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

WARNING

A stent cannot be repositioned or removed after the deployment threshold has been exceeded.

PRECAUTION

The system is intended for use by physicians who have received appropriate training.

PREPARATION OF THE DELIVERY SYSTEM FOR INSERTION - VASCULAR INDICATIONS

1. **Initial Preparation of the Delivery System**
   - Carefully remove the delivery system from its protective packaging.
   - Visually inspect the entire device for damage or defects.
   - Visually check that the leading end of the stent is covered by the exterior tube.
   - Ensure that no stent wires have perforated the exterior tube.

2. Flushing the Delivery System

- Attach a 10 ml (cc) syringe filled with sterile saline to stopcock on extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After flushing the delivery system, close the stopcock and remove the syringe.
- Re-verify that the leading end of the stent is covered by the exterior tube. Do not use device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant and such use may cause lumen injury.

PREPARATION OF THE DELIVERY SYSTEM FOR INSERTION - NON VASCULAR INDICATIONS

1. Initial Preparation of the Delivery System

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire device for damage or defects.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

2. Flushing the Delivery System

- Attach a 10 ml (cc) syringe filled with sterile saline to stopcock on extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After flushing the delivery system, visually check that any excess saline is drained from the delivery system.
- Re-verify that the leading end of the stent is covered by the exterior tube. Do not use device if the open end of the exterior tube has moved exposing stent wires. Proper device function cannot be assured during implant and such use may cause lumen injury.

HOW SUPPLIED

The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis are supplied sterile and intended for single use only. The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis are sterilized by ethylene oxide gas.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling & Storage

Do not expose delivery catheter to organic solvents, e.g., isopropyl alcohol. Such an exposure can cause delivery catheter to become brittle. Rotate inventory so that products are used prior to the "Use By" date on package label.

Store in a cool, dry, dark place.

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRANSHEPATIC BILIARY

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary are indicated for use in the treatment of biliary strictures produced by malignant neoplasms.

CONTRAINDICATIONS

Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary include:

- Use of the device in very small intrahepatic ducts.
- Stenting of a perforated duct, where leakage from the duct could be exacerbated by the prosthesis and leakage could occur across the mesh of the stent.
- All of the customary contraindications associated with the percutaneous transhepatic manipulation of 6-9F (2.0-3.0 mm) caliber catheters (e.g.: bleeding disorders unresponsive to vitamin K or blood product therapy).

WARNINGS

- The safety and effectiveness for use in the vascular system have not been established except for the following WALLSTENT product codes that are also indicated for improving central venous luminal diameter in the innominate and subclavian veins following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract: M001711320, M001711340, M001711360, M001711380, H965402110, H965402120, H965402130, H965402100.
- Stenting across a major bifurcation may prevent or hinder future endoscopic access or other procedures.
- Stents cannot be repositioned after the deployment threshold has been exceeded.
- Final stent placement resulting in an excessive length of stent protruding into the duodenum or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The device should not be re-sterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.
- **MRI Safe:** The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis have shown no deflection or torque in the area of maximum spatial gradient (450 gauss centimeter) of a 1.5 tesla MRI system under conditions that produced a Specific Absorption Rate (SAR) of 1.3 W/Kg.

Imaging artifacts affect the region of interest at the location of the device (artifact ratio 0.8 to 7.0), while areas away from the device appear unaffected by their presence.

COMPLICATIONS

Complications associated with the use of the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic Biliary may include the usual complications reported for conventional biliary stents and transhepatic procedures such as infection, stent misplacement, stent migration, and stent obstruction secondary to tumor in-growth through the stent, tumor overgrowth at the stent ends, or sludge occlusion.

OPERATIONAL INSTRUCTIONS

Recommended Material for Implant

Prepare the following material using sterile technique:

- 10 ml (cc) syringe filled with sterile saline.
- Non-hemostatic introducing sheath, approximately 10-12 cm long (6F (2.0 mm) for 6F (2.0 mm) delivery system, 7F (2.3 mm) for 7F (2.3 mm) delivery system and 9F (3.0 mm) for 8F (2.7 mm) delivery system).
- 0.035 in (0.89 mm) guidewire of appropriate length.

Device Selection

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant.

After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

TRANSHEPATIC PROCEDURE

1. Place a 0.035 in (0.89 mm) exchange guidewire transhepatically into the duodenum and remove the drainage catheter. Dilate the liver tract if indicated.
2. Dilate the biliary stricture with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
3. Remove the balloon catheter, leaving the guidewire in place.
4. Having prepared the delivery system as previously described, insert it into the introducer sheath and over the guidewire.
5. Use the radiopaque marker bands to identify the area to be dilated and stented.

Note: Always use an introducer sheath for the implant procedure, to protect both the liver tract and the puncture site, in the event a partially deployed stent were to be removed.

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6. Guidelines for stent positioning:
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   - The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radiographic visualization of the stent itself is necessary.
   - Maintain the delivery system as straight as possible during deployment of the stent.

7. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Caution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible duct damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 10.

8. Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

9. To complete stent deployment immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Caution: A stent cannot be repositioned after the deployment threshold has been exceeded.

10. To remove a partially deployed stent, first reconstrain the stent (see step 8). The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

    As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

11. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
12. Using standard operative procedures, perform routine cholangiography to demonstrate location and patency of the stent.
13. The implanted stent length should allow for adequate overlapping into the non-strictured duct to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.
14. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery catheter.

DEVICE SIZES

The WALLSTENT™ RP Endoprosthesis Transhepatic Biliary is available in the following diameters: 8 & 10 mm.

The WALLSTENT™ Endoprosthesis Transhepatic Biliary is available in the following diameter: 12 mm.

RELATED ARTICLES

1. Adam A, Chetty N, Roddie M, Yeung E, Benjamin IS. Self expandable stainless steel endoprosthesis for treatment of bile duct obstruction. AJR 1991; 156:321-325.
2. Dick R, Gilliams A, Dooley JS, Hobbs KEF. Stainless steel mesh stents for biliary strictures. Journal of Interventional Radiology 1989; 4:95-98.
3. Gilliams A, Dick R, Dooley JS, Wallsten H, El-Din A. Self expandable stainless steel braided endoprosthesis for biliary strictures. Radiology 1990; 174:137-140.
4. LaBerge JM, Doherty M, Gordon RL, Ring EJ. Hilar malignancy: treatment with an expandable metallic transhepatic biliary stent. Radiology 1990; 177:793-797.
5. Lammer J, Klein GE, Kleinert R, Hausegger K, Einspieler R. Obstructive jaundice: use of expandable metal endoprosthesis for biliary drainage. Radiology 1990; 177: 789-792.
6. Neuhaus H, Hagenmüller F, Griebel M, Classen M. Percutaneous cholangioscopic or transpapillary insertion of self-expanding biliary metal stents. Gastrointestinal Endoscopy 1991; 37:31-37.

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TRACHEOBRONCHIAL

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

With the exception of the following WALLSTENT Codes which are approved for Venous or TIPS indications, the safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death: H965402100, H965402110, H965402120, H965402130, H965403100, H965403110, H965403120, H965403130, H965403300, H965403310, H965403320, H965403330, M001711320, M001711340, M001711360, M001711380.

CONTRAINDICATIONS

Contreindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial include:

- Use of the device in very small bronchials which could impede catheter removal.
- All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system.

WARNINGS

- Stenting across a major bifurcation may prevent or hinder future access or other procedures.
- Use of the device across bifurcations or side branches could impede airflow to the affected portion of the lung.
- Stents cannot be repositioned after the deployment threshold has been exceeded.
- Stents should not be placed near or across the cricopharyngeus.
- Use of a laser on or around the surface of the stent may result in damage to the stent.

PRECAUTIONS

- The device is intended for use by physicians who have received appropriate training.
- The device should not be resterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

MR **Magnetic Resonance Conditional**

Non-clinical testing has demonstrated that WALLSTENT Tracheobronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT™ Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

COMPLICATIONS

Complications associated with the use of the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial may include the usual complications reported for conventional tracheobronchial stents such as infection, stent misplacement, stent migration, and stent obstruction secondary to tumor or granuloma ingrowth through the stent, tumor or granuloma overgrowth at the stent ends, or mucous occlusion or perforation.

OPERATIONAL INSTRUCTIONS

Recommended Material for Implant

Prepare the following material using sterile technique:

- 10 ml (cc) syringe filled with sterile saline.
- 0.035 in (0.89 mm) guidewire of appropriate length.

Device Selection

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant.

After considering the nominal, implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. Should two stents be required to cover the lesion, place the distal stent first followed by the proximal stent, and allow for generous overlapping.

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

TRACHEOBRONCHIAL PROCEDURE

1. Place a 0.035 in (0.89 mm) exchange guidewire through the stricture.

   Note: Predilatation, with an appropriate dilator, of the stricture may be performed prior to stent implantation at the option of the physician.

2. Having prepared the delivery system as described, insert it over the guidewire.
3. Guidelines for stent positioning:
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   - The marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of

the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.

- Maintain the delivery system as straight as possible during deployment of the stent.

4. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Caution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system may cause misalignment of the stent and possible damage. The stent should deploy easily. Do not deploy the stent if unusual force is required, since this may indicate a failed device. To remove the device, see step 7.

5. Assess stent position and reposition if desired. To reposition, first reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

6. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Caution: A stent cannot be repositioned after the deployment threshold has been exceeded.

7. To remove a partially deployed stent, first reconstrain the stent (see step 5). The entire delivery system can be pulled back. The delivery system can then be removed, with the guidewire left in place.

   As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

8. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
9. The implanted stent length should allow for adequate overlapping into the non-strictured area to compensate for further tumor progression and stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.
10. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

DEVICE SIZES

The WALLSTENT™ RP Endoprosthesis Tracheobronchial is available in the following diameters: 5, 6, 7, 8 & 10 mm.

The WALLSTENT™ Endoprosthesis Tracheobronchial is available in the following diameters: 12, 14, 16, 18, 20, 22 & 24 mm.

RELATED ARTICLES

1. Rousseau, H, et al. Self-expandable prostheses in the tracheobronchial tree. Radiology 1993; 188: 199-203.

WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

TIPS

DEVICE DESCRIPTION

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transjugular Intrahepatic Portosystemic Shunt (TIPS) are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus delivery system. The stent is composed of biomedical superalloy wire with a radiopaque core, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, highly radiopaque and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. Radiopaque marker bands situated adjacent to the leading and trailing ends of the stent facilitate imaging during deployment. The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035 in (0.89 mm) guidewire. The delivery system may be inserted through a 7F (2.3 mm) sheath (10 mm stent) or 9F (3.0 mm) sheath (12 mm stent).

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS are indicated for creation of intrahepatic shunt connections between the portal venous system and the hepatic vein for prophylaxis of variceal bleeding in the treatment of portal hypertension and its complications in patients who have previously failed conventional treatment techniques.

CONTRAINDICATIONS

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS are contraindicated for use in:

- Patients with associated occlusion of the portal or hepatic vein.
- Patients with gastric varices secondary to splenic vein thrombosis.

WARNING

Treatment may exacerbate pulmonary hypertension or congestive heart failure in patients with severely compromised cardiovascular or pulmonary function.

PRECAUTIONS

- A stent cannot be repositioned or removed after the deployment threshold has been exceeded.
- The device is intended for use by physicians who have received appropriate training in interventional radiological techniques involving the liver and biliary tree. TIPS should be done by a physician who performs this procedure regularly and who is prepared to follow and monitor patients for shunt patency on a long term basis. In addition the TIPS procedure should be performed only at facilities adequate to manage critically ill patients and where surgical expertise is available if needed.

- The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis TIPS are intended for single use only. The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspect to compromise, it should not be used.
- The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS should NOT be resterilized.
- Ultrasonographic or angiographic follow-up is recommended for post-TIPS monitoring of shunt status.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT TIPS is MR Conditional for single and overlapping lengths up to 94 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg

RF Heating

Under the scan conditions defined above, WALLSTENT TIPS is expected to produce a maximum in-vivo temperature rise of 0.64°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS

Adverse events recorded during the clinical trial of the WALLSTENT TIPS Endoprosthesis included:

- Death – <30 days 15% & >30 days 15%
- Encephalopathy – 30% increased
- Hepatic Artery Thrombosis/Liver Failure – 1%
- Hepatic Lobe Infarction – 1%
- Hepatic or Portal Vein Occlusion or Stenosis – 1%
- Hyperbilirubinemia secondary to bile duct puncture – 1%
- Intra-abdominal Hemorrhage secondary to: liver capsule/ vessel puncture – 3%
- Pulmonary hypertension/edema/Adult Respiratory Distress Syndrome – 1%
- Puncture Site Hematoma – 1%
- Recurrence of Esophageal Varices – 10%
- Sepsis/Infection – 6%
- Shock – 5%
- Shunt Stenosis or Occlusion – 17%

Additional adverse events associated with TIPS, although not observed in the clinical study include:

- Disseminated Intravascular Coagulation
- Pneumonia
- Pulmonary Embolism

- Stent Migration
- Stent Misplacement
- Vessel Rupture

The risks associated with the use of contrast media angiography (allergic type reactions, hypertension, shock, death) should also be considered, as fluoroscopy and angiography are recommended during the stent implant procedure.

CLINICAL SUMMARY

A multicenter trial at eight USA centers in 101 patients was conducted to evaluate the safety and efficacy of the 10 mm diameter WALLSTENT TIPS Endoprosthesis when implanted to create an intrahepatic shunt. This shunt connected the portal venous system and the hepatic vein for the treatment of portal hypertension in patients who had previously failed conventional treatment techniques.

Results for major endpoints were compared to sclerotherapy and surgery historical controls. Key patient demographic data for study patients are summarized in **Table 1** with **Figure 1** illustrating the liver status by both Child's and Child-Pugh classification schemes. Class A patients have less advanced liver disease, Class B are moderate risk patients with significantly compromised liver function and Class C are severely compromised patients, with minimal remaining liver function.

Table 1. Demographics (n=97)*

Age (Yrs)†	56 ± 13 (22 – 86)	
Gender (%)	61 Male; 39 Female	
Karnofsky Score†,§	77 ± 20 (20 – 100)	
Varice (#pts) ¢	93 Esophageal 54 Gastric	
Liver Status (%)	Child's A 27, B 51, C 22 Child-Pugh A 26, B 40, C 34	
# Treatments Pre-TIPS	3, Range 1 – 12	
Pre-TIPS Treatments	Sclerotherapy Sclero + Other Medical Balloon Banding Laser None	37% 43% 7% 4% 2% 1% 5%
Etiology	Alcohol Only ETOH + Other Cryptogenic Hepatitis Other	40% 26% 17% 9% 8%
Pre-TIPS (mmHg)†	23.3 ± 6.9 (7.0 – 42.0)	
Flow Direction‡	67 Hepatopetal 25 Hepatofugal	

* Analysis on 97/101 patients. Four excluded for not meeting study inclusion/exclusion criteria.
† Mean ± SD, (range).
§ Karnofsky scale ranges from 10 = moribund to 100 = normal.
‡ Flow unknown in five patients.
¢ Many patients exhibited both esophageal and gastric varices.

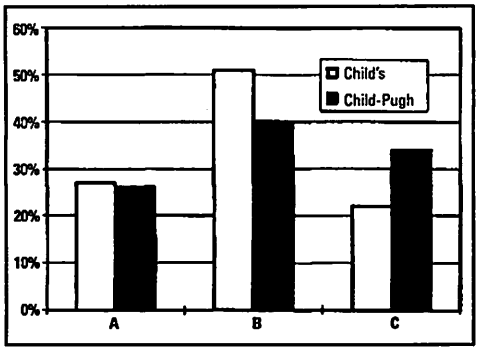

Figure 1. Liver Status

Table 2 presents the effectiveness data. Procedure success addresses the issues of successful creation of a TIPS with variceal decompression, as evidenced by a portosystemic gradient <20 mm Hg. Shunt success was measured by maintenance of shunt patency, a portosystemic gradient <20 mm Hg or the absence of renewed filling of varices at six months post-implant. Maintenance of shunt patency is also reflected in the frequency of intervention required post-TIPS.

Table 2. Effectiveness Measures*

Procedure Success		
Initial†	93 (96%)	
At Discharge	96 (99%)	
Adjunctive Embolization	25 (26%)	
Portocaval Pressure Gradients		
Pre Device	23.2 ± 6.9 mmHg	
Post Device	9.7 ± 4.8 mmHg	
Gradient Decrease		
Initial	13.2 ± 5.1 mmHg	
Six Months	10.2 ± 3.9 mmHg	
Shunt Success		
Patency‡	30 Days	180 Days
Primary	0.90 ± 0.06	0.69 ± 0.11
Primary Assisted	0.98 ± 0.03	0.92 ± 0.06
Secondary	0.99 ± 0.02	0.98 ± 0.04
Intervention Post TIPS		
0 interventions	57 patients (59%)	
1 intervention	28 patients (29%)	
2 interventions	10 patients (10%)	
3 interventions	2 patients (2%)	
Average Interventions/pt	0.6/patient	
Average Time to Intervention	97 days	

Numbers are mean ± SD or number (%) for the indicated group.
* A total of 101 patients enrolled, four excluded from analysis, N=97.
† Three patients required shunt modification prior to discharge.
‡ Life table analysis: value given is life table estimate ± 1.96 (SE).

Figures 2-4 illustrate the Kaplan-Meier analysis for primary, primary assisted and secondary patency. The dashed lines on the figures represent the upper and lower 95% confidence interval boundaries. Primary patency is defined as the time until shunt intervention; primary assisted as the time until shunt occlusion; and secondary as the time until loss of shunt function.

