U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K134031 - 1417 pages
COMPANY:	BOSTON SCIENTIFIC CORPORATION (BOSTSCIEE)
PRODUCT:	CATHETERS, TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS (LOX)
SUMMARY:	Product: THREADER MONORAIL MICRO-DILATATION CATHETER, THREADER OVER-THE-WIRE MI
DATE REQUESTED:	Mar 22, 2016
DATE PRINTED:	Mar 22, 2016
Note:	Printed

K134031

JUN 2 1 2014

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Cardiovascular Division One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222		
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-494-1522 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com		
Date Prepared	January 27, 2014		
Proprietary Name(s)	Threader™ Monorail™ Micro-Dilatation Catheter Threader™ Over-The-Wire Micro-Dilatation Catheter		
Common Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter		
Product Code	LOX		
Classification	Class II, 21 CFR Part 870.5100		
Predicate Devices	Emerge™ PTCA Dilatation Catheter (1.20 mm)	K130391	July 10, 2013
	CrossBoss™ Catheter	K102725	May 10, 2011
	Coyote™ PTA Balloon Dilatation Catheter	K111295	May 31, 2011
	Asahi Corsair Microcatheter	K083127	February 3, 2009
Device Description	The Boston Scientific Threader™ Micro-Dilatation Catheter is a sterile, single-use, intravascular medical device. The catheter consists of a shaft with a semi-compliant balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter (1.2 mm) and length (12 mm) at recommended pressures. The Threader™ Micro-Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. There is a single radiopaque marker band located in the center of the balloon body to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance.		
Intended Use of Device	The Threader™ Micro-Dilatation Catheter is intended for dilatation of stenosis in coronary arteries or bypass grafts.		

Indications for Use	The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion. The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another. The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.
Comparison of Technological Characteristics	The Threader™ Micro-Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices: Emerge™ PTCA Dilatation Catheter (1.20 mm), K130391 (cleared July 10, 2013); CrossBoss™ Catheter, K102725 (cleared May 10, 2011); Coyote™ PTA Dilatation Catheter, K111295 (cleared May 31, 2011); and Asahi Corsair Microcatheter, K083127 (cleared February 3, 2009).
Performance Data	The Threader™ Micro-Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. 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 testing and, therefore, these devices may be considered substantially equivalent to the predicate devices. The following biocompatibility and chemical characterization tests were completed on the Threader™ Micro-Dilatation Catheter: Cytotoxicity Sensitization Intracutaneous Reactivity Acute Systemic Toxicity Materials Mediated Pyrogenicity Hemolysis (Direct Contact & Extract) Complement Activation Coagulation In Vitro Hemocompatibility USP Physicochemical The following in-vitro performance tests were completed on the Threader™ Micro-Dilatation Catheter: Effective Length Shaft Inner and Outer Diameter Balloon Crossing Profile Balloon Preparation, Deployment, and Retraction Withdrawal into a Guide Catheter Balloon Rated Burst Pressure Balloon Fatigue (Repeat Inflations) Balloon Compliance Balloon Inflation/Deflation Time Catheter Bond Strength Tip Pull Test Flexibility and Kink Torque Strength Radiopacity Coating Integrity Particulate Evaluation Catheter Body Burst Pressure Contrast Media Flow Rate

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Threader™ Micro-Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.

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

July 21, 2014

Boston Scientific Corporation
Ms. Vicky Hagens
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K134031
Trade/Device Name: Threader Monorail Micro-Dilatation Catheter, Threader Over-the-Wire Micro-Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 16, 2014
Received: June 17, 2014

Dear Ms. Hagens,

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K134031

Device Name: Threader™ Monorail™ Micro-Dilatation Catheter
Threader™ Over-The-Wire Micro-Dilatation Catheter

Indications for Use:

The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

K134031

Boston Scientific

Cardiovascular
One Scimed Place
Maple Grove, MN 55311-1566
763.494.1700 Tel
www.bostonscientific.com

FDA CDRH DMC
DEC 31 2013
Received

December 30, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Notification
Threader™ Micro-Dilatation Catheter

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 Threader™ Micro-Dilatation Catheter. The Threader device is a Class II Standard PTCA Catheter per 21 CFR 870.5100(a)(2). The product code is LOX. The Threader device is not an in vitro diagnostic device (IVD).

The Threader Micro-Dilatation Catheter is a new 1.2 mm diameter x 12 mm length balloon catheter that is based on BSC's Emerge 1.20 mm PTCA Dilatation Catheter (K130391), with changes that reduce the crossing profile and improve deliverability to assist the physician in the treatment of coronary lesions. There have been no prior submissions to FDA for the Threader 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 Threader Micro-Dilatation Catheter 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 807 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
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X

Question	Yes	No
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

A copy of the Acceptance Checklist for Traditional 510(k)s, from the FDA Guidance for Industry and FDA Staff, *Refuse to Accept Policy for 510(k)s*, issued on December 31, 2012, is included at the end of the submission. Notations have been made in the checklist to indicate the submission sections where the requested information may be found.

This notification is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
800-553-5878 (extension 41522)
763-494-2222 (fax)
vicky.hagens@bsci.com

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)

BOSTON SCIENTIFIC CORP
ONE SCIMED PLACE
REGULATORY AFFAIRS - A380
MAPLE GROVE
HENNEPIN
MN 55311-1566
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****5240

2. CONTACT NAME
Vicky Hagens
2.1 E-MAIL ADDRESS
vicky.hagens@bsci.com
2.2 TELEPHONE NUMBER (include Area code)
763-494-2832
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
763-494-2222

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:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] 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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm 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
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[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) Trade Secret

02-Dec-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA
01752

Check No. : (b) (4)

Date
12/05/2013

Account # (b) (4)

FOOD AND DRUG ADMINISTRATION
ATTN GOVERNMENT LOCKBOX 956733
1005 CONVENTION PLAZA
SAINT LOUIS MO 63101

Document	Reference Document	Date	Deductions	Gross Amount
(b) (4)				

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

(b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
12/30/2013	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Boston Scientific Corporation	Establishment Registration Number *(if known)* 2134265		
Division Name *(if applicable)* Interventional Cardiology	Phone Number *(including area code)* (763) 494-1522		
Street Address One Scimed Place	FAX Number *(including area code)* (763) 494-2222		
City Maple Grove	State / Province MN	ZIP/Postal Code 55311	Country USA
Contact Name Vicky L. Hagens			
Contact Title Principal Regulatory Affairs Specialist	Contact E-mail Address vicky hagens@bsci.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	H74939189xx120	**2**	H74939191xx120	3	H749M2000A0	4	H74939185xxxxx
5	H74939186xxxxx	**6**		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K130391	1	Emerge™ PTCA Dilatation Catheter	1	Boston Scientific Corporation
2	K102725	2	CrossBoss™ Catheter	2	Boston Scientific Corporation
3	K111295	3	Coyote™ PTA Balloon Dilatation Catheter	3	Boston Scientific Corporation
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Threader™ Monorail Micro-Dilatation Catheter	1	H7493926912120
2	Threader™ Over-The-Wire Micro-Dilatation Catheter	2	H7493927012120
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
LOX

C.F.R. Section *(if applicable)*
21 CFR Part 870.5100

Device Class

☐ Class I ☒ Class II

☐ Class III ☐ Unclassified

Classification Panel
Cardiovascular Devices

Indications *(from labeling)*

The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name Boston Scientific Corporation		Establishment Registration Number 2134265
Division Name *(if applicable)* Interventional Cardiology		Phone Number *(including area code)* (763) 494-1700
Street Address Two Scimed Place		FAX Number *(including area code)* ( )
City Maple Grove	State / Province MN	ZIP/Postal Code 55311 / Country USA
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )
City	State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )
City	State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					

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Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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Boston Scientific

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December 30, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Notification
Threader™ Micro-Dilatation Catheter

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 Threader™ Micro-Dilatation Catheter. The Threader device is a Class II Standard PTCA Catheter per 21 CFR 870.5100(a)(2). The product code is LOX. The Threader device is not an in vitro diagnostic device (IVD).

The Threader Micro-Dilatation Catheter is a new 1.2 mm diameter x 12 mm length balloon catheter that is based on BSC's Emerge 1.20 mm PTCA Dilatation Catheter (K130391), with changes that reduce the crossing profile and improve deliverability to assist the physician in the treatment of coronary lesions. There have been no prior submissions to FDA for the Threader 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 Threader Micro-Dilatation Catheter 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 807 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
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X

Question	Yes	No
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

A copy of the Acceptance Checklist for Traditional 510(k)s, from the FDA Guidance for Industry and FDA Staff, *Refuse to Accept Policy for 510(k)s*, issued on December 31, 2012, is included at the end of the submission. Notations have been made in the checklist to indicate the submission sections where the requested information may be found.

This notification is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
800-553-5878 (extension 41522)
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Boston Scientific

Threader™ Micro-Dilatation Catheter

Traditional 510(k) Notification

Volume 1 of 3

Submitted by:
Boston Scientific Corporation
One Scimed Place
Maple Grove MN 55311

December 30, 2013

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Section 1 Indications for Use Statement

The Indications for Use Statement follows this page.

Indications for Use

510(k) Number (if known): _____

Device Name: Threader™ Monorail™ Micro-Dilatation Catheter
Threader™ Over-The-Wire Micro-Dilatation Catheter

Indications for Use:

The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 2 510(k) Summary

The 510(k) Summary follows this page.

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Cardiovascular Division One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222		
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-494-1522 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com		
Date Prepared	December 20, 2013		
Proprietary Name(s)	Threader™ Monorail™ Micro-Dilatation Catheter Threader™ Over-The-Wire Micro-Dilatation Catheter		
Common Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter		
Product Code	LOX		
Classification	Class II, 21 CFR Part 870.5100		
Predicate Devices	Emerge™ PTCA Dilatation Catheter (1.20 mm)	K130391	July 10, 2013
	CrossBoss™ Catheter	K102725	May 10, 2011
	Coyote™ PTA Balloon Dilatation Catheter	K111295	May 31, 2011
Device Description	The Boston Scientific Threader™ Micro-Dilatation Catheter is a sterile, single-use, intravascular medical device. The catheter consists of a shaft with a semi-compliant balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter (1.2 mm) and length (12 mm) at recommended pressures. The Threader™ Micro-Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. There is a single radiopaque marker band located in the center of the balloon body to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance.		
Intended Use of Device	The Threader™ Micro-Dilatation Catheter is intended for dilatation of stenosis in coronary arteries or bypass grafts.		

Indications for Use

The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Comparison of Technological Characteristics

The Threader™ Micro-Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate devices: Emerge™ PTCA Dilatation Catheter (1.20 mm), K130391 (cleared July 10, 2013); CrossBoss™ Catheter, K102725 (cleared May 10, 2011); and Coyote™ PTA Dilatation Catheter, K111295 (cleared May 31, 2011).

Performance Data

The Threader™ Micro-Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. 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 testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following biocompatibility and chemical characterization tests were completed on the Threader™ Micro-Dilatation Catheter:

Cytotoxicity	Hemolysis (Direct Contact & Extract)
Sensitization	Complement Activation
Intracutaneous Reactivity	Coagulation
Acute Systemic Toxicity	In Vitro Hemocompatibility
Materials Mediated Pyrogenicity	USP Physicochemical

The following in-vitro performance tests were completed on the Threader™ Micro-Dilatation Catheter:

Effective Length	Catheter Bond Strength
Shaft Inner and Outer Diameter	Tip Pull Test
Balloon Crossing Profile	Flexibility and Kink
Balloon Preparation, Deployment, and Retraction	Torque Strength
Withdrawal into a Guide Catheter	Radiopacity
Balloon Rated Burst Pressure	Coating Integrity
Balloon Fatigue (Repeat Inflations)	Particulate Evaluation
Balloon Compliance	Catheter Body Burst Pressure
Balloon Inflation/Deflation Time	Contrast Media Flow Rate

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Threader™ Micro-Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific predicate devices.

Section 3 Truthful and Accurate Statement

The Truthful and Accurate Statement follows this page.

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 Principal 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 review of the substantial equivalence of this device have been knowingly omitted from this submission.

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Regulatory Affairs
Boston Scientific Corporation

December 27, 2013

Date

Section 4 Class III Summary and Certification

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

Section 5 Financial Certification or Disclosure Statement

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

Section 6 Declarations of Conformity and Summary Reports

This section is not applicable to a Traditional 510(k) submission.

Section 7 Executive Summary

Common or Usual Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter	
Trade Name(s)	Threader™ Monorail™ Micro-Dilatation Catheter Threader™ Over-The-Wire Micro-Dilatation Catheter	
Product Code	LOX	
Classification of Device	PTCA catheters are Class II devices according to 21 CFR 870.5100.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-494-1522 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device. However, this notification has followed the recommendations in the FDA guidance, *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010.	
Establishment Registration Numbers	**Owner / Operator:**	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
	Manufacturing Facilities:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facility:	Boston Scientific – Coventry 8 Industrial Drive Coventry, Rhode Island, 02816
Predicate Devices	Emerge™ PTCA Dilatation Catheter (1.20 mm) K130391 Cleared July 10, 2013 CrossBoss™ Catheter K102725 Cleared May 10, 2011 Coyote™ PTA Balloon Dilatation Catheter K111295 Cleared May 31, 2011	

Section 7 Executive Summary

Intended Use	The Threader Micro-Dilatation Catheter is intended for dilatation of stenosis in coronary arteries or bypass grafts.
Indications for Use	The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion. The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another. The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.
Comparison of Required Technological Characteristics	The Threader Micro-Dilatation Catheter incorporates substantially equivalent device materials and design, fundamental technology, manufacturing processes, sterilization process, and intended use as those featured in the primary predicate device, Emerge PTCA Dilatation Catheter (1.20 mm). CrossBoss Catheter is included as a second predicate to support substantial equivalence of the stainless steel coil construction used in the shaft of the Threader catheter. Coyote PTA Balloon Dilatation Catheter is included as a third predicate because Threader uses the same packaging as Coyote. A more detailed comparison of the device to the predicates is provided in **Section 9, Substantial Equivalence Discussion**.
Summary of Non-Clinical Testing	Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. 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, safety and performance testing, the Threader Micro-Dilatation Catheter is appropriate for the intended uses and is considered to be substantially equivalent to the predicates.

Section 8 Device Description

This section is organized as follows:

Section	Content	Page
8.1	General Description and Product Matrix	8-2
8.2	Device Components	8-3
8.3	Packaging and Labeling Description	8-11

Section 8 Device Description

Section 8.1 General Description and Product Matrix

The Threader Micro-Dilatation Catheters are sterile, single-use, intravascular medical devices used to widen coronary artery blockages.

The catheters consist of a shaft with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The Threader Micro-Dilatation Catheter is offered in both the Monorail (MR) and Over-The-Wire (OTW) platform. Both versions (MR and OTW) incorporate Boston Scientific PowerCoil™ technology, which consists of a polymer-sheathed stainless steel coil.

The Threader Micro-Dilatation Catheter for use in the coronary system will only be available in a balloon diameter of 1.2 mm and a balloon length of 12 mm. The primary predicate for the Threader device is the Emerge 1.20 mm PTCA Dilatation Catheter (K130391, cleared July 10, 2013), which has a balloon diameter of 1.20 mm and is offered in balloon lengths of 8, 12, 15, and 20 mm.

The Threader product numbers (UPNs) are shown in **Table 8-1: Catalog Numbers for Threader Devices**.

Table 8-1: Catalog Numbers for Threader Devices

Product Name and Description	Platform	Balloon Dimensions (mm)		UPN
		Diameter	Length	
Threader MR 1.2 mm x 12 mm	Monorail	1.2	12	H7493926912120
Threader OTW 1.2 mm x 12 mm	Over-The-Wire	1.2	12	H7493927012120

Section 8 Device Description

Section 8.2 Device Components

The Threader Micro-Dilatation Catheter primarily incorporates the same design, materials, operating principles, fundamental scientific technology, manufacturing processes, sterilization process, and intended use as the previously-cleared Emerge 1.20 mm PTCA Dilatation Catheter (K130391). The stainless steel ribbon coil used in Threader to reinforce the shaft is not used in the Emerge predicate, but is similar in construction to the multi-filar stainless steel coil used in the CrossBoss Catheter predicate. As described in **Section 8.3**, the packaging used for Threader is the same as that used in another BSC product, Coyote PTA Dilatation Balloon Catheter.

Diagrams of the Threader MR and OTW Micro-Dilatation Catheters are shown in **Figure 8-1: Threader Monorail (MR) Micro-Dilatation Catheter** and **Figure 8-2: Threader Over-The-Wire (OTW) Micro-Dilatation Catheter**.

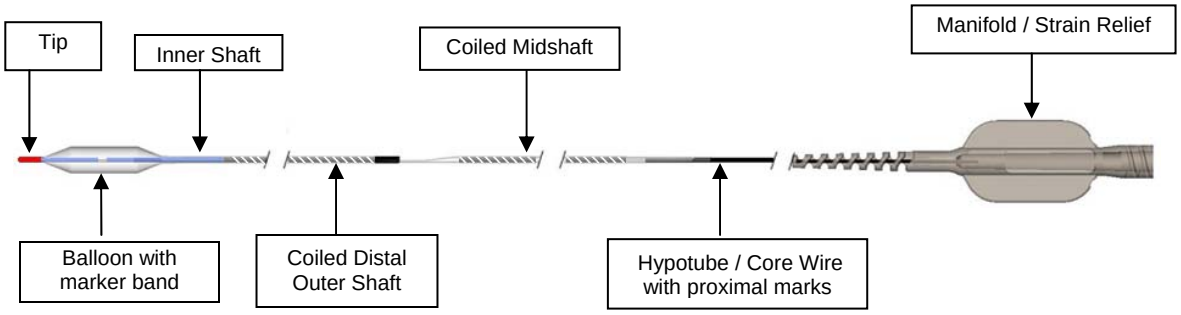


Figure 8-1: Threader Monorail (MR) Micro-Dilatation Catheter

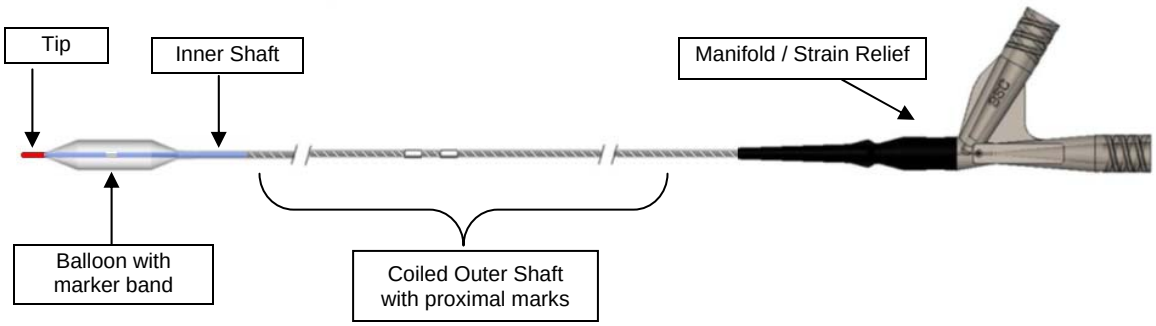


Figure 8-2: Threader Over-The-Wire (OTW) Micro-Dilatation Catheter

Section 8 Device Description

Section 8.2 Device Components

The catheter bond locations on the MR and OTW models are shown in **Figure 8-3: Bond Locations for Threader Monorail (MR)** and **Figure 8-4: Bond Locations for Threader Over-The-Wire (OTW)**.

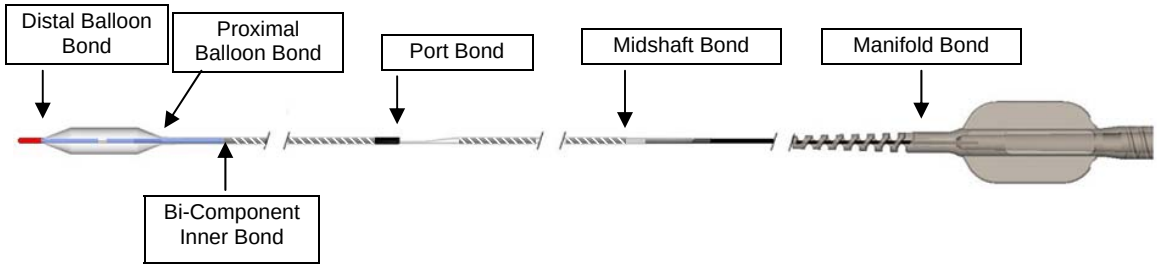


Figure 8-3: Bond Locations for Threader Monorail (MR)

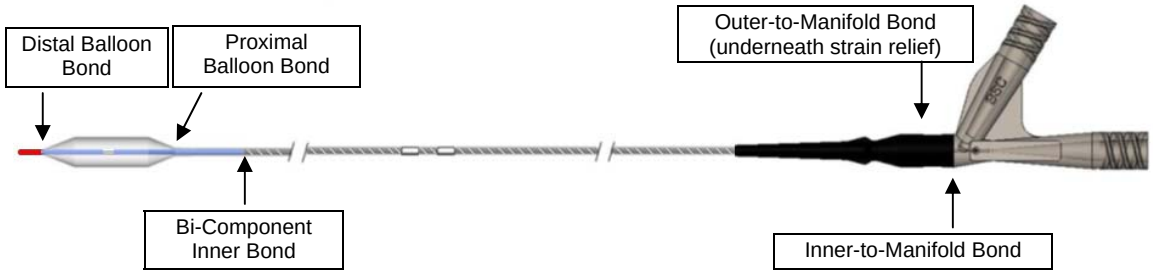


Figure 8-4: Bond Locations for Threader Over-The-Wire (OTW)

Prints for the Threader MR (90897542) and OTW (90897544) catheters are provided in **Appendices 8-A1** and **8-A2**, respectively.

Section 8 Device Description

Section 8.2 Device Components

The Threader Micro-Dilatation Catheters are constructed with the following components:

Table 8-2: Threader MR and OTW Components

Threader MR Components	Threader OTW Components
• Tip • Balloon • Radiopaque marker band • Inner Shaft • Coiled Distal Outer Shaft • Coiled Midshaft • Hypotube • Core Wire • Strain Relief • Manifold	• Tip • Balloon • Radiopaque marker band • Inner Shaft • Coiled Outer Shaft • Strain Relief • Manifold

Common Components in Threader MR and OTW Micro-Dilatation Catheters:
The distal sections of the Threader MR and OTW catheters are identical; therefore, the following components are used in both catheter models:

Tip:
The tip is composed of a (b) (4) polymer which is gradually tapered to facilitate the advancement of the catheter through the stenosis or stent to be dilated. The tapered shape of the tip creates a smooth transition from the guidewire to the balloon. The Threader tip component is identical to the Emerge tip component.

Balloon:
The Threader balloon component is made from an extrusion of (b) (4) material. The Threader balloon is located near the distal tip of the catheter and is designed to provide an inflatable segment of known diameter and length at recommended pressures. Like the Emerge balloon, the Threader balloon material is made from (b) (4) (b) (4)), but the polymer grade used in Threader (b) (4) (b) (4) than the polymer grade used in Emerge (b) (4) Both resins are medical-grade, sourced from the same supplier, and have a history of safe use in BSC medical device balloons.

Radiopaque Marker Band:
A single marker band is centered within the balloon body to facilitate accurate balloon placement under fluoroscopy. The marker band is made of (b) (4), located under the balloon, and is crimped/swaged to the inner shaft. The Threader marker band is made from the same material as the Emerge marker band. To allow for reduced

crossing profile, the dimensions of the Threader marker band are slightly different than Emerge. The cross-sectional inner and outer diameters of the Threader marker band are slightly smaller, while maintaining the same wall thickness. In order to retain overall marker band mass, the length of the Threader marker band is slightly longer.

Inner Shaft:
Both the proximal and distal inner shaft components are extruded in three layers: an inner layer composed of (b) (4) an outer layer composed of (b) (4) and a middle layer (or tie layer) composed of (b) (4)

The extruded inner components (proximal and distal) used in Threader are equivalent to those used in Emerge, but the distal inner is (b) (4) and undergoes (b) (4)

With the exception of (b) (4) the inner shafts used for Threader OTW and Threader MR catheters are identical. MR catheters have (b) (4) (b) (4). On OTW catheters, the (b) (4)

Threader MR-Specific Components:
The following components are used only in the Monorail catheter model:

Coiled Distal Outer Shaft:
The proximal portion of the distal outer shaft consists of a stainless steel coil covered with a (b) (4) The distal portion of the distal outer shaft does not contain the coil, so that it can be necked to a smaller diameter and wall thickness to be bonded to the balloon. The proximal end of the distal outer shaft overlaps the midshaft and helps to form the port weld. The Threader coiled distal outer shaft is different from the Emerge distal outer shaft, which is (b) (4) Additional information on the Threader coiled distal outer shaft is provided in **Section 9**.

Coiled Midshaft:
The midshaft consists of a stainless steel coil covered with (b) (4) The proximal end of the midshaft is bonded to the hypotube. The coiled midshaft provides a continuation of the inflation lumen, joining the hypotube to the distal catheter sections (inner and outer) through the port weld. The Threader coiled midshaft is different from the Emerge midshaft, which is (b) (4) tube. Additional information on the Threader coiled midshaft is provided in **Section 9**.

Hypotube / Core Wire (with Proximal Marks):
The proximal end of the Threader catheter is a single-lumen, (b) (4) hypotube, (b) (4) The hypotube serves as an inflation lumen connecting the manifold to the midshaft. Proximal marks on the hypotube indicate the exit of the balloon catheter tip out of the guide catheter (one narrow proximal mark at 90 cm and one wider proximal mark at 100 cm). To provide kink resistance at the transition from the hypotube to the coiled midshaft, a (b) (4) core wire is welded to the

hypotube and extends through the midshaft tube into the distal tube section. In addition, the core wire provides kink resistance and support to the port weld. The Threader hypotube/core wire assembly has slightly different dimensions, but uses the same materials and welding technology as the Emerge hypotube/core wire assembly.

Strain Relief / Manifold:
The MR manifold has a single connection port allowing access to the catheter's inflation/deflation lumen. The manifold has several areas for printing key catheter information such as model name, size and lot number. (b) (4) . The Threader MR manifold is the same as the Emerge MR manifold.

Threader OTW-Specific Components:
The following components are used only in the Over-The-Wire catheter model:

Coiled Outer Shaft (with Proximal Marks):
The proximal portion of the coiled outer shaft consists of a stainless steel coil covered with (b) (4) The distal portion of the shaft does not contain the coil, so that it can be necked to a smaller diameter and wall thickness to be bonded to the balloon. Proximal marks on the shaft indicate the exit of the balloon catheter tip out of the guide catheter (one proximal mark at 90 cm and two proximal marks at 100 cm). The sheath overlaps the coil on the proximal end of the shaft to form a bond with the manifold. The Threader coiled outer shaft is different from the Emerge (b) (4) outer shaft, which is an extruded polymer tube made of (b) (4) (b) (4) Additional information on the Threader coiled distal outer shaft is provided in **Section 9**.

Strain Relief / Manifold:
The OTW manifold is a dual-port manifold, with one port that allows for connection to an inflation device, and another for insertion of a guidewire. The manifold has two areas for printing key catheter information such as model name, size and lot number. The strain relief, in addition to providing a gradual stiffness transition from the manifold to the proximal shaft, has a raised bump that provides an interference fit with the carrier tube in which the catheter is packaged, thus keeping the device in place during shipping and handling. The Threader OTW manifold is the same as the Emerge OTW manifold.

Threader MR and OTW Catheter Bonds:
The Threader catheter bonds (distal balloon, proximal balloon, bi-component inner, port, midshaft, and manifold, as described below) are similar to those of the predicate Emerge catheter. The components are overlapped and bonded in the same way using the same methods, but with some differences in dimensions and materials.

Distal Balloon Bond:
The distal bond is composed of a balloon-to-inner bond and tip-to-inner bond. The balloon-to-inner bond overlaps the distal balloon waist and the distal inner shaft. The tip-to-inner bond overlaps the tip and distal inner shaft components.

Section 8 Device Description

Section 8.2 Device Components

Proximal Balloon Bond:
The proximal balloon bond is formed by (b) (4) the overlapped region of the proximal balloon waist and the distal end of the MR coiled distal outer shaft or the OTW coiled outer shaft components.

Bi-Component Inner Bond:
The bi-component inner bond is formed by putting the distal inner and the proximal inner end-to-end (no overlap). A (b) (4) is then placed over the butt joint creating an overlap with both inner components. Heat is then applied to the overlap region (b) (4)

Port Bond (MR only):
The port bond is the bond between the inner shaft, the coiled midshaft, and the coiled distal outer. The inner shaft is placed within the distal outer to create a coaxial lumen with a port designed for guidewire access at the proximal end. The components of the port bond are shown in **Figure 8-5: Threader MR Port Bond**. The port bond is formed (b) (4) the outer component (blue), the proximal section of the inner component (green) and midshaft (black) together. See **Figure 8-6: Cross Section of the Threader MR Port Bond** for a cross section of the port bond.

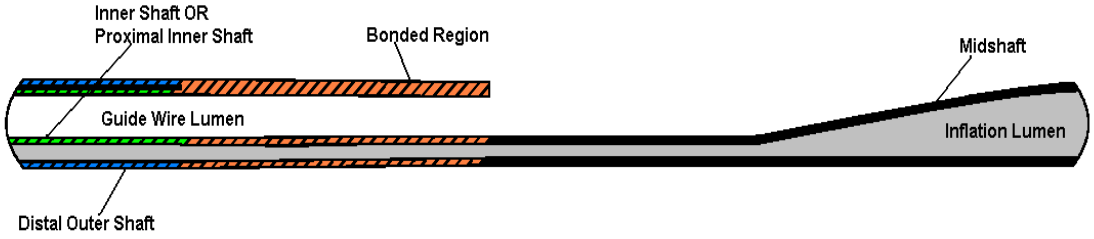


Figure 8-5: Threader MR Port Bond

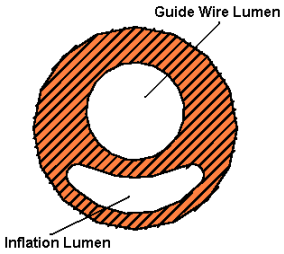


Figure 8-6: Cross Section of the Threader MR Port Bond

Section 8 Device Description

Section 8.2 Device Components

Midshaft Bond (MR only):
The midshaft bond is formed by (b) (4) to the overlap of the proximal end of the midshaft tube and the distal end of the hypotube. This overlap region (b) (4) .

Manifold Bond (MR only):
The MR manifold bond is formed when the manifold is (b) (4) onto the proximal end of the hypotube.

Inner/Outer to Manifold Bond (OTW only):
The OTW manifold bond is composed of a proximal inner-to-manifold bond and a proximal outer-to-manifold bond. The bonds are formed by establishing an overlap between the proximal inner shaft and the manifold, as well as the sheath of the outer shaft and the manifold, and (b) (4)

Threader Coatings:
Threader catheters are coated with hydrophilic and hydrophobic coatings to enhance the deliverability of the catheter in challenging clinical scenarios. These are the same coatings used in the Emerge predicate device. The only difference is in the length of the coatings.

Shaft Coating - ZGlide:
Threader catheters are coated with a hydrophilic coating (ZGlide) on the distal portion of the catheter shaft. Approximately 18 cm of the MR shaft and 58 cm of the OTW shaft is coated with ZGlide. The remainder of the shaft (approximately 130 cm for MR and 90 cm for OTW) is uncoated.

The purpose of the hydrophilic ZGlide coating is to facilitate deliverability, as the hydrophilic coating makes the catheter slippery when hydrated.

Balloon Coating – ZGlide and Xtra:
Threader balloons are coated with a hydrophobic coating (Xtra) in addition to the hydrophilic coating (ZGlide). The ZGlide is applied and cured first, followed by the Xtra. The Xtra coating covers the balloon and extends about (b) (4) onto the shaft.

The second coating, Xtra, is a (b) (4) that is used on the balloons, on top of the ZGlide. (b) (4)

(b) (4)

Section 8 Device Description

Section 8.2 Device Components

(b) (4) is evaluated as part of the coating integrity and particulates testing, and it is also evaluated during balloon burst testing. Results from testing of these properties are provided in **Section 15, Performance Testing – Bench**.

Section 8 Device Description

Section 8.3 Packaging and Labeling Description

The Threader Micro-Dilatation Catheters use the same packaging as the Coyote PTA Balloon Dilatation Catheters (K111295, cleared May 31, 2011). The packaging configuration for Threader is a single barrier package, intended to protect the device through ethylene oxide (EO) sterilization, distribution, handling and storage, and to maintain a sterile barrier throughout the product shelf life. The packaging used for Coyote and Threader has been tested to support a shelf life up to 37 months (see **Section 15.5**). The planned shelf life for Threader is 2 years (see **Section 11**).

Each individual Threader catheter has a product mandrel inserted into the inner lumen of the distal end of the device and a balloon protector over the balloon. It is loaded into a polymeric protective carrier tube which is coiled and held in shape by a series of carrier tube clips. For the Monorail device, a single CLIP-IT clip is attached to one of the carrier tube clips. The Threader device is secured within the carrier tube by means of a design feature of the device manifold/strain relief. The coiled tube containing the catheter is placed inside a pouch composed of (b) (4) A compliance chart is also placed inside the pouch, and then the pouch is heat sealed. The pouch assembly, along with the DFU (directions for use) booklet is placed in a shelf carton. Each pouch assembly and shelf carton is labeled with content identification and traceability information. The product configuration is single-pack (one product per package) and facilitates easy storage and transport. The individually-boxed shelf cartons are inserted into shipping containers and sterilized by EO and then shipped to BSC distribution centers. All devices are provided non-pyrogenic and sterile and are intended for one procedure use only.

Table 8-3: Threader Packaging Components lists all of the Threader packaging components (along with print or part numbers), and describes the function of each component. Each component is assigned a number (in column 'No.') that corresponds to a numbered component on the Threader device print provided in **Appendix 8-A1** (MR) or **Appendix 8-A2** (OTW), or on the packaging configuration drawings provided in **Appendix 8-A3** (MR) or **Appendix 8-A4** (OTW).

Section 8 Device Description

Section 8.3 Packaging and Labeling Description

Table 8-3: Threader Packaging Components

Packaging Component	Print/Part Number	Function	No.
See Threader prints for numbered components (**Appendices 8-A1** and **A2**)			
Product Mandrel	(b) (4) (b) (4)	The product mandrel fits the inner lumen of the distal end of the device. The mandrel maintains the inner diameter of the inner lumen and prevents kinking of the distal end of the catheter during manufacturing, shipping and handling.	**A1** -16 **A2** -15
Balloon Protector	(b) (4)	The balloon protector covers the device balloon and provides protection to the balloon during shipping and handling (b) (4)	**A1** -15 **A2** -14
See Threader packaging configuration drawings for numbered components (**Appendices 8-A3** and **A4**)			
Carrier Tube Clips	(b) (4)	The carrier tube clips are (b) (4) clips used to retain the carrier tube in a flat coiled form.	**A3** -15 **A4** -15
Carrier Tube	(b) (4)	The carrier tube is a section of (b) (4) tubing coiled into a flat spiral. This tubing encloses and protects the device during shipping and handling.	**A3** -16 **A4** -16
CLIP-IT Clip	(b) (4)	One CLIP-IT clip is attached directly to a modified carrier tube clip (Monorail only).	**A3** -17
Compliance Chart Label	(b) (4)	The compliance chart label is a paper reference label used primarily to provide balloon sizing and growth information at the point of device use. Removing the liner from the back of the chart exposes a pressure-sensitive adhesive that allows the chart to be placed at a location convenient to the physician. The compliance chart label is contained within the sealed pouch (sterile barrier assembly).	**A3** -19 **A4** -19

Section 8 Device Description

Section 8.3 Packaging and Labeling Description

Packaging Component	Print/Part Number	Function	No.
Pouch	(b) (4)	The pouch is constructed (b) (4) providing a sterile barrier that ensures the sterility of the contents through distribution and shelf life. The (b) (4) allows for sterilant gasses to pass into the pouch to sterilize the contents and then be flushed back out again.	**A3** -20 **A4** -20
Pouch Labels	(b) (4)	The pouch label is a paper label that is applied to the poly side of the pouch and provides critical product information (i.e., name, device size, product description, contents, catalog number, use-by date, lot number, etc.). See **Section 10** for labeling information.	**A3** -21 **A4** -21
Shelf Carton	(b) (4)	The shelf carton enhances product appearance and identification, facilitates shelf storage of the product, and provides product protection during shipping and handling.	**A3** -22 **A4** -22
Carton Label	(b) (4)	The carton label is a paper label that is applied to the carton and provides critical product information (i.e., name, device size, product description, contents, catalog number, use-by date, lot number, etc.). The printed label also includes peelable sections carrying product specific information in addition to a scannable primary barcode. The carton label is a 3-sided label that wraps around and secures the bottom tuck-flap/end panel of the carton. See **Section 10** for labeling information.	**A3** -23 **A4** -23

Section 8 Device Description

Section 8.3 Packaging and Labeling Description

Packaging Component	Print/Part Number	Function	No.
Directions for Use (DFU)	(b) (4)	The DFU is a paper manual (booklet) that details all critical product information (i.e., device description, intended use, indications for use, contraindications, warnings and precautions, adverse events, etc.). See **Section 10** for DFU content.	**A3** -24 **A4** -24
Closure Strip	(b) (4)	The closure strip is applied at one end of the shelf carton; the other end is sealed by the shelf carton label.	**A3** -25 **A4** -25
Shipping container	(b) (4)	Shelf carton assemblies are contained in a corrugated Regular Slotted Container (RSC). The shipping container facilitates shipment of the product and provides product protection during shipping and handling.	**A3** -26 **A4** -26

The DFU, carton labeling, and pouch labeling are located in **Section 10, Labeling**. The packaging components are shown in the engineering drawings in **Appendices 8-A1** and **8-A2** and in packaging configuration drawings in **Appendices 8-A3** and **8-A4.**

Appendix 8 Device Description

The following documents are included in this Appendix:

Appendix	Title
8-A1	Threader MR Device Print (90897542)
8-A2	Threader OTW Device Print (90897544)
8-A3	Threader MR Packaging Configuration Drawing (90897547)
8-A4	Threader OTW Packaging Configuration Drawing (90897549)

(b)(4) Design

(b)(4) Design

(b)(4) Design

(b)(4) Design

(b)(4) Design

(b)(4) Design

Section 9 Substantial Equivalence Discussion

Substantial Equivalence Statement

There are three BSC predicate devices used to support the substantial equivalence of the new Threader Micro-Dilatation Catheter:

Device Name	510(k) Number	Date Cleared
Emerge PTCA Dilatation Catheter (1.20 mm)	K130391	July 10, 2013
CrossBoss Catheter	K102725	May 10, 2011
Coyote PTA Balloon Dilatation Catheter	K111295	May 31, 2011

Threader is based on the Emerge 1.20 mm catheter, with changes that reduce the crossing profile and improve deliverability to assist the physician in the treatment of coronary lesions. Threader and Emerge have many attributes in common, and Emerge is the primary predicate for Threader. The other two predicates are used for very specific attributes in which Threader is different from Emerge. CrossBoss is used as a predicate for the coiled shaft construction and Coyote is used as a predicate for packaging components. For these reasons, CrossBoss and Coyote are not included in the main comparison tables in this section. Instead, they are included in two tables at the end of the section that cover those specific attributes.

The Threader Micro-Dilatation Catheter has substantially equivalent intended use and indications for use as the Emerge 1.20 mm PTCA Dilatation Catheter (K130391, cleared July 10, 2013). **Table 9-1** compares the intended uses and indications for use of Emerge and Threader.

Section 9 Substantial Equivalence Discussion

Table 9-1: Substantial Equivalence Comparison – Intended Use and Indications for Use

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Proposed Device Threader	Comment
Device Name	Emerge PTCA Dilatation Catheter	Threader Micro-Dilatation Catheter	New trade name; updated generic name emphasizing the availability of a single small (1.2 mm) device diameter.
Common Name	Standard PTCA Catheter	Standard PTCA Catheter	Same
Regulation Number	21 CFR 870.5100	21 CFR 870.5100	Same
Product Code	LOX	LOX	Same
Intended Use	Emerge is intended for dilatation of stenosis in coronary arteries or bypass grafts.	Threader is intended for dilatation of stenosis in coronary arteries or bypass grafts.	Same
Intended Use/ Indications for Use Statements on DFU	The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).	The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion. The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another. The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.	Same as Emerge indication statement, reworded for clarity. Expanded indication statement, supported by animal study data (see **Section 16**). Expanded indication statement, supported by bench data (**Section 15**) and animal study data (**Section 16**).

Section 9 Substantial Equivalence Discussion

The Threader Micro-Dilatation Catheter has substantially equivalent technological characteristics as the Emerge 1.20 mm PTCA Dilatation Catheter (K130391, cleared July 10, 2013). **Table 9-2** summarizes the substantial equivalence of the Threader catheter design to the Emerge catheter, and describes the specific attributes for which the CrossBoss and Coyote predicates are used.

Table 9-2: Substantial Equivalence Comparison – Catheter Design

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Proposed Device Threader	Comment
Guide Catheter Compatibility	MR: 5 F (0.056 in./1.42 mm) OTW: 6 F (0.066 in./1.68 mm)	MR: 5 F (0.056 in./1.42 mm) OTW: 6 F (0.066 in./1.68 mm)	Same
Guidewire Compatibility	MR: 0.014 in. (0.36 mm) OTW: 0.014 in. (0.36 mm)	MR: 0.014 in. (0.36 mm) OTW: 0.014 in. (0.36 mm)	Same
Shaft Flexibility	Standard and “Push”	Standard	Threader is only available in the Standard shaft design.
Effective Length	MR: 144 cm OTW: 143 cm	MR: 150 cm OTW: 150 cm	Threader length is slightly longer than Emerge, to allow clinician to reach narrow distal lesions.
Nominal Balloon Diameters	1.20 mm	1.2 mm	Same
Balloon Lengths	8, 12, 15 and 20 mm	12 mm	Threader is only available in one balloon length.
Nominal Balloon Pressure	6 atm	6 atm	Same
Rated Burst Pressure (RBP)	18 atm	14 atm	Threader RBP is lower (b) (4)
Bumper Tip Material	(b) (4) (Color: Red)	(b) (4) (Color: Red)	Same
Product Mandrel	(b) (4)	(b) (4)	Same
Balloon Material	(b) (4)	(b) (4)	(b) (4) both are medical grade, from same supplier: (b) (4)
Balloon Protector	(b) (4) (Color: Blue)	(b) (4) (Color: Blue)	Same

Section 9 Substantial Equivalence Discussion

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Proposed Device Threader	Comment
Marker Band	(b) (4) marker band	(b) (4) marker band	Same material; slightly different dimensions (see **Section 16.2**).
Inner Shaft Materials (MR and OTW)	Distal Inner Portion (Standard): Inner layer: (b) (4) Middle layer: (b) (4) Outer layer: (b) (4) Proximal Inner Segment (Standard): Inner layer (b) (4) Middle layer: (b) (4) Outer layer: (b) (4)	Distal Inner Portion: Inner layer: (b) (4) Middle layer: (b) (4) Outer layer: (b) (4) Proximal Inner Segment: Inner layer (b) (4) Middle layer: (b) (4) Outer layer: (b) (4)	Threader is the same as Emerge 1.20 Standard.
Bi-Component Inner Welding Sleeve	(b) (4)	(b) (4)	Same
Distal Outer Shaft (MR)	(b) (4)	Stainless steel coil (b) (4)	Threader has stainless steel coil-reinforced shaft constructions that are different from the Emerge shafts, but are similar in construction to the CrossBoss shaft, K102725 (see **Catheter Shaft Construction** section below). The Threader sheath materials (the exposed surfaces) are the same as the corresponding shaft materials used in the Emerge predicate.
Midshaft (MR)	(b) (4)	Stainless steel coil (b) (4)	
Outer Shaft (OTW)	(b) (4)	Stainless steel coil (b) (4)	
Core Wire (MR)	(b) (4)	(b) (4)	Same
Hypotube Material (MR)	(b) (4)	(b) (4)	Same
Proximal Marks (MR)	(b) (4)	(b) (4)	Same
Proximal Marks (OTW)			Same

Section 9 Substantial Equivalence Discussion

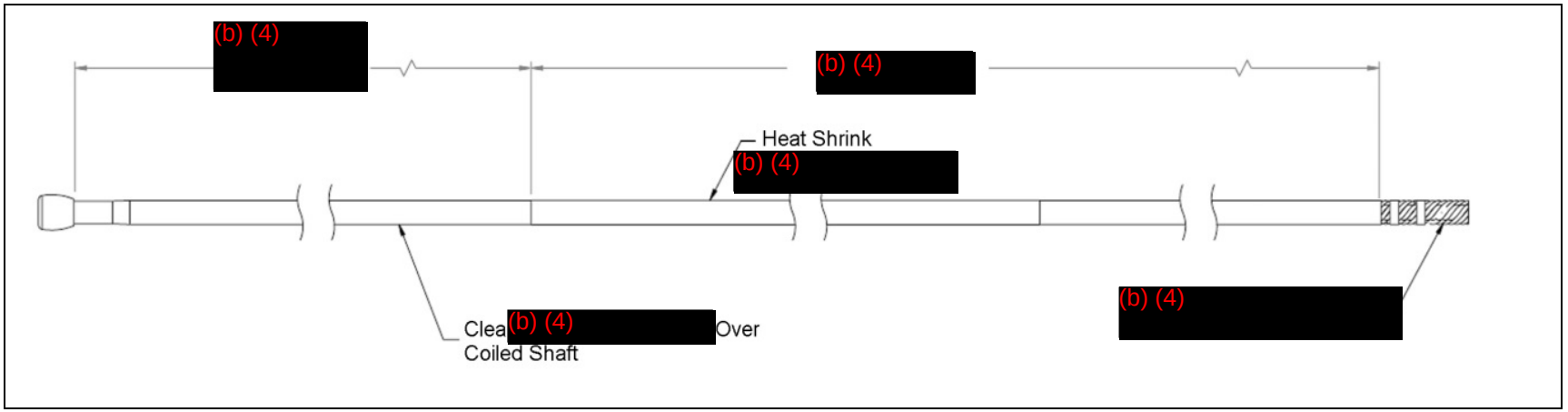
Attribute	Predicate Device Emerge 1.20 mm (K130391)	Proposed Device Threader	Comment
Manifold (MR)	(b) (4)	(b) (4)	Same
Strain Relief (OTW)			Same
Manifold (OTW)			Same
Adhesive (MR Midshaft Bond)			Same
Adhesive (OTW Manifold Bond)			Same
Hydrophilic Coating	ZGlide	ZGlide	Same
Hydrophobic Coating	Xtra (silicone)	Xtra (silicone)	Same
Hydrophilic (ZGlide) Coating Length (tip, balloon & shaft)	MR coating length: (b) (4) OTW coating length: (b) (4)	MR coating length: 20 cm OTW coating length: 60 cm	Threader OTW has a longer ZGlide coating length than Emerge.
Balloon Coating Configuration	ZGlide + Xtra	ZGlide + Xtra	Same
Balloon Folding	(b) (4)	(b) (4)	Same
Packaging	Single-pack (one product per package) Sterile Barrier Pouch: (b) (4) Shelf carton contains one pouch	Single-pack (one product per package) Sterile Barrier Pouch: (b) (4) Shelf carton contains one pouch	Threader uses the same general configuration as Emerge; the Threader pouch and carton are the same as those used for Coyote, K111295 (see **Table 9-4**).
Shelf Life	Monorail: 32 months Over-The-Wire: 24 months	Monorail: 24 months Over-The-Wire: 24 months	After successful completion of accelerated aging tests, Threader (MR and OTW) will have the same shelf life as Emerge OTW (see **Section 11** and **Section 15.4**).
Biocompatibility	All biocompatibility testing has been completed.	All biocompatibility testing has been completed.	See **Section 12** for test results.
Sterilization Method	100% ethylene oxide (b) (4)	100% ethylene oxide (b) (4)	Same

Section 9 Substantial Equivalence Discussion

Catheter Shaft Construction

The Threader device incorporates a shaft construction containing a stainless steel coil, similar to the construction of the CrossBoss shaft. The CrossBoss Catheter is a percutaneous catheter intended to be used in conjunction with a guidewire in order to access discrete regions of the coronary or peripheral vasculature. CrossBoss is constructed of a (b) (4) stainless steel shaft, covered with (b) (4). The (b) (4) stainless steel shaft is designed to achieve the optimal balance between torque and push. A schematic of the CrossBoss Catheter shaft is shown in **Figure 9-1**.