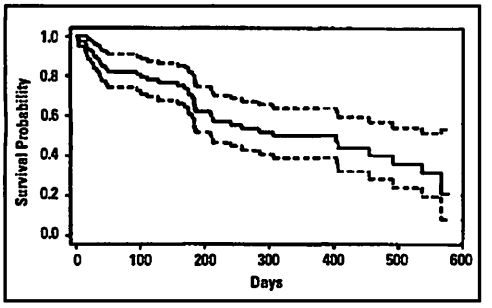

Figure 2. Primary Patency: Kaplan-Meier Survival Analysis (with 95% CI)

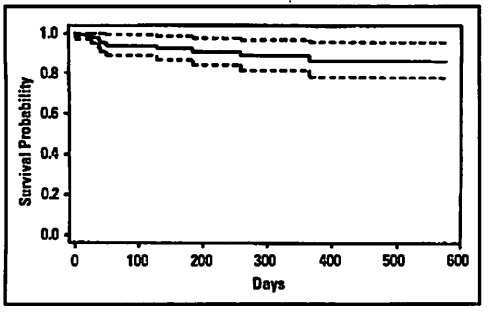

Figure 3. Primary Assisted Patency: Kaplan-Meier Survival Analysis (with 95% CI)

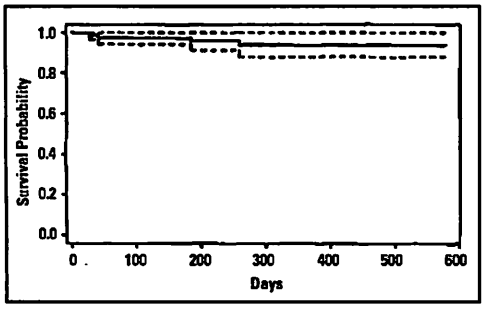

Figure 4. Secondary Patency: Kaplan-Meier Survival Analysis (with 95% CI)

Table 3 presents the safety data. The safety measures of survival and rebleeding were assessed using meta analysis comparing sclerotherapy and surgery historical controls to the study population.

Table 3. Safety Measures Meta Analysis to Literature*

Survival	Survival Rate	p value
TIPS vs Surgery @ 108 days	75.4 vs 61.2	0.02
TIPS vs Sclerotherapy @ 106 days	74.9 vs 69.8	0.33
Freedom from Rebleeding	**Success Rate**	**p value**
TIPS vs Surgery @ 151 days	85.1 vs 94.4	0.014
TIPS vs Sclero @ 182 days	82.7 vs 63.2	0.00005

* Comparison of study data to sclerotherapy and surgery literature using weighted average.

There are statistically significant differences between classification groups with Class A survival being greater than Class B, which is greater than Class C. Table 4 presents patient survival information.

Table 4. Patient Survival and Associated Events Description (n=97)

Category	Child-Pugh Class	n	%	Clinical Course	n	%
Early† (<30 days)	A	1	1	• Systemic Disease Progression	7	7
	B	2	2	• Gastrointestinal Bleeding	5	5
	C	12	12	• TIPS-Related	2	2
	Overall	15	15	• Incarcerated Bowel Loop Sepsis	1	1
Late‡ (>30 days)	A	1	1	• Systemic Disease Progression	9	9
	B	5	5	• Sepsis or Septic Shock	3	3
	C	9	9	• Bronchial Bleed or Pneumonia	2	2
	Overall	15	15	• Brain Abscess	1	1
Overall		30	31			

†Mean time to early death was 13.4 days, range 2 – 29 days.
‡Mean time to late death was 139.1 days, range 31 – 375 days.

Rebleeding did not occur in 84% of the study population. **Table 5** details the frequency and events description of those patients with rebleed episodes. There were no statistically significant differences between classification groups for rebleed.

Table 5. Rebleed (n=97)

Episodes	n	%	Events Description	n	%
None	81	84	• Shunt intervention, sclerotherapy or embolization	10	10
One	10	10	• No intervention	4	4
Two	2	2	• Bronchial Bleed	1	1
Three	3	3	• Death	1	1
Four	1	1			
Overall	16	16			

Mean time to rebleed was 59 days, range 6 – 165 days.

Figures 5 and **6** illustrate the Kaplan-Meier estimates of the time to death and rebleed, respectively for all study patients. The dashed lines on the figures represent the upper and lower 95% confidence interval boundaries.

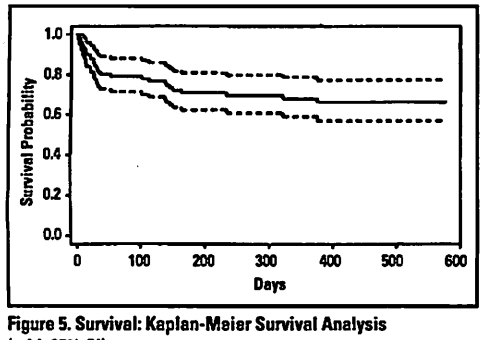

Figure 5. Survival: Kaplan-Meier Survival Analysis (with 95% CI)

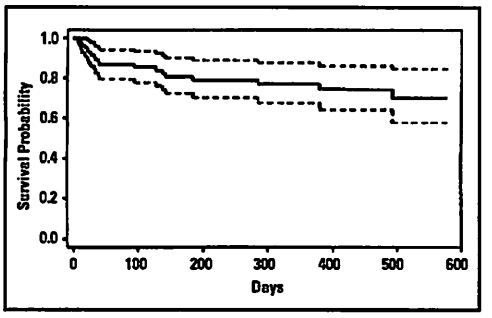

Figure 6. Rebleeding: Kaplan-Meier Survival Analysis (with 95% CI)

Table 6 presents information on the 29 patients with increased encephalopathy post-TIPS. Encephalopathy (Hepatic) is characterized as apathy, somnolence, psychic irritative symptoms, or coma associated with cirrhosis of the liver and attributed to the passage of toxic nitrogenous substances from the portal to systemic circulation. Encephalopathy patients are categorized as mild, moderate or severe and **Figure 7** illustrates the distribution of patients with increased encephalopathy post-TIPS by category and the percentage controlled with standard medical therapy. Of the 29 patients, 22 (76%) were controlled with standard medical therapy.

Table 6. Post TIPS Increased Encephalopathy (n=97)

Category	n	%	Clinical Sequelae	n	%
Mild	8	8	• Controlled	8	8
Moderate	12	12	• Controlled	10	10
			• Controlled ⌧Systemic Disease Progression ⌧Death	2	2
Severe	9	9	• Controlled/improved	4	4
			• Controlled ⌧Systemic Disease Progression ⌧Death	3	3
			• Uncontrolled ⌧Systemic Disease Progression ⌧Death	1	1
			• Bronchial Bleeding (non-TIPS related) ⌧Death	1	1
Overall	29	30			

Thirty-one of the 97 patients exhibited some level of encephalopathy pre-TIPS, of which six died predischarge and of the remaining 25 patients, 20 improved or where unchanged.

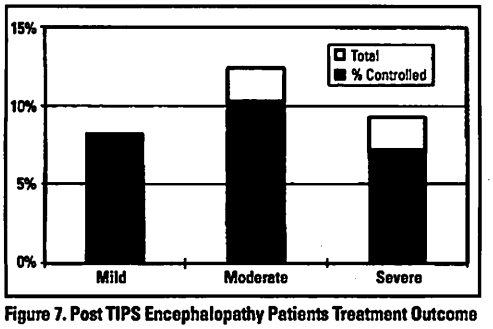

Figure 7. Post TIPS Encephalopathy Patients Treatment Outcome

Two patient characteristics typically associated with portal hypertension are encephalopathy and ascites. Encephalopathy was previously defined, and ascites is the accumulation of serous fluid in the peritoneal cavity. **Figure 8** illustrates the change in occurrence of these characteristics over time post-TIPS.

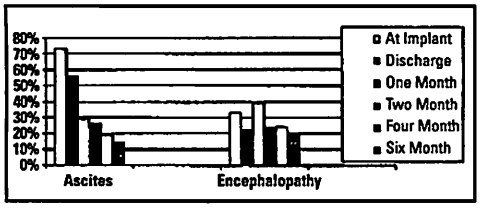

Figure 8. Encephalopathy and Ascites Over Time

Table 7 presents TIPS procedure portography related complications and the clinical sequela. In 22 reported events 16 (70%) required no medical treatment.

Table 7. Portography-Related Complications* (n=97)

Complication	n	%	Clinical Sequelae	n	%
Liver Capsule Puncture	15	16	• None • Transfusion Only • Transfusion ⌫Surgery ⌫Death	12 2 1	12 2 1
Bile Duct Puncture	11	11	• None	11	11
Hepatic Artery Puncture	3	3	• None • Puncture ⌫Thrombosis ⌫Systemic Disease Progression ⌫Death (Shunt was Patent)	2 1	2 1
Main Portal Vein Puncture	1	1	• None	1	1
Hematoma	1	1	• None	1	1
Overall	22	23			
Delivery System Failures (210 delivery system attempts in 97 pts., n=210)					
Per Delivery System Attempt	15	7	• Stent would not deploy • Would not prime or hold pressure	11 4	5 2

Thirty-one events occurred in 22 patients.

OPERATIONAL INSTRUCTIONS

Preparation of the Delivery System for Insertion

1. **Recommended Material for Implant**

   Prepare the following material using sterile technique:

   - 10 ml (cc) syringe filled with sterile saline.
   - Contrast media.
   - 0.035 in (0.89 mm) extra stiff guidewire of appropriate length. (eg. 180 cm).
   - 9F (3.0 mm) sheath with a check valve (eg. 40 cm).
   - Curved angiographic catheter.
   - Transjugular catheter (eg.-45 cm long, 9F (3.0 mm) catheter; 55 cm curved, 16 gauge needle).
   - 8 mm diameter balloon catheter (10 mm stent) or 10 mm diameter balloon catheter (12 mm stent).

2. **Device Selection**

   Having calculated the distance between the hepatic vein and portal vein segments and allowing for post-implant stent shortening (due to continued expansion), determine the stented length necessary to adequately connect the target vein segments.

   Should multiple stents be required, place the distal stent (i.e.-portal vein segment) first followed by the proximal (i.e.-hepatic vein segment) stent. Both stents should have the same diameter and length. Allow for generous stent overlapping, to avoid extension of the proximal stent end into the vena cava.

3. **Initial Preparation of the Delivery System**
   - Carefully remove the delivery system from its protective packaging.
   - Visually inspect the entire device for damage or defects.
   - Visually check that the leading end of the stent is covered by the exterior tube.
   - Ensure that no stent wires have perforated the exterior tube.
4. **Flushing the Delivery System**
   - Attach a 10 ml (cc) syringe filled with sterile saline to the extension tube stopcock.
   - Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
   - After flushing the delivery system, close the stopcock and remove the syringe.
   - Reverify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved proximally exposing the ends of the stent wires.

TIPS PROCEDURE

Catheterization

Note: The exact technique used to gain catheter access to the targeted placement site is selected at the discretion of the implanting physician. One proposed access technique is outlined as follows:

- With the patient in a slight Trendelenburg position, the right internal jugular vein is accessed percutaneously.
- An appropriate size sheath with a check valve is placed through the right atrium to the origin of the inferior vena cava.
- A curved angiographic catheter is manipulated into a large hepatic vein (either the right or middle hepatic vein). The sheath is advanced over the catheter into the hepatic vein.
- The angiographic catheter is exchanged for a transjugular catheter with curved 16 gauge needle.
- The needle is advanced from the hepatic vein, through the parenchyma, into a portal vein branch using external ultrasound guidance.
- A rigid guidewire is advanced down to the mesenteric or splenic vein.
- The 16 gauge needle is removed and a 65 cm long, 5F (1.7 mm) catheter is introduced through the transjugular catheter.
- Portal pressure and a portal venogram are obtained.
- The 5F (1.7 mm) catheter is exchanged over the guidewire for an appropriate size balloon.
- The balloon is inflated across the parenchymal tract with sufficient pressure to eliminate the waist in the balloon.
- The sheath is advanced as far as possible into the parenchymal track and the catheter and dilating balloon are removed, leaving the rigid guidewire in the mesenteric or splenic vein.
- Having prepared the delivery system as previously described, insert it over the rigid guidewire.
- Once the stent has been advanced into the portal vein, the length of the segment to be shunted is mapped by injecting contrast through the check flow sheath in the hepatic vein, and through the central lumen of the delivery system in the portal vein.

Device Deployment Procedure

Guidelines for Stent Positioning

1. Position the leading marker band so that the leading end of the stent releases into the main or right portal vein just proximal to its bifurcation.
2. The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. In order to assure precise stent placement, fluoroscopic visualization of the stent itself is necessary.
3. Maintain the delivery system as straight as possible during deployment of the stent.
4. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and *gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.*

Caution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see **step 7.**

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5. Assess stent position and reposition if desired. To reposition, reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

Note: To facilitate reconstrainment, the delivery system may be flushed with heparinized saline.

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6. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Caution: A stent cannot be repositioned after the deployment threshold has been exceeded.

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7. To remove a partially deployed stent, first reconstrain the stent (see **step 5**). The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

   As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.
8. After the stent is correctly positioned and fully deployed, an injection of contrast media may be made through the internal tube lumen to confirm adequate proximal and distal positioning of the stent.

If little or no flow is seen through the shunt, an injection through the check flow side arm determines how much additional shunt length is required to reach the hepatic vein.

If necessary, a second stent may be deployed an appropriate distance within the first so that its proximal end opens into the hepatic vein. The diameter and length of the second stent *should equal that* of the first.

9. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed.
10. Repeat portal pressures and venography following removal of the delivery system.
11. If the pressure gradient reads between 15 and 20 mm Hg and variceal filling occurs (i.e. the coronary vein is visualized on venography), the shunt may be dilated with an appropriately sized high pressure balloon. If the pressure gradient remains between 15 and 20 mm Hg, and variceal filling persists after balloon dilation of the tract, additional embolization therapy may be indicated. If, after balloon dilation and embolization therapy have been performed, the pressure gradient is still above 20 mm Hg and massive filling of varices is noted, a second parallel TIPS should be placed.

    The instructions for a second TIPS procedure are identical to the preceding instructions.
12. After demonstrating adequate portal decompression, reverse the Trendelenburg position and remove the catheters.

DEVICE SIZES

The WALLSTENT™ RP Endoprosthesis TIPS is available in the following diameter and deployed length (nominal):

Diameter	Deployed Length
mm	mm
10	42

The WALLSTENT™ Endoprosthesis TIPS is available in the following diameters and deployed lengths (nominal):

Diameter	Deployed Length
mm	mm
10	68
10	94
12	40
12	60
12	90

Deployed lengths reflect expansion to nominal stent diameter: constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction.

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WALLSTENT™ RP Endoprosthesis

WALLSTENT™ Endoprosthesis

VENOUS

DEVICE DESCRIPTION

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus Delivery System.

- The stent is composed of biomedical superalloy wire with a radiopaque core braided in a tubular mesh configuration.
- The delivery system is composed of co-axial tubes which allow reconstrainment as indicated by the limit marker and has radiopaque marker bands which aid in accurate placement of the stent.

The WALLSTENT RP Endoprosthesis Venous is available in the following diameter: 10 mm.

The WALLSTENT Endoprosthesis Venous is available in the following diameters: 12, 14 & 16 mm.

Stent diameter selected should be approximately 1.0 mm to 2.0 mm larger than the vessel diameter desired. Deployed lengths reflect expansion to desired vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction. On average, a 0.5 mm change in diameter yields a 10-15% change in length. Once the desired vessel diameter is reached, no additional reduction in stent length should occur.

Table 1. Stent Sizing Specifications

WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous Vessel Diameter and Approximate Implanted Stent Length						
Order Number	Fully Opened Stent Diameter/Length		Stent Length When Implanted in Specified Vessel Diameter			
	Diam.	Length	Nominal Vessel Diam.	Stent Length	Nominal Vessel Diam.	Stent Length
	mm	mm	mm	mm	mm	mm
71-132	10	20	8	33	9	27
71-134	10	42	8	54	9	48
71-136	10	68	8	77	9	69
71-138	10	94	8	115	9	103
40210	12	20	10	31	11	26
40211	12	40	10	51	11	47
40212	12	60	10	73	11	66
40213	12	90	10	110	11	100
40310	14	20	12	33	13	27
40311	14	40	12	50	13	46
40312	14	60	12	72	13	65
40313	14	90	12	107	13	98
40330	16	20	14	28	15	23
40331	16	40	14	49	15	45
40332	16	60	14	70	15	64
40333	16	90	14	105	15	97

INDICATIONS FOR USE/INTENDED USE

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are indicated for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥30% for a vein ≤10 mm in diameter or ≥50% for a vein >10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are the innominate and subclavian veins, ranging from 8.0 mm to 15 mm in diameter.

CONTRAINDICATIONS

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are contraindicated for use in patients with bleeding disorders unresponsive to vitamin K or blood product therapy.

WARNINGS

- Implantation of the stent should be performed only by physicians who have received appropriate training.
- Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The long-term outcome following repeat dilation of venous stents is unknown at present.
- When multiple stents are required, stent materials should be of similar composition.
- Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration. Refer to Table 1 for sizing information.

PRECAUTIONS

Stent Placement Precautions

- The target lesion should be predilated with a conventional balloon angioplasty catheter prior to stent placement.
- Do not release the stent if unusual force is required. If the stent does not deploy easily, use another device.
- Do not advance the delivery catheter without the guidewire extending from the tip.
- Do not fully deploy the stent if it is not properly positioned in the vessel.
- Do not advance a partially (≤50%) deployed stent. Reconstrain and then move distally. Partially deployed stents can be pulled proximally, if necessary.
- Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see step 10 in the Procedure Section.
- A stent cannot be repositioned after the deployment threshold has been exceeded.
- Implanting a stent may lead to dissection of the vessel distally, and/or proximally, to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., surgery, further dilation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by the stenting of the more proximal lesion(s). Stenting in this order obviates the need to cross the proximal stent in the placement of the distal stent and reduces the chance for dislodging the proximal stent.

- Stenting across a major side branch could obstruct the side branch and prevent or hinder percutaneous access or future interventions.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular site. Complications can include bleeding, hematoma or pseudoaneurysm.

Stent/System Removal Precautions

- If Stent/System removal is required prior to full deployment, and when the stent is ≤50% deployed, first attempt to reconstrain the stent and remove as described in step 8 of the Procedure Section. If the stent cannot be reconstrained, remove the entire Stent/System as follows:

  Hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.
- Failure to follow these steps could potentially result in loss of, or damage to, the stent or delivery system.

Post Implant Precautions

- Care must be exercised when crossing a newly deployed stent with intravascular ultrasound (IVUS), or a guidewire, or a balloon catheter to avoid disrupting the stent geometry.
- Be aware of the location of stented venous lesions. Dislodging stents with catheters or other transluminal devices may produce unexpected stent migration.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated that WALLSTENT™ Venous is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or lessGauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤1 W/kg for patient landmarks above the umbilicus (patient navel) and ≤2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus

RF Heating

Under the scan conditions defined above, WALLSTENT Venous is expected to produce a maximum in-vivo temperature rise of 3.1°C after 15 minutes of continuous scanning.

Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

ADVERSE EVENTS

Observed Adverse Events

A total of 42 patients were enrolled in the multi-center study of WALLSTENT™ Venous Endoprosthesis for central lesions. This study was conducted at 12 investigational sites.