Figure 9-1: CrossBoss Catheter Shaft



The coiled stainless steel shaft of the Threader device is designed to maximize force transmission and kink resistance, while minimizing the device cross sectional area. A schematic of the Threader Monorail catheter is shown in **Figure 9-2**. The Monorail catheter has two different coiled shaft regions, the coiled distal outer shaft on the left (b) (4) and the coiled midshaft on the right (b) (4). A schematic of the Threader Over-The-Wire catheter is shown in **Figure 9-3**. The Over-The-Wire catheter has one coiled shaft region, the coiled outer shaft (b) (4)

Figure 9-2: Threader Monorail Catheter

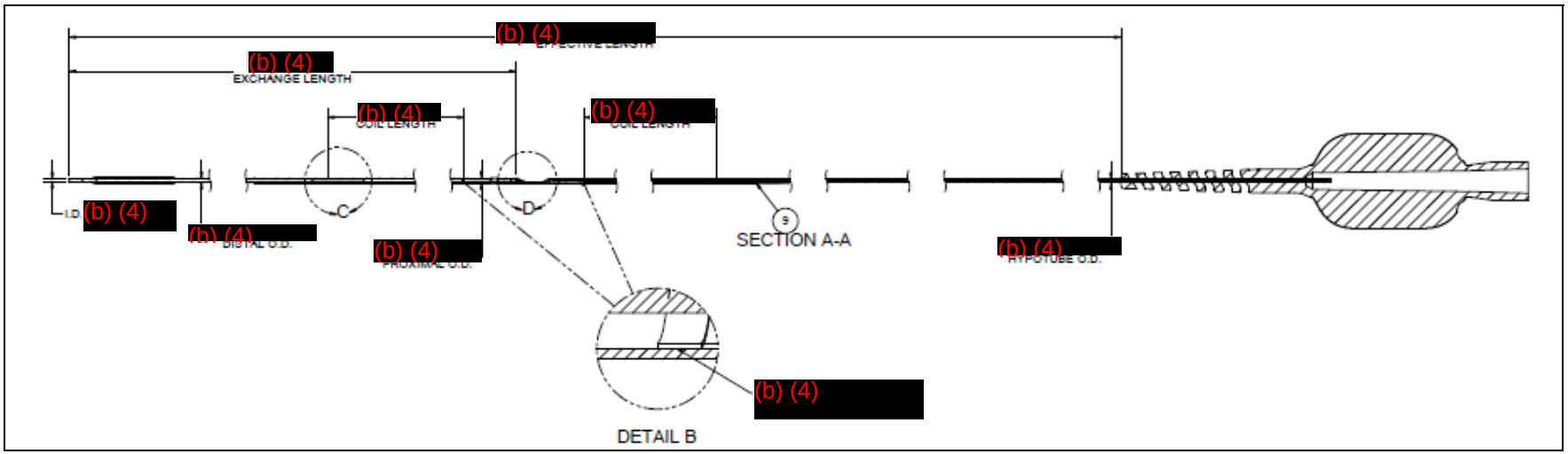
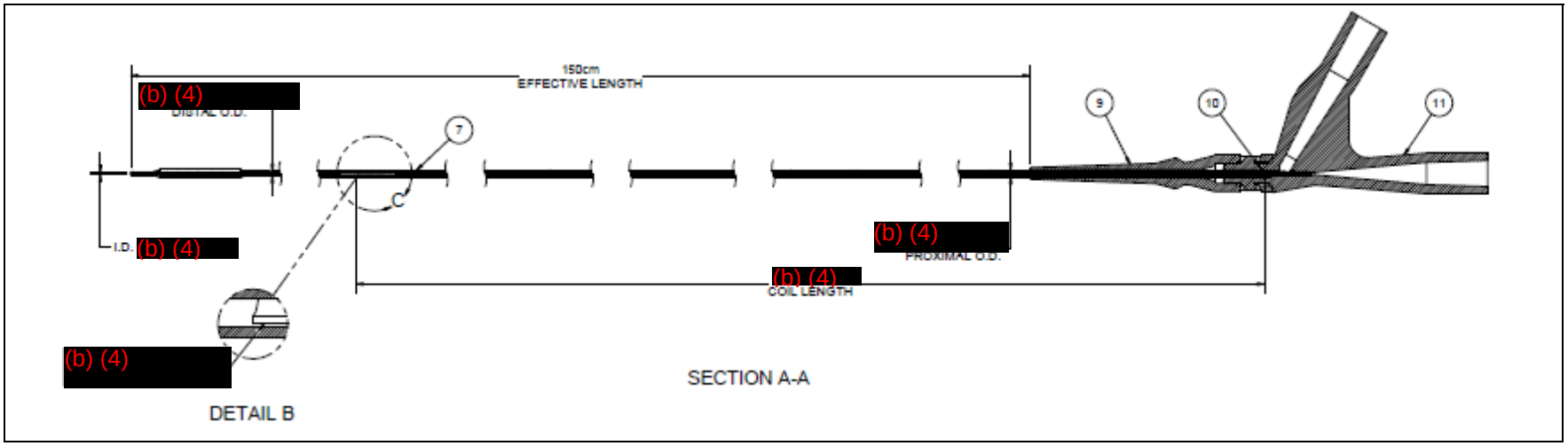


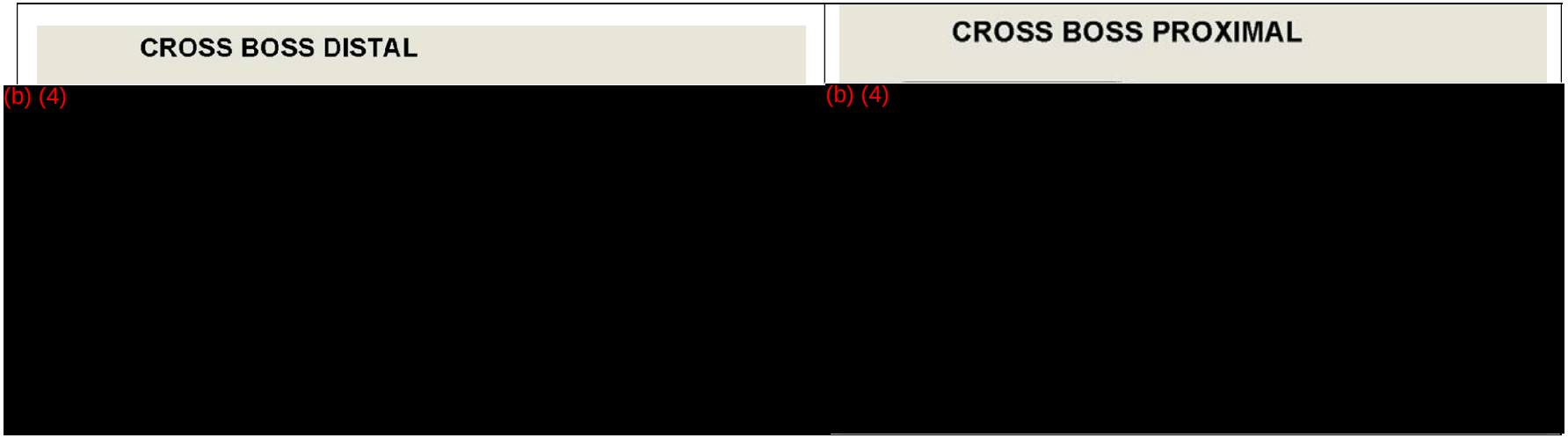
Figure 9-3: Threader Over-The-Wire Catheter



Section 9 Substantial Equivalence Discussion

Schematics of the distal and proximal CrossBoss catheter cross sections are shown in **Figure 9-4**, showing the stainless steel coil materia(b) (4)), the sheath materials (b) (4) , and the cross section dimensions. The outer surface of the CrossBoss coil is covered by a polymer sheath. The inner surface of the CrossBoss coil rides on the guidewire and is a blood-contacting surface.

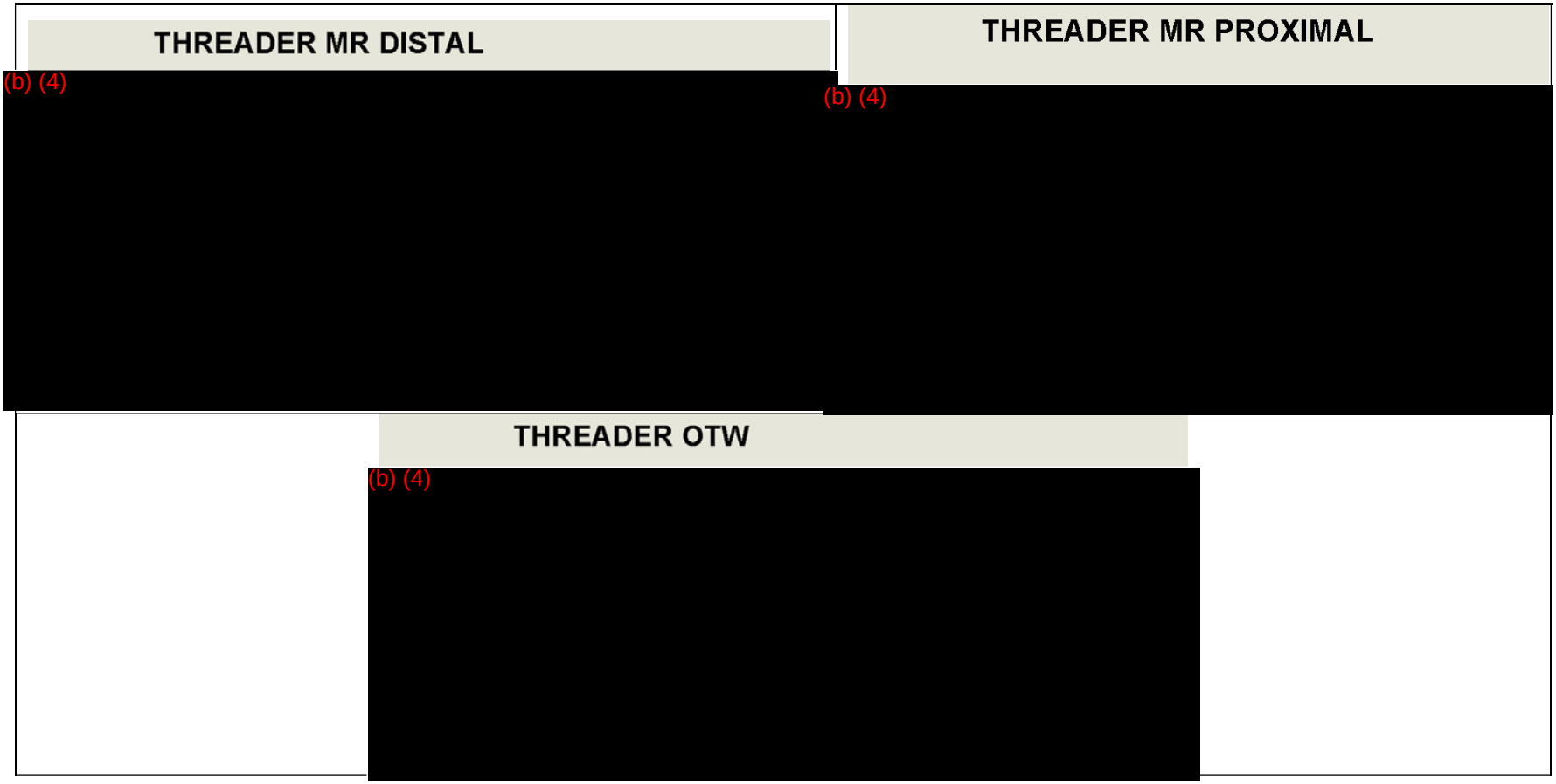
Figure 9-4: CrossBoss Coiled Shaft Cross Sections



Section 9 Substantial Equivalence Discussion

Schematics of the Threader catheter cross sections are shown in **Figure 9-5**, showing the stainless steel coil material (b) (4) the sheath materials (b) (4), the inner materials (b) (4), and the cross section dimensions. The outer surface of the Threader coil is covered by a polymer sheath. The inner surface of the Threader coil is protected by the proximal and distal inner shaft. The Threader stainless steel coil does not have any patient contact.

Figure 9-5: Threader Coiled Shaft Cross Sections



Section 9 Substantial Equivalence Discussion

Table 9-3 summarizes the substantial equivalence of the Threader coil shaft construction to the CrossBoss coil shaft construction.

Table 9-3: Substantial Equivalence Comparison – Coil Shaft Construction

Attribute	Predicate Device CrossBoss (K102725)	Proposed Device Threader	Comment
Guidewire Compatibility	0.014 in. (0.36 mm)	0.014 in. (0.36 mm)	Same
Catheter Length	135 cm (working length)	150 cm (effective length)	Catheter lengths are similar.
Stainless Steel Coil Dimensions	(b) (4)		Coil dimensions are similar. The differences are appropriate for the different devices.
Coil Material	Stainless steel coil (b) (4)	Stainless steel coil (b) (4)	Both are stainless steel. The difference between the (b) (4) is of minor significance since the stainless steel coil is covered with a polymer sheath.
Polymer Sheath Material (outer surface of coil)	(b) (4)	(b) (4)	Different polymers are used, as appropriate for the different devices. The Threader sheath materials are the same as the corresponding shaft materials used in the Emerge predicate.
Inner Polymer Material (inner surface of coil)	None (coil is blood-contacting)	(b) (4) outer layer of proximal inner shaft) (b) (4) (outer layer of distal inner shaft) (coil is not blood-contacting)	For Threader, the inner surface of the stainless steel coil is protected by the tri-layer inner shaft component.

Section 9 Substantial Equivalence Discussion

Threader Packaging Design

Threader uses the same packaging components as the Coyote predicate (K111295). A summary of the Threader and Coyote packaging design attributes is provided in **Table 9-4**.

Table 9-4: Substantial Equivalence Comparison – Packaging Design

Attribute	Predicate Device Coyote (K111295)	Proposed Device Threader	Comment
Pouch Material	(b) (4) [redacted]		Same
Pouch Dimensions			Same
Carton Material			Same
Carton Dimensions			Same

Summary of Changes

The Threader device is different from the primary predicate, Emerge 1.20 mm PTCA Dilatation Catheter, in the following ways:

- Expanded indication statements, supported by test data in **Section 15** and **Section 16**.
- Stainless steel coil technology, substantially equivalent to stainless steel coil in CrossBoss.
- Packaging components (pouch, carton), identical to those used for Coyote.

Substantial Equivalence Conclusion

The proposed device (Threader Micro-Dilatation Catheter) is substantially equivalent to the predicate devices (Emerge 1.20 mm PTCA Dilatation Catheter, K130391, cleared July 10, 2013; CrossBoss Catheter, K102725, cleared May 10, 2011; Coyote PTA Balloon Dilatation Catheter, K111295, cleared May 31, 2011) in its technological characteristics, intended use, indications, materials, manufacturing processes, packaging, sterilization method, and general specifications. The differences between Threader and its predicates do not raise any new questions of safety and effectiveness, as demonstrated by the successful completion of testing in **Section 15** and **Section 16**.

Section 10 Labeling

The labeling, including the Directions for Use (DFU), provides a clear and concise means of communicating product information to the customer. The labeling for the Threader Micro-Dilatation Catheter includes the following components:

- Pouch Label
- Pre-printed Pouch Graphics
- Shelf Carton Label
- Pre-printed Shelf Carton Graphics
- Compliance Chart Label
- Directions for Use (DFU)

Copies of Threader labeling are provided in **Appendix 10**.

Pouch and shelf carton labels for the devices are provided in **Appendices 10-A1** and **10-A3**, respectively. These labels are representative of the content and layout for the proposed commercial devices. The pre-printed graphics for the pouch and shelf carton are provided in **Appendices 10-A2** and **10-A4**, respectively. Compliance chart labels are provided in **Appendix 10-A5**.

The DFU for the proposed Threader device is substantially equivalent to the DFU of the Emerge predicate. The primary differences are:

- The Emerge predicate uses an electronic DFU as it has separate product numbers for the US and OUS markets. Threader will use a paper DFU as it will have global product numbers. While the proposed Threader DFU only includes English, the final DFU will be translated into other languages for global distribution.
- Threader will only be provided in one balloon size, so there are no tables showing a balloon matrix.
- The intended use/indications for use statements have been updated.
- Information on the EMERGE clinical study has been removed, as that study was conducted with the Emerge predicate, not with the proposed Threader device.
- Operational instructions have been updated to include specific information on guidewire exchange and hand injection of contrast media.
- Wording throughout the DFU has been updated and clarified with the assistance of BSC's medical director.

The predicate Emerge DFU is provided in **Appendix 10-A6.** The proposed Threader DFU is provided in **Appendix 10-A7**.

Appendix 10 Labeling

The following documents are included in this Appendix:

Appendix	Title
10-A1	Pouch Labels
10-A2	Pre-Printed Pouch Graphics
10-A3	Shelf Carton Labels
10-A4	Pre-Printed Shelf Carton Graphics
10-A5	Compliance Chart Labels
10-A6	Predicate Emerge Directions for Use (DFU)
10-A7	Proposed Threader Directions for Use (DFU)

Boston Scientific

1.2mm x12mm

Threader™

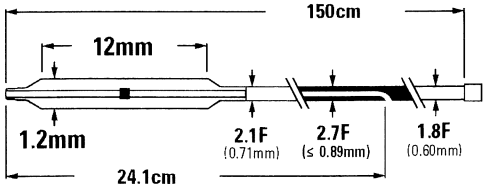
MONORAIL

Micro-Dilatation Catheter

Catéter de microdilatación, Cathéter de microdilatation, Mikro-Dilatationskatheter, Catetere microdilatatore, Micro-dilatatiekatheter, マイクロ拡張カテーテル, Mikrodilatationskateter, Μικροκαθετήρας διαστολής, Cateter de Micro-Dilatação, Mikrodilatationskateter, Mikrotágító katéter, Mikrodilatační katétr, Mikrocewnik rozszerzający, Mikrodilatasjonskateter, Mikro Dilatasyon Kateteri

Contents (1)

CL (1) Includes CLIPIT™ Hypotube Clip



GW R 0.014in (≤0.36mm) Recommended Guidewire

GC R 5F (≥0.056in/1.42mm) Recommended Guide Catheter

atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30
15.0 - 1520		1.31
16.0 - 1621		1.33

*Rated Burst Pressure. DO NOT EXCEED.

REF Catalog No. 39269-1212

Use By 2000-12

UPN Product No. H7493926912120

LOT 12345678

STERILE EO Sterilized using ethylene oxide.

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90840131-01A

CE 0344

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

Threader™
MONORAIL
1.2mm x 12mm
REF 39269-1212
LOT 12345678

Threader™
MONORAIL
1.2mm x 12mm
REF 39269-1212
LOT 12345678

+H7493926912120R

+$$8011200123456 78RM

Boston Scientific

1.2mm x 12mm

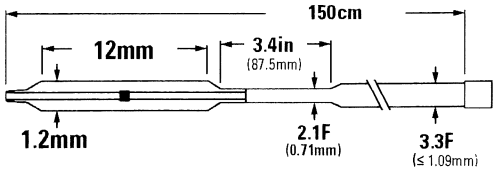
Threader™

OVER-THE-WIRE

Micro-Dilatation Catheter

Catéter de microdilatación, Cathéter de microdilatation, Mikro-Dilatationskatheter, Catetere microdilatatore, Micro-dilatatiekatheter, マイクロ拡張カテーテル, Mikrodilatationskateter, Μικροκαθετήρας διαστολής, Cateter de Micro-Dilatação, Mikrodilatationskateter, Mikrotágító katéter, Mikrodilatační katétr, Mikrocewnik rozszerzający, Mikrodilatasjonskateter, Mikro Dilatasyon Kateteri

Contents (1)



atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
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9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30
15.0 - 1520		1.31
16.0 - 1621		1.33

*Rated Burst Pressure. DO NOT EXCEED.

GW R **0.014in** (≤ 0.36mm) **Recommended Guidewire**

GC R **6F** (≥ 0.066in/1.68mm) **Recommended Guide Catheter**

REF Catalog No. **39270-1212**

Use By **2000-12**

UPN Product No. **H7493927012120**

LOT **12345678**

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Maple Grove, MN 55311 USA

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

+H7493927012120J

+$$8011200123456 78JE

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 International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

Legal Manufacturer

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
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(Master Brand Template 90218088AE)
Pouch, MB
9.63 x 11
90558003-01A

Threader™

MONORAIL

Micro-Dilatation Catheter

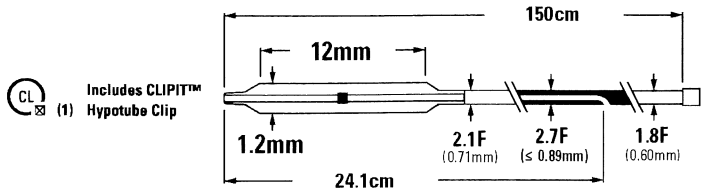
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1.2mm x12mm

Contents (1)

atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.



CL (1) Includes CLIPIT™ Hypotube Clip

GW R 0.014in (≤0.36mm) Recommended Guidewire

GC R 5F (≥0.056in/1.42mm) Recommended Guide Catheter

REF Catalog No. **39269-1212**

Use By **2000-12**

Threader™ MONORAIL 1.2 mm 12 mm REF 39269-1212 2000-12

Threader™ MONORAIL 1.2 mm 12 mm

90244534-01

90840149-01A

CE 0344

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

Threader™
MONORAIL
1.2mm x 12mm
REF 39269-1212
LOT 12345678

Threader™
MONORAIL
1.2mm x 12mm
REF 39269-1212
LOT 12345678

+H7493926912120R

+$$8011200123456781RM

UPN Product No. **H7493926912120** LOT **12345678**

STERILE EO Sterilized using ethylene oxide.

Threader™

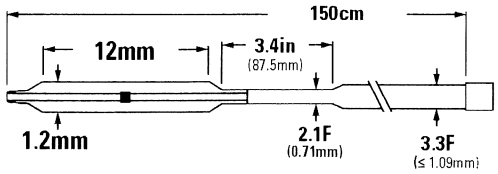
OVER-THE-WIRE

Micro-Dilatation Catheter

Catéter de microdilatación, Cathéter de microdilatation, Mikro-Dilatationskatheter, Catetere microdilatatore, Micro-dilatatiekatheter, マイクロ拡張カテーテル, Mikrodilatationskateter, Μικροκαθετήρας διαστολής, Cateter de Micro-Dilatação, Mikrodilatationskateter, Mikrotágító katéter, Mikrodilatační katétr, Mikrocewnik rozszerzający. Mikrodilatasjonskateter, Mikro Dilatasyon Kateteri

1.2mm x 12mm

Contents (1)



atm - kPa Pressure		1.2mm Balloon
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*Rated Burst Pressure. DO NOT EXCEED.

GW R **0.014in** (≤ 0.36mm) **Recommended Guidewire**

GC R **6F** (≥ 0.066in/1.68mm) **Recommended Guide Catheter**

REF Catalog No. **39270-1212**

Use By **2000-12**

Threader™

OVER-THE-WIRE

1.2 mm | 12 mm

REF 39270-1212

2000-12

Threader™ OVER-THE-WIRE 1.2 mm | 12 mm

90244534-01

90840150-01A

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

+H7493927012120J

CE 0344

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

+$$8011200123456 78JE

UPN Product No. **H7493927012120**

LOT **12345678**

STERILE EO **Sterilized using ethylene oxide.**



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CMYK Image (Target PANTONE 347C Green)
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Artwork Colors
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Carton, MB
9.75 x .5 x 11.20
90832641-02A
Uses Label Template 90347922ab

Threader™

MONORAIL

Micro-Dilatation Catheter

atm - kPa PRESSURE		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
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10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30
15.0 - 1520		1.31
16.0 - 1621		1.33

***Rated Burst Pressure. DO NOT EXCEED.**

90375893-01

90840144-01A

Threader™

OVER-THE-WIRE

Micro-Dilatation Catheter

atm - kPa PRESSURE		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
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10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30
15.0 - 1520		1.31
16.0 - 1621		1.33

***Rated Burst Pressure. DO NOT EXCEED.**

90375893-01

90840146-01A

Boston Scientific

90822295-01

2013-10
< EN >

Emerge™

MONORAIL®

OVER-THE-WIRE

PTCA Dilatation Catheter

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Table 4. Typical Emerge PTCA Dilatation Catheter Balloon Compliance 4

WARRANTY 4

℞ 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.

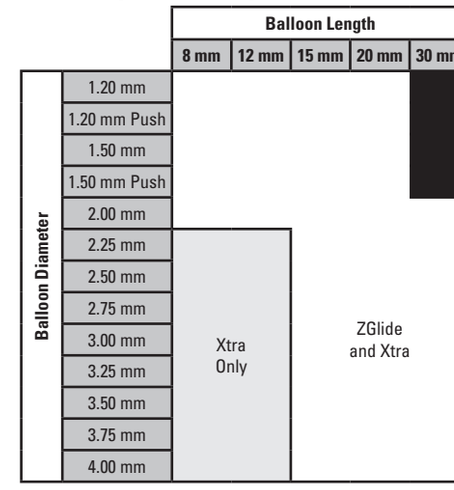
After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Boston Scientific Emerge Over-The-Wire PTCA Dilatation Catheter and Emerge Monorail PTCA Dilatation Catheter. The generic name of the device is Over-The-Wire Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter/Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

The Emerge Over-The-Wire (OTW) and Emerge Monorail (MR) Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheters, from Boston Scientific, are Over-The-Wire and rapid exchange catheters, respectively, with a semi-compliant balloon near the distal tip. The distal section of both catheters (and the proximal section of the OTW catheter) is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 in (0.36 mm) to facilitate advancement of the catheter to and through the stenosis or stent to be dilated. The proximal section of the rapid exchange catheter is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The OTW catheter has a dual luer port hub: one for inflation/deflation of the balloon, the other for guidewire lumen access. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the catheter. The catheter's tip is tapered to facilitate advancement of the catheter to and through the stenosis or stent. In addition to the standard design, the 1.20 mm and 1.50 mm catheters are offered in "Push" models that provide different performance characteristics. All shafts have ZGlide™ (hydrophilic) coating. For MR, the ZGlide is located from the guidewire port to just proximal of the proximal balloon waist. For OTW, the ZGlide is located from distal of the proximal marks to just proximal of the proximal balloon waist. All balloons have Xtra™ (hydrophobic) coating and some balloons have ZGlide applied from the distal tip to just proximal of the balloon, per Table 1.

Table 1. Emerge Balloon Coatings



The effective length of the OTW is 143 cm and the rapid exchange catheter is 144 cm. Marks on the proximal portion of the catheter shaft indicate the exit of the balloon catheter tip out of the guide catheter (one at 90 cm and two at 100 cm).

Radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the catheter's balloon segment. The 1.20 mm and 1.50 mm models have one radiopaque marker band, while all other models have two radiopaque marker bands. A CLIPIT® Hypotube Clip is provided with the Emerge Monorail PTCA Catheter to aid in handling of the catheter.

Contents

Quantity	Material
1	Emerge (Monorail or Over-The-Wire) PTCA Dilatation Catheter
1	CLIPIT Hypotube Clip (Monorail Catheter only)

INTENDED USE/INDICATIONS FOR USE

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-4.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

Note: Bench testing was conducted with Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters and marketed Boston Scientific balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design. All stents should be deployed in accordance with the manufacturer's indications and instructions for use.

CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

Boston Scientific (Master Brand DFU Template 8.2677in x 11.6929in A4, 90105918 AM) DFU, MB, Emerge, English, 90822295-01D

Black (K) ΔE ≤5.0

WARNINGS

General Warnings

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA as treatment of this patient population carries special risk.

Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated.

Use extreme caution and careful judgment in patients who have severe reaction to contrast agents that cannot be adequately pre-medicated.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate, or be less than, the diameter of the vessel just proximal and distal to the stenosis.

Use the balloon catheter prior to the "Use By" date specified on the package.

Catheter Handling

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Catheter Placement and Removal

When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.

Do not exceed the balloon rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure.

Use of a pressure monitoring device is recommended to prevent over pressurization.

If difficulty is experienced during balloon inflation, do not continue; remove the catheter.

Before withdrawing the balloon catheter, visually confirm complete balloon deflation by fluoroscopy.

Balloon catheter retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vascular access site. Complications can include but are not limited to bleeding, hematoma, or pseudoaneurysm.

PRECAUTIONS

General Precautions

The compatibility of the device has not been evaluated for the delivery of materials (e.g., drugs, alcohol, or stem cells) through the guidewire lumen, other than those required for normal use.

The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.

Catheter Handling

Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.

Caution should be taken not to overtighten a hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

Catheter Placement

Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.

Care should be taken to control the position of the guide catheter tip during manipulation of the balloon catheter.

When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

Do not expand the balloon if it is not properly positioned in the vessel.

Models not specified within step J of the Insertion Procedure have not been evaluated for simultaneous use of two balloon catheters in a guide catheter.

In the case of simultaneous use of two Emerge™ balloon catheters in one guide catheter, care should be taken when introducing, torquing, and removing guide wires and balloon catheters to avoid entanglement.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) that may be associated with the use of a PTCA Dilatation Catheter include, but are not limited to, the following:

- abrupt closure
- acute myocardial infarction
- angina or unstable angina
- arrhythmia, including ventricular fibrillation
- arteriovenous fistula
- cardiac tamponade/pericardial effusion
- cardiogenic shock
- cerebrovascular accident/stroke
- coronary aneurysm
- coronary artery bypass graft surgery
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury
- death
- drug reactions, allergic reaction to contrast medium
- embolism
- hemodynamic compromise
- hemorrhage or hematoma
- hypo/hypertension
- infection
- minor vessel trauma
- myocardial ischemia
- percutaneous re-intervention
- pseudoaneurysm (at site of catheter insertion)
- pyrogenic reaction
- renal failure
- respiratory insufficiency
- restenosis of the dilated vessel
- side branch occlusion
- slow flow/no reflow
- thrombosis
- total occlusion of the coronary artery or bypass graft
- transient ischemic attack
- vasovagal reactions
- ventricular irritability/dysfunction
- vessel trauma requiring surgical repair or intervention
- volume overload

OVERVIEW OF CLINICAL STUDY

EMERGE Clinical Study

Study Purpose

The objective of the EMERGE study was to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter when used to initially treat the stenotic portion of coronary arteries or bypass grafts.

Study Design

The EMERGE study was a prospective, open label, multi-center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter in subjects with stenotic coronary arteries or bypass grafts during percutaneous coronary intervention (PCI).

Sixty (60) subjects were treated at 3 US sites with the Emerge 1.20 mm PTCA Dilatation Catheter to pre-dilate coronary arteries or bypass grafts during their index procedure. All subjects were to be screened according to the protocol inclusion and exclusion criteria and were followed through hospital discharge.

The primary endpoint was device procedural success consisting of successful delivery, inflation, deflation and withdrawal of the study balloon; no evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline related to the study balloon; final TIMI flow grade of 3 at the conclusion of the PCI procedure.

The secondary clinical endpoints measured through hospital discharge included in-hospital MACE (cardiac and non-cardiac death, MI and TVR); in-hospital stent thrombosis within the target vessel; clinically significant arrhythmias requiring intervention.

Subjects were followed through hospital discharge.

Demographics

A total of 60 subjects with 67 target lesions were enrolled in the study at 3 US sites. The subject population was predominantly male (71.7%) and Caucasian (95.0%) with an average age of 61 years. Most subjects had a history of medically treated hyperlipidemia (85.0%) and hypertension (93.3%) with a history of PCI (61.7%), myocardial infarction (23.3%) and coronary bypass surgery (18.3%). Medically-treated diabetic subjects accounted for 35% of the subject population, of which 16.7% were insulin-requiring.

Baseline Lesion Characteristics

A total of 67 target lesions were treated in the study, of which 97% (65/67) were located in native coronary arteries and 3.0% (2/67) in bypass graft. The average reference vessel diameter was 2.6 ± 0.5 mm, average minimum lumen diameter was 0.7 ± 0.4 mm, average diameter stenosis was 73.0% ± 12.6%, and average lesion length was 15.5 ± 14.7 mm. Total occlusion was observed in 10.4% (7/67) of target lesions.

Very severe stenosis was the primary lesion characteristic in 40.0% (4/10) of all Push devices used in the trial. Pushability was the primary physician preference in 60.0% (6/10) of all Push devices used in the trial. Preference of the Standard model was given mainly for tortuosity 20.4% (11/54), calcification 20.4% (11/54) and very severe stenosis 27.8% (15/54) lesion characteristics. Deliverability was the primary physician preference in 51.9% (28/54) followed by Pushability in 27.8% (15/54) of all Standard devices used in the trial.

Primary Endpoint (Device Procedural Success)

As illustrated in **Table 2**, 98.3% (59/60) of subjects and 98.5% (66/67) of lesions achieved device procedural success, including successful delivery, inflation, deflation and withdrawal of the Emerge 1.20 mm PTCA Dilatation Catheter. Device procedural failure was observed in 1.7% (1/60) of subjects and 1.5% (1/67) of lesions and was related to unsuccessful delivery (i.e. failure to cross a lesion) of the study device. No procedural complications were observed in the intent-to-treat subject population. This included no vessel perforation, no flow-limiting dissection, and no reduction in TIMI flow from baseline. Furthermore, 100% (60/60) of subjects and 100% (67/67) of lesions had a final TIMI flow grade of 3 at the conclusion of the PCI procedure.

Table 2. Primary Endpoint Outcomes

	EMERGE Subjects (N=60)	EMERGE Lesions (N=67)
Device Procedural Success	98.3% (59/60)	98.5% (66/67)
Device Procedural Failure	1.7% (1/60)	1.5% (1/67)
Failure of delivery, inflation/deflation and withdrawal	1.7% (1/60)	1.5% (1/67)
Vessel perforation, flow limiting disection or reduction in TIMI flow	0.0% (0/60)	0.0% (0/67)
Failure of final TIMI flow	0.0% (0/60)	0.0% (0/67)

Numbers are % (Count/Sample Size), and based on number of subjects and lesions with site reported data.

Secondary Clinical Endpoint (Safety Events)

As illustrated in **Table 3**, the in-hospital major adverse cardiac events were observed in 6.7% (4/60) of the subjects. The non-Q-wave MI rate was 6.7% (4/60), characterized by elevation of post-procedure creatine kinase-myoglobin band (CK-MB) levels to >3.0 times upper limit of normal (ULN). The Q-wave MI rate was 0% (0/60). The all-cause death and TVR rates were 0% (0/60). The in-hospital stent thrombosis rate, per Academic Research Consortium (ARC), was 0% (0/60). No clinically significant arrhythmias requiring intervention were observed in this study.

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Table 3. Secondary Endpoint Outcomes

	EMERGE Subjects (N=60)
In-hospital MACE	6.7% (4/60)
All Death or MI	6.7% (4/60)
All Death	0.0% (0/60)
MI	6.7% (4/60)
Q-Wave MI	0.0% (0/60)
Non-Q-Wave MI	6.7% (4/60)
TVR, Overall	0.0% (0/60)
TVR, PCI	0.0% (0/60)
TVR, CABG	0.0% (0/60)
TLR, Overall	0.0% (0/60)
TLR, PCI	0.0% (0/60)
TLR, CABG	0.0% (0/60)
TVR Remote, Overall	0.0% (0/60)
TVR Remote, PCI	0.0% (0/60)
TVR Remote, CABG	0.0% (0/60)
In-hospital ARC Stent Thrombosis	0.0% (0/60)
In-hospital Clinical Significant Arrhythmias	0.0% (0/60)

Numbers are % (Count/Sample Size), and based on number of subjects with site reported and CEC adjudicated data.

Conclusion

The results of the EMERGE™ study support the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter and its intended use as a pre-dilatation catheter in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).

HOW SUPPLIED

Non-pyrogenic.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE

Store in a cool, dry, dark place.

INSTRUCTIONS FOR USE

One or more of each of the following materials are required for PTCA with the Emerge Over-The-Wire or Emerge Monorail® PTCA Dilatation Catheter.

Description

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set (for femoral approach only)
- Femoral or brachial guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.066 in (1.68 mm) (Emerge Over-The-Wire PTCA Catheter)
- Femoral or brachial guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.056 in (1.42 mm) (Emerge Monorail PTCA Catheter)
- Vial of contrast medium
- Sterile saline or heparinized normal sterile saline
- Inflation device with manometer
- Emerge Over-The-Wire PTCA Dilatation Catheter(s)
- Emerge Monorail PTCA Dilatation Catheter(s)
- ≤0.014 in (0.36 mm) x 300 cm guidewire(s) (Emerge Over-The-Wire PTCA Catheter)
- ≤0.014 in (0.36 mm) x 185 cm guidewire(s) (Emerge Monorail PTCA Catheter)
- 10, 12 or 20 ml (cc) luer-lock syringe
- Hemostatic adapter
- Three-way stopcock
- CLIPIT® Clip (Emerge Monorail PTCA Catheter only)
- Torque device

Inspection Prior to Use

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended. Do not use if sterile package is damaged.

Note: Do not continue to use the catheter if damage occurs or sterility is compromised during use.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air.

Catheter Selection

The inflation diameter of the balloon catheter must not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired catheter, use a smaller diameter catheter to pre-dilate the stenosis to facilitate passage of a more appropriately-sized catheter.

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon catheter (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For Emerge Over-The-Wire PTCA Catheters, the mandrel will slide off with the balloon catheter protector. For Emerge Monorail PTCA Catheters, remove the mandrel distally after removing the balloon protector.

   Caution: If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the catheter and replace with another.

3. The Emerge Monorail PTCA Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body.

   Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

4. Prepare the catheter for purging. Fill a luer lock syringe or inflation device with appropriate balloon catheter inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile saline). **Do not use air or any gaseous medium to inflate the balloon catheter.**
5. Connect a three-way stopcock to the port fitting on the catheter. Flush through the stopcock. Connect syringe or inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread causing subsequent leakage and use care when connecting the catheter to avoid damage (e.g., shaft kink).
6. Hold the syringe or inflation device with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger or open stopcock to air.
7. Remove the syringe or inflation device and evacuate all air from the barrel.
8. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If bubbles persist, check luer connections. If bubbles still persist, inflate the balloon to verify that there are no leaks present prior to insertion. Do not use the balloon catheter if there are any leaks.
9. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointing upwards.
10. Disconnect the syringe used in preparation. Verify that a meniscus of contrast medium is evident in both the balloon catheter port and the inflation device connection to ensure a fluid to fluid connection. Adding a drop of inflation medium to the port may be necessary. Securely couple the inflation device to the balloon catheter port of the catheter.
11. Open the stopcock to the catheter and leave on neutral.

Insertion Procedure

1. Guidewire Lumen Flush.
   A. For Emerge Monorail PTCA Catheters, flush the guidewire lumen of the catheter with sterile saline through the distal tip of the catheter.
   B. For Emerge Over-The-Wire PTCA Catheters, flush the guidewire lumen of the catheter with sterile saline through the guidewire port of the catheter hub.
   C. Check for bends, kinks and other damage. Do not use if any defects are noted.
2. Catheter Advancement
   A. Prepare the vascular access site according to standard practice.
   B. Maintain neutral pressure on the inflation device attached to the catheter.
   C. Insert a guidewire through the hemostatic adapter following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.
   D. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then across the stenosis or stent.
   E. Backload the distal tip of the catheter onto the guidewire ensuring that the guidewire exits the midsection opening in the Emerge Monorail PTCA Catheter or the wire port of the Emerge Over-The-Wire PTCA Catheter manifold. When loading or exchanging the catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

      Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

   F. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the catheter.
   G. Carefully advance the catheter through the hemostatic adapter while the balloon is fully deflated. If unusual resistance is felt, do not advance the catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

      Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

   H. Connect the side port of the guide catheter hemostatic adapter to the proximal pressure recording/infusion line or manifold assembly, which permits proximal pressure recording or infusion through the guide catheter.
   I. Advance the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis or stent to be dilated. Use the radiopaque marker bands as a reference point. The outside edges of the marker bands indicate the balloon shoulders on the 2.00-4.00 mm models; the 1.20-1.50 mm models have a single central marker band. Balloon inflation should not be undertaken if the balloon is not properly positioned within the stenosis or stent.
   J. Simultaneous Use of Two Balloon Catheters in a Guide Catheter: Bench and preclinical testing has shown that one 4.00 x 30 mm (or smaller) Monorail balloon catheter and one 3.25 x 20 mm (or smaller) Monorail balloon catheter can be inserted simultaneously into a 6F (minimum 0.070" ID) guide catheter and two 4.00 x 30 mm (or smaller) Over-the-Wire balloon catheters can be inserted into an 8F (minimum 0.088" ID) guide catheter with acceptable compatibility. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical study. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.
3. Catheter Inflation
   A. Inflate the balloon slowly to the appropriate pressure to perform PTCA or post-dilatation of a stent. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to

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Table 2 or to the balloon compliance chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA or post-dilatation of a stent, deflate the balloon by pulling negative pressure on the inflation device until the balloon is fully deflated. Bench testing has demonstrated that, on average, the deflation times range from 2 to 18 seconds, dependent upon balloon volume.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon expansion should be used to properly judge the optimum expanded balloon diameter as compared to the proximal and distal coronary artery diameter(s). Repeat inflation of balloon until the desired result is achieved.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (Emerge™ Over-The-Wire PTCA Catheter) or step 6 – Catheter Exchange Procedure (Emerge Monorail® PTCA Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery has not abruptly occluded. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the knurled knob on the hemostatic adapter.

C. The Emerge Monorail PTCA Catheter may be coiled once and secured using the CLIPIT® Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to the catheter being inserted in the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

5. Catheter Exchange Procedure (Emerge Over-The-Wire PTCA Catheter)

The Emerge Over-The-Wire PTCA Catheters typically require two operators to exchange. To perform a catheter exchange, execute the following steps:

A. Loosen the knurled knob on the hemostatic adapter.

B. The primary operator holds the hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. The secondary operator is positioned near the foot of the patient and should maintain the guidewire position in the coronary artery by holding the guidewire stationary and confirming guidewire position at all times under fluoroscopy while the primary operator begins pulling the catheter out of the guide catheter.

D. Withdraw the deflated catheter until the catheter tip exits the hemostatic adapter.

E. Close the knurled knob on the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the stenosis or stent.

F. Prepare the next catheter to be used as described in the Catheter Preparation section.

G. Back load the new catheter onto the guidewire as described under step 2 – Catheter Advancement – and continue the procedure.

6. Catheter Exchange Procedure (Emerge Monorail PTCA Catheter)

The Emerge Monorail PTCA Catheters have been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

A. Loosen the knurled knob on the hemostatic adapter.

B. Hold the guidewire and hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. Maintain the guidewire position in the coronary artery by holding the guidewire stationary. Begin pulling the catheter out of the guide catheter while monitoring the guidewire position under fluoroscopy.

D. Withdraw the deflated catheter until the opening in the guidewire lumen is reached (approximately 25 cm proximal to the balloon catheter tip).

E. Carefully slide the flexible, distal portion of the catheter out of the hemostatic adapter, and tighten the knurled knob onto the guidewire to hold it securely in place. Completely remove the catheter from the guidewire while maintaining guidewire position across the stenosis.

F. Prepare the next catheter to be used as described in the Catheter Preparation section.

G. Back load the new catheter onto the guidewire as described under step 2 – Catheter Advancement – and continue the procedure.

REFERENCES

The physician should consult current medical practice literature on PTCA, such as that published by the American College of Cardiology/American Heart Association.