Patients from the WALLSTENT Venous Endoprosthesis study form the basis of the observed events described in Table 2.

Five (5) patients enrolled in the WALLSTENT Venous Endoprosthesis Study died during the trial. None of these deaths occurred in the first 6 months following the WALLSTENT procedure and none were considered device related. The cause of death was reported as follows: (1) hyperkalemia 475 days post procedure; (2 and 3) cardiac arrest at 343 and 631 days post procedure; (4) septicemia with peripheral vascular disease and gangrene 902 days post procedure; (5) stomach cancer 276 days post procedure.

Table 2. Safety Results, WALLSTENT™ Venous Endoprosthesis Central Patients (n=42)

Adverse Event	Result	95% C.I.
General Events		
Death	11.9% (5/42)	[4.0%, 25.6%]
Surgical Revision	4.8% (2/42)	[0.6%, 16.2%]
Access abandoned from central lesion	40.5% (17/42)	[25.6%, 56.7%]
Access abandoned from peripheral graft	21.4% (9/42)	[10.3%, 36.8%]
Non-Stent-Related Events		
Graft Occlusion/Restenosis	45.2% (19/42)	[29.8%, 61.3%]
Pseudoaneurysm	16.7% (7/42)	[7.0%, 31.4%]
Infection	14.3% (6/42)	[5.4%, 28.5%]
Hematoma	4.8% (2/42)	[0.6%, 16.2%]
Stent-Related Events		
Stent Restenosis	76.2% (32/42)	[60.5%, 87.9%]
Stent Thrombosis	50.0% (21/42)	[34.2%, 65.8%]
Migration	2.4% (1/42)	[0.1%, 12.6%]
Edema	40.5% (17/42)	[25.6%, 56.7%]

Results are percent (count/sample size) of all patients experiencing the event, and reflect each patient's entire study experience regardless of length of follow-up.

Mean ± SD (sample size) (min, max) length of follow-up in days: 350.5±299.4 (42) (4.0, 1434). Confidence intervals are based on exact limits.

Note: Surgical revision refers to those events where the graft was revised, but not abandoned. Patients reporting edema are a subset of patients with stent restenosis/thrombosis.

Additional clinical safety data were retrospectively obtained on 12 patients enrolled in a physician's registry study of the WALLSTENT Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. Four deaths were reported among these 12 patients. The reported cause and time of occurrence of these deaths is: sepsis at 16 days post-procedure, aspiration pneumonia at 32 days post-procedure, myocardial infarction/subdural hematoma at 81 days post-procedure, and hypotension at 240 days post procedure.

Adverse events related to either the stent or the stent implant procedure included stent thrombosis (5), stent restenosis (8), stent migration (3), and an allergic reaction to contrast media (1). The three stent migrations in this physician single-center study and the one stent migration in the multi-center WALLSTENT Venous Endoprosthesis central lesion study were attributed to incorrect sizing of the stent and/or dislodgment with the guide catheter. All of the stent migration cases were treated with a percutaneous procedure and none resulted in abandonment of the access site.

Potential Adverse Events

Potential adverse events associated with use of the WALLSTENT™ Venous Endoprosthesis may include the usual adverse events reported for conventional percutaneous transluminal angioplasty such as: hemorrhage, infection, contrast media reactions, dissection, distal emboli, graft rupture, graft/vein thrombosis or occlusion, perforation of the vein, suture disruption of the anastomosis, thromboembolism or transient spasm.

Potential adverse events associated with the WALLSTENT Venous Endoprosthesis are stent misplacement, stent migration, or vein perforation.

Observed Device Malfunctions

Two incidents of stent malfunction were reported in the central venous lesion study. In one incident, the delivery system failed to deploy. In the second incident, the stent did not fully expand.

CLINICAL STUDIES

A total of 42 patients at 12 investigational sites within the United States were enrolled in a prospective, multi-center, non-randomized study with a historical percutaneous transluminal angioplasty (PTA) control cohort to investigate the safety and efficacy of the WALLSTENT Venous Endoprosthesis for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis.

Primary Endpoint: The primary endpoint for the WALLSTENT Venous Endoprosthesis trial was circuit secondary patency at 6 months. Circuit Secondary Patency is defined as the proportion of patients, over time, that have an occluded vessel that is successfully opened. Failure of circuit secondary patency occurs at the time the dialysis site is abandoned due to the inability to treat the stenosis, or occlusion of either the central lesion under consideration or any other peripheral or de novo central lesion.

Other endpoints evaluated include:

Stent Primary Patency, defined as the proportion of patients, over time, that have had uninterrupted (intervention-free) patency since the initial procedure. Primary patency ends at the first occurrence of one of the following: initial re-intervention for the purpose of treating patency of the central lesion; anatomical failure (50% or greater stenosis) of the central lesion; or when the dialysis site is abandoned due to the inability to treat the original central lesion. If percent stenosis of the central lesion is undetermined, the occurrence of arm/face edema indicates the end of primary patency.

Stent Secondary Patency, defined as the time to failure of the access site due to stenosis or occlusion of the stented central lesion. Anatomical failure (>50% stenosis) of the central lesion which is not successfully reopened is also considered failure of stent secondary patency. Patients failing circuit secondary patency due to other peripheral lesions, problems at the access site (e.g. pseudoaneurysm, infection), or a de novo central lesion that does not involve the stent margin, do not fail stent secondary patency. These patients are censored from analysis at the date of the last follow-up documenting patency of the stent.

Patency rates were estimated by means of Kaplan-Meier Survival Analysis.

Patient Eligibility: Patients were eligible for the study if they were on chronic hemodialysis and had a central venous stenosis which was treatable with PTA. If the PTA failed to reduce the stenosis to less than 50% in patients with a vein >10 mm in diameter, or 30% in a vein ≤10 mm in diameter, the patient received a WALLSTENT Venous Endoprosthesis. If the PTA was successful, but the stenosis recurred within 4 months, the patient received a WALLSTENT Venous Endoprosthesis.

Study Methods: Clinical follow-up was obtained at 1 week, 2 months, 6 months, and every 6 months thereafter until study conclusion, or the graft site was abandoned. Baseline quantitative

angiography was performed pre-procedure, following balloon angioplasty, following device deployment, and at the 2-month and 6-month visit. The stent primary patency, stent secondary patency, and circuit secondary patency were analyzed.

Results: Among the 42 patients enrolled in the study, lesions involved the innominate vein in 14, subclavian vein in 23, and both subclavian and innominate veins in 5 patients. The mean lesion length was 25.8 mm (±18.8, range = 2.0-81.6 mm). Multiple stents were implanted in 5 patients (11.9%). A total of 28.6% of the patients (12/42) had occluded (100% stenosis) veins at the time of the study enrollment.

Initial intraoperative success, as measured by the reduction in stenosis to <30%, or angiographic demonstration of an increase in venous outflow, was achieved in 100% of patients. Analysis of the clinical data demonstrated a 74.3% circuit secondary patency rate at six months for the WALLSTENT Venous Endoprosthesis study group, compared to a 50% secondary patency rate for the historical control of percutaneous transluminal angioplasty (PTA), resulting in a highly significant statistical difference (p<0.0003). The WALLSTENT Venous Endoprosthesis was found to provide superior efficacy in the central venous patient cohort when compared to the historical control (PTA).

Baseline demographic and lesion characteristics were individually regressed on time to loss of circuit secondary patency to assess possible predictors of clinical outcome (univariate analysis). Presence of an occluded lesion pre-procedure was significantly associated with circuit secondary patency (p=0.022). The same variables were analyzed using stepwise selection to identify a multivariate predictor model. Presence of a totally occluded lesion pre-procedure was the only variable associated with time to loss of circuit secondary patency (p=0.0072). Implantation of multiple stents approached significance in the multivariate model (p=0.062).

Principal Efficacy and Safety results are summarized in Table 3.

Table 3. Principal Efficacy and Safety Results, BSC Patients (n=42)

Efficacy Measures	Result	95% C.I.
Device Success	100.0% (42/42)	[91.6%,100.0%]
Initial Intraoperative Success:		
Criterion 1: 30% Residual Stenosis	64.3% (27/42)	[48.0%,78.4%]
Criterion 2: Increased Venous Flow	90.5% (38/42)	[77.4%,97.3%]
Met Either Criteria	100.0% (42/42)	[91.6%,100.0%]
Acute Procedure Success	64.3% (27/42)	[48.0%,78.4%]
Initial Clinical Success	95.8% (23/24)	[78.9%,99.9%]
Pre-PTA RVD (mm)	12.6±3.7 (42) (3.0,20.1)	[11.5,13.7]
Post-Stent MLD (mm)	8.8±2.8 (39) (3.7,20.2)	[7.9,9.7]
Post-Stent %DS	24.1±18.4 (42) (0.0,63.0)	[18.5,29.6]
6-Month RVD (mm)	10.4±3.3 (25) (4.0,18.3)	[9.1,11.7]
6-Month MLD (mm)	3.0±2.7 (26) (0.0,11.0)	[1.9,4.0]
6-Month %DS	67.9±29.1 (26) (9.0,100.0)	[56.7,79.1]
Patency		
6-Month Stent Primary Patency (K-M)24.4%		[9.8%,39.0%]
6-Month Stent Secondary Patency (K-M)82.5%		[69.7%,95.2%]
6-Month Circuit Secondary Patency (K-M)74.3%		[60.6%,88.1%]
Stent Restenosis	76.2% (32/42)	[60.5%,87.9%]
Arm-Face Edema	40.5% (17/42)	[25.6%,56.7%]
Safety Measures	**Result**	**95% C.I.**
Major In-Hospital Event	0.0% (0/42)	[0.0%,8.4%]
Out-of-Hospital (Stent-Related) Event		
Stent Thrombosis	50.0% (21/42)	[34.2%,65.8%]
Migration	2.4% (1/42)	[0.1%,12.6%]
Death	11.9% (5/42)	[4.0%,25.6%]

Results are mean ± SD (sample size) (min, max) for continuous variables, and percent (count/sample size) for binary variables.

Black (K) ΔE ≤5.0

Confidence intervals for binomial proportions are based on exact limits.

Patency rates are Kaplan-Meier estimates at 180 days; confidence intervals based on Greenwood standard errors.

RVD = Reference Vessel Diameter.

MLD = Minimum Lumen Diameter.

%DS = percent diameter stenosis which refers to "within lesion" measurement technique.

Device Success = Stent(s) deployed completely.

Initial Intraoperative Success, Criterion 2 = angiographic demonstration of an increase in venous outflow (visualization of less collateral flow, more rapid rate of contrast media clearing or less reflux flow post-procedure).

Acute Procedure Success = ≤30% residual stenosis and absence of major in-hospital event.

Initial Clinical Success = <20% recirculation fraction one week post-procedure. (Note: incomplete number of assessments (n=24) reflects a change in clinical practice during the course of the study in which many institutions stopped using recirculation fractions to monitor patients.)

Stent Restenosis = within stent %DS of 50% or greater, or in the absence of angiography, the presence of arm-face edema.

Stent Thrombosis = total thrombotic stent occlusion documented by angiography. (Note: Stent Thrombosis is a subset of stent restenosis).

Additional clinical efficacy data was also retrospectively obtained on 12 patients enrolled in a physician's registry study of the WALLSTENT™ Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. The enrollment criteria for this study were similar to the multi center WALLSTENT Venous Endoprosthesis central lesion study. A Kaplan-Meier Survival analysis estimated the six-month circuit secondary patency, stent primary patency, and stent secondary patency rates at 68.6%, 33.8%, and 75%, respectively, for this patient cohort.

PATIENT SELECTION AND TREATMENT

Individualization of Treatment

The risks and benefits of using the WALLSTENT Venous Endoprosthesis should be carefully considered for each patient before use. Stenting is generally avoided in those patients at heightened risk of bleeding (e.g., bleeding disorders unresponsive to Vitamin K or blood product therapy, see Contraindications.)

Premorbid conditions that increase the risk of a poor initial result should also be considered. The relationship of baseline and procedural variables to failure of circuit secondary patency was examined. Presence of an occluded lesion pre-procedure was the only statistically significant predictor for failure of circuit secondary patency. Implantation of multiple stents approached significance in one analysis.

Use in Special Population

The safety and effectiveness of the WALLSTENT Venous Endoprosthesis have not been established for the following:

- Veins that are smaller than 8.0 mm or larger than 15 mm.
- Where stenting would not allow for sufficient puncture sites of the hemodialysis access.
- Where damage to a diseased or injured vessel may occur due to the self-expanding nature of the stent.
- Veins other than the innominate or subclavian.
- Lesions at or within 5 mm of the arterial anastomosis.
- When significant intraluminal thrombus is present after thrombolytic therapy.
- Multiple lesions greater than 4 cm apart.
- Patients for longer than 6 months.

OPERATIONAL INSTRUCTIONS

Preparation of the Delivery System for Insertion

1. **Recommended Material for Implant:**

   Prepare the following material using sterile technique:

   - 10 ml (cc) syringe filled with sterile saline.
   - 6F (2 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 6F (2 mm) delivery system.
   - 7F (2.3 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 7F (2.3 mm) delivery system.

- 9F (3.0 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 8F delivery system.
- 10F (3.3 mm) hemostatic introducing sheath, approximately 10-12 cm long, for the 9F delivery system.
- 0.035 in (0.89 mm) guidewire of appropriate length.

2. **Device Selection**

   Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant. After considering the nominal implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage. (See Table 1) Should two stents be required to cover the lesion, place the distal stent first, followed by the proximal stent, and allow for generous overlapping. Deployed lengths reflect expansion to nominal vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployment length, depending upon the degree of constriction.

3. **Initial Preparation of the Instrument:**
   - Carefully remove the delivery system from its protective packaging.
   - Visually inspect the entire device for damage or defects.
   - Visually check that the leading end of the stent is covered by the exterior tube.
   - Ensure that no stent wires have perforated the exterior tube.
4. **Flushing the Delivery System:**
   - Attach a 10 ml (cc) syringe filled with sterile saline to the stopcock on the extension tube.
   - Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
   - After priming the delivery system, close the stopcock and remove the syringe.
   - Verify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the trailing end, exposing stent wires. Proper device function cannot be assured during implant, and such use may cause vessel injury.

VENOUS PROCEDURE

1. Use radiopaque marker bands to identify the area to be dilated and stented.
2. Place a 0.035 in (0.89 mm) exchange guidewire percutaneously into the vessel to be treated.
3. Dilate the venous lesion with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
4. Remove the balloon catheter, leaving the guidewire in place.
5. Having prepared the delivery system as previously described, insert the delivery system into the appropriate size introducer sheath and over the guidewire.

Note: Always use an introducer sheath for the implant procedure, to protect the puncture site, in the event a partially deployed stent were to be removed.

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6. Guidelines for Stent Positioning:
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   - The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.

- Maintain the delivery system as straight as possible during deployment of the stent.

7. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Precaution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see step 10.

8. Assess stent position and reposition if desired. To reposition, reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

Note: To facilitate reconstrainment, the delivery system may be flushed with heparinized saline.

9. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube.

Precaution: A stent cannot be repositioned after the deployment threshold has been exceeded.

10. To remove a partially deployed stent, first reconstrain the stent (see step 8). If the stent cannot be reconstrained, remove the entire Stent/System as follows: Hold the T-connector securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

    As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

11. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed. If desired, repeat balloon dilation inside the implanted stent may be performed to achieve nominal stent diameter. For this procedure, a new balloon dilatation catheter is recommended.

12. Using standard operative procedures, perform routine venography to demonstrate location and patency of the stent.

13. The implanted stent length should allow for adequate overlapping into the non-strictured vessel to compensate for further stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.

If, prior to initial stent implantation, it is expected that a second stent will be necessary to cover the lesion, cover the distal end of the lesion with the first stent and use the second stent to cover the proximal portion of the lesion. This will minimize interference with placement of the second stent by the previously deployed stent.

14. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

PATIENT INFORMATION

Physicians will be provided, separately, copies of a Patient Guide that includes information on Venous stenosis, the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Venous, and the stent implant procedure.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

REF Catalog Number
Referência

Consult instructions for use.
Consulte as instruções de Utilização

Contents
Conteúdo

EC REP EU Authorized Representative
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante Legal

LOT Lot
Lote

Recyclable Package
Embalagem Reciclável

Use By
Validade

AUS Australian Sponsor Address
Endereço do Patrocinador Australiano

ARG Argentina Local Contact
Contacto local na Argentina

BRA Brazil Local Contact
Contacto local no Brasil

Do Not Resterilize
Não reesterilize

Do not use if package is damaged.
Não utilize se a embalagem estiver danificada.

GW R Recommended Guidewire
Fio-guia Recomendado

IS R Recommended Introducer Sheath
Bainha Introdutora Recomendada

STERILE EO Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.

For single use only. Do not reuse.
Apenas para uma única utilização. Não reutilize.

MR Magnetic Resonance Conditional
Ressonância magnética - utilização condicional

37

Black (K) ΔE ≤5.0

Boston Scientific (Master Brand DFU Template 3in x 9in Global, 90106040AP), DFU, MB, WALLSTENT ENDO, EN/PT 91079000-01A_pretrans

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

BRA **Brazil Local Contact**

Para informações de contato da Boston Scientific do Brasil Ltda, por favor, acesse o link www.bostonscientific.com/bra

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

MR **Magnetic Resonance Conditional**

Black (K) ΔE ≤5.0

Hi Ms. Koo,

I have received your request-Is the date location sufficient in this summary? If not, please let me know what the standard date location is, and I can update as applicable. Please note that I have also updated the document footer to reference the 510(k) number.

Kind Regards,
Carah

From: Koo, Lily [mailto:Lily.Koo@fda.hhs.gov]
Sent: Tuesday, May 17, 2016 9:13 AM
To: Kucharski, Carah
Cc: Levelle, Amy; K152842@docs.fda.gov
Subject: K152842 FDA Interactive Request
Importance: High

Dear Carah Kucharski,

I am emailing you on behalf of Ms. Amy Levelle to request a dated 510(k) Summary for your K152842 submission. Please provide this information by 2PM EST.

Thank you,

Lily Koo, Ph.D.
Senior Staff Fellow / Reviewer
FDA/CDRH/ODE/DAGRID/RPDB
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone #: (301) 796-6267
E-mail: lily.koo@fda.hhs.gov<mailto:lily.koo@fda.hhs.gov>

Hi Carah,

There is one more item we need you to address. You have "Boston Scientific" as part of your trade name listed in the 510(k) Summary but not in the IFU statement page. Can you confirm your trade name? Please provide a revised 510(k) summary or IFU page so the trade name is consistent between these two documents.