Table 4. Typical Emerge PTCA Dilatation Catheter Balloon Compliance

	Balloon Size										
Pressure atm (kPa)	**1.20 mm**	**1.50 mm**	**2.00 mm**	**2.25 mm**	**2.50 mm**	**2.75 mm**	**3.00 mm**	**3.25 mm**	**3.50 mm**	**3.75 mm**	**4.00 mm**
3.0 (304)	1.09	1.39	1.86	2.06	2.28	2.53	2.76	3.01	3.19	3.45	3.66
4.0 (405)	1.13	1.45	1.93	2.14	2.37	2.61	2.85	3.10	3.30	3.58	3.80
5.0 (507)	1.16	1.48	1.99	2.20	2.44	2.68	2.93	3.18	3.39	3.67	3.88
6.0 (608) Nominal	1.20	1.52	2.03	2.26	2.50	2.75	3.00	3.26	3.46	3.75	3.96
7.0 (709)	1.23	1.55	2.07	2.31	2.55	2.81	3.06	3.33	3.52	3.81	4.04
8.0 (811)	1.26	1.58	2.10	2.34	2.59	2.85	3.11	3.37	3.57	3.86	4.09
9.0 (912)	1.28	1.60	2.13	2.38	2.62	2.88	3.15	3.41	3.61	3.90	4.14
10.0 (1013)	1.31	1.62	2.15	2.40	2.65	2.91	3.18	3.45	3.64	3.95	4.18
11.0 (1115)	1.33	1.64	2.18	2.42	2.67	2.94	3.21	3.48	3.68	3.98	4.22
12.0 (1216)	1.35	1.65	2.19	2.44	2.69	2.96	3.23	3.51	3.72**	4.02**	4.25**
13.0 (1317)	1.37	1.66	2.21	2.46	2.72	2.99	3.26	3.54	-	-	-
14.0 (1419)	1.39	1.68*	2.23**	2.48**	2.74**	3.02**	3.28**	3.57**	-	-	-
15.0 (1520)	1.41	-	-	-	-	-	-	-	-	-	-
16.0 (1621)	1.42	-	-	-	-	-	-	-	-	-	-
17 (1723)	1.43	-	-	-	-	-	-	-	-	-	-
18.0 (1824)	1.45*	-	-	-	-	-	-	-	-	-	-
19.0 (1925)	1.46	-	-	-	-	-	-	-	-	-	-
20.0 (2027)	1.48	-	-	-	-	-	-	-	-	-	-

* Rated Burst Pressure. Do not exceed.
** Rated Burst Pressure and Stent Rated Burst Pressure. Do not exceed.

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.**

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Boston Scientific

Threader™

MONORAIL™

OVER-THE-WIRE

Micro-Dilatation Catheter

Directions for Use **2**

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Threader™

MONORAIL™

OVER-THE-WIRE

Micro-Dilatation Catheter

℞ 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. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

Boston Scientific Threader Over-The-Wire Micro-Dilatation Catheter and Threader Monorail Micro-Dilatation Catheter. The generic name of the device is Over-The-Wire Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter/Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

The Threader Over-The-Wire (OTW) and Threader Monorail (MR) Micro-Dilatation Catheters, from Boston Scientific, are Over-The-Wire and rapid exchange catheters, respectively, with a semi-compliant balloon near the distal tip. The Threader OTW and Threader MR catheters are offered in a 1.2 x 12 mm configuration. The distal section of both catheters (and the proximal section of the OTW catheter) is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 in (0.36 mm) to facilitate advancement of the catheter to the stenosis or through a previously placed stent prior to dilatation.

The proximal section of the rapid exchange catheter is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The PowerCoil™ technology makes up the mid-shaft and distal section which consists of a polymer-sheathed stainless steel coil. The OTW catheter has a dual luer port hub: one for inflation/deflation of the balloon, the other for guidewire lumen access. The PowerCoil technology makes up the proximal shaft of the OTW catheter which consists of a polymer-sheathed stainless steel coil. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the catheter prior to use. The catheter's tip is tapered to facilitate advancement of the catheter to the stenosis or through a previously placed stent prior to dilatation. The shafts have ZGlide™ (hydrophilic) coating. For MR, the distal 22 cm of the device including the balloon and tip are coated with ZGlide. For OTW, the distal 60 cm of the device including the balloon and tip are coated with ZGlide. In addition, both MR and OTW devices have Xtra™ (hydrophobic) coating applied to the tip and balloon.

The effective length of both the OTW and MR devices is 150 cm. Marks on the proximal portion of the catheter shaft indicate the imminent exit of the balloon catheter tip out of the guide catheter (mark present at 90 cm and at 100 cm).

A radiopaque marker band, in conjunction with fluoroscopy, aids in the placement of the catheter's balloon segment. The Threader has one radiopaque marker band located in the center of the balloon body. A CLIPIT™ Hypotube Clip is provided with the Threader Monorail Micro-Dilatation Catheter to aid in handling the catheter.

Contents

One (1) Threader (Monorail or Over-The-Wire) Micro-Dilatation Catheter

One (1) CLIPIT Hypotube Clip (Threader Monorail Micro-Dilatation Catheter Only)

INTENDED USE/INDICATIONS FOR USE

The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion.

The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

CONTRAINDICATIONS

The Threader Guide Catheter is contraindicated for use in:

- Unprotected left main coronary artery disease.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
- Use prior to the "use by" date as indicated on the label.
- Use extreme caution and careful judgment in patients for whom anticoagulation is contraindicated.
- Use extreme caution and careful judgment in patients who have reaction to contrast agents that cannot be adequately pre-medicated.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be performed.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate, or be less than, the diameter of the vessel just proximal and distal to the stenosis.

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- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the balloon rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure.
- Use of a pressure monitoring device is recommended to prevent over or under pressurization.
- If difficulty is experienced during balloon inflation, do not continue; remove the catheter.
- Before withdrawing the balloon catheter, visually confirm complete balloon deflation by fluoroscopy.
- Balloon catheter retrieval methods (use of additional wires, snares and/or forceps) may result in trauma to the treated vessel and/or the vascular access site. Complications can include but are not limited to bleeding, hematoma, pseudoaneurysm or dissection.

PRECAUTIONS

- The compatibility of the device has not been evaluated for the delivery of materials (e.g. alcohol or nitroglycerine, stem cells, etc.) through the guidewire lumen, other than those required for normal use.
- The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.
- Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Caution should be taken not to overtighten a hemostatic adapter around the catheter shaft as lumen constriction may occur, possibly affecting inflation/deflation of the balloon.
- Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
- Care should be taken to control the position of the guide catheter tip during manipulation of the balloon catheter.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.
- Do not expand the balloon if it is not properly positioned in the vessel.
- In the case of simultaneous use of two Threader™ balloon catheters in one guide catheter, care should be taken when introducing, rotating, and removing guidewires and balloon catheters to avoid entanglement.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) that may be associated with the use of a Micro-Dilatation Catheter include, but are not limited to, the following:

- abrupt closure
- acute myocardial infarction
- angina or unstable angina
- arrhythmia, including ventricular fibrillation
- arteriovenous fistula
- cardiac tamponade/pericardial effusion
- cardiogenic shock
- cerebrovascular accident/stroke
- coronary aneurysm
- coronary artery bypass graft surgery
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury, possibly requiring surgical repair or intervention
- death
- drug reactions, including allergic reaction to contrast medium
- embolism
- hemodynamic compromise
- hemorrhage or hematoma
- hypo/hypertension
- infection
- minor vessel spasm
- myocardial ischemia
- pseudoaneurysm (at vascular access site)
- pyrogenic reaction
- renal failure
- respiratory insufficiency
- restenosis of the dilated vessel
- side branch occlusion
- slow flow/no reflow
- target vessel re-intervention
- thrombosis
- total occlusion of the coronary artery or bypass graft
- transient ischemic attack
- vasovagal reaction
- volume overload

HOW SUPPLIED

- Non-pyrogenic
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

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Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

One or more of each of the following materials are required for PTCA but not supplied with the Threader™ Over-The-Wire or Threader Monorail™ Micro-Dilatation Catheter.

Description

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set (for femoral approach only)
- Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.066 in (1.68 mm) (Threader Over-The-Wire Micro-Dilatation Catheter)
- Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.056 in (1.42 mm) (Threader Monorail Micro-Dilatation Catheter)
- Contrast medium
- Sterile saline or heparinized normal sterile saline
- Inflation device with manometer
- ≤0.014 in (0.36 mm) x 300 cm guidewire(s) (Threader Over-The-Wire Micro-Dilatation Catheter)
- ≤0.014 in (0.36 mm) x 185 cm guidewire(s) (Threader Monorail Micro-Dilatation Catheter)
- 10, 12 or 20 ml (cc) luer-lock syringe
- Hemostatic adapter
- Three-way stopcock
- Guidewire torqueing device

Inspection Prior to Use

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended. Do not use if sterile package is damaged.

Note: Do not continue to use the catheter if damage occurs or sterility is compromised during use.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air using only the contrast medium.

Catheter Selection

The inflation diameter of the balloon catheter must not exceed the diameter of the coronary artery proximal and distal to the stenosis.

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon catheter (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For Threader Over-The-Wire Micro-Dilatation Catheters, the mandrel will slide off with the balloon catheter protector. For Threader Monorail Micro-Dilatation Catheters, remove the mandrel distally after removing the balloon protector.

Caution: If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the catheter and replace with another.

3. The Threader Monorail Micro-Dilatation Catheter may be coiled once and secured using the CLIPIT™ Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body.

Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

4. Prepare the catheter for purging. Fill a luer lock syringe or inflation device with appropriate balloon catheter inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile saline). **Do not use air or any gaseous medium to inflate the balloon catheter.**
5. Connect a three-way stopcock to the port fitting on the catheter. Flush through the stopcock taking care to ensure that the balloon cannot be inflated. Connect syringe or inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread causing subsequent leakage and use care when connecting the catheter to avoid damage (e.g., shaft kink).
6. Hold the syringe or inflation device with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger or open stopcock to air.
7. Remove the syringe or inflation device and evacuate all air from the barrel.
8. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If bubbles persist, check luer connections. If bubbles still persist, inflate the balloon to verify that there are no leaks present prior to insertion. Do not use the balloon catheter if there are any leaks.
9. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointing upwards.
10. Disconnect the syringe used in preparation. Verify that a meniscus of contrast medium is evident in both the balloon catheter port and the inflation device connection to ensure a fluid to fluid connection. Adding a drop of inflation medium to the port may be necessary. Securely couple the inflation device to the balloon catheter port of the catheter.
11. Open the stopcock to the catheter and leave on neutral.

Insertion Procedure

1. Guidewire Lumen Flush
   A. For the Threader Monorail Micro-Dilatation Catheter, flush the guidewire lumen of the catheter with sterile saline through the distal tip of the catheter.

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B. For the Threader™ Over-The-Wire Micro-Dilatation Catheter, flush the guidewire lumen of the catheter with sterile saline through the guidewire port of the catheter hub.

C. Check for bends, kinks and other damage. Do not use if any defects are noted.

2. Catheter Advancement

A. Prepare the vascular access site according to standard practice.

B. Maintain neutral pressure on the inflation device attached to the catheter.

C. Insert a guidewire through the hemostatic adapter following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.

D. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then position the distal wire in the desired location.

E. Backload the distal tip of the catheter onto the guidewire ensuring that the guidewire exits the midsection opening in the Threader Monorail™ Micro-Dilatation Catheter or the wire port of the Threader Over-The-Wire Micro-Dilatation Catheter manifold. When loading or exchanging the catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

F. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the balloon catheter.

G. Carefully advance the catheter through the hemostatic adapter while the balloon is fully deflated. If unusual resistance is felt, do not advance the catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

H. Advance the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis to be dilated. Use the center radiopaque marker band as a reference point. Balloon inflation should not be undertaken if the balloon is not properly positioned within the stenosis.

I. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that contrast media is needed, withdraw the guidewire and hand-inject contrast media through the catheter hub with a syringe.

J. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that an alternative guidewire is needed, remove the guidewire while holding the hub of the Over-The-Wire Micro-Dilatation Catheter in place. Once the guidewire has been removed from the patient, an alternative guidewire can be introduced into the hub of the Over-The-Wire Micro-Dilatation Catheter and advanced to the distal tip of the catheter.

K. Simultaneous use of two balloon catheters in a guide catheter (Kissing Balloon): Bench and preclinical testing has shown that one Threader Monorail Micro-Dilatation catheter and one 3.25 x 20 mm (or smaller) Emerge Monorail PTCA Dilatation balloon catheter can be inserted simultaneously into a 6F (minimum 0.070 in ID) guide catheter and one Threader Over-The-Wire Micro-Dilatation Catheter and one 3.25 x 20 mm (or smaller) Emerge Over-The-Wire Dilatation can be inserted into an 8F (minimum 0.088 in ID) guide catheter with acceptable compatibility. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical study. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.

3. Catheter Inflation

A. Inflate the balloon slowly to the appropriate pressure to perform PTCA. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to the balloon compliance table or chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA, deflate the balloon by pulling negative pressure on the inflation device until the balloon is fully deflated. Bench testing has demonstrated that the deflation times range from 2 to 5 seconds.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon expansion should be used to properly judge the optimum expanded balloon diameter as compared to the proximal and distal coronary artery diameter(s). Repeat inflation of balloon until the desired result is achieved.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (Threader Over-The-Wire Micro-Dilatation Catheter) or step 6 – Catheter Exchange Procedure (Threader Monorail Micro-Dilatation Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery has not abruptly occluded. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the hemostatic adapter.

C. The Threader Monorail Micro-Dilatation Catheter may be coiled once and secured using the CLIPIT™ Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; CLIPIT is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to the catheter being inserted in the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

5. Catheter Exchange Procedure (Threader Over-The-Wire Micro-Dilatation Catheter)

The Threader Over-The-Wire Micro-Dilatation Catheter typically requires two operators to exchange. To perform a catheter exchange, execute the following steps:

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A. Loosen the hemostatic adapter.

B. The primary operator holds the hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. While maintaining guidewire position, withdraw the deflated catheter until the catheter tip exits the hemostatic adapter.

D. Close the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the stenosis.

E. Prepare the next device and load onto the guidewire as described in step 2.

F. Continue the procedure.

6. Catheter Exchange Procedure (Threader™ Monorail™ Micro-Dilatation Catheter)

The Threader Monorail Micro-Dilatation Catheter has been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

A. Loosen the hemostatic adapter.

B. Hold the guidewire and hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. Maintain the guidewire position in the coronary artery by holding the guidewire stationary. Begin pulling the deflated catheter out of the guide catheter while maintaining the guidewire position under fluoroscopy.

D. Withdraw the catheter until the opening in the guidewire lumen is reached (approximately 25 cm proximal to the balloon catheter tip).

E. While maintaining guidewire position, carefully slide the flexible, distal portion of the catheter out of the hemostatic adapter, and tighten the hemostatic adapter onto the guidewire to hold it securely in place. Completely remove the catheter from the guidewire while maintaining guidewire position.

F. Prepare the next device and load onto the guidewire as described in step 2.

G. Continue the procedure.

Typical Threader Micro-Dilatation Catheter Balloon Compliance

Pressure		Balloon size is listed as mm (nominal = 6.0 atm) *Rated Burst Pressure. DO NOT EXCEED.
atm	kPa	1.2 mm
3.0	304	1.06
4.0	405	1.11
5.0	507	1.15
6.0 (nominal)	608	1.18
7.0	709	1.21
8.0	811	1.23
9.0	912	1.24
10.0	1013	1.26
11.0	1115	1.27
12.0	1216	1.28
13.0	1317	1.29
14.0*	1419	1.30
15.0	1520	1.31
16.0	1621	1.33

Note: Over inflation may result in burst of the balloon or shaft.

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**.

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REF
Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência


Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização


Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Conteúdo

EC REP
EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.


Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante Legal

LOT
Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN
Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto


Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável


Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS
Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano


For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.



Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize


Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.



Recommended Guidewire
Guía recomendada
Guide recommandé
Empfohlener Führungsdraht
Filoguida consigliato
Aanbevolen voerdraad
Fio-guia Recomendado



Recommended Guide Catheter
Catéter guía recomendado
Cathéter guide recommandé
Empfohlener Führungskatheter
Catetere guida consigliato
Aanbevolen geleidekatheter
Cateter-guia Recomendado

STERILE EO
Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.



Includes CLIPIT™ Hypotube Clip
Incluye pinza de hipotubo CLIPIT™
Inclut un clip de l'hypotube CLIPIT™
Enthält CLIPIT™ Hypotube-Klemme
Include clip per ipotubo CLIPIT™
Bevat CLIPIT™-hypotubeclip
Inclui o Clipe para Hipotubo CLIPIT™

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Do not use if package is damaged.

Recyclable Package

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Section 11 Sterilization and Shelf Life

Sterilization Method

The Threader Micro-Dilatation Catheters will be sterilized using 100% ethylene oxide (EO) gas in a validated cycle(b) (4) Sterilization loads are monitored to verify acceptable values for critical parameters, e.g., pressure, vacuum, temperature and time.

The(b) (4) sterilization cycle is validated using both physical parameters and biological indicators. Boston Scientific qualifies devices for sterilization by using product models inoculated with a minimum of 10^6 *Bacillus atrophaeus* spores and then exposing them to the sterilizing conditions. 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.

Sterilization Site

Boston Scientific Corporation – Coventry
8 Industrial Drive
Coventry, Rhode Island, 02816
USA

Sterility Assurance Level

The(b) (4) sterilization cycle is validated and controlled in accordance with EN ISO 11135-1, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*, and designed to provide a minimum Sterility Assurance Level (SAL) of 10^{-6}.

EO Residuals

The Threader catheters will meet the ethylene oxide (EO) and ethylene chlorohydrin (ECH) residual limits as specified in EN ISO 10993-7, *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*.

Bacterial Endotoxin

The Threader catheters 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.*

Section 11 Sterilization and Shelf Life

Product and Package Shelf Life

The product shelf life testing supports a 3-month shelf life at this time. The package shelf life testing supports a 37-month shelf life. Upon FDA acceptance of the accelerated aging shelf life protocol (described in **Section 15.4, Product Shelf Life Testing**) and clearance of the device, and successful completion of the 2-year accelerated aging shelf life testing, the labeling will be updated to reflect a 2-year shelf life.

Section 12 Biocompatibility

This section is organized as follows:

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12.2	Biocompatibility Testing	12-6
12.3	Biocompatibility Test Results	12-10

Section 12 Biocompatibility

Section 12.1 Device Material Composition

All of the materials of the proposed device, Threader Micro-Dilatation Catheter, are substantially equivalent to the materials of the predicate device, Emerge 1.20 mm PTCA Dilatation Catheters, cleared under K130391. The components and materials used in the Threader devices are summarized in **Table 12-1**. Information on patient-contacting and non-patient-contacting colorants is provided in **Tables 12-2** and **12-3**, respectively.

Table 12-1: Threader Components and Materials

Component	Material
Balloon	(b) (4)
Bumper Tip	(b) (4)
Marker Bands	(b) (4)
Inner Shaft	Distal Inner Inner layer: (b) (4)) Middle layer: (b) (4) Outer layer (b) (4) Proximal Inner Inner layer: (b) (4) Middle layer: (b) (4) Outer layer: (b) (4)
Bi-Component Inner Welding Sleeve	(b) (4)
Distal Outer Shaft (MR)	Stainless steel coil / (b) (4)
Outer Shaft (OTW)	Stainless steel coil / (b) (4)
Midshaft (MR)	Stainless steel coil / (b) (4)
Manifold Bond Adhesive (OTW)	(b) (4)
Midshaft Bond Adhesive (MR)	(b) (4)
Corewire (MR)	(b) (4) I
Hypotube (MR)	(b) (4)
Proximal Marks (OTW)	(b) (4)
Manifold	(b) (4)
Strain Relief (OTW)	(b) (4)
Hydrophilic Coating	ZGlide (b) (4)
Hydrophobic Coating	Xtra (b) (4)
Balloon Protector	(b) (4)
Product Mandrel	(b) (4)

Section 12 Biocompatibility

(b) (4)

[redacted]

Section 12 Biocompatibility

(b) (4)

[redacted]

Section 12 Biocompatibility

Section 12.1 Device Material Composition

BSC's toxicology staff have conducted a Chemical Safety Assessment (CSA) on the patient-contacting materials used to manufacture the Threader catheter (90901970, included in **Appendix 12-A1**). Additionally, prior Chemical Safety Assessments covering the same patient-contacting materials and patient-contacting colorants were provided in Appendix 12.0 of the Emerge 510(k) Notification (K113220, submitted October 31, 2011). All of the Chemical Safety Assessments concluded that the chemical safety risk of the materials used in the Threader catheter was acceptable.

Section 12 Biocompatibility

Section 12.2 Biocompatibility Testing

The basis for the Threader biocompatibility testing was the FDA guidance document, "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*," dated September 8, 2010.

With the exception of the balloon, all patient-contacting materials used in the Threader device are the same as those used in the Emerge predicate device.

Both Threader MR and OTW platforms contain existing materials with a history of safe use. Although individual components/materials have been previously tested in predicate products, a full set of biocompatibility testing has been performed for Threader MR as a whole in order to assess possible interactions between component materials. Tests were selected based on Threader catheters being categorized as limited exposure (≤ 24 hrs), externally communicating, circulating blood contact devices by ISO 10993-1 categorization. Additionally, USP physicochemical testing was performed to meet BSC's internal requirements. All biocompatibility testing was conducted per Good Laboratory Practice (GLP) regulation 21 CFR 58 with appropriate consideration of ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process. All studies were conducted at laboratories which are accredited to ISO 17025.

As outlined in **Table 12-4**, with the exception of (b) (4)), all of the patient-contacting materials found in Threader MR are also found in Threader OTW with no differences in formulations, processing, sterilization, or chemical additives. Since Threader MR is representative, the biocompatibility testing conducted on Threader MR is applicable to Threader OTW. The in vitro screening tests for cytotoxicity and hemolysis were performed on the final Threader OTW to further confirm biocompatibility, as shown in the results section.

Table 12-4: Comparison of Threader MR and OTW Patient-Contacting Components

Threader MR			Threader OTW			Comments
Component	Chemical Name/ Formulation/Grade	Component Weight (g)	Component	Chemical Name/ Formulation/Grade	Component Weight (g)	
(b) (4)						

Section 12 Biocompatibility

Section 12.2 Biocompatibility Testing

Threader MR			Threader OTW			Comments
Component	Chemical Name/ Formulation/Grade	Component Weight (g)	Component	Chemical Name/ Formulation/Grade	Component Weight (g)	
(b) (4)						

Section 12 Biocompatibility

Section 12.2 Biocompatibility Testing

Threader MR			Threader OTW			Comments
Component	Chemical Name/ Formulation/Grade	Component Weight (g)	Component	Chemical Name/ Formulation/Grade	Component Weight (g)	
(b) (4)						

*BSC's toxicology staff have conducted a Chemical Safety Assessment (CSA) on the materials used to manufacture the Threader catheter (90901970, included in **Appendix 12-A1**). Additionally, prior Chemical Safety Assessments covering the same patients-contacting materials and patient-contacting colorants were provided in Appendix 12.0 of the Emerge 510(k) Notification (K113220, submitted October 31, 2011). All of the Chemical Safety Assessments concluded that the chemical safety risk of the materials used in the Threader catheter was acceptable.