Thanks,
Amy

From: Kucharski, Carah [mailto:Carah.Kucharski@bsci.com]
Sent: Tuesday, May 17, 2016 10:23 AM
To: Koo, Lily
Cc: Levelle, Amy; K152842@docs.fda.gov
Subject: RE: K152842 FDA Interactive Request

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Phone #: (301) 796-6267
E-mail: lily.koo@fda.hhs.gov
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dissemination, distribution. copying. or other action based on the content of this communication is NOT AUTHORIZED. If you have received this document in error. please immediately notify us by email or telephone found above.
This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Silver Spring, MD 20993-0002
Phone #: (301) 796-6267
E-mail: lily.koo@fda.hhs.gov
*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=300&D=330&B=331&E=&S=E*https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=434&E=&S=*

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tps://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=434&E=&S=

510k Summary

Per 21 CFR §807.92

May 17th, 2016

Common or Usual Name	Self-Expanding Stent	
Trade Name(s)	Boston Scientific WALLSTENT™ RP Endoprosthesis Tracheobronchial and Boston Scientific WALLSTENT™ Endoprosthesis Tracheobronchial	
Product Code	JCT – Prosthesis, Tracheal, Expandable	
Classification of Device	The WALLSTENT Endoprosthesis Tracheobronchial device has been classified as Class II devices according to 21 CFR 878.3610 – Esophageal Prosthesis.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	**Owner /Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 3005099803
	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
Predicate Devices	WALLSTENT™ Tracheobronchial Endoprosthesis K992510 cleared November 18, 1999.	

Intended Use/ Indications for Use	The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
Description of Device	The WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial are comprised of two components: The implantable metallic stent and the UNISTEP Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89mm) guidewire.
Comparison of Required Technological Characteristics	The proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial is substantially equivalent to the existing Wallstent Endoprosthesis Tracheobronchial cleared by FDA under premarket notification K992510 (November 18, 1999). WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has the same intended use, scientific technology, design, sterilization method, and packaging as the applicable predicate device. The only difference is to the MR Safety labeling information within the Directions for Use. Bench testing in accordance with current FDA guidance supports a labeling as MR Conditional.
Summary of Non-Clinical Test Summary	Bench testing was performed in accordance with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11, 2014) to support labeling as MR Conditional. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALSLTENT Endoprosthesis Tracheobronchial (K992510).

October 14, 2015</br></br>
Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K152842. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K152842, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist within 180 days, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Amy Levelle, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the <a
href="http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf">Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <a
href="http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf">http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

 *** This is a system-generated email notification ***

December 22, 2015</br></br> We have reviewed your submission K152842/S001 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K152842/S001 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is June 19, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Amy Levelle, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

November 6, 2015</br></br>
Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K152842/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Amy Levelle.

 *** This is a system-generated email notification ***

May 19, 2016</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Amy Levelle.

 *** This is a system-generated email notification ***

510k Summary

Per 21 CFR §807.92

May 18th, 2016

Common or Usual Name	Self-Expanding Stent	
Trade Name(s)	WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial	
Product Code	JCT – Prosthesis, Tracheal, Expandable	
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Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K152842
Boston Scientific Corporation
Device Trade Name: Wallstent Rp Endoprosthesis Tracheobronchial, Wallstent Endoprosthesis Tracheobronchial
Contact Name: Carah Kucharski

DEFICIENCY LIST

1. (b)(4)

- (b)(4)

- (b)(4)

(b)(4)

a. (b)(4)

b. (b)(4)

c. (b)(4)

(b)(4)

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2. (b)(4)

3. (b)(4)

a. (b)(4)

b. (b)(4)

(b)(4)

c. (b)(4)

4. (b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152842

Device Name
WALLSTENT™ RP Endoprosthesis Tracheobronchial/ WALLSTENT™ Endoprosthesis Tracheobronchial

Indications for Use *(Describe)*
The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Office of Chief Information Officer
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2016

Boston Scientific Corporation
Ms. Carah Kucharski
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K152842
Trade/Device Name: WALLSTENT™ RP Endoprosthesis Tracheobronchial,
WALLSTENT™ Endoprosthesis Tracheobronchial
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: April 18, 2016
Received: April 19, 2016

Dear Ms. Kucharski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Department of Health & Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation & Office of In-Vitro Diagnostics and Radiological Health

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K152842 Date Received by DCC: Sep 29, 2015

Lead Reviewer: Amy LeVelle

Branch: RPDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):				X	
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion		X			
Comments: The classification regulation identified in the cover letter is different from the classification identified in the 510(k) summary. Please provide a consistent classification throughout your submission.					
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended* format. *(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.		X		X	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.		X			
Comments: Your cover letter states that there were no prior 510k, IDE, PMA submissions. It does not state there were no other prior submissions, such as a pre-submission. Please clearly state there were no prior submissions for the subject device.					
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.	X				
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:				X	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.		X			
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
Comments: You have identified two separate devices, Wallstent RP and Wallstent. Please provide a description of each device for which clearance is requested.					
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*				X	
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation		X			
Comments: Please provide a comparison of the technological characteristics, including design, materials, method of placement, method of deployment, size ranges, and performance specifications as indicated in the device specific guidance.					
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X			X	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).		X			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X			
Comments: (a) The Indications for Use in the proposed directions for use are not identical to the indications for use form. Please note that contraindications should be provided in a separate section of your labeling. Also, you have provided several different indications for use statements in your labeling for devices other than for tracheobronchial use. Please note that the scope of your submission should be limited to what is stated in the IFU form. (b) Your device labels do not include all applicable warnings, such as single use only, Rx only, MRI conditional, etc. Please add applicable warnings to your device labels.					
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.	X				
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X				
d) *Sterility* Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	X				
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	X				
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
X Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
X Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
Does require electrical safety evaluation					
X Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
Does require EMC evaluation					
X Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	X				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
is an in vitro diagnostic device.					
X is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Amy K. Levelle -S Digitally signed by Amy K. Levelle -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Amy K. Levelle -S, 0.9.2342.19200300.100.1.1=2000378253 Date: 2015.10.14 17:38:22 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2016

Boston Scientific Corporation
Ms. Carah Kucharski
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K152842
Trade/Device Name: WALLSTENT™ RP Endoprosthesis Tracheobronchial,
WALLSTENT™ Endoprosthesis Tracheobronchial
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: April 18, 2016
Received: April 19, 2016

Dear Ms. Kucharski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152842

Device Name
WALLSTENT™ RP Endoprosthesis Tracheobronchial/ WALLSTENT™ Endoprosthesis Tracheobronchial

Indications for Use *(Describe)*
The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary

Per 21 CFR §807.92

May 18th, 2016

Common or Usual Name	Self-Expanding Stent	
Trade Name(s)	WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial	
Product Code	JCT – Prosthesis, Tracheal, Expandable	
Classification of Device	The WALLSTENT Endoprosthesis Tracheobronchial device has been classified as Class II devices according to 21 CFR 878.3610 – Esophageal Prosthesis.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	**Owner /Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 3005099803
	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
Predicate Devices	WALLSTENT™ Tracheobronchial Endoprosthesis K992510 cleared November 18, 1999.	

Intended Use/ Indications for Use	The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
Description of Device	The WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial are comprised of two components: The implantable metallic stent and the UNISTEP Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89mm) guidewire.
Comparison of Required Technological Characteristics	The proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial is substantially equivalent to the existing Wallstent Endoprosthesis Tracheobronchial cleared by FDA under premarket notification K992510 (November 18, 1999). WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has the same intended use, scientific technology, design, sterilization method, and packaging as the applicable predicate device. The only difference is to the MR Safety labeling information within the Directions for Use. Bench testing in accordance with current FDA guidance supports a labeling as MR Conditional.
Summary of Non-Clinical Test Summary	Bench testing was performed in accordance with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment,* dated December 11, 2014) to support labeling as MR Conditional. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALSLTENT Endoprosthesis Tracheobronchial (K992510).

510k Summary

Per 21 CFR §807.92

May 18th, 2016

Common or Usual Name	Self-Expanding Stent	
Trade Name(s)	WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial	
Product Code	JCT – Prosthesis, Tracheal, Expandable	
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Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com	
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	Manufacturing Facility:	Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
Predicate Devices	WALLSTENT™ Tracheobronchial Endoprosthesis K992510 cleared November 18, 1999.	

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Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALSLTENT Endoprosthesis Tracheobronchial (K992510).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K152842
Boston Scientific Corporation
Device Trade Name: Wallstent Rp Endoprosthesis Tracheobronchial, Wallstent Endoprosthesis Tracheobronchial
Contact Name: Carah Kucharski

DEFICIENCY LIST

1. (b)(4)

- (b)(4)
- (b)(4)

(b)(4)

a. (b)(4)

b. (b)(4)

c. (b)(4)

(b)(4)

(b)(4)

2. (b)(4)

3. (b)(4)

a. (b)(4)

b. (b)(4)

(b)(4)

c. (b)(4)

4. (b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152842

Device Name
WALLSTENT™ RP Endoprosthesis Tracheobronchial/ WALLSTENT™ Endoprosthesis Tracheobronchial

Indications for Use *(Describe)*
The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Department of Health & Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation & Office of In-Vitro Diagnostics and Radiological Health

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K152842 Date Received by DCC: Sep 29, 2015

Lead Reviewer: Amy LeVelle

Branch: RPDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):				X	
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion		X			
Comments: The classification regulation identified in the cover letter is different from the classification identified in the 510(k) summary. Please provide a consistent classification throughout your submission.					
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended* format. *(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.		X		X	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.		X			
Comments: Your cover letter states that there were no prior 510k, IDE, PMA submissions. It does not state there were no other prior submissions, such as a pre-submission. Please clearly state there were no prior submissions for the subject device.					
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.	X				
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:				X	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.		X			
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
Comments: You have identified two separate devices, Wallstent RP and Wallstent. Please provide a description of each device for which clearance is requested.					
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*				X	
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation		X			
Comments: Please provide a comparison of the technological characteristics, including design, materials, method of placement, method of deployment, size ranges, and performance specifications as indicated in the device specific guidance.					
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X			X	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).		X			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X			
Comments: (a) The Indications for Use in the proposed directions for use are not identical to the indications for use form. Please note that contraindications should be provided in a separate section of your labeling. Also, you have provided several different indications for use statements in your labeling for devices other than for tracheobronchial use. Please note that the scope of your submission should be limited to what is stated in the IFU form. (b) Your device labels do not include all applicable warnings, such as single use only, Rx only, MRI conditional, etc. Please add applicable warnings to your device labels.					
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.	X				
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X				
d) Sterility Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	X				
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	X				
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent *product degradation*	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
X Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
X Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
Does require electrical safety evaluation					
X Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
Does require EMC evaluation					
X Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	X				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	×				
36) If literature is referenced in the submission, submission includes:			×		
37) For each completed animal study, the submission provides the following:			×		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
	is an in vitro diagnostic device.				
×	is not an in vitro diagnostic device.				
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Amy K. Levelle -S Digitally signed by Amy K. Levelle -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Amy K. Levelle -S, 0.9.2342.19200300.100.1.1=2000378253 Date: 2015.10.14 17:38:22 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Department of Health & Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation & Office of In-Vitro Diagnostics and Radiological Health

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K152842 Date Received by DCC: Oct 23, 2015

Lead Reviewer: Amy LeVelle

Branch: RPDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended* format. *(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.	X				
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.	X				
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.			X		
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X				
d) Sterility Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	X				
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	X				
a) The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				
H. Software					
Submission states that the device: (one of the below must be checked)					
	Does contain software/firmware				
X	Does not contain software/firmware				
	Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)				
	X Software/firmware information not needed for this device (e.g., surgical suture, condom)				
	Software/firmware information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
	Does require electrical safety evaluation				
X	Does not require electrical safety evaluation				
	Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Electrical safety information not needed for this device (e.g., surgical suture, condom)				
	Electrical safety information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
	Does require EMC evaluation				
X	Does not require EMC evaluation				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	X				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X				
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
is an in vitro diagnostic device.					
X is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Amy K. Levelle -S Digitally signed by Amy K. Levelle -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Amy K. Levelle -S, 0.9.2342.19200300.100.1.1=2000378253 Date: 2015.11.05 12:02:14 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 18, 2016

Boston Scientific Corporation
Ms. Carah Kucharski
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K152842
Trade/Device Name: ~~Wallstent~~ WALLSTENT™ RpP Endoprosthesis Tracheobronchial, ~~Wallstent~~ WALLSTENT™ Endoprosthesis Tracheobronchial
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: ~~September 28~~April 18, ~~2015~~2016
Received: ~~September 29~~April 19, ~~2015~~2016

Commented [TPS1]: The Summary notes that Boston Scientific is part of the trade name; however, the letter and the IFU don't. Can you clarify with the sponsor what they want their trade name to be?

Commented [AL2]: 510k summary has been updated to remove boston scientific

Commented [TPS3]: Note the dates of the most recent supplement

Commented [AL4]: Corrected

Dear Ms. Kucharski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection ~~Control,~~Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial: MR Conditional labeling

Date: Memo: 12/1/2015

To: Amy Levelle
CDRH\ODE\DAGRID\RPDB

From: Maria Iacono
CDRH\OSEL\DBP

Maria Iacono -S (Affiliate)

Digitally signed by Maria Iacono -S (Affiliate)
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001006258, cn=Maria Iacono -S (Affiliate)
Date: 2015.12.03 17:15:06 -05'00'

Re: K152842/S001 WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial self-expanding stents

Recommendation: The testing and labeling for radio-frequency induced heating are adequate. I have no deficiencies and recommend clearance.

DEVICE DESCRIPTION

The WALLSTENT™ device is offered in both a standard profile (8-12 French) and Reduced Profile (RP) system, for 6-7 French systems (see Table 8-1). Both systems are comprised of two components: the implantable metallic stent and the UNISTEP™ Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self- expanding (see figure below).

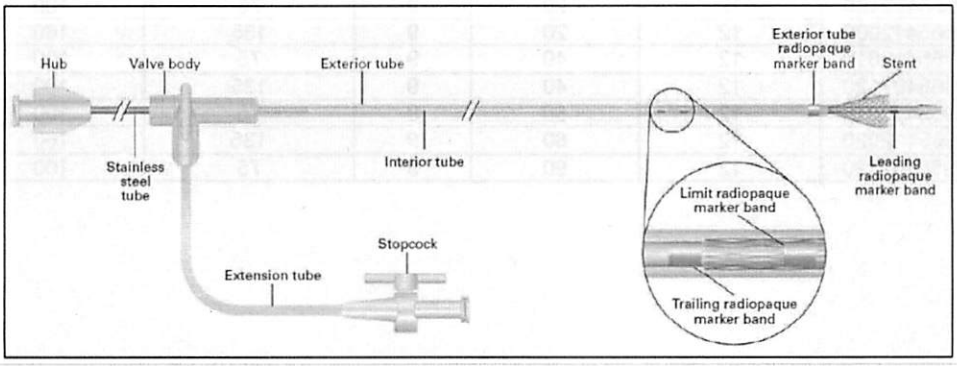


Table 8-1: UPNs for WALLSTENT Endoprosthesis Tracheobronchial

US Product Code	Stent Diameter [mm]	Stent Length [mm]	Catheter OD [FR]	Catheter Working Length [cm]	Catheter Total Length [cm]
M001711000	5	20	6	75	100
M001711010	5	20	6	135	160
M001711020	5	40	6	75	100
M001711030	5	40	6	135	160
M001711040	5	55	6	75	100
M001711050	5	55	6	135	160
M001711060	5	80	6	75	100
M001711070	5	80	6	135	160
M001711080	6	20	6	75	100
M001711090	6	20	6	135	160
M001711100	6	45	6	75	100
M001711110	6	45	6	135	160
M001711120	6	60	6	75	100
M001711130	6	60	6	135	160
M001711140	6	90	6	75	100
M001711150	6	90	6	135	160
M001711160	7	20	6	75	100
M001711170	7	20	6	135	160
M001711180	7	40	6	75	100
M001711190	7	40	6	135	160
M001711200	7	60	6	75	100
M001711210	7	60	6	135	160
M001711220	7	90	6	75	100
M001711230	7	90	6	135	160
M001711240	8	20	6	75	100
M001711250	8	20	6	135	160
M001711260	8	40	6	75	100
M001711270	8	40	6	135	160
M001711280	8	60	6	75	100
M001711290	8	60	6	135	160
M001711300	8	80	6	75	100
M001711310	8	80	6	135	160
M001711320	10	20	6	75	100
M001711330	10	20	6	135	160
M001711340	10	42	7	75	100
M001711350	10	42	7	135	160
M001711360	10	68	7	75	100
M001711370	10	68	7	135	160
M001711380	10	94	7	75	100
M001711390	10	94	7	135	160
H965402100	12	20	9	75	100
H965412000	12	20	9	135	160
H965412010	12	40	9	75	100
H965402120	12	40	9	135	160
H965412020	12	60	9	75	100
H965412020	12	60	9	135	160
H965402130	12	90	9	75	100

H965412030	12	90	9	135	160
H965403100	14	20	10	75	100
H965403110	14	40	10	135	160
H965403120	14	60	10	75	100
H965403130	14	90	10	75	100
H965403300	16	20	10	75	100
H965403310	16	40	10	75	100
H965403320	16	60	10	75	100
H965403330	16	90	10	75	100
H965404110	18	40	11	75	100
H965404120	18	60	11	75	100
H965404130	18	90	11	75	100
H965404300	20	40	11	75	100
H965404310	20	55	11	75	100
H965404320	20	80	11	75	100
H965404500	22	35	11	75	100
H965404510	22	45	11	75	100
H965404520	22	70	11	75	100
H965405100	24	35	12	75	100
H965405110	24	45	12	75	100
H965405120	24	70	12	75	100

INDICATIONS FOR USE

The WALLSTENT™ RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

REGULATORY HISTORY

The purpose of this submission is to modify the MR safety section of the Directions for Use (DFU) for the WALLSTENT Endoprosthesis Tracheobronchial cleared for marketing under K992510 (November 18th, 1999). Predicate device labeling approved in K992510 did not include MR safety information (though language was added as part of cumulative changes). New MR safety information states "MR Conditional" and lists the conditions that the device is safe to be scanned within.

The MRI language in the proposed DFU was finalized through Real-Time Reviews of the WALLSTENT Endoprosthesis TIPS (P930031) and WALLSTENT Endoprosthesis Venous (P980033) products, which share a DFU with WALLSTENT Endoprosthesis Tracheobronchial. The Real-Time Reviews were approved under P930031/S054 and P980033/S043 on August 12th, 2015.