The specific biocompatibility tests listed in the FDA PTCA Guidance were addressed in the Threader biocompatibility test plan as follows:

Biocompatibility Tests listed in the FDA PTCA Guidance	**Threader Biocompatibility Test Plan**
Cytotoxicity	Tested (MR and OTW)
Sensitization	Tested (MR)
Hemocompatibility – hemolysis (direct contact and extract)	Tested (MR and OTW)
Hemocompatibility – immunology (complement activation C3a and SC5b-9)	Tested (MR)
Hemocompatibility – in vivo thromboresistance	Previously tested, see rationale below
Genotoxicity	Not tested, see rationale below
Material-Mediated Pyrogenicity	Tested (MR)

Rationale for Use of Prior Hemocompatibility (Thrombogenicity) Testing
Canine in vivo thrombogenicity was not conducted because the Threader catheter does not contain any materials or geometries novel to medical devices. The Threader device is entirely built using materials that have a history of safe use in medical devices. Additionally, in vivo thrombogenicity was previously performed on the predicate Emerge device, which has the same device coating and surface characteristics as the Threader device under assessment. Threader micro geometry and macro geometry is equivalent to that of Emerge. Therefore, results from the prior Emerge in vivo thrombogenicity study are applicable to Threader and are included in **Section 12.3**.

Additionally, patient use of anticoagulants prior to the procedure also reduces the risk of thrombosis. The Threader DFU (Directions for Use) carries the following warning: "Use extreme caution and careful judgment in patients for whom anticoagulation is contraindicated."

In conclusion, the Threader device does not contain any novel materials nor does it introduce novel micro- or macro-scale geometries. Therefore, the Threader catheter does not pose an unacceptable risk of vascular thrombosis and additional in vivo thrombogenicity testing is not required.

Rationale for Omission of Genotoxicity Testing

According to FDA's PTCA Catheter Guidance, genotoxicity testing should be performed if new materials are included that have never been used in blood-contacting devices or implants, in order to evaluate the genotoxic response to any particulates and leachables which still may be present after the catheter is removed from the body.

The chemical constituents present in the Threader materials have a history of safe use in blood contacting medical devices. The Threader Chemical Safety Assessment (CSA) has concluded that the materials do not pose any genotoxicity risks under the intended use (**Appendix 12-A1**).

Rationale for Omission of Packaging Testing

In accordance with EN ISO 10993-1, biocompatibility testing shall be considered for materials and devices that come in direct or indirect contact with the body. Finished product is packaged and sterilized in its final configuration. The samples assessed for biocompatibility testing are finished products and therefore contact the packaging materials during processing and sterilization. The risk for packaging to introduce harmful substances onto the product has been considered by conducting biocompatibility testing of the finished product in accordance with the ISO 10993 standard. Because biocompatibility test results were acceptable, the hazard risk of the packaging materials is considered acceptable. Therefore, direct testing of the packaging materials is considered unnecessary. Furthermore, no new packaging materials are being introduced for Threader. All packaging materials are the same as those used in the Coyote predicate device (K111295).

Test Article Selection and Preparation

All biocompatibility testing was conducted on packaged and sterilized finished devices with lot/batch traceability of all materials and manufacturing processes. Samples were sterilized two times in their final packaging using EO sterilization cycle (b) (4) The testing lab was instructed to not cut the device and to record the condition of the extract in the test reports. An extraction temperature of 50°C was used in all tests where applicable, per FDA Guidance. The sample size and surface area, as well as sample preparation and reference materials, comply with the requirements of ISO 10993-12, Sample Preparation and Reference Material.

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

Each biocompatibility test met its acceptance criteria. Therefore, the Threader device and packaging are considered biocompatible for their intended use. **Table 12-6** and **Table 12-7** summarize the biocompatibility test results for Threader Monorail (MR) and Over-The-Wire (OTW) devices, respectively. The test reports are provided in **Appendix 12-A**, as indicated in the tables. The biocompatibility tests were conducted prior to the assignment of the commercial device name of Threader. As a result, the device name in the reports is (b) (4) which was the development name for the device. Threader and (b) (4) are synonymous.

Table 12-6: Biocompatibility Testing Summary for Threader Monorail (MR)

Appendix	Test Performed / Applicable ISO 10993 Part No.	Test Lab and Report No.	Extract Conditions*	Test Article	Results
12-A2	MEM Elution Cytotoxicity/ Part 5	(b) (4) Report # 188582	E-MEM with 5% Fetal Bovine Serum / 24 ± 2 hrs at 37 ± 1°C Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Grade 0
12-A3	Guinea Pig Maximization Sensitization/Part 10	(b) (4) Report # 188577	NS / CSO / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Sensitization rate: 0
12-A4	Intracutaneous Reactivity/ Part 10	(b) (4) Report # 188578	NS / CSO / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Score 0/0
12-A5	Acute Systemic Injection/ Part 11	(b) (4) Report # 188579	NS / CSO / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass No signs of toxicity

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

Appendix	Test Performed / Applicable ISO 10993 Part No.	Test Lab and Report No.	Extract Conditions*	Test Article	Results
12-A6	Materials Mediated Rabbit Pyrogen/Part 11	(b) (4) Report # 188580	NS / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Non-pyrogenic
12-A7	Hemolysis Direct Contact & Extract/Part 4	(b) (4) Report # 188584	Blood, direct / PBS / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Hemolytic index: 0.1% direct method; 0.0% extract method
12-A8	Partial Thromboplastin Time/ Part 4	(b) (4) Report # 188581	Blood Plasma, direct Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass 100% of negative control
12-A9	In Vitro Hemocompatibility Assay/Part 4	(b) (4) Report # 188583	NS / Blood /1 hr at 37 ± 2°C Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Results comparable to Reference Control WBC: 108% RBC: 98% Hemoglobin: 98% Hematocrit: 99% Platelet: 109%
12-A10	Complement Activation/ Part 4	(b) (4) Report # 188576	Serum, direct Sample surface area = (b) (4) ^{2}	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Negative for C3a, Negative for SC5b-9

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

Appendix	Test Performed / Applicable ISO 10993 Part No.	Test Lab and Report No.	Extract Conditions*	Test Article	Results
12-A11	USP Physicochemical <661>	(b) (4) Report # 936878	Purified Water / 70°C for 24 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Non-volatile residue: (b) (4) Residue on ignition: (b) (4) Heavy metal (b) (4) Buffering capacity: (b) (4)
12-A12	In Vivo Thromboresistance/ Part 4	(b) (4) 11T_48343_03	Not applicable; direct implant in jugular vein, 4 ± 0.5 hours non-heparinized canine model	Test: Emerge OTW with ZGlide 4.00 mm x 30 mm H7493919530400 Lot # 13935104 Control: Apex OTW with Bioslide 4.00 mm x 30 mm H7493895830400 Lot # 13959792	Test: None to moderate thrombosis (b) (4) Control: Slight to Moderate thrombosis (b) (4) Conclusion: Test article and control are similar in thromboresistance

* Extract Conditions:
NS= Normal Saline (polar)
CSO= Cottonseed Oil (non-polar)
PBS= Phosphate Buffered Saline
E-MEM+FBS = Eagle's Minimal Essential Medium with 5% Fetal Bovine Serum

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

As noted in **Section 12.2**, many of the biocompatibility tests conducted on the Threader MR devices are applicable to the Threader OTW devices. Those tests are listed in the OTW table with Threader MR as the test article.

Table 12-7: Biocompatibility Testing Summary for Threader Over-The-Wire (OTW)

Appendix	Test Performed / Applicable ISO 10993 Part No.	Test Lab and Report No.	Extract Conditions*	Test Article	Results
12-A13	MEM Elution Cytotoxicity/ Part 5	(b) (4) Report # 188663	E-MEM with 5% Fetal Bovine Serum /24 ± 2 hrs at 37 ± 1°C Sample surface area = (b) (4)	Threader OTW 1.2 mm x 12 mm x 150 cm H7493927012120 Lot # 16210869	Pass Grade 0
12-A3	Guinea Pig Maximization Sensitization/Part 10	(Report # 188577	NS / CSO / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Sensitization rate: 0
12-A4	Intracutaneous Reactivity/ Part 10	(b) (4) Report # 188578	NS / CSO / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Score 0/0
12-A5	Acute Systemic Injection/ Part 11	(b) (4) Report # 188579	NS / CSO / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass No signs of toxicity
12-A6	Materials Mediated Rabbit Pyrogen/Part 11	(b) (4) Report # 188580	NS / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b) (4)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Non-pyrogenic

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

Appendix	Test Performed / Applicable ISO 10993 Part No.	Test Lab and Report No.	Extract Conditions*	Test Article	Results
12-A14	Hemolysis Direct Contact & Extract/Part 4	(b) (4) Report # 188664	Blood, direct / PBS / 50 ± 2°C for 72 ± 2 hrs Sample surface area = (b)	Threader OTW 1.2 mm x 12 mm x 150 cm H7493927012120 Lot # 16210869	Pass Hemolytic index: 0.0% direct method; 0.0% extract method
12-A8	Partial Thromboplastin Time/ Part 4	(b) (4) Report # 188581	Blood Plasma, direct Sample surface area = (b)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass 100% of negative control
12-A9	In Vitro Hemocompatibility Assay/Part 4	(b) (4) Report # 188583	NS / Blood /1 hr at 37 ± 2°C Sample surface area = (b)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Results comparable to Reference Control WBC: 108% RBC: 98% Hemoglobin: 98% Hematocrit: 99% Platelet: 109%
12-A10	Complement Activation/ Part 4	(Report # 188576	Serum, direct Sample surface area = (b)	Threader MR 1.2 mm x 12 mm x 150 cm H7493926912120, Lot # 16200986	Pass Negative for C3a, Negative for SC5b-9
12-A15	USP Physicochemical <661>	(b) (4) Report # 937170	Purified Water / 70°C for 24 hrs Sample surface area = (b)	Threader OTW 1.2 mm x 12 mm x 150 cm H7493927012120 Lot # 16210869	Pass Non-volatile residue: (b) (4) Residue on ignition: (b) (4) Heavy metal: (b) (b) Buffering capacity: (b) (4)

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

Appendix	Test Performed / Applicable ISO 10993 Part No.	Test Lab and Report No.	Extract Conditions*	Test Article	Results
12-A12	In Vivo Thromboresistance/ Part 4	(b) (4) 11T_48343_03	Not applicable; direct implant in jugular vein, 4 ± 0.5 hours non-heparinized canine model	Test: Emerge OTW with ZGlide 4.00 mm x 30 mm H7493919530400 Lot # 13935104 Control: Apex OTW with Bioslide 4.00 mm x 30 mm H7493895830400 Lot # 13959792	Test: None to moderate thrombosis (b) (4) Control: Slight to Moderate thrombosis (b) (4) Conclusion: Test article and control are similar in thromboresistance

* Extract Conditions:
NS= Normal Saline (polar)
CSO= Cottonseed Oil (non-polar)
PBS= Phosphate Buffered Saline
E-MEM+FBS = Eagle's Minimal Essential Medium with 5% Fetal Bovine Serum

Section 12 Biocompatibility

Section 12.3 Biocompatibility Test Results

Conclusions

The articles tested for biocompatibility were representative of the product matrix and packaging for the Threader catheter. The testing was conducted on finished devices that were sterilized in their packaging materials. The study reports were reviewed and each test met its acceptance criteria. Therefore, the Threader Micro-Dilatation Catheter and its packaging are considered biocompatible for their intended use under ISO 10993-1 category: externally communicating device, < 24 hour contact with circulating blood exposure.

Appendix 12 Biocompatibility

The following documents are included in this Appendix:

Appendix	Title
12-A1	Chemical Safety Assessment, Threader Patient-Contacting Materials
12-A2	MR MEM Elution Cytotoxicity (188582)
12-A3	MR Sensitization (188577)
12-A4	MR Intracutaneous Reactivity (188578)
12-A5	MR Acute Systemic Injection (188579)
12-A6	MR Rabbit Pyrogen (188580)
12-A7	MR Hemolysis Direct Contact & Extract (188584)
12-A8	MR Partial Thromboplastin Time (188581)
12-A9	MR In Vitro Hemocompatibility (188583)
12-A10	MR Complement Activation (188576)
12-A11	MR USP Physicochemical (936878)
12-A12	Emerge In Vivo Thromboresistance (11T_48343_03)
12-A13	OTW MEM Elution Cytotoxicity (188663)
12-A14	OTW Hemolysis Direct Contact & Extract (188664)
12-A15	OTW USP Physicochemical (937170)

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December 30, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Notification
Threader™ Micro-Dilatation Catheter

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 Threader™ Micro-Dilatation Catheter. The Threader device is a Class II Standard PTCA Catheter per 21 CFR 870.5100(a)(2). The product code is LOX. The Threader device is not an in vitro diagnostic device (IVD).

The Threader Micro-Dilatation Catheter is a new 1.2 mm diameter x 12 mm length balloon catheter that is based on BSC's Emerge 1.20 mm PTCA Dilatation Catheter (K130391), with changes that reduce the crossing profile and improve deliverability to assist the physician in the treatment of coronary lesions. There have been no prior submissions to FDA for the Threader 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 Threader Micro-Dilatation Catheter 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 807 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
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X

Question	Yes	No
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

A copy of the Acceptance Checklist for Traditional 510(k)s, from the FDA Guidance for Industry and FDA Staff, *Refuse to Accept Policy for 510(k)s*, issued on December 31, 2012, is included at the end of the submission. Notations have been made in the checklist to indicate the submission sections where the requested information may be found.

This notification is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
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Boston Scientific

Threader™ Micro-Dilatation Catheter

Traditional 510(k) Notification

Volume 2 of 3

Submitted by:
Boston Scientific Corporation
One Scimed Place
Maple Grove MN 55311

December 30, 2013

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Section 13 Software

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

Section 14 Electromagnetic Compatibility and Electrical Safety

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

Section 15 Performance Testing – Bench

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Section 15 Performance Testing – Bench

Section 15.1 Introduction

Balloon Catheter Testing Guidance

The performance testing presented in this section follows the recommendations in the FDA guidance, *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010.

Bench Testing Approach

The bench testing plan for the Threader device is similar to the bench testing plan for the predicate device, Emerge PTCA Dilatation Catheter (1.20 mm), provided in Traditional 510(k) Notification K130391 (February 14, 2013).

General Design Verification Test Information

All test units were built by trained operators using controlled production processes and qualified equipment. All test builds met the build requirements specified in the respective protocol. All Design Verification manufacturing records are stored per site level documentation requirements.

Design verification testing was conducted on completed product that was 2x sterilized (unless otherwise indicated) using the BSC2000-2 sterilization cycle.

There is only one device size for Threader (1.2 x 12 mm), available in two platforms (Monorail and Over-The-Wire). For tests where the platform (MR or OTW) is critical to the testing, both MR and OTW were tested. For other tests where the platform is not relevant, either platform could be tested. These situations are described in the sample selection sections for the individual tests.

All relevant bench test data are summarized in **Section 15**. The summaries include the elements requested in the PTCA Guidance. Raw data, test methods, protocols, and reports for all tests are available upon request.

Data Analysis

The statistical performance criteria used for bench testing were based on the risk analysis documented in the Hazard Analysis and Product Failure Modes and Effects Analysis (FMEA). Risk analysis provides an overall frame work for assessing risk, taking into account the intended use, performance, and risks of the device, both from the perspective of the clinical procedure as well as the design and processes associated with device manufacturing.

Table 15-1: Minimum Performance Requirements for Nominal and Challenge Builds for Each Risk Index Type, extracted from Corp WI SUD Design Verification 90744436 indicates the minimum performance requirements of both nominal and

challenge test/use condition builds for each risk index type. The risk indices are derived from the Hazard Analysis and Product FMEA sections of the risk analysis based on the clinical effect of the failure mode and the expected occurrence levels. The use of appropriate alternate statistics is permitted with written justification outlining its suitability in meeting performance requirements.

Table 15-1: Minimum Performance Requirements for Nominal and Challenge Builds for Each Risk Index Type

Data Type	Confidence	FMEA Level	Minimum Levels	
			Defective	Reliability
Variable (Nominal)	95%	2	0.3%	99.7%
		1	5.0%	95.0%
		0 / Not in FMEA	Performance requirement or sample size defined by the team*	
Attribute (Nominal)	90%	2	1.0%	99.0%
		1	3.0%	97.0%
		0 / Not in FMEA	Performance requirement or sample size defined by the team*	
Challenge Test/Use Condition	90%	2	10%	90%
		1	20%	80%
		0 / Not in FMEA	Limit and/or Challenge testing conducted at team's discretion	

*The sample size used and the performance level demonstrated are documented in each test section.

Note: When using sampling plans "Defective" is the Lot Tolerance Percent Defective (LTPD) value.

The acceptance criteria are identified separately for each test presented in **Section 15**, with the statistical performance requirements based on the risk indices as detailed in the table above. The sample sizes required to meet the acceptance criteria were calculated using previous data and/or known FDA requirements. Each test section outlines the sample size selected in order to demonstrate the required performance level and confidence level to support the specification. Performance attributes associated with higher risk indices are required to comply to the specifications with higher statistical conformance and confidence than those associated with lower risks.

For each performance attribute, a sampling plan is selected that demonstrates the required performance level is achieved with the desired confidence. Variable sampling plans are applied separately to each measurable characteristic. For attribute sampling plans, those characteristics with the same performance level may be grouped together, and tested as a group.

Variable sampling plans require measurements that follow the normal distribution. The average or mean ($\overline{X}$) and the standard deviation(s) of these measurements are calculated and used to analyze the data. The normal distribution is used to estimate the number of units falling outside the specification limit. Before using a variable sampling

plan, a test for normality is performed. Variable sampling plans take slightly different forms depending on whether the specification is 1- or 2-sided. The following formulas are used to analyse the data, where Ppk ($\hat{P}_{pk}$) represents the actual performance of the process during the study.

1-Sided – Only Lower Specification Limit (LSL):

$$\hat{P}_{pk} = \frac{\overline{X} - LSL}{3\,s}$$

The test meets the performance requirements if $\hat{\mathrm{P}}_{\mathrm{pk}} \geq \mathrm{P}_{\mathrm{pk}}$.

1-Sided - Only Upper Specification Limit (USL):

$$\hat{\mathrm{P}}_{\mathrm{pk}} = \frac{\mathrm{USL} - \overline{\mathrm{X}}}{3\,\mathrm{s}}$$

The test meets the performance requirements if $\hat{\mathrm{P}}_{\mathrm{pk}} \geq \mathrm{P}_{\mathrm{pk}}$.

2-Sided - Lower and Upper Specification Limits (LSL, USL):

$$\hat{\mathrm{P}}_{\mathrm{pk}} = \frac{\mathrm{Min}\left(\mathrm{USL} - \overline{\mathrm{X}}, \overline{\mathrm{X}} - \mathrm{LSL}\right)}{3\,\mathrm{s}}$$

$$\hat{\mathrm{P}}_{\mathrm{p}} = \frac{\mathrm{USL} - \mathrm{LSL}}{6\,\mathrm{s}}$$

The test meets the performance requirements if $\hat{\mathrm{P}}_{\mathrm{pk}} \geq \mathrm{P}_{\mathrm{pk}}$.

In some cases the same test units were used for multiple tests, for example dimensional verification tests. Also, in some cases multiple sample sizes were used for the same variable performance attributes. In this case, the P_{pk} requirement is based on the smallest sample size as this provides the worst case P_{pk} requirements (lowest).

Secondary Statistical Analysis

For variable data, the tolerance limits for normal distributions of the testing results were determined by the methods described in “Techniques of Statistical Analysis,” C. Eisenhart, M.W. Hastay, and W.A. Wallis, ed., McGraw-Hill, New York, 1947. Depending on the product performance concern, a one-sided Upper or Lower tolerance limit was calculated, or a two-sided Upper and Lower tolerance limit was calculated. This approach is covered in the above referenced text (Eisenhart, et al.).

Section 15 Performance Testing – Bench

Section 15.1 Introduction

A table of factors for one-sided and two-sided tolerance limits for normal distributions is found in “Factors for One-Sided Tolerance Limits and for Variables Sampling Plans,” by D.B. Owen, Sandia Corporation Monograph SCR-607, available from the Clearing House for Federal Scientific and Technical Information, U.S. Department of Commerce, Springfield, VA 22151.

Other sample values:
n = sample for each balloon size
x = sample mean for each balloon size
s = sample standard deviation for each balloon size

With the values for n, x and s, and the k-factor for the appropriate confidence and conformance requirements for one-sided or two-sided tolerance limits for normal distributions, the one-sided or two-sided tolerance limit can be calculated. The formula for these limits is as follows:

UTL = Mean + ((Std. Dev.) x (k factor))
LTL = Mean - ((Std. Dev.) x (k factor))

These formulae can only be used if the data are considered normal. Unless stated otherwise, the best fit underlying distribution of the test data was demonstrated as normal, by either the Anderson Darling Normality Test or the Anderson Darling Goodness-of-Fit Statistic. Alternatively, by assessing the skewness and kurtosis of the sample data set, it may be deemed appropriate to use normal statistics to infer tolerance limits. In cases where normal statistics could not be used on the raw data, the Minitab Box-Cox transformation function was used to predict a suitable transformation. In all of these cases, the upper and lower tolerance limits were predicted by the formulas above.

If the underlying distribution was indicated as non-normal and the Anderson Darling Normality Test or the Anderson Darling Goodness-of-Fit Statistic indicated that an alternative distribution was a better predictor, a reliability analysis was performed to assess conformance with the acceptance criteria.

For attribute type data, the Lot Tolerance Percent Defective (LTPD) values were determined using Sampling Programs software in conjunction with the “Guide to Acceptance Sampling”, by Dr. Wayne A. Taylor, Taylor Enterprises, Inc, 1992.

Where relevant, the confidence statements resulting from the statistical analysis are detailed in the Results sections for each test.

Section 15 Performance Testing – Bench

Section 15.2 Master Table

To assist the reviewer, a master table of bench test data included in the submission is provided in **Table 15-2: Master Table of the Threader Micro-Dilatation Catheter Testing**. Devices tested and numbers of samples tested are included, both for nominal (time zero) testing as well as shelf life testing. References are included to the sections where nominal and shelf life results are located. Test articles are identified so that it is clear where data from other devices have been leveraged. Threader shelf life data from the 3-month accelerated aging (AA) time point are included in this submission. Information on prior submission of data is also provided. Most of the test methods used in the bench testing of the Threader devices are the same test methods used in testing the Emerge predicate (K130391). In a few cases, new test methods (not previously submitted to FDA) have been used for testing Threader. These new test methods are included in **Appendix 15**, as noted in the specific test results sections.

Table 15-2: Master Table of the Threader Micro-Dilatation Catheter Testing

Section Number: Test and/or Study Name	Test Article	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=0	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=shelf life	Pass/ Fail	Submission References for Previously-Submitted Data and Leverage Justification, if Applicable
15.3.1: Effective Length, T=0 15.4.1: Effective Length, T=3 Month AA	Threader devices	Not applicable	Not applicable	Pass (based on refer-enced analysis)	Not applicable
15.3.2: Outer Diameter (Catheter Shaft), T=0 15.4.2: Outer Diameter (Catheter Shaft), T=3 Month AA	Threader devices	1.2 x 12 MR ([redacted]) 1.2 x 12 OTW ([redacted])	1.2 x 12 MR ([redacted]) 1.2 x 12 OTW ([redacted])	Pass	Not applicable
15.3.3: Inner Diameter (Catheter Shaft), T=0 15.4.3: Inner Diameter (Catheter Shaft), T=3 Month AA	Threader devices	Not applicable	Not applicable	Pass (based on refer-enced testing)	Not applicable
15.3.4: Balloon Crossing Profile, T=0 15.4.4: Balloon Crossing Profile, T=3 Month AA	Threader devices	1.2 x 12 MR ([redacted]) 1.2 x 12 OTW ([redacted])	1.2 x 12 MR ([redacted]) 1.2 x 12 OTW ([redacted])	Pass	Not applicable

Section 15 Performance Testing – Bench

Section 15.2 Master Table

Section Number: Test and/or Study Name	Test Article	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=0	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=shelf life	Pass/ Fail	Submission References for Previously-Submitted Data and Leverage Justification, if Applicable
15.3.5: Balloon Preparation, Deployment, and Retraction (DDR), T=0 15.4.5: Balloon Preparation, Deployment, and Retraction (DDR), T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.6: Balloon Withdrawal into a Guide Catheter, T=0 15.4.6: Balloon Withdrawal into a Guide Catheter, T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.7: Balloon Rated Burst Pressure (RBP), T=0 15.4.7: Balloon Rated Burst Pressure (RBP), T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.8: Balloon Fatigue (Repeat Balloon Inflations), T=0 15.4.8: Balloon Fatigue (Repeat Balloon Inflations), T=3 Month AA	Threader devices	1.2 x 12 MR (b)	1.2 x 12 MR (b)	Pass	Not applicable
15.3.9: Balloon Compliance Labeling (Diameter vs. Pressure), T=0 15.4.9: Balloon Compliance (Diameter vs. Pressure), T=3 Month AA	Threader devices	1.2 x 12 MR (b)	1.2 x 12 MR (b)	Pass	Not applicable
15.3.10: Balloon Deflation and Inflation Time, T=0 15.4.10: Balloon Deflation and Inflation Time, T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.11: Catheter Bond Strength, T=0 15.4.11: Catheter Bond Strength, T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable

Section 15 Performance Testing – Bench

Section 15.2 Master Table

Section Number: Test and/or Study Name	Test Article	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=0	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=shelf life	Pass/ Fail	Submission References for Previously-Submitted Data and Leverage Justification, if Applicable
15.3.12: Tip Pull Test (Tip Bond Tensile), T=0 15.4.12: Tip Pull Test (Tip Bond Tensile), T=3 Month AA	Threader devices	1.2 x 12 MR (b)	1.2 x 12 MR (b)	Pass	Not applicable
15.3.13: Flexibility and Kink, T=0 15.4.13: Flexibility and Kink, T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.14: Torque Strength, T=0 15.4.14: Torque Strength, T=3 Month AA	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.15: Radiopacity, T=0 (results reported in Section 16.2: Radiopacity Studies)	NC Quantum Apex devices	Not specified	Not applicable	Pass	Submitted for NC Quantum Apex, P860019/S241 Leverage Justification: Marker bands are substantially equivalent; see Section 16.2
15.3.16: Coating Integrity, T=0 15.4.15: Coating Integrity, T=3 Month AA	Threader devices	Shaft: 1.2 x 12 MR (b) Balloon: 1.2 x 12 MR (b)	Shaft: 1.2 x 12 MR (b) Balloon: 1.2 x 12 MR (b)	Pass	Not applicable
15.3.17: Particulate Evaluation, T=0 15.4.16: Particulate Evaluation, T=3 Month AA	Threader devices Emerge devices (for reference)	1.2 x 12 MR (b) 1.2 x 12 OTW (b) 1.20 x 12 MR (b)	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Pass	Not applicable
15.3.18: Catheter Body Burst Pressure, T=0 15.4.17: Catheter Body Burst Pressure, T=3 Month AA	Threader devices	1.2 x 12 OTW (b)	1.2 x 12 OTW (b)	Pass	Not applicable

Section 15 Performance Testing – Bench

Section 15.2 Master Table

Section Number: Test and/or Study Name	Test Article	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=0	Catheter Size (Diameter and Length in mm) and Number of Catheters (n) T=shelf life	Pass/ Fail	Submission References for Previously-Submitted Data and Leverage Justification, if Applicable
15.3.19: Contrast Media Flow Rate, T=0 15.4.18: Contrast Media Flow Rate, T=3 Month AA	Threader devices	(results reported in Section 16.1)	Not applicable	Pass	Not applicable
15.3.20: Kissing Balloon Force Bench Testing, T=0	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Not applicable	Pass	Not applicable
15.3.21: Kissing Balloon Dye Flow Bench Testing, T=0	Threader devices	1.2 x 12 MR (b) 1.2 x 12 OTW (b)	Not applicable	Pass	Not applicable
	Apex devices (for reference)	4.00 x 30 MR (b) 4.00 x 30 OTW (b)			

Section 15 Performance Testing – Bench

Section 15.3 Design Verification Testing

The results of the nominal (time zero) design verification testing are presented in this section. **Table 15-3: Summary of Applicable Nominal (Time Zero) Design Verification Testing** lists the tests that were completed, as required by the FDA PTCA Guidance, and the sections where the results are located.

Table 15-3: Summary of Applicable Nominal (Time Zero) Design Verification Testing

Test		Reference
Dimensional and Functional Attributes	Delivery System Dimensional Verification	**Section 15.3.1** Effective Length **Section 15.3.2** Outer Diameter (Catheter Shaft) **Section 15.3.3** Inner Diameter (Catheter Shaft) **Section 15.3.4** Balloon Crossing Profile
	Balloon Preparation, Deployment and Retraction	**Section 15.3.5** Balloon Preparation, Deployment, and Retraction (DDR) **Section 15.3.6** Balloon Withdrawal into a Guide Catheter (MR & OTW)
	Balloon Rated Burst Pressure (RBP)	**Section 15.3.7** Balloon Rated Burst Pressure (RBP)
	Balloon Fatigue (Balloon Repeat Inflations)	**Section 15.3.8** Balloon Fatigue (Repeat Balloon Inflations)
	Balloon Compliance (Diameter vs. Pressure)	**Section 15.3.9** Balloon Compliance Labeling (Diameter vs. Pressure)
	Balloon Inflation and Deflation Time	**Section 15.3.10** Balloon Deflation and Inflation Time
	Catheter Bond Strength	**Section 15.3.11** Catheter Bond Strength (Full Unit Tensile)
	Tip Pull Test	**Section 15.3.12** Tip Pull Test (Tip Bond Tensile)
	Flexibility and Kink Test	**Section 15.3.13** Flexibility and Kink
	Torque Strength	**Section 15.3.14** Torque Strength
	Radiopacity	**Section 15.3.15** Radiopacity (see **Section 16.2**)
	Coating Integrity	**Section 15.3.16** Coating Integrity

Section 15 Performance Testing – Bench

Section 15.3 Design Verification Testing

Test		Reference
	Particulate Evaluation	**Section 15.3.17** Particulate Evaluation
Additional Tests for Catheters Intended for Infusion of Contrast Media or Other Fluids	Catheter Body Burst Pressure	**Section 15.3.18** Catheter Body Burst Pressure
	Contrast Media Flow Rate	**Section 15.3.19** Contrast Media Flow Rate
Additional Tests for Catheters Intended for In-Stent Restenosis for Stent Expansion following Stent Deployment	Balloon Rated Burst Pressure (in Stent)	Not applicable (device not intended for In-Stent Restenosis (ISR) or stent expansion)
	Balloon Fatigue (Repeat Balloon Inflations; in Stent)	

All Threader nominal (time zero) design verification testing has been successfully completed. The test results are summarized in the sub-sections that follow.

(b)(4)Design Verification Test Results

(b)(4)Design Verification Test Results

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(b)(4)Design Verification Test Results

Section 15 Performance Testing – Bench

Section 15.4 Product Shelf Life Testing

The results of the accelerated (shelf life) design verification testing are presented in this section.

Shelf Life Parameters
Testing was conducted, as applicable, in accordance with the *FDA Guidance "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*," September 8, 2010. Where applicable, exceptions have been noted and justified.

Device shelf-life testing is conducted on product to demonstrate that the functional properties of the device and its packaging are maintained through the labeled shelf life. The test methods used for Threader shelf life testing are the same methods used for nominal (T=0) testing. The product shelf life testing supports a 3-month shelf life at this time. Upon FDA approval of the accelerated aging shelf life protocol (as described in this section) and successful completion of the 2-year accelerated aging shelf life testing, the labeling will be updated to reflect a 2-year shelf life.

Where applicable, the nominal baseline data (from **Section 15.3**) are also included in the shelf life results section for informational purposes. It should be noted that all acceptance criteria defined by BSC were met, which required performance to the specification at baseline (time zero) and at shelf life.

Design verification test units were subjected to two sterilization cycles. Aging units were then placed in an environmental chamber at the following conditions for accelerated aging (AA):

- Temperature: 47°C ± 2°C
- Relative Humidity (RH): 60% ± 20%

The BSC Q_{10} accelerated aging prediction model uses the Arrhenius kinetics rate equation to calculate the parameters used for accelerated aging. This equation is based upon the reaction rate of chemical processes doubling in rate for every 10°C increase in temperature above the recommended ambient storage temperature (25°C).

$$t = \frac{T}{2^{\frac{(b-a)}{10}}}$$

where,
t = time required for product to be at an elevated temperature
T = the shelf life period being sought
b = elevated temperature being used
a = the ambient storage temperature expected for standard product storage during its actual shelf life

Table 15-41: Summary of Applicable Accelerated Aging (AA) Design Verification Testing lists the tests that were completed, as required by the FDA PTCA Guidance, and the sections where the results are located.

Table 15-41: Summary of Applicable Accelerated Aging (AA) Design Verification Testing

Test		Reference
Dimensional and Functional Attributes	Delivery System Dimensional Verification	**Section 15.4.1** Effective Length **Section 15.4.2** Outer Diameter (Catheter Shaft) **Section 15.4.3** Inner Diameter (Catheter Shaft) **Section 15.4.4** Balloon Crossing Profile
	Balloon Preparation, Deployment and Retraction	**Section 15.4.5** Balloon Prep, Deployment, and Retraction (DDR) **Section 15.4.6** Balloon Withdrawal into a Guide Catheter
	Balloon Rated Burst Pressure (RBP)	**Section 15.4.7** Balloon Rated Burst Pressure (RBP)
	Balloon Fatigue (Balloon Repeat Inflations)	**Section 15.4.8** Balloon Fatigue (Repeat Balloon Inflations)
	Balloon Compliance (Diameter vs. Pressure)	**Section 15.4.9** Balloon Compliance (Diameter vs. Pressure)
	Balloon Inflation and Deflation Time	**Section 15.4.10** Balloon Deflation and Inflation Time
	Catheter Bond Strength	**Section 15.4.11** Catheter Bond Strength
	Tip Pull Test	**Section 15.4.12** Tip Pull Test (Tip Bond Tensile)
	Flexibility and Kink Test	**Section 15.4.13** Flexibility and Kink
	Torque Strength	**Section 15.4.14** Torque Strength
	Coating Integrity	**Section 15.4.15** Coating Integrity
	Particulate Evaluation	**Section 15.4.16** Particulate Evaluation

Section 15 Performance Testing – Bench

Section 15.4 Product Shelf Life Testing

Test		Reference
Additional Tests for Catheters Intended for Infusion of Contrast Media or Other Fluids	Catheter Body Burst Pressure	**Section 15.4.17** Catheter Body Burst Pressure
	Contrast Media Flow Rate	**Section 15.4.18** Contrast Media Flow Rate
Additional Tests for Catheters Intended for In-Stent Restenosis for Stent Expansion following Stent Deployment	Balloon Rated Burst Pressure (in Stent)	Not applicable (device not intended for In-Stent Restenosis (ISR) or stent expansion)
	Balloon Fatigue (Repeat Balloon Inflations; in Stent)	

Note: During accelerated aging of the 3 month units, the relative humidity (RH) was in and out of tolerance (60% ± 20%) from August 29, 2013 at approximately 3:00 a.m. through August 30, 2013 at approximately 8:00 a.m. The total duration was 23 hours in which the RH went as low as 22.4% and as high as 58.5%. This out of tolerance is not believed to be significant since the duration was less than 24 hours. Per Corporate SOP, Product Aging for BSC Products, 90176569, any excursion during accelerated aging will be documented and investigated. The duration of the study was not increased due to the short length of time the RH was out of tolerance. All testing requirements established by the protocol were met.

All Threader accelerated (shelf life) design verification testing has been successfully completed. The test results are summarized in the sub-sections that follow.

(b)(4)Product Shelf Life Testing Report

(b)(4)Product Shelf Life Testing Report

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(b)(4)Product Shelf Life Testing Report

Section 15 Performance Testing – Bench

Section 15.5 Packaging Design Verification Including Shelf Life Testing

Packaging Design Verification Including Shelf Life Testing

This section describes the packaging testing and test results for the Threader catheter. The packaging was designed taking into consideration compatibility with the device materials, the sterilization process, the labeling, the physical, chemical and microbial protection required and the user's requirements at the point of use.

The purpose of packaging testing is to demonstrate that the packaging system performs as intended. The packaging system must protect the device through sterilization, distribution, handling, and storage, provide product traceability, and maintain a sterile barrier.

Below is a summary of package integrity testing and user interface testing that was conducted on non-aged and aged product.

Table 15-93: Packaging Integrity and User Interface Testing

Test Name	Purpose
Sterile Barrier Integrity (Pouch Seal Strength)	Measures seal strength of the pouch materials.
Sterile Barrier Integrity (Dye Penetration)	Verifies that the pouch seal is free of channels, pinholes, or other barrier breaches.
Sterile Barrier Integrity (Visual Inspection)	Verifies the sterile package is free of channels, leaks, gaps, or other barrier imperfections that could indicate a breach of sterile barrier integrity.
Seal Integrity (Visual Inspection)	Verifies that the pouch seal is free of channels, gaps, or other barrier imperfections and does not have any fiber tears.
Label Adhesion and Print Quality	Verifies that the labels remain intact and that the printing remains clear and legible.
DFU Print Quality	Verifies that the DFU printing remains clear and legible.
Shelf Carton Condition	Verifies that the shelf carton remains intact and retains the device.
Manifold Securement and Removal Force	Verifies that the tab of the device can be removed from the carrier tube without using excessive force as defined by the hub removal force specification.
Catheter Removal from Carrier Tube	Verifies that the catheter can be removed from the carrier tube and must meet a removal force specification.

Section 15 Performance Testing – Bench

Section 15.5 Packaging Design Verification Including Shelf Life Testing

Purpose

Packaging design verification testing was conducted to verify that the packaging meets the pre-defined performance / functional and user interface requirements after 2x sterilization and distribution challenge testing at T=0 and an accelerated aged condition.

Test Sample Preparation

At the T=0 time point, the test units were subjected to 2x sterilization and then distribution tested (following ISTA 2A).

Aging units were accelerated aged to the following formula:

$$t = \frac{T}{2^{\frac{(b-a)}{10}}}$$

- t = time required for product to be in an elevated temperature
- T = the shelf life period being sought
- b = elevated temperature being used
- a = the ambient storage temperature expected for standard product storage during its real shelf life

Accelerated aging was run at the following parameters to simulate 37-month shelf life:

- t = 141 days
- T = 37 months
- b = 55°C
- a = 25°C

Test Samples and Rationale

(90850499, 90862605)

All packaging materials and components used for Threader are identical to those used in the Coyote™ PTA Balloon Dilatation Catheters (K111295, cleared May 31, 2011) and Runway™ Guide Catheter (K033441, cleared November 21, 2003). Therefore, some testing of the Coyote and/or Runway packaging materials in the T=0 distribution and aged states (37-months AA) will be leveraged for Threader, as applicable. This leveraging is acceptable since the other devices have more mass than the Threader device and are therefore considered worst case for package integrity testing.

Threader catheters use the same manifold design as the Emerge predicate (K130391). Emerge used the same manifold design as the Apex PTCA Dilatation Catheter (P860019/S208). Therefore, the manifold securement and removal testing conducted on the Apex product was previously leveraged for Emerge, and is leveraged again for Threader.

Threader was tested directly for carrier tube withdrawal, as the carrier tube used on Threader is longer than that used in the Emerge predicate. Results of all new and leveraged data are presented below for review.

(b)(4)Packing Test Results

(b)(4)Packing Test Results

(b)(4)Packing Test Results

(b)(4)Packing Test Results

(b)(4)Packing Test Results

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December 30, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Notification
Threader™ Micro-Dilatation Catheter

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 Threader™ Micro-Dilatation Catheter. The Threader device is a Class II Standard PTCA Catheter per 21 CFR 870.5100(a)(2). The product code is LOX. The Threader device is not an in vitro diagnostic device (IVD).

The Threader Micro-Dilatation Catheter is a new 1.2 mm diameter x 12 mm length balloon catheter that is based on BSC's Emerge 1.20 mm PTCA Dilatation Catheter (K130391), with changes that reduce the crossing profile and improve deliverability to assist the physician in the treatment of coronary lesions. There have been no prior submissions to FDA for the Threader 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 Threader Micro-Dilatation Catheter 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 807 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
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X

Question	Yes	No
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

A copy of the Acceptance Checklist for Traditional 510(k)s, from the FDA Guidance for Industry and FDA Staff, *Refuse to Accept Policy for 510(k)s*, issued on December 31, 2012, is included at the end of the submission. Notations have been made in the checklist to indicate the submission sections where the requested information may be found.

This notification is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

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Boston Scientific

Threader™ Micro-Dilatation Catheter

Traditional 510(k) Notification

Volume 3 of 3

Submitted by:
Boston Scientific Corporation
One Scimed Place
Maple Grove MN 55311

December 30, 2013

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Appendix 15 Performance Testing – Bench

The following documents are included in this Appendix:

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15-A1	Catheter Tensile Test Method (90861012), Rev. AA and Rev. AB
15-A2	Proximal Balloon Bond Tensile Test Method (90180627)
15-A3	Particulates for POBA with Slipcoat Test Method (90904039)
15-A4	Threader Wire Lumen Burst Pressure Report (90910597)

(b)(4)Design Verification Test Results

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Section 16 Performance Testing – Animal

The animal studies conducted to support the Threader Micro-Dilatation Catheter program are summarized in this section. The study protocols and reports are included in **Appendix 16**.

Section	Content	Page
16.1	Design/Usability Validation	16-2
16.2	Radiopacity Studies	16-7

Section 16 Performance Testing – Animal

Section 16.1 Design/Usability Validation

A non-GLP animal study was conducted to support Design Validation (CFR 820.30(g)) and product labeling of the Threader device. User assessments were conducted to evaluate the intended needs and primary operating functions of the device in an acute animal study. Successful performance of the Threader device in a nonclinical study provides evidence of device usability under anticipated clinical conditions.

Purpose

Design Validation: To ensure that the Threader catheter conforms to user needs and intended uses through acute animal assessments

Labeling: To support the DFU intended use statements and operational instructions regarding the use of Threader OTW catheters guidewire exchange and hand-injection of contrast media.

This study supports the following indication statements in the proposed Threader DFU:

> *The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.*
>
> *The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.*

and the following operational instructions located in Step 2 of the Insertion Procedure section in the proposed Threader DFU:

> *I. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that contrast media is needed, withdraw the guidewire and hand-inject contrast media through the catheter hub with a syringe.*
>
> *J. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that an alternative guidewire is needed, remove the guidewire while holding the hub of the Over-The-Wire Micro-Dilatation Catheter in place. Once the guidewire has been removed from the patient, an alternative guidewire can be introduced into the hub of the Over-The-Wire Micro-Dilatation Catheter and advanced to the distal tip of the catheter.*

GLP Compliance

This non-GLP animal study was not intended to be conducted in full accordance with the United States Food and Drug Administration (FDA) Good Laboratory Practice Regulations, 21 CFR Part 58. In place of GLP compliance, data integrity was supported by governing SOPs and processes at the external testing facility and within BSC, as follows:

Section 16 Performance Testing – Animal

Section 16.1 Design/Usability Validation

The local (US) test facility is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) and licensed by the USDA. A written protocol was reviewed and approved by the test facility Institutional Animal Care and Use Committees (IACUC) prior to conducting the study. The study was conducted in accordance with protocols and standard operating procedures (SOPs) of the test facility.

Test devices were production-equivalent units, built to print specifications by trained operators using controlled production processes and qualified equipment, and assigned unique identification numbers. Test device manufacturing data and traceable identity numbers were recorded on shop floor paperwork and stored by Boston Scientific in the Design History File. Test device identification numbers were recorded on study datasheets.

Study conduct was monitored for adherence to the protocols, and changes were documented by amendments and deviations. Data were recorded on protocol specific datasheets and were reviewed and signed by the clinical investigators who performed the evaluations. Study protocols, reports, and datasheets were retained by Boston Scientific.

Sample Selection and Rationale

Both MR and OTW devices were tested in the Threader Design/Usability Validation activities. Only one size exists for each type.

Animal Model Rationale

The porcine model is an established animal model for acute performance studies, which is accepted by regulatory agencies. The porcine heart, coronary, and peripheral arterial systems are of similar size and anatomical structure compared to humans, allowing for use of standard guide catheters and curves. Coronary arteries can be accessed via the carotid or femoral arteries, to simulate delivery of devices in a clinical setting. Arterial vessel diameter and length permits evaluation of device sizes offered in the product matrix, and arterial anatomy provides comparable tortuosity to evaluate device performance.

Methodology and Acceptance Criteria

(90849468, 90899335)

Table 16-1 describes each of the requirements evaluated and the criteria used to determine acceptable performance. These studies were performed on devices that are representative of the final Threader design. The study protocol is included in **Appendix 16-A1**.

Section 16 Performance Testing – Animal

Section 16.1 Design/Usability Validation

Table 16-1: Animal Study Methodology and Acceptance Criteria

Requirement	Evaluation Method	Acceptance Criteria
(b) (4)		

Section 16 Performance Testing – Animal

Section 16.1 Design/Usability Validation

Requirement	Evaluation Method	Acceptance Criteria
(b) (4)		

Results
(90899336)

Study 13-120N was conducted on (b) (4) (b) (4). The investigator provided (b) observations for each user need on both the MR and OTW platforms, for a total sample size of (b) observations per user need.

All evaluations were successful. The results are summarized in **Table 16-2**. The study report is included in **Appendix 16-A2**.

Section 16 Performance Testing – Animal

Section 16.1 Design/Usability Validation

Table 16-2: Results of Threader MR and OTW Acute Performance Animal Assessment

User Need Evaluated	Pass/ Fail
(b) (4)	Pass
	Pass
	Pass
	Pass
	Pass
	Pass
	Pass
	Pass
	Pass
	Pass
	Pass

Protocol Deviations

There were no protocol deviations during this study.

Conclusions

The objectives of the study were met. Threader catheters were evaluated to assess the ability to meet user needs in a nonclinical setting. The results confirm that Threader catheters meet user needs and are capable of performing as intended in a clinical environment. In addition, the results support the indication and DFU statements regarding the ability to deliver contrast media through the inner lumen and the ability to exchange guidewires during use.