SCOPE

The scope of this review is limited to the MR radiofrequency (RF) induced heating testing and labeling.

REVIEW OF SPONSOR SUBMISSION

Test Sample Device Size Justifications

The WALLSTENT Technical Report (Appendix L) completed testing for all WALLSTENT products marketed by Boston Scientific, including those with the Reduced Profile (RP), Uni, and Endoprosthesis systems. While these versions of the WALLSTENT brand may differ in stent sizes and indications, all WALLSTENT models utilize the same braiding biomedical superalloy wire called Elgiloy (an alloy of cobaltchromium-nickel-molybdenum) surrounding a Tantalum core. Therefore, a worst-case size selection across any of these product versions will represent a worst-case for all models, as they utilize the

same materials and processing methods. WALLSTENT Endoprosthesis Tracheobronchial device testing of RF heating utilized the 24mm x 70mm size of the WALLSTENT Uni Endoprosthesis model.

- Wallstent Uni single configuration (73 mm measured – 70 mm nominal x 24 mm) and
- Wallstent Uni overlapped configuration (120 mm x 24 mm)

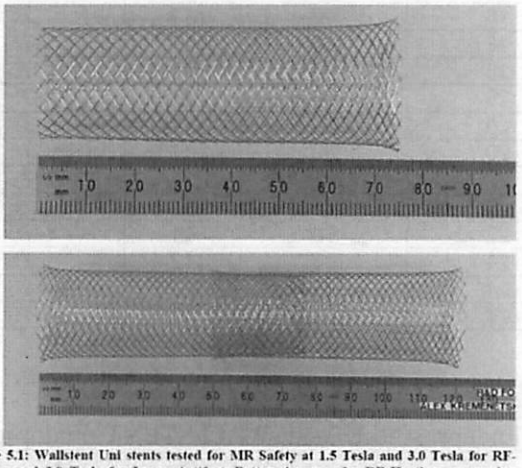


Figure 5.1: Wallstent Uni stents tested for MR Safety at 1.5 Tesla and 3.0 Tesla for RF-Heating and 3.0 Tesla for Image Artifact. Bottom image – for RF Heating, an overlap condition of a maximum 20 mm of overlap length was studied on a pair of Wallstent Uni stents.

Summary of RF-heating test: methods and results

The modeling of the MRI RF-heating utilized results from in-vitro testing conducted by MR:Comp. The following procedure was used to scale and model in-vitro test data into a human form simulation.

1. (b)(4)
(b)(4)

Note of the reviewer.
The sponsor is aware that the measurements were performed following the protocol described in ASTM F2182-02a which is not up-to-date. The current standard for measurements is the ASTM F2182-11a. The sponsor compares the two standards and clarifies why the chosen setup does not create a protocol deviation from ASTM F2182-11a.

- (b)(4)
(b)(4)

- (b)(4)
(b)(4)

(b)(4)

(b)(4)

(b)(4)

2. (b)(4)

(b)(4)

(b)(4)

3. (b)(4)

(b)(4)

(b)(4)

Note of the reviewer.
From the files of the P930031/S054 and P980033/S04 Real-Time Reviews:
-"*P930031_S054 P980033_S043 Responses to Questions 23Apr2015*"
-"*002_P930031_S054 P980033_S043 Review Responses V1*"
-"*003_Nyenhuis Report bsci_wall_stent_mri_7jul15*"

The sponsor is aware that 73 mm and 120 mm long stents are not the worst case for heating. Determination of the worst case length was provided in the document bsci_wall_stent_mri_7_jul_15.doc (see also figure 1.1. above). For the 3 Tesla case, the resonant length of greatest heating was between 80 and 100mm. The figure above suggests that the heating results (obtained with an overlapped stent of 120 mm) are still valid, because the exact resonance point for all configurations is cushioned by an extra rise in temperature captured in the uncertainty calculations (i.e., 36% uncertainty).

Labeling

15.3.1. WALLSTENT® (RP) Endoprosthesis DFU MRI Section

(to also be included on symbol definition page on the last page of the DFU)
Non-clinical testing has demonstrated that WALLSTENT™ TracheoBronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- **Static magnetic field of 1.5 or 3.0 Tesla**
- **Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less**
- **Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg**

RF Heating
Under the scan conditions defined above, WALLSTENT Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact
In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations
It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

Note of the reviewer.
The dimensions of the subject device and its placement in the tracheobronchial tree do not raise any additional safety concerns that would not have been addressed by the review of the MR safety testing information for P930031 (Wallstent (RP) Endoprosthesis TIPS).
The labeling of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial Self-Expanding Stent can be accepted in its current form.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/RDB
WO66 RM2547
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6963

Premarket Notification 510(k) Review

Date: December 22, 2015

Reviewer: Amy Levelle

Subject: Traditional 510(k)# K152842

Applicant: Boston Scientific Corporation	**Device Trade Name:** Wallstent Rp Endoprosthesis Tracheobronchial, Wallstent Endoprosthesis Tracheobronchial
Contact Name: Carah Kucharski	**Contact Title:** Regulatory Affairs Specialist
Correspondent Firm: Boston Scientific Corporation	**Phone:** (763) 255-0738 **Email:** carah.kucharski@bsci.com
Received Date: September 29, 2015	**Due Date:** January 21, 2016
Pro Code(s): JCT **Class:** II **Reg #:** 878.3720	**Reg Name:** Tracheal Prosthesis

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K992510	JCT	Wallstent Tracheobronchial Endoprosthesis And Unistep Plus Delivery System	Boston Scientific Corp.

Review Summary

The subject device is a tracheobronchial stent with the following Indications for Use: "The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms." It is for Rx use. The sponsor indicates that this submission is for a change to the MR labeling of the device.

RTA1 (10/14/2015) (b)(4)

(b)(4)

(b)(4)

(b)(4)

Recommendation
I recommend that the Wallstent Rp Endoprosthesis Tracheobronchial, Wallstent Endoprosthesis Tracheobronchial is/are in need of Additional Information (AINN)

Review Team

Lead Reviewer	Amy Levelle (CDRH/ODE/DAGID/RDB)
MR Consultant	Maria Iacono (CDRH/OSEL/DBP)

I. Purpose and History

TPLC Information Recall Information Historyfalls

The sponsor is submitting this for a change in the MR labeling of their device. They also indicate that they consolidated the labeling for the different cleared/approved indications for their device. The current submission is for the tracheobronchial indication; however, they also have Venous, TIPS, and biliary indications for their device. These devices differ regarding the available sizes and application in the human body.

In 2006, the sponsor was sent a letter by ODE regarding their Wallstent Tracheobronchial Endoprosthesis. This was provided in Appendix F of the 510(k) submission. This letter communicates two safety concerns:

- There was a 2005 Public Health Notice for Metallic Tracheal Stents in Patients with Benign Airway Disorders which identified safety issues and concluded that metallic stents should be avoided in benign conditions. Therefore, the sponsor was requested to remove the indication for "benign strictures".
- The MDRs demonstrated reasonable likelihood that the device may be used off label in the cardiovascular system and result in harm to the patient. The sponsor was requested to make labeling modifications to 1.) Remove all vascular terminology from the device labeling, and 2.) Add the following "Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death."

In 2011, the firm, Boston Scientific, sent an "Urgent Medical Device Field Correction" letter dated May 25, 2011 to its customers. The letter described the product, the problem and actions to be taken. The letter states that no product is being recalled and asks consignees not to return the product. The letter was intended to clarify and re-emphasize that Tracheobronchial Endoprosthesis stents are NOT currently cleared by the FDA for use in benign tracheobronchial strictures.

Lead Reviewer's Comment: *Review of MDRs occurring in last 5 years indicates there have been many new events related to the off label use of their device in the vasculature. It is unclear whether their combined labeling for multiple indications is appropriate or if this may lead to an increase in the off label use, since it also includes the DFU for vascular use along with their tracheobronchial stents. There have also been numerous events of stent fractures, difficulty to deploy, and migration of the stent. The sponsor should justify the adverse events related to their device, including the off label use of their device.*

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo

The content of the 510(k) Summary is incomplete. The sponsor has not provided the date the summary was prepared.

Reviewer Recommendation

The 510(k) Summary/Statement is **not** acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	Yes	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	Yes	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is…	a single use device(s) (SUD)	☐
The environment for use of the device/system includes…	MR, Home, Hospital, Transport	☐
Is the device a combination product?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (battery or wall powered)?	No, the device is not electrical	☐

Check the attributes that are applicable to this submission.

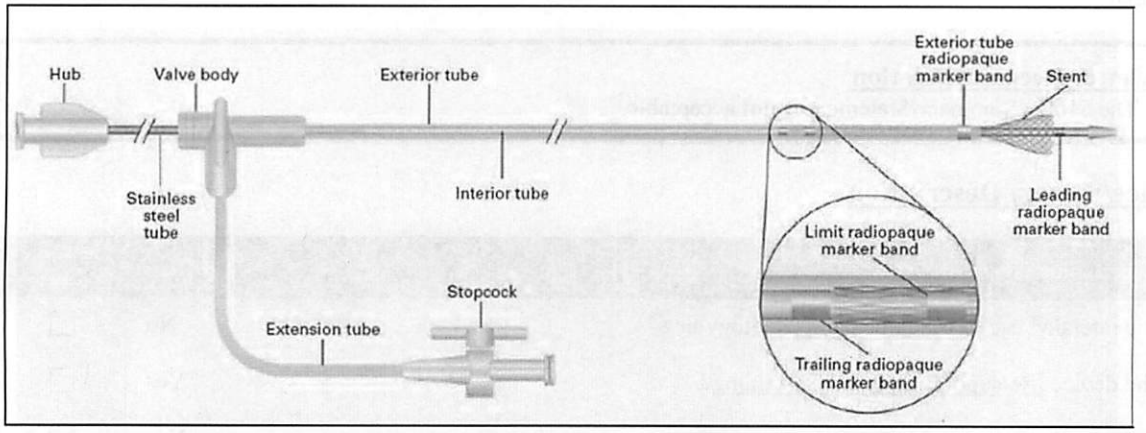
	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

The WALLSTENT and WALLSTENT™ RP Endoprosthesis Tracheobronchial and are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
The WALLSTENT™ device is offered in both a standard profile (8-12 French) and Reduced Profile (RP) system, for 6-7 French systems. Both systems are comprised of two components: The implantable metallic stent and the UNISTEP™ Plus delivery system.

The stent is composed of superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self- expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during

delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm diameter) have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035in (0.89mm) guidewire.



WALLSTENT Endoprosthesis Tracheobronchial

Immediately prior to the procedure, sterile saline or contrast media is passed through the stopcock and extension tube into the valve body and allowed to displace air in the coaxial tubing assembly. After flushing, the system is positioned at the lesion site, and the outer tube is retracted, releasing the stent and allowing it to self-expand. With the stent partially released, the system can be reconstrained by the outer tube of the delivery system if repositioning is desired.

UPNs for WALLSTENT Endoprosthesis Tracheobronchial

US Product Code	Stent Diameter [mm]	Stent Length [mm]	Catheter OD [FR]	Catheter Working Length [cm]	Catheter Total Length [cm]
M001711000	5	20	6	75	100
M001711010	5	20	6	135	160
M001711020	5	40	6	75	100
M001711030	5	40	6	135	160
M001711040	5	55	6	75	100
M001711050	5	55	6	135	160
M001711060	5	80	6	75	100
M001711070	5	80	6	135	160
M001711080	6	20	6	75	100
M001711090	6	20	6	135	160
M001711100	6	45	6	75	100
M001711110	6	45	6	135	160
M001711120	6	60	6	75	100
M001711130	6	60	6	135	160
M001711140	6	90	6	75	100
M001711150	6	90	6	135	160
M001711160	7	20	6	75	100
M001711170	7	20	6	135	160
M001711180	7	40	6	75	100
M001711190	7	40	6	135	160
M001711200	7	60	6	75	100

M001711210	7	60	6	135	160
M001711220	7	90	6	75	100
M001711230	7	90	6	135	160
M001711240	8	20	6	75	100
M001711250	8	20	6	135	160
M001711260	8	40	6	75	100
M001711270	8	40	6	135	160
M001711280	8	60	6	75	100
M001711290	8	60	6	135	160
M001711300	8	80	6	75	100
M001711310	8	80	6	135	160
M001711320	10	20	6	75	100
M001711330	10	20	6	135	160
M001711340	10	42	7	75	100
M001711350	10	42	7	135	160
M001711360	10	68	7	75	100
M001711370	10	68	7	135	160
M001711380	10	94	7	75	100
M001711390	10	94	7	135	160
H965402100	12	20	9	75	100
H965412000	12	20	9	135	160
H965412010	12	40	9	75	100
H965402120	12	40	9	135	160
H965412020	12	60	9	75	100
H965412020	12	60	9	135	160
H965402130	12	90	9	75	100
H965412030	12	90	9	135	160
H965403100	14	20	10	75	100
H965403110	14	40	10	135	160
H965403120	14	60	10	75	100
H965403130	14	90	10	75	100
H965403300	16	20	10	75	100
H965403310	16	40	10	75	100
H965403320	16	60	10	75	100
H965403330	16	90	10	75	100
H965404110	18	40	11	75	100
H965404120	18	60	11	75	100
H965404130	18	90	11	75	100
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H965404510	22	45	11	75	100
H965404520	22	70	11	75	100
H965405100	24	35	12	75	100
H965405110	24	45	12	75	100
H965405120	24	70	12	75	100

The proposed WALLSTENT Endoprosthesis Tracheobronchial is constructed with the following components, unchanged from the predicate:

☐ Hub	☐ Stainless Steel Tube	☐ Extension Tube	☐ Stopcock	☐ Valve Body
☐ Exterior Tube	☐ Interior Tube	☐ Stent	☐ Marker Bands	☐ Tip

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Third-party Components and Accessories: N/A

Reviewer Recommendation
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K152842 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☒	☐	☐	☐	☐	☐	☐	☐
No	☐	☒	☒	☒	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Predicate(s)

Submission#: K992510 Rx/OTC: Rx

Intended Population:

Indications for Use: The wallstent tracheobronchial endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer's Comment: *The sponsor has removed the indication for benign strictures. This was in response to a 2006 letter from ODE informing the sponsor of a 2005 FDA Public Health Notification related to the use of these devise in benign strictures. The IFU statement is otherwise unchanged. This is acceptable.*

Reviewer Recommendation
The Comparison of the Indications for Use is acceptable.

V. Comparison of Technology to Predicate Devices

This submission is for a modification to the labeling to add that the device is "MR Conditional". The same MRI language in the proposed submission was already approved under Real-Time Reviews of the WALLSTENT Endoprosthesis TIPS (P930031) and WALLSTENT Endoprosthesis Venous (P980033) products, which share a combined labeling with WALLSTENT Endoprosthesis Tracheobronchial.

The sponsor also indicates the following cumulative changes have been made since prior clearance which did not require a 510(k):

1. **Stopcock Resin Change:** Due to supplier discontinuation, the 477L HDPE resin in the stopcock handle (non-patient contacting) was changed to an equivalent T60-800 HDPE resin. Applicable design verification and biocompatibility testing was conducted, which demonstrates that the stopcock manufactured with the new HDPE handle resin continues to meet specifications. ***-This is not patient contacting- Adequate.***

2. **Carton Glue Change:** Due to supplier discontinuation, the carton glue, Superlok 61, was replaced with an equivalent alternate glue, Superlok 260. The glue is used to keep cartons closed and is considered non-patient contacting. The new glue was previously used on identical carton materials on different products at other BSC sites. Applicable design verification was completed on those cartons to demonstrate that cartons continue to meet design and sterilization requirements. ***–This change was for the carton and does not affect the sterile pouch- Adequate.***

3. **PFOA-Free PTFE Manufacturing Aid:** (b)(4) (b)(4) (b)(4) ***– Inadequate.***

4. **Tear-Tab Closure Strip:** (b)(4) (b)(4) ***Inadequate.***

5. **Carton Paperboard Tolerance:** The specification tolerance for carton paperboard thickness of packaging the 8-24mm stent sizes was updated to remove the micron tolerance requirement. Paperboard is now accepted to the standard tolerance of 0.001 inch. No verification or validation was required because the specification has not changed, only the tolerance requirements.- ***Adequate.***

6. **Branding Updates:** As a corporate branding alignment initiative, minor DFU and label dimension updates were implemented. No material or supply grade changes occurred, and all design verification testing remains valid.-***Adequate.***

7. **DFU and Labeling Updates:** Because all DFU and labeling changes are to content only, no design verification, sterilization, or biocompatibility testing was required to ensure that products continue to meet required specifications. See **Table 9-2** for a detailed DFU comparison between predicate and proposed DFUs, and **Appendicies I** and **J** for the predicate and proposed DFUs and proposed labels, respectively.

   a. **Consolidated DFUs:** (b)(4)
   (b)(4)

   Inadequate.

   b. **Benign Indication Removal:** Per FDA request (**Appendix F**), the benign indication portion of the WALLSTENT Endoprosthesis Tracheobronchial indications for use ("or in benign strictures after all alternative therapies have been exhausted") was removed from the indications for use. This change narrowed the indications for use, and does not raise questions of comparative safety and/or effectiveness as compared to the predicate.- ***Adequate.***

   c. **Vascular Indications Warnings and Preparation Instructions:** (b)(4)
   (b)(4)

   (b)(4) ***Inadequate***

   d. **MRI Language:** MRI language was added based on current testing to indicate that the device shows no deflection or torque in a 1.5T MR machine, as well as expected image artifact information (see **Table 9-2**). This language is removed in the proposed device and replaced with the language proposed below in **Section 15.** ***–This has been reviewed by the MR consultant and found acceptable- Adequate.***

   e. **General Formatting:** General formatting and clarification updates to the DFU and labels were implemented, including UDI implementation and a legal manufacturer address change. - ***Adequate.***

Lead Reviewer's Comments: *The change to add MR conditional labeling does not alter the intended use or raise new safety/effectiveness questions. The sponsor has provided adequate performance data to support the new MR labeling. The sponsor also indicates that there have been several cumulative changes since the prior clearance which require further justification. There appear to have been some changes in the materials or their processing and the sponsor should clarify this as well as whether there has been any impact on sterilization. The sponsor should also justify labeling changes which have been made.*

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is **not** acceptable.

VI. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Undo	**No**

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Yes	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Yes	☐
Appropriate labeling inside device?	Inapplicable	☐
Appropriate label/indicator outside device?	No	☒
Appropriate Manual labeling?	No	☒
Is appropriate home use information included in the labeling?	Inapplicable	☐
What MRI safety information does the labeling contain?	MR Conditional	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

The following has been added to the labeling regarding MR compatibility.

15.3.1. WALLSTENT® (RP) Endoprosthesis DFU MRI Section

(to also be included on symbol definition page on the last page of the DFU)
Non-clinical testing has demonstrated that WALLSTENT™ TracheoBronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg

RF Heating
Under the scan conditions defined above, WALLSTENT Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact
In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations
It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

Consultants Comments: *The dimensions of the subject device and its placement in the tracheobronchial tree do not raise any additional safety concerns that would not have been addressed by the review of the MR safety testing information for P930031 (Wallstent (RP) Endoprosthesis TIPS). The labeling of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial Self-Expanding Stent can be accepted in its current form.*

The sponsor has added the following statement under the indications for use section in their labeling:

> With the exception of the following WALLSTENT Codes which are approved for Venous or TIPS indications, the safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/ or death: H965402100, H965402110, H965402120, H965402130, H965403100, H965403110, H965403120, H965403130, H965403300, H965403310, H965403320, H965403330, M001711320, M001711340, M001711360, M001711380.

Lead Reviewer's Comments: *The sponsor has provided acceptable MR labeling as noted by the MR consultant.* (b)(4)
(b)(4)

Reviewer Recommendation
The Labeling is **not** acceptable.

VII. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Undo	No
Sterility Consult Needed?	Undo	No

The device is single use and provided ethylene oxide sterile. There have been no changes to the sterilization processes.

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Undo	No
Biocompatibility Consult Needed?	Undo	No

The sponsor indicates that there have been no material changes.

Reviewer Recommendation
The Biocompatibility is acceptable.

IX. Software/Firmware

The device does not contain any software.

Reviewer Recommendation
The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

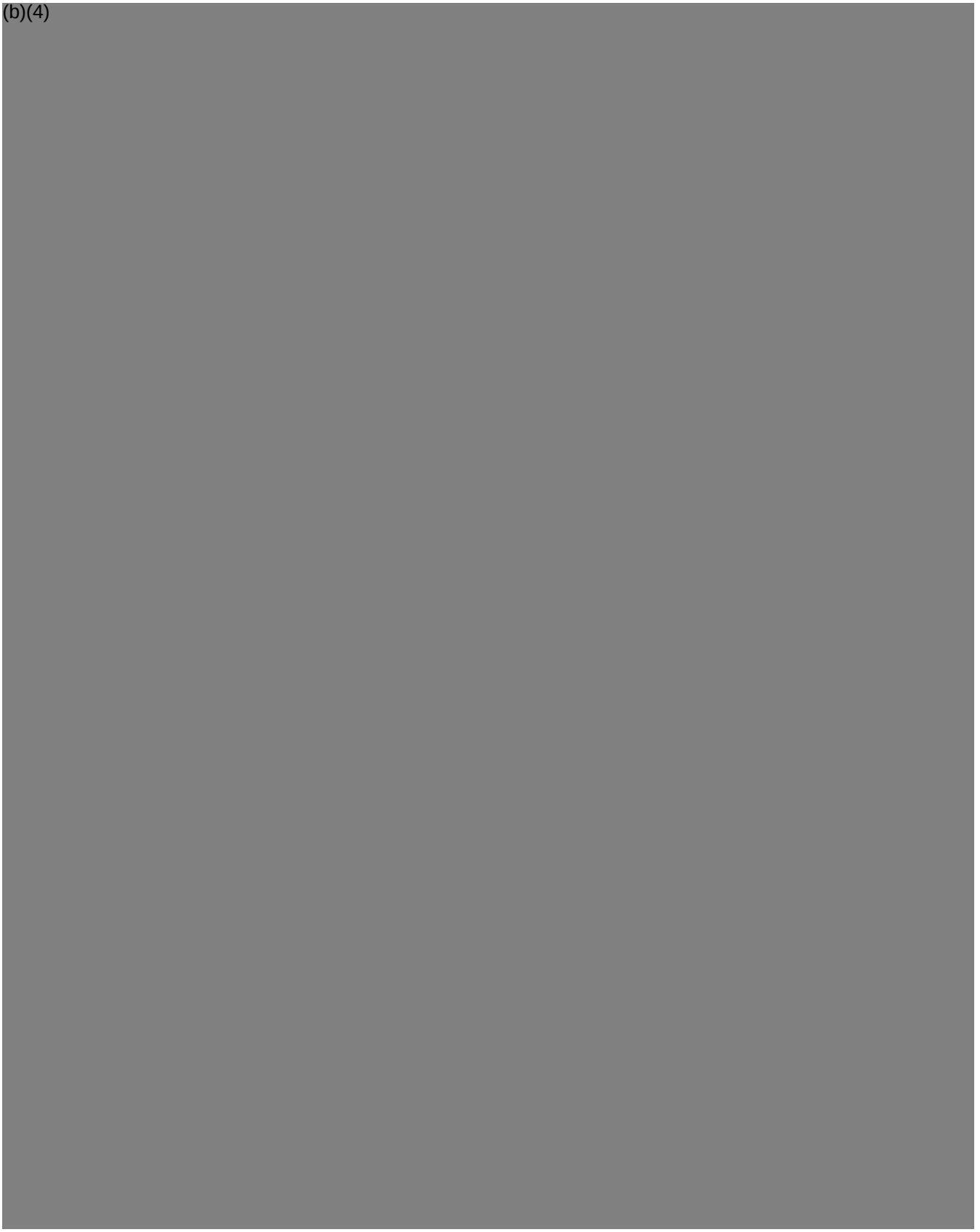
The device does not contain any electrical components.

Reviewer Recommendation
The EMC, EMT and Risk Analysis are acceptable.

XI. Performance Testing

(b)(4)

(b)(4)



point for all configurations is cushioned by an extra rise in temperature captured in the uncertainty calculations (i.e., 36% uncertainty).

Consultant's Recommendation: *The testing and labeling for radio-frequency induced heating are adequate. I have no deficiencies and recommend clearance.*

B Animal Testing

N/A- No animal testing is necessary.

C Clinical Testing

N/A- No clinical testing is necessary.

Reviewer Recommendation
The Performance Testing is acceptable.

XII. Kit Certification

N/A

XIII. Manufacturing Information

N/A

XIV. References

N/A

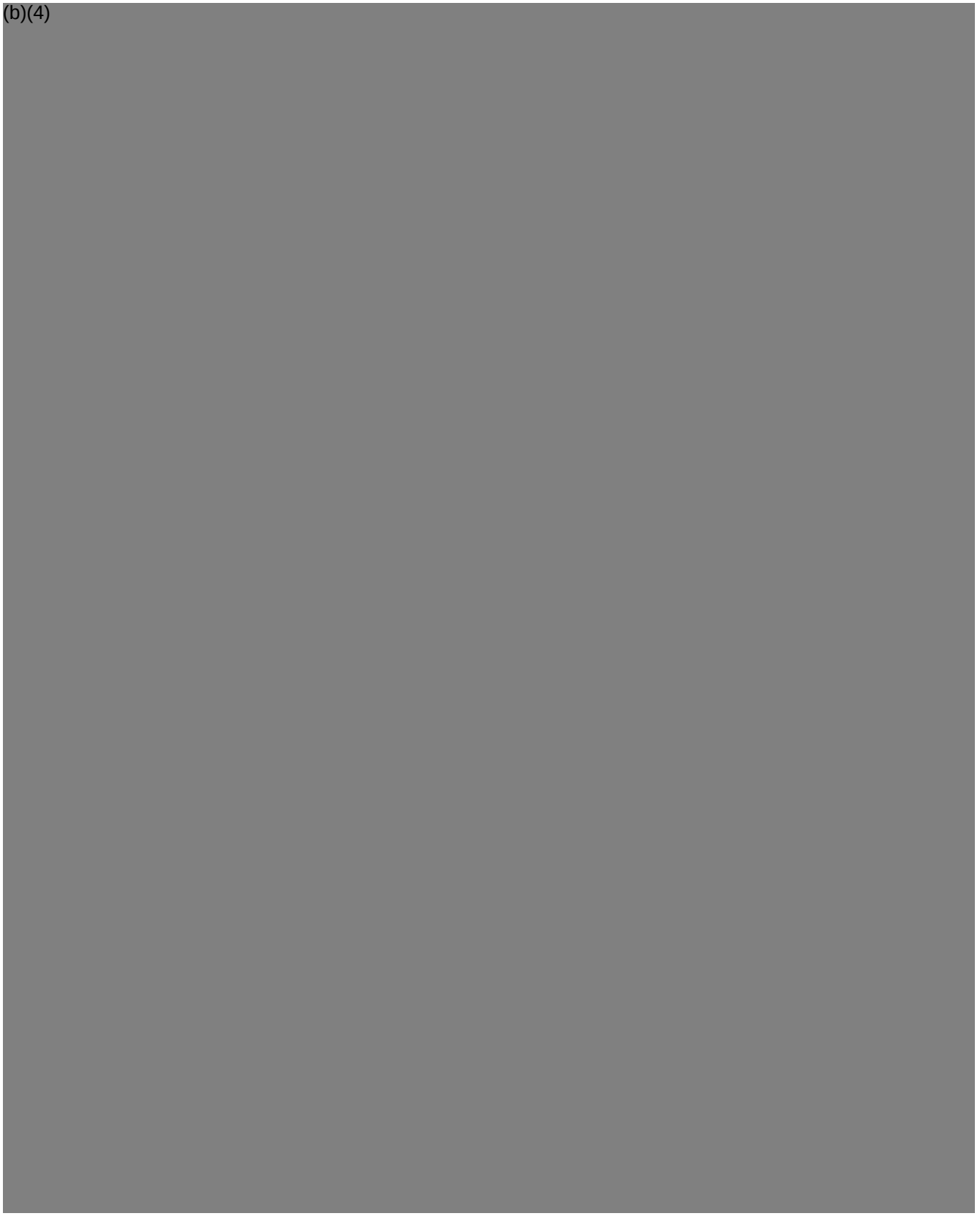
XV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☐	☐

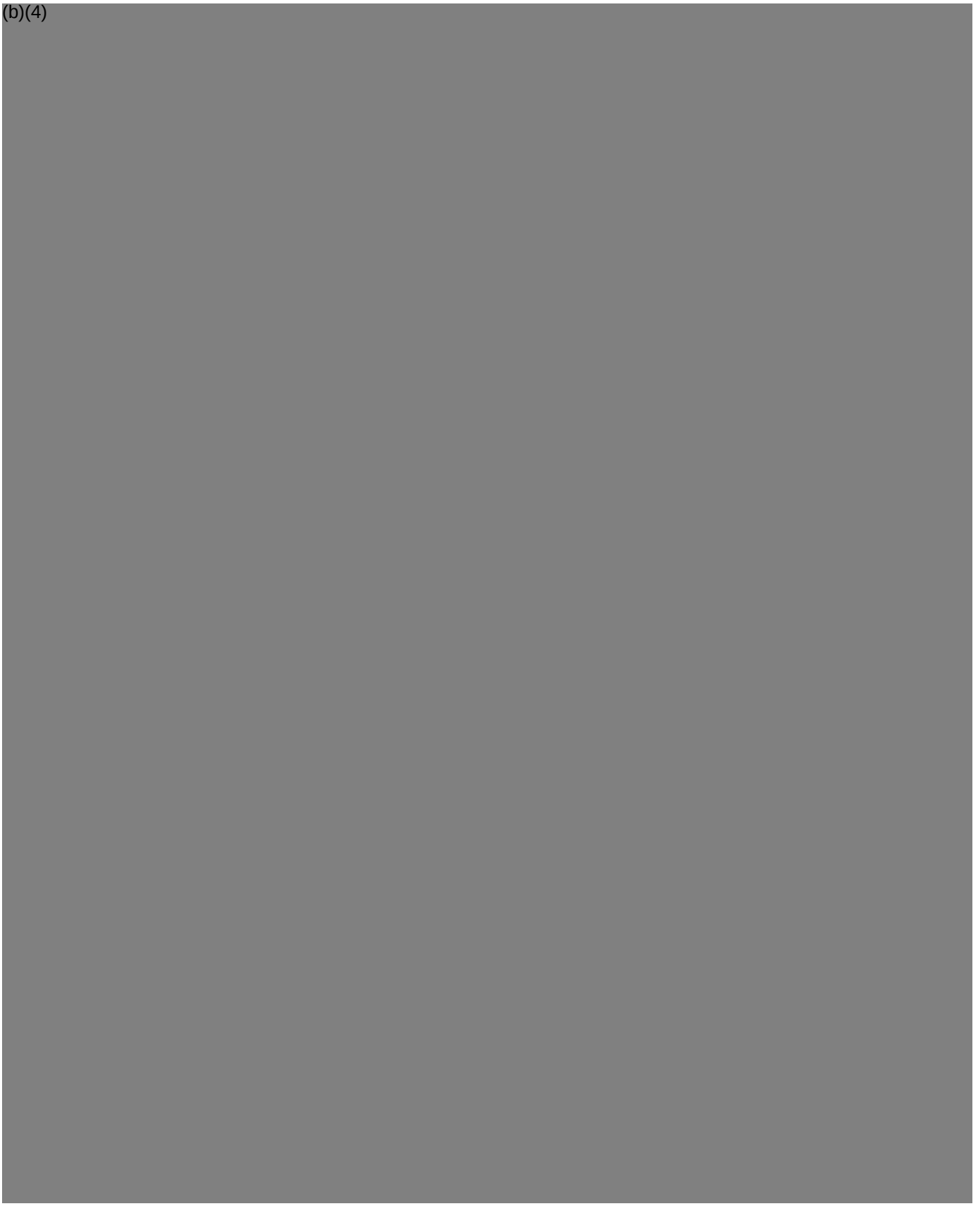
XVI. Original Deficiencies

(b)(4)

(b)(4)



(b)(4)



(b)(4)

XVII. Contact History

N/A

Digital Signature Concurrence Table	
Reviewer Sign-Off	Amy K. Levelle -S Digitally signed by Amy K. Levelle -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Amy K. Levelle -S, 0.9.2342.19200300.100.1.1=2000378253 Date: 2015.12.23 01:37:31 -05'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DAGID/RDB
WO66 RM2547
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6963

Premarket Notification 510(k) Review

Date: May 16, 2016

Reviewer: Amy Levelle

Subject: Traditional 510(k)# K152842/S002

Applicant: Boston Scientific Corporation	**Device Trade Name:** Wallstent Rp Endoprosthesis Tracheobronchial, Wallstent Endoprosthesis Tracheobronchial
Contact Name: Carah Kucharski	**Contact Title:** Regulatory Affairs Specialist
Correspondent Firm: Boston Scientific Corporation	**Phone:** (763) 255-0738 **Email:** carah.kucharski@bsci.com
Received Date: September 29, 2015	**Due Date:** January 21, 2016
Pro Code(s): JCT **Class:** II **Reg #:** 878.3720	**Reg Name:** Tracheal Prosthesis

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K992510	JCT	Wallstent Tracheobronchial Endoprosthesis And Unistep Plus Delivery System	Boston Scientific Corp.

Review Summary

The subject device is a tracheobronchial stent with the following Indications for Use: "The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms." It is for Rx use. The sponsor indicates that this submission is for a change to the MR labeling of the device.

RTA1 (10/14/2015) The submission was Refuse to Accept based on various administrative reasons. (b)(4)

(b)(4)

(b)(4)

S002 The sponsor has adequately resolved the outstanding deficiencies as discussed in detail in the memo below. Therefore, substantial equivalence is recommended.

Recommendation
I recommend that the Wallstent Rp Endoprosthesis Tracheobronchial, Wallstent Endoprosthesis Tracheobronchial is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer	Amy Levelle (CDRH/ODE/DAGID/RDB)
MR Consultant	Maria Iacono (CDRH/OSEL/DBP)

I. Purpose and History

TPLC Information Recall Information Historyfalls

The sponsor is submitting this for a change in the MR labeling of their device. They also indicate that they consolidated the labeling for the different cleared/approved indications for their device. The current submission is for the tracheobronchial indication; however, they also have Venous, TIPS, and biliary indications for their device. These devices differ regarding the available sizes and application in the human body.

In 2006, the sponsor was sent a letter by ODE regarding their Wallstent Tracheobronchial Endoprosthesis. This was provided in Appendix F of the 510(k) submission. This letter communicates two safety concerns:

- There was a 2005 Public Health Notice for Metallic Tracheal Stents in Patients with Benign Airway Disorders which identified safety issues and concluded that metallic stents should be avoided in benign conditions. Therefore, the sponsor was requested to remove the indication for "benign strictures".
- The MDRs demonstrated reasonable likelihood that the device may be used off label in the cardiovascular system and result in harm to the patient. The sponsor was requested to make labeling modifications to 1.) Remove all vascular terminology from the device labeling, and 2.) Add the following "Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death."

In 2011, the firm, Boston Scientific, sent an "Urgent Medical Device Field Correction" letter dated May 25, 2011 to its customers. The letter described the product, the problem and actions to be taken. The letter states that no product is being recalled and asks consignees not to return the product. The letter was intended to clarify and re-emphasize that Tracheobronchial Endoprosthesis stents are NOT currently cleared by the FDA for use in benign tracheobronchial strictures.

Lead Reviewer's Comment: *Review of MDRs occurring in last 5 years indicates there have been many new events related to the off label use of their device in the vasculature. It is unclear whether their combined labeling for multiple indications is appropriate or if this may lead to an increase in the off label use, since it also includes the DFU for vascular use along with their tracheobronchial stents. There have also been numerous events of stent fractures, difficulty to deploy, and migration of the stent. The sponsor should justify the adverse events related to their device, including the off label use of their device.*

S002: The proposed change to combine the labeling was previously reviewed in add-to-file submitted under K992510 in July of 2006 (after the February 2006 safety letter). Therefore, this change has already been accepted by FDA following the 2006 safety notice. Furthermore, the sponsor provided an MDR analysis of the off label use over the last 5 years (Jan 2011- Dec 2015). The sponsor reports out of total

of 108,682 recorded sales, 68 reports related to off-label use. The analysis of the 68 off-label use MDRs found that only 2 (2.9%) involved use of a device size in an indication (Subclavian Vein) that was referenced elsewhere in the DFU. The other 66 complaints were in anatomy locations not indicated by any of the four Wallstent RP Endoprothesis or Wallstent Endoprothesis indications. Therefore, the combined labeling for the Wallstent RP Endoprothesis and Wallstent Endoprothesis is unlikely to be a contributor to off-label use.

Of 108,682 sales, the sponsor reported only 1 complaint related to stent fractures, 27 for difficulty to deploy, and 22 for migration of the stent during the analyzed time period. Only 3 analyzed MDRs resulted in a patient complication and 6 MDRs required post-procedure physician intervention. These 6 events were related to a use not approved for any product code of this US device family. The complaint rates are relatively low and remain within anticipated levels per risk management. This is acceptable.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo

Reviewer Recommendation

The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	Yes	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	Yes	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is...	a single use device(s) (SUD)	☐
The environment for use of the device/system includes...	MR, Home, Hospital, Transport	☐
Is the device a combination product?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (battery or wall powered)?	No, the device is not electrical	☐

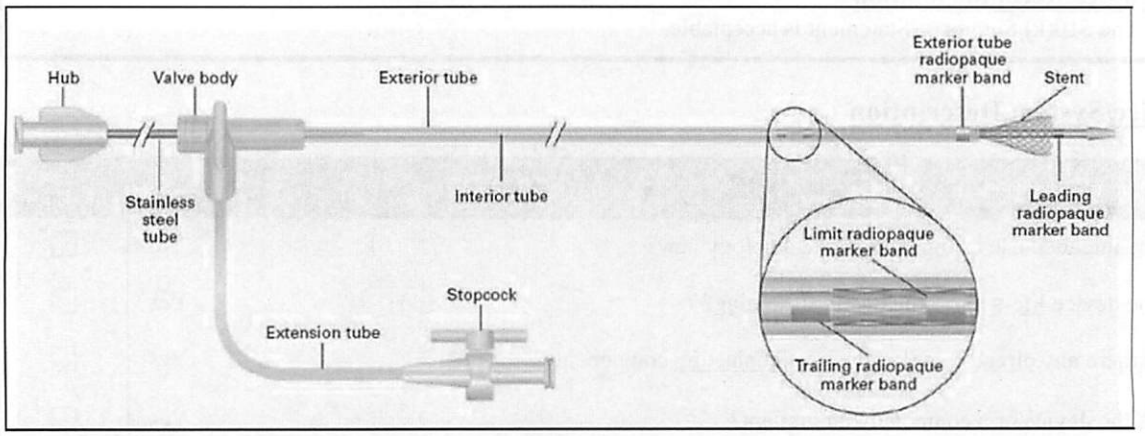
Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐

Device Characteristics					Inadequate Or Marked
No	☒	☒	☒	☒	
Unknown	☐	☐	☐	☐	
Device Description Table: Summary of important device characteristics					

The WALLSTENT and WALLSTENT™ RP Endoprosthesis Tracheobronchial and are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
The WALLSTENT™ device is offered in both a standard profile (8-12 French) and Reduced Profile (RP) system, for 6-7 French systems. Both systems are comprised of two components: The implantable metallic stent and the UNISTEP™ Plus delivery system.

The stent is composed of superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self- expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm diameter) have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035in (0.89mm) guidewire.



WALLSTENT Endoprosthesis Tracheobronchial

Immediately prior to the procedure, sterile saline or contrast media is passed through the stopcock and extension tube into the valve body and allowed to displace air in the coaxial tubing assembly. After flushing, the system is positioned at the lesion site, and the outer tube is retracted, releasing the stent and allowing it to self-expand. With the stent partially released, the system can be reconstrained by the outer tube of the delivery system if repositioning is desired.

UPNs for WALLSTENT Endoprosthesis Tracheobronchial

US Product Code	Stent Diameter [mm]	Stent Length [mm]	Catheter OD [FR]	Catheter Working Length [cm]	Catheter Total Length [cm]
M001711000	5	20	6	75	100
M001711010	5	20	6	135	160
M001711020	5	40	6	75	100
M001711030	5	40	6	135	160

M001711040	5	55	6	75	100
M001711050	5	55	6	135	160
M001711060	5	80	6	75	100
M001711070	5	80	6	135	160
M001711080	6	20	6	75	100
M001711090	6	20	6	135	160
M001711100	6	45	6	75	100
M001711110	6	45	6	135	160
M001711120	6	60	6	75	100
M001711130	6	60	6	135	160
M001711140	6	90	6	75	100
M001711150	6	90	6	135	160
M001711160	7	20	6	75	100
M001711170	7	20	6	135	160
M001711180	7	40	6	75	100
M001711190	7	40	6	135	160
M001711200	7	60	6	75	100
M001711210	7	60	6	135	160
M001711220	7	90	6	75	100
M001711230	7	90	6	135	160
M001711240	8	20	6	75	100
M001711250	8	20	6	135	160
M001711260	8	40	6	75	100
M001711270	8	40	6	135	160
M001711280	8	60	6	75	100
M001711290	8	60	6	135	160
M001711300	8	80	6	75	100
M001711310	8	80	6	135	160
M001711320	10	20	6	75	100
M001711330	10	20	6	135	160
M001711340	10	42	7	75	100
M001711350	10	42	7	135	160
M001711360	10	68	7	75	100
M001711370	10	68	7	135	160
M001711380	10	94	7	75	100
M001711390	10	94	7	135	160
H965402100	12	20	9	75	100
H965412000	12	20	9	135	160
H965412010	12	40	9	75	100
H965402120	12	40	9	135	160
H965412020	12	60	9	75	100
H965412020	12	60	9	135	160
H965402130	12	90	9	75	100
H965412030	12	90	9	135	160
H965403100	14	20	10	75	100
H965403110	14	40	10	135	160
H965403120	14	60	10	75	100
H965403130	14	90	10	75	100
H965403300	16	20	10	75	100
H965403310	16	40	10	75	100
H965403320	16	60	10	75	100
H965403330	16	90	10	75	100
H965404110	18	40	11	75	100

H965404120	18	60	11	75	100
H965404130	18	90	11	75	100
H965404300	20	40	11	75	100
H965404310	20	55	11	75	100
H965404320	20	80	11	75	100
H965404500	22	35	11	75	100
H965404510	22	45	11	75	100
H965404520	22	70	11	75	100
H965405100	24	35	12	75	100
H965405110	24	45	12	75	100
H965405120	24	70	12	75	100

The proposed WALLSTENT Endoprosthesis Tracheobronchial is constructed with the following components, unchanged from the predicate:

☐ Hub	☐ Stainless Steel Tube	☐ Extension Tube	☐ Stopcock	☐ Valve Body
☐ Exterior Tube	☐ Interior Tube	☐ Stent	☐ Marker Bands	☐ Tip

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Third-party Components and Accessories: N/A

Reviewer Recommendation
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K152842 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☒	☐	☐	☐	☐	☐	☐	☐
No	☐	☒	☒	☒	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Predicate(s)

Submission#: K992510 Rx/OTC: Rx

Intended Population:

Indications for Use: The wallstent tracheobronchial endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer's Comment: *The sponsor has removed the indication for benign strictures. This was in response to a 2006 letter from ODE informing the sponsor of a 2005 FDA Public Health Notification related to the use of these devise in benign strictures. The IFU statement is otherwise unchanged. This is acceptable.*

Reviewer Recommendation
The Comparison of the Indications for Use is acceptable.

V. Comparison of Technology to Predicate Devices

This submission is for a modification to the labeling to add that the device is "MR Conditional". The same MRI language in the proposed submission was already approved under Real-Time Reviews of the WALLSTENT Endoprosthesis TIPS (P930031) and WALLSTENT Endoprosthesis Venous (P980033) products, which share a combined labeling with WALLSTENT Endoprosthesis Tracheobronchial.

The sponsor also indicates the following cumulative changes have been made since prior clearance which did not require a 510(k):

1. **Stopcock Resin Change:** Due to supplier discontinuation, the 477L HDPE resin in the stopcock handle (non-patient contacting) was changed to an equivalent T60-800 HDPE resin. Applicable design verification and biocompatibility testing was conducted, which demonstrates that the stopcock manufactured with the new HDPE handle resin continues to meet specifications. ***-This is not patient contacting- Adequate.***

2. **Carton Glue Change:** Due to supplier discontinuation, the carton glue, Superlok 61, was replaced with an equivalent alternate glue, Superlok 260. The glue is used to keep cartons closed and is considered non-patient contacting. The new glue was previously used on identical carton materials on different products at other BSC sites. Applicable design verification was completed on those cartons to demonstrate that cartons continue to meet design and sterilization requirements. ***–This change was for the carton and does not affect the sterile pouch- Adequate.***

3. **PFOA-Free PTFE Manufacturing Aid:** (b)(4) (b)(4) (b)(4) ***– Inadequate (Deficiency).***

4. **Tear-Tab Closure Strip:** (b)(4) (b)(4)

(b)(4)

Inadequate (Deficiency).

5. **Carton Paperboard Tolerance:** The specification tolerance for carton paperboard thickness of packaging the 8-24mm stent sizes was updated to remove the micron tolerance requirement. Paperboard is now accepted to the standard tolerance of 0.001 inch. No verification or validation was required because the specification has not changed, only the tolerance requirements.- ***Adequate.***

6. **Branding Updates:** As a corporate branding alignment initiative, minor DFU and label dimension updates were implemented. No material or supply grade changes occurred, and all design verification testing remains valid.-***Adequate.***

7. **DFU and Labeling Updates:** (b)(4)
(b)(4)

   a. **Consolidated DFUs:** (b)(4)
   (b)(4)

   Inadequate (Deficiency).

   b. **Benign Indication Removal:** Per FDA request (**Appendix F**), the benign indication portion of the WALLSTENT Endoprosthesis Tracheobronchial indications for use ("or in benign strictures after all alternative therapies have been exhausted") was removed from the indications for use. This change narrowed the indications for use, and does not raise questions of comparative safety and/or effectiveness as compared to the predicate.- ***Adequate.***

   c. **Vascular Indications Warnings and Preparation Instructions:** (b)(4)
   (b)(4)

   (b)(4) - ***Inadequate (Deficiency)***

   d. **MRI Language:** MRI language was added based on current testing to indicate that the device shows no deflection or torque in a 1.5T MR machine, as well as expected image artifact information (see **Table 9-2**). This language is removed in the proposed device and replaced with the language proposed below in **Section 15.** ***–This has been reviewed by the MR consultant and found acceptable- Adequate.***

e. **General Formatting:** General formatting and clarification updates to the DFU and labels were implemented, including UDI implementation and a legal manufacturer address change. - ***Adequate.***

Lead Reviewer's Comments: *The change to add MR conditional labeling does not alter the intended use or raise new safety/effectiveness questions. The sponsor has provided adequate performance data to support the new MR labeling. The sponsor also indicates that there have been several cumulative changes since the prior clearance which require further justification. There appear to have been some changes in the materials or their processing and the sponsor should clarify this as well as whether there has been any impact on sterilization. The sponsor should also justify labeling changes which have been made.*

S002: The sponsor has provided justification that the changes made do not impact the biocompatibility or sterility of the device. The change to PTFE manufacturing has been previously approved in 2013 under a 135 day supplement under P930031/S040. The sponsor provided information in the previous submission to demonstrate the change in processing does not alter the chemical properties or biocompatibility of the device. This included extractions studies, FTIR analysis, and biocompatibility data, which was previously reviewed and accepted by FDA. The sponsor has also provided an MDR analysis to justify that the combined labeling does not contribute to off label use. The sponsor has adequately resolved the outstanding deficiencies and their comparison to the predicate supports substantial equivalence.

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is acceptable.

VI. Labeling

Labeling Review Needed?	**Yes**	Undo
Usability Consult Needed?	Undo	**No**

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Yes	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Yes	☐
Appropriate labeling inside device?	Inapplicable	☐
Appropriate label/indicator outside device?	Yes	☐
Appropriate Manual labeling?	Yes	☐
Is appropriate home use information included in the labeling?	Inapplicable	☐

What MRI safety information does the labeling contain?	MR Conditional	☐
Labeling Table: A summary of the adequacy of several labeling requirements.		

The following has been added to the labeling regarding MR compatibility.

15.3.1. WALLSTENT® (RP) Endoprosthesis DFU MRI Section

(to also be included on symbol definition page on the last page of the DFU)
Non-clinical testing has demonstrated that WALLSTENT™ TracheoBronchial is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- **Static magnetic field of 1.5 or 3.0 Tesla**
- **Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less**
- **Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg**

RF Heating
Under the scan conditions defined above, WALLSTENT Tracheobronchial is expected to produce a maximum in-vivo temperature rise of 3.51°C after 15 minutes of continuous scanning.

Image Artifact
In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

Recommendations
It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

Consultants Comments: (b)(4)
(b)(4)

(b)(4)

Lead Reviewer's Comments: (b)(4)
(b)(4)

S002: (b)(4)
(b)(4)

the vascular system has not been established and can result in serious harm and/ or death.

(b)(4)

(b)(4) This is acceptable and the deficiencies are resolved.

Reviewer Recommendation
The Labeling is acceptable.

VII. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Undo	No
Sterility Consult Needed?	Undo	No

The device is single use and provided ethylene oxide sterile. There have been no changes to the sterilization processes.

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Undo	No
Biocompatibility Consult Needed?	Undo	No

The sponsor indicates that there have been no material changes.

Reviewer Recommendation
The Biocompatibility is acceptable.

IX. Software/Firmware

The device does not contain any software.

Reviewer Recommendation
The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

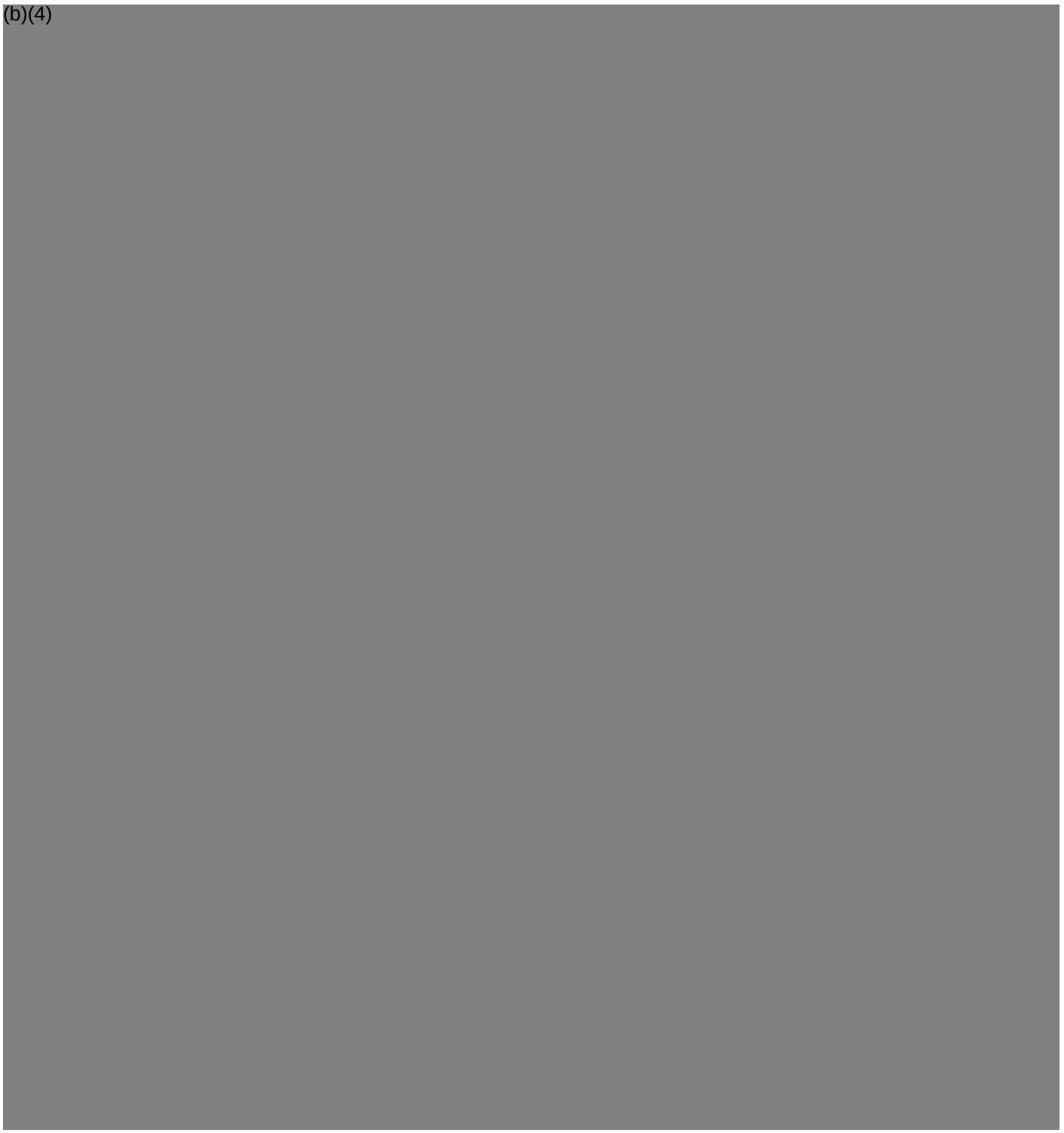
The device does not contain any electrical components.

Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

XI. Performance Testing

(b)(4)



(b)(4)

B Animal Testing

N/A- No animal testing is necessary.

C Clinical Testing

N/A- No clinical testing is necessary.

Reviewer Recommendation
The Performance Testing is acceptable.

XII. Kit Certification

N/A

XIII. Manufacturing Information

N/A

XIV. References

N/A

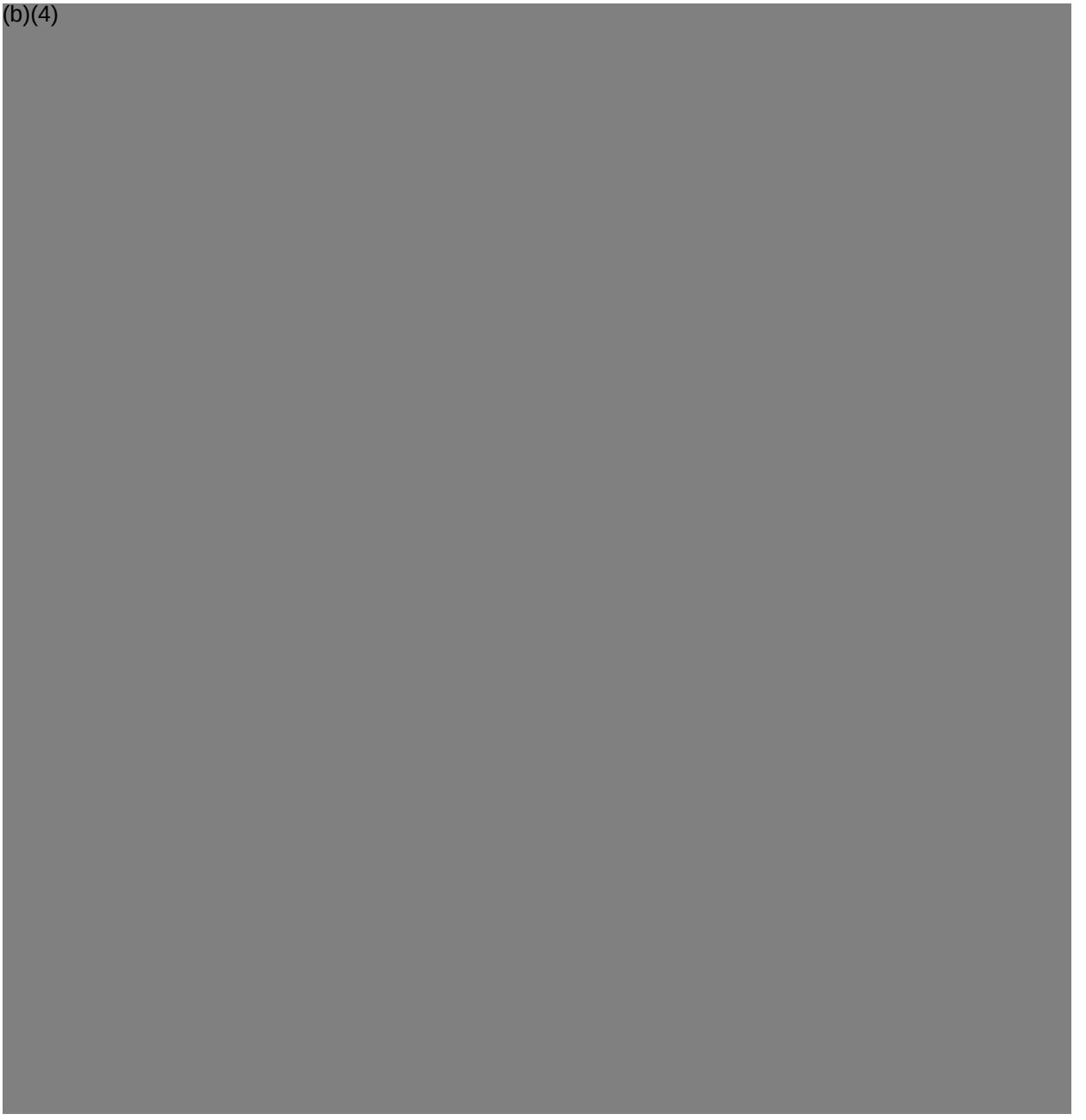
XV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device:		
Do the devices have the same technological characteristics?	☒	☐

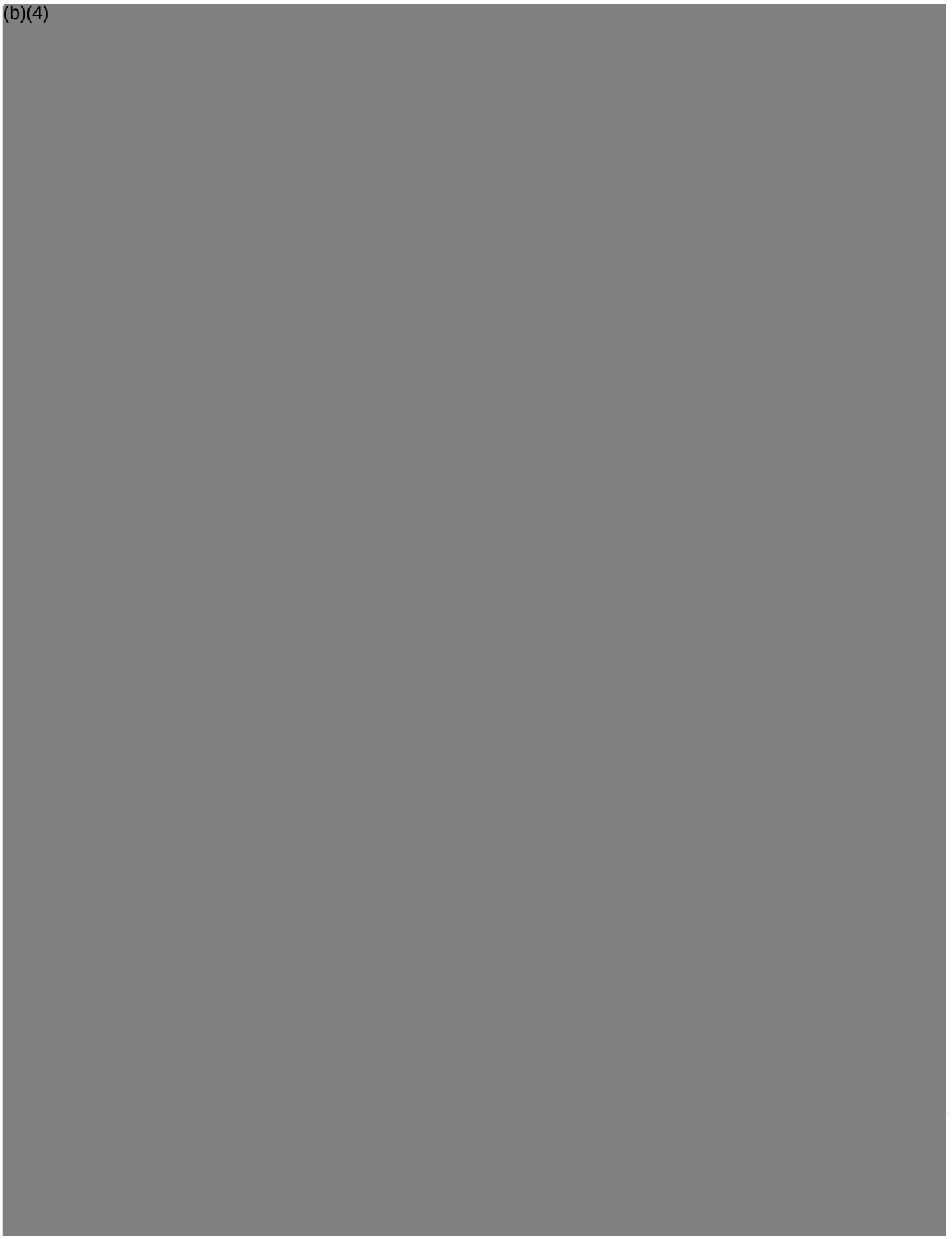
XVI. Original Deficiencies

(b)(4)

(b)(4)



(b)(4)



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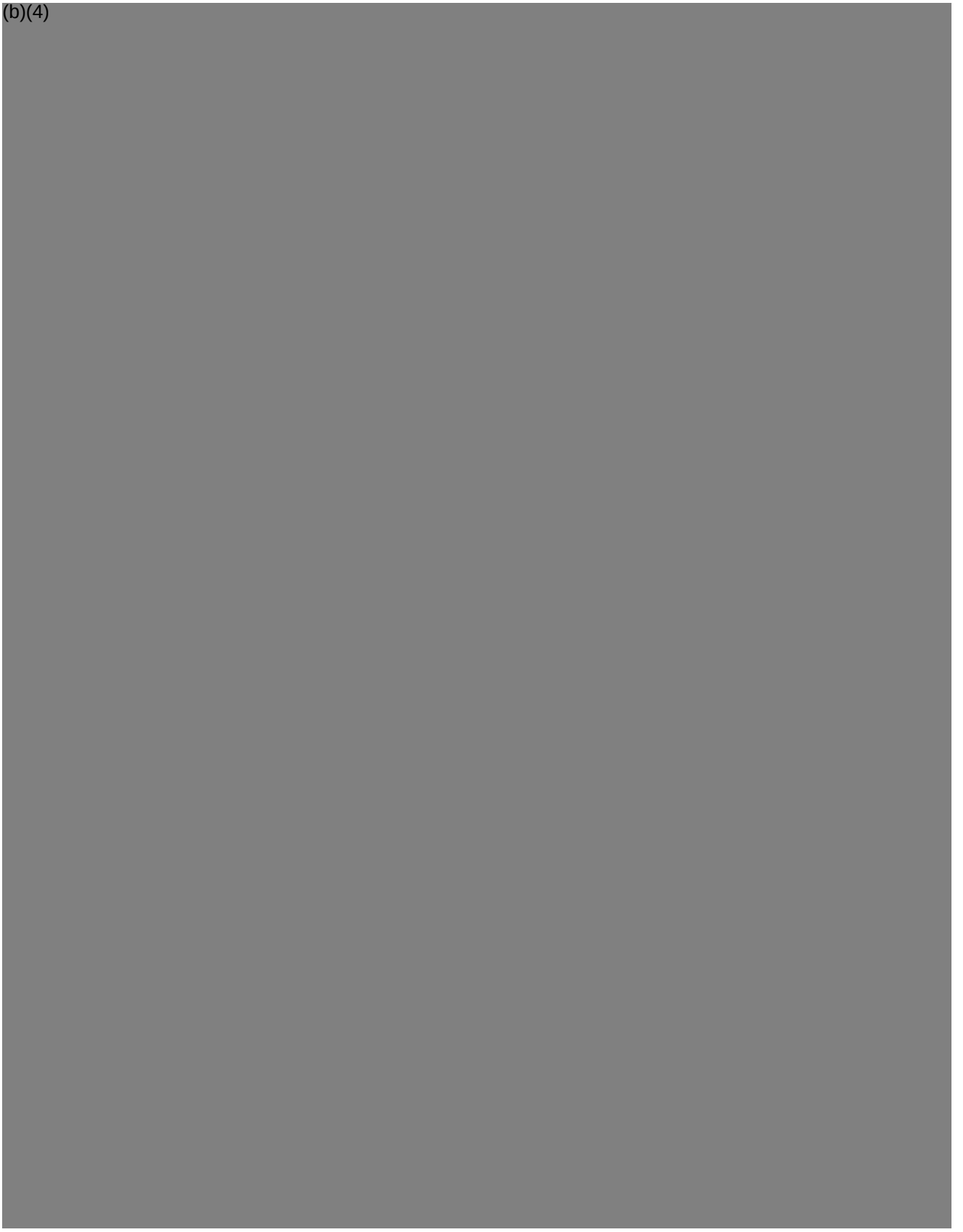

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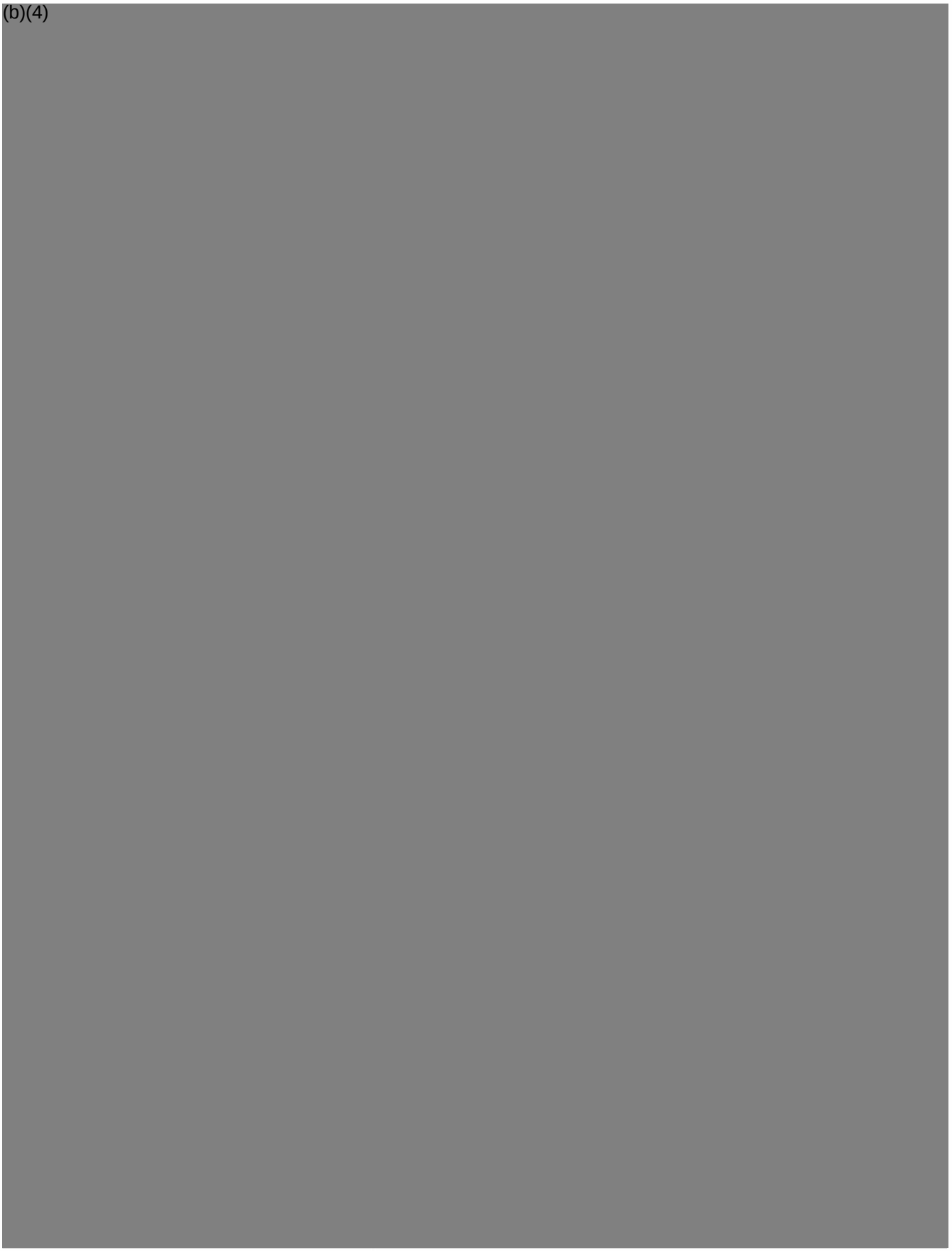

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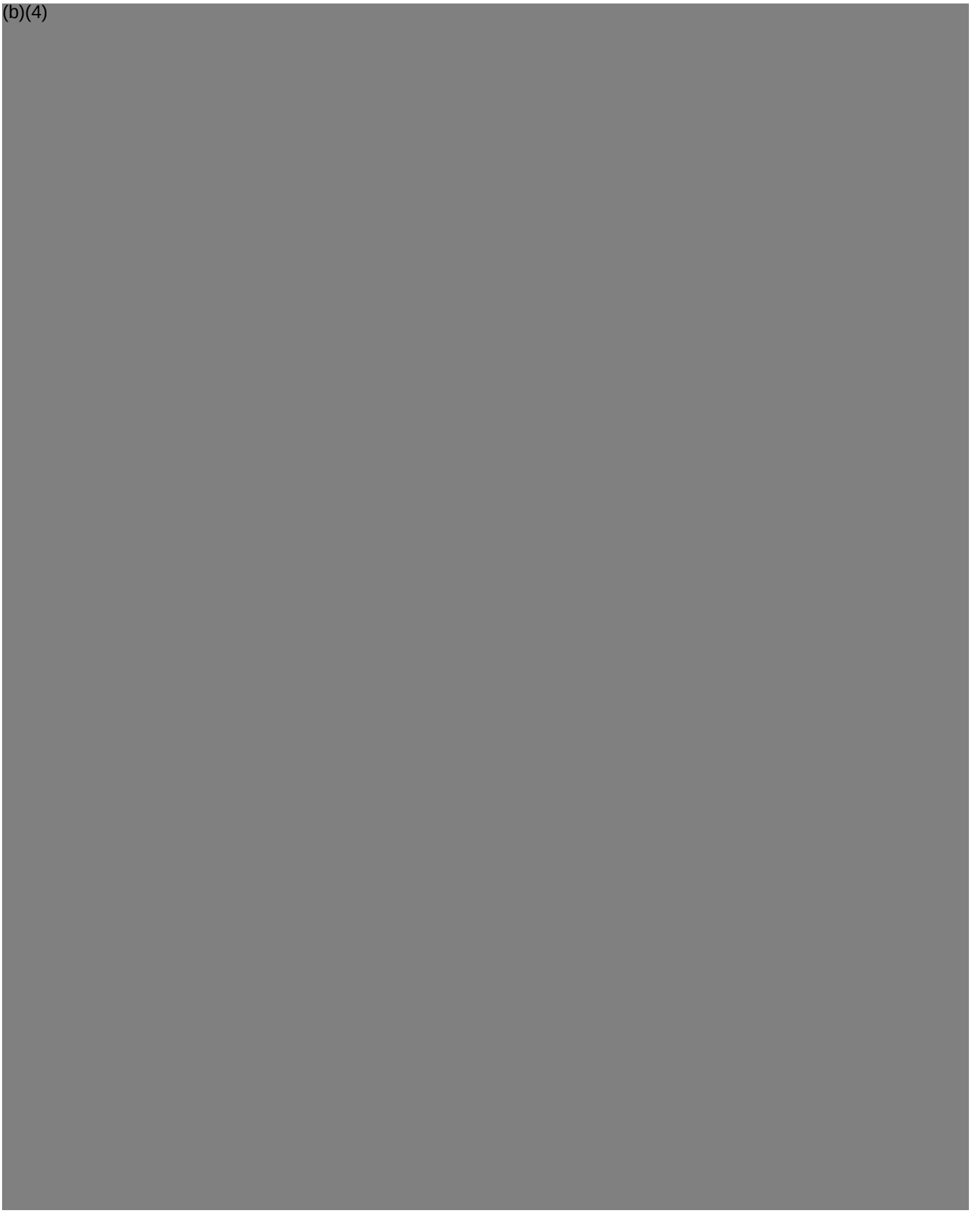

(b)(4)

[redacted]

Reviewer's Comment: *Response Adequate.* (b)(4) [redacted] (b)(4) [redacted] *This is acceptable.*

XVII. Contact History

3/29/2016 A brief phone call was held at the sponsor's request to clarify the deficiencies and discuss their proposed responses to the deficiencies.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Amy K. Levelle -S Digitally signed by Amy K. Levelle -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Amy K. Levelle -S, 0.9.2342.19200300.100.1.1=2000378253 Date: 2016.05.16 19:21:04 -04'00'