Section 16 Performance Testing – Animal

Section 16.2 Radiopacity Studies

Introduction – Radiopacity Studies

The materials used in the radiopaque marker bands for Threader are identical to those used on commercial BSC devices: Emerge (predicate), Apex and NC Quantum Apex. The wall thickness of the Threader marker band is the same as the wall thickness of the marker bands used on Emerge, Apex and NC Quantum Apex, but the Threader marker band has a slightly smaller inner and outer diameter in order to match the smaller inner shaft component on Threader. To compensate, the length of the Threader marker band is slightly longer. These dimensional differences result in a (b)(4)Design Variation in marker band mass for Threader, compared to the predicate, which will maintain marker band visibility under fluoroscopy. BSC has determined that the marker band and marker band visibility for Threader are substantially equivalent to the predicate device and prior preclinical testing is sufficient to support the radiopacity requirement.

Purpose

BSC conducted 3 non-GLP animal studies to assess the radiopacity of the predicate marker bands. These animal studies were performed on the NC Quantum Apex PTCA Dilatation Catheter (P860019/S241, approved April 16, 2010), which uses the same marker bands as the predicate Emerge device. Results of marker band visibility from the NC Quantum Apex studies are representative of marker band visibility for the predicate Emerge device, and also support marker band visibility for Threader, for the reasons stated above.

The following porcine studies were conducted on NC Quantum Apex to assess acute performance:

- ***BSC Study Number 09-042N***
- ***BSC Study Number 08-111N S8***
- ***BSC Study Number 09-054N***

The objectives of BSC's nonclinical animal studies were:

- To ensure that the NC Quantum Apex catheter conforms to user needs and intended uses through an acute animal assessment

The only results from these studies that are applicable to Threader are the marker band results, which are summarized here. These studies were previously reviewed by FDA as part of the approval of NC Quantum Apex (P860019/S241) and clearance of the Emerge 1.20 mm predicate (K130391).

GLP Compliance

These non-GLP animal studies were not intended to be conducted in full accordance with the United States Food and Drug Administration (FDA) Good Laboratory Practice Regulations, 21 CFR Part 58. In place of GLP compliance, data integrity was supported by governing SOPs and processes within BSC and the external testing facilities, as follows:

The local (US) test facilities were accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) and licensed by the USDA. International test facilities were fully authorized by the relevant regulatory institutions to practice animal research. Written protocols were reviewed and approved by the US test facility Institutional Animal Care and Use Committees (IACUC), or by similar international test facility committees, prior to conducting the studies. The studies were conducted in accordance with protocols and standard operating procedures (SOPs) of the respective test facilities.

Test devices were production-equivalent units, built to print specifications by trained operators using controlled production processes and qualified equipment, and assigned unique identification numbers. Test device manufacturing data and traceable identity numbers were recorded on shop floor paperwork and stored by Boston Scientific in the Design History File. Test device identification numbers were recorded on study datasheets.

Study conduct was monitored for adherence to the protocols, and changes were documented by amendments and deviations. Data were recorded on protocol specific datasheets and were reviewed and signed by the clinical investigators who performed the evaluations. Study protocols, reports, and datasheets were retained by Boston Scientific.

Animal Model Rationale

The porcine model is an established animal model for acute performance studies, which is accepted by regulatory agencies. The porcine heart, coronary, and peripheral arterial systems are of similar size and anatomical structure compared to humans, allowing for use of standard guide catheters and curves. Coronary arteries can be accessed via the carotid or femoral arteries, to simulate delivery of devices in a clinical setting. Arterial vessel diameter and length permits evaluation of device sizes offered in the product matrix, and arterial anatomy provides comparable tortuosity to evaluate device performance.

Section 16 Performance Testing – Animal

Section 16.2 Radiopacity Studies

Device Model Selection Rationale

Marker band radiopacity is dependent on the marker band OD, wall thickness, length and material. All NC Quantum Apex products use the same marker band part number. Therefore, any size or model of NC Quantum Apex was acceptable for this evaluation and no specific sizes were specified in the protocol. The observations were made using the sizes and models that were appropriate for other objectives of the animal studies. Minimum numbers of investigators and observations were specified, as shown in **Table 16-3**.

Table 16-3: Radiopacity Sample Size

Test Facility	Device Size and Model	Minimum Sample Size (# of Observations)
LyChron (Study 09-042N)	Any size/model	Minimum # of evaluators = (b) Minimum # of total observations = (b)
RTC (Study 08-111N S8)	Any size/model	Minimum # of evaluators = (b) Minimum # of total observations = (b)
IMM (Study 09-054N)	Any size/model	Minimum # of evaluators = (b) Minimum # of total observations = (b)

Methodology and Acceptance Criteria

(90495873, 90502053, 90508618)

Study 09-042N was conducted on (b) (4), (b) (4) investigators. Study 08-111N S8 was conducted on (b) (4) investigators. Study 09-054N was conducted on (b) (4) investigators.

Investigators were asked to assess the visibility of the NC Quantum Apex marker bands relative to the Quantum Maverick marker bands, in a deployed TAXUS Element (ION) stent. Acceptance criteria stated marker band visibility could not be significantly worse than Quantum Maverick and must be rated as acceptable. For the comparative testing, NC Quantum Apex was rated on a 1-5 scale compared to Quantum Maverick (1 = significantly worse, 2 = slightly worse, 3 = equivalent, 4 = slightly better and 5 = significantly better) and the data were normalized relative to Quantum Maverick (Quantum Maverick was represented by a value of 3).

The acceptance criteria text varied slightly by site, depending on the protocol, the number of investigators and the number of planned observations. The radiopacity acceptance criteria are summarized in **Table 16-4**. The study protocols are included in **Appendices 16-A3**, **16-A5**, and **16-A7**.

Table 16-4: Radiopacity Acceptance Criteria

Test Facility	Acceptance Criteria
(b) (4)	[redacted]

Results
(90508956, 90510612, 90522281)

The radiopacity results are summarized in **Tables 16-5**, **16-6** and **16-7**. All results were acceptable. The study reports are included in **Appendices 16-A4**, **16-A6**, and **16-A8**.

Section 16 Performance Testing – Animal

Section 16.2 Radiopacity Studies

Table 16-5: Average Normalized Performance

Test Facility	Average NC Quantum Apex Performance	Acceptance Criteria	Result (Pass/Fail)
LyChron (09-042N)	(b)	(b)	Pass
RTC (08-111N S8)	(b)	(b)	Pass
IMM (09-054N)	(b)	(b)	Pass

Table 16-6: Individual Performance (No. of observations with rank = 1)

Test Facility (Physicians)	Total Observations	(b) (4)	(b) (4)	Acceptance Criteria	Result (Pass/Fail)
LyChron (b)	(b)	(b	(b)	(b) (4)	Pass
RTC (b)	(b	(b	(b)	(b) (4)	Pass
IMM (b)	(b)	(b	(b)	(b) (4)	Pass

Table 16-7: Individual Performance (acceptability ratings)

Test Facility (Physicians)	Total Observations	Acceptable Observations	Percent of Acceptable	Acceptance Criteria	Result (Pass/Fail)
LyChron (b)	(b)	(b)	(b)	(b) (4)	Pass
RTC (b)	(b	(b	(b)	(b) (4)	Pass
IMM (b)	(b)	(b)	(b)	(b) (4)	Pass

Conclusions

All marker band visibility results from the NC Quantum Apex acute animal studies passed acceptance criteria, demonstrating acceptable radiopacity. Because the marker band component used on Threader is substantially equivalent to the marker band used on the Emerge, NC Quantum Apex, and Apex devices, the Threader device marker band visibility is considered acceptable based on results from the preclinical assessment performed on the NC Quantum Apex device.

Appendix 16 Performance Testing – Animal

The following documents are included in this Appendix:

Appendix	Title
16-A1	Threader Design/Usability Validation Protocol (90899335)
16-A2	Threader Design/Usability Validation Report (90899336)
16-A3	LyChron 09-042N Protocol (90495873)
16-A4	LyChron 09-042N Report (90508956)
16-A5	RTC 08-111N S8 Protocol (90502053)
16-A6	RTC 08-111N S8 Report (90510612)
16-A7	IMM 09-054N Protocol (90508618)
16-A8	IMM 09-054N Report (90522281)

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Section 17 Performance Testing – Clinical

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

The completed Certificate of Compliance with Requirements of ClinicalTrials.gov Data Bank (Form FDA 3674) is provided in **Appendix 17-A1**.

Appendix 17 Performance Testing – Clinical

The following documents are included in this Appendix:

Appendix	Title
17-A1	Form FDA-3674 (Certificate of Compliance with Requirements of ClinicalTrials.gov Data Bank)

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Boston Scientific Corporation

2. Date of the Application/Submission Which This Certification Accompanies
12/30/2013

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
One Scimed Place

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Maple Grove

State/Province/Region
MN

Country
USA

ZIP or Postal Code
55311

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 763-494-1700

(Fax): 763-494-2222

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

PTCA Dilatation Catheter (LOX), Class II, Threader Monorail Micro-Dilatation Catheter, H7493926912120

PTCA Dilatation Catheter (LOX), Class II, Threader Over-The-Wire Micro-Dilatation Catheter, H7493927012120

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Vicky L. Hagens	Principal Regulatory Affairs Specialist

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*		
One Scimed Place		
Address 2 *(Apartment, suite, unit, building, floor, etc.)*		
City	State/Province/Region	ZIP or Postal Code
Maple Grove	MN	55311
Country		
USA		

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 763-494-1522

(Fax): 763-494-2222

14. Date of Certification

12/20/2013

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign



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 15 minutes and 45 minutes (depending on the type of application/ submission) 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."

Section 18 Acceptance Checklist

The FDA Acceptance Checklist for Traditional 510(k)s follows this page.

Contains Nonbinding Recommendations

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.

510(k) Number: _____ Date Received by DCC: _____

Lead Reviewer Name: _____ Branch: _____ Division: _____ Office: _____

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 RTA and that element will be assessed during substantive 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."		
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."		
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.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.		
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."		
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.		
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 - 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.		

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 – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	☐	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☐	☐
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…).*	☐	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☐	☐
Comments:		

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.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☐		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		☐		☐
		a.	Device trade name or proprietary name	☐		☐
		b.	Device common name	☐		☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☐		☐
		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.*		☐		☐
		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.*		☐		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☐	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	☐	☐
		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).*		☐		☐
		Comments:				

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	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).*		☐	☐	☐
		Comments:				
	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.*		☐	☐	
		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:				
	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.*		☐	☐	☐

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.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		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.*		☐		☐
		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	☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments:				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, 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.*	☐	☐	☐
		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 information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	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:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☐		☐
		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.	☐		☐
		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.*	☐	☐	☐
		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).*		☐	☐	☐
		Comments:				

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	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.*			☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐		☐
		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.*	☐	☐	☐
		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.*	☐	☐	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☐		☐
		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/DeviceRegulationandGuidan*	☐		☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			ce/ComplianceActivities/ucm072746.htm).			
		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.	☐		☐
		Comments:				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☐		☐
		b.	Technology, including features, materials, and principles of operation	☐		☐
		Comments:				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), 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)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in*		☐	☐	☐

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.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.				
		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		☐		☐
		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)	☐		☐
		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 21 CFR 801 Subpart D	☐		☐
		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.*		☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		Comments:				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☐		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	☐	☐	☐
		Comments:				
	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.*	☐	☐	☐
		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.*	☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		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.*	☐	☐	☐
		Comments:				
	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.*		☐	☐	☐
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*) ☐ 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*					☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	the checklist. *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments:					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☐	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	☐	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☐	☐
		Comments:				
	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.)	☐		☐
		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 report is not required.*	☐		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		e.	Sterility Assurance Level (SAL) stated	☐		☐
		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.*			☐	
		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:				
	25.	a.	If there are requirements regarding sterility, such as special	☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			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.*			
		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.*	☐	☐	☐
		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*			

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.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			special controls document have been addressed should be assessed during the substantive review.			
		Comments:				
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.*		☐	☐	☐
		Comments:				
	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.*		☐	☐	☐
		Comments:				
	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.		☐		☐
		Comments:				
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*) ☐ are					☐

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.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
	☐ 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."*				
	Comments:				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☐		☐
		Comments:			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐		☐
		Comments:			
	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).	☐		☐
		Comments:			
H.	**Software**				

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.				
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.	**Yes**	**N/A**	**No**
	Submission states that the device: (*one of the below must be checked*) ☐ does ☐ 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."*			☐
	Comments:			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern	☐		☐
	Comments:			
	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).	☐		☐
	Comments:			
I.	**EMC and Electrical Safety**			
	Submission states that the device: (*one of the below must be checked*) ☐ does ☐ does not require EMC and Electrical Safety evaluation.			☐

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.					
		• Any "No" answer will result in a "Refuse to Accept" decision. • 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.	**Yes**	**N/A**	**No**
	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."*				
	Comments:				
	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).	☐		☐
		Comments:			
	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).	☐		☐
		Comments:			

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
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.*				☐	
	Comments:					
	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.*		☐	☐	☐
		Comments:				
	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.*	☐	☐	☐
		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	☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			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.*			
		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:				
	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.*			☐	
		a.	Legible reprints or a summary of each article	☐		☐
		b.	Discussion of how each article is applicable to support the	☐		☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			substantial equivalence of the subject device to the predicate.			
		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,*			☐	
		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:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☐ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
		a.	Precision/reproducibility	☐	☐	☐
		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 type).	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				
	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	☐	☐	☐

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.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			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.*			
		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:				

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

K134031 | 5001

Boston Scientific

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January 29, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
JAN 30 2014
Received

RE: K134031
Response to RTA Hold
Threader™ Micro-Dilatation Catheter

Dear Sir or Madam:

Boston Scientific Corporation (BSC) submits the enclosed information as Additional Information for 510(k) Premarket Notification K134031 for the Threader™ Micro-Dilatation Catheter. This submission provides a response to the missing elements identified in FDA's Refuse to Accept (RTA) checklist, sent on January 13, 2014.

This information is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
763-494-2222 (fax)
vicky.hagens@bsci.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
1/29/2014		K134031

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Boston Scientific Corporation	2134265		
Division Name *(if applicable)*	Phone Number *(including area code)*		
Interventional Cardiology	(763) 494-1522		
Street Address	FAX Number *(including area code)*		
One Scimed Place	(763) 494-2222		
City	State / Province	ZIP/Postal Code	Country
Maple Grove	MN	55311	USA
Contact Name			
Vicky L. Hagens			
Contact Title	Contact E-mail Address		
Principal Regulatory Affairs Specialist	vicky hagens@bsci.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify):*
  Response to RTA hold

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	H74939189xx120	**2**	H74939191xx120	3	H749M2000A0	4	H74939185xxxxx
5	H74939186xxxxx	**6**	CSW150-26N	7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K130391	1	Emerge™ PTCA Dilatation Catheter	1	Boston Scientific Corporation
2	K102725	2	CrossBoss™ Catheter	2	Boston Scientific Corporation
3	K111295	3	Coyote™ PTA Balloon Dilatation Catheter	3	Boston Scientific Corporation
4	K083127	4	Asahi Corsair Microcatheter	4	Asahi Intecc Co., Ltd.
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Threader™ Monorail Micro-Dilatation Catheter	1	H7493926912120
2	Threader™ Over-The-Wire Micro-Dilatation Catheter	2	H7493927012120
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K134031	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: LOX

C.F.R. Section *(if applicable)*: 21 CFR Part 870.5100

Classification Panel: Cardiovascular Devices

Device Class

☐ Class I ☒ Class II

☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name Boston Scientific Corporation		Establishment Registration Number 2134265
Division Name *(if applicable)* Interventional Cardiology		Phone Number *(including area code)* (763) 494-1700
Street Address Two Scimed Place		FAX Number *(including area code)* ( )
City Maple Grove	State / Province MN	ZIP/Postal Code 55311 / Country USA
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )
City	State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )
City	State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	See Attachment 1				
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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 control

Boston Scientific

Cardiovascular
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January 29, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K134031
Response to RTA Hold
Threader™ Micro-Dilatation Catheter

Dear Sir or Madam:

Boston Scientific Corporation (BSC) submits the enclosed information as Additional Information for 510(k) Premarket Notification K134031 for the Threader™ Micro-Dilatation Catheter. This submission provides a response to the missing elements identified in FDA's Refuse to Accept (RTA) checklist, sent on January 13, 2014.

This information is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
763-494-2222 (fax)
vicky.hagens@bsci.com

Boston Scientific

Additional Information for 510(k) Notification
K134031
Threader™ Micro-Dilatation Catheter

Response to RTA Hold
(January 13, 2014)

Volume 1 of 2

Submitted by:
Boston Scientific Corporation
One Scimed Place
Maple Grove MN 55311

January 29, 2014

The Acceptance Checklist feedback for 510(k) K134031 (received from FDA on January 13, 2014) identified the numbered items below (in bold) as incomplete. Boston Scientific Corporation (BSC)'s response is provided following each numbered item.

8) Administrative: Please provide the requested form (Form 3654) for each referenced standard.

BSC Response:

The requested FDA 3654 forms [Standards Data Report for 510(k)s] are provided in **Attachment 1** for standards that were referenced in the Threader 510(k) submission, as follows:

Sterilization activities (Section 11 of the submission) were performed based on the following standards:

Number	Title
EN 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
EN ISO 10993-7:2008/ AC:2009	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
AAMI ST72	Bacterial Endotoxin – Test methodologies, routine monitoring and alternatives to batch testing
USP <85>	Bacterial Endotoxins Test
USP <161>	Transfusion and Infusion Assemblies and Similar Medical Devices

Biocompatibility testing (Section 12 of the submission) was performed based on the following standards:

Number	Title
EN ISO 10993-1:2009 +AC 2010	Biological evaluation of medical devices – Part 1: Evaluation & Testing within a Risk Management process
EN ISO 10993-4:2009	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2009	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
USP <661>	Containers-Plastics

The following standards were used in the assessment of certain aspects of product performance testing (Section 15 of the submission):

Number	Title
USP <788>	Particulate Matter in Injections
EN ISO 10555-1:2009	Sterile, single-use intravascular catheters – Part 1: General Requirements

15) Substantial Equivalence: You have not provided a comparison and discussion of the Indications for Use for the CrossBoss from which the catheter shaft construction is leveraged. FDA notes that the CrossBoss is indicated to facilitate the placement of guidewires beyond stenotic coronary lesions (specifically including chronic total occlusions) prior to PTCA or stent intervention. This is similar to the newly proposed indication to "provide support to facilitate the placement of guidewires in the coronary vasculature." CTOs have not been referenced in the subject device Indications for Use but the technology used to cross CTOs appears to be included in this new device. FDA notes that a 147-patient clinical trial was conducted to support the CTO indication. These items should clearly be discussed in your Substantial Equivalence discussion.

BSC Response:

Threader Device Summary: Threader is a new PTCA dilatation catheter that has been specially designed to be a highly-deliverable device in complex lesions. The Threader device functions in the same way as existing balloon catheters and features a reduced profile on the distal end for enhanced crossing and flexibility, and coiled shaft technology to maximize pushability. The construction incorporates features from other BSC devices that are new to balloon catheters. This is the reason for multiple predicates in addition to the Emerge PTCA balloon catheter.

Scientific Justification for Shaft Construction Technology:
BSC has chosen to use the CrossBoss catheter as a predicate device to support substantial equivalence of a polymer-sleeved stainless steel coil as an established technology in catheter shafts. Since the Threader MR and OTW catheters will navigate through standard PTCA accessories and typical vasculature much like CrossBoss, BSC believes this use of CrossBoss as a predicate for the shaft construction is appropriate. BSC does not believe that the use of polymer-sleeved stainless steel coils in the Threader device promotes or facilitates CTO crossing similar to CrossBoss. As supporting justification, additional comparison of the relevant Threader and CrossBoss shaft components is provided:

- **Coiled Stainless Steel Shaft Components:** The Threader MR and OTW devices contain (b) (4) stainless steel (b) (4) coils (b) (4) (b) (4) This coil technology, not previously used in BSC PTCA balloons, promotes pushability of the catheter while maintaining substantial flexibility and kink resistance that improves the handling and deliverability of PTCA devices. This is quite dissimilar to the (b) (4) CrossBoss (b) (4) construction, which is specifically designed for a high level of torsional rigidity to facilitate rapid spinning of the device, as enabled by the "Fast Spin Torque Device" included with the CrossBoss product.

- **Polymeric Distal Shaft:** The distal (b) (4) section of the Threader MR and OTW devices (including the balloon and tip) contains no coiled shaft. As with all highly-deliverable PTCA balloon catheters, the torsional rigidity of this portion of the catheter is relatively low and does not provide the ability to rotate the balloon or tip of the catheter during normal use. In the CrossBoss device, the coiled shaft extends the length of the catheter, to the tip.

- **Tip:** The Threader MR and OTW devices have a standard PTCA balloon tip construction that is not conducive to creating sub-intimal channels like the CrossBoss tip design. The CrossBoss device is specifically designed with a large blunted tip to reduce risk of perforation while navigating around or through CTOs with minimal guidance from a guidewire. Threader and all other BSC POBA catheters have small, tapered tips that require significant guidance from the wire or perforation is likely.

Considering the above justification, BSC believes there is sufficient scientific rationale for the inclusion of the stainless steel coil shaft construction technology to improve pushability and thus deliverability. In addition, the above technical comparison clarifies that the CrossBoss' suitability to treat CTO lesions (per the CTO indication) is dependent on additional technical features that are not being incorporated into the Threader design.

Scientific Justification for Guidewire Indication:
BSC is not requesting a Threader indication to place guidewires beyond stenotic coronary lesions (specifically including CTOs), similar to the CrossBoss indication. BSC is also not requesting a Threader indication for use in the peripheral vasculature similar to the Corsair indication (Corsair has been added as a predicate via this response). Rather, as a specialty catheter with features of both a PTCA balloon and a microcatheter, the new Threader guidewire indication statements ("provide basic guidewire support" and "guidewire exchange") are intended to differentiate the Threader clinical utility from that of the CrossBoss and Corsair predicates. The inclusion of these statements seems to be supported by specific recommended testing in FDA's PTCA Guidance. As stated above, an additional predicate (Asahi Corsair Microcatheter, K083127, cleared February 3, 2009) is being added to the Threader 510(k) submission.

Table 1: Threader Predicates

Device Name	510(k) Number	Date Cleared
Emerge PTCA Dilatation Catheter (1.20 mm)	K130391	July 10, 2013
CrossBoss Catheter	K102725	May 10, 2011
Coyote PTA Balloon Dilatation Catheter	K111295	May 31, 2011
Asahi Corsair Microcatheter	K083127	February 3, 2009

As a result of adding Corsair, Section 2 (510(k) Summary) and Section 7 (Executive Summary) of the submission have been updated and are included in **Attachment 2** and **Attachment 3**, respectively.

The Corsair predicate has a guidewire indication. A comparison of the indication statements and classification information is provided in **Table 2** (for all devices except Coyote, which was only used as a predicate for the packaging components).

Table 2: Comparison of Indication Statements of Threader and Predicates

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Predicate Device CrossBoss (K102725)	Predicate Device Corsair (K083127)	Proposed Device Threader	Discussion
Device Name	Emerge PTCA Dilatation Catheter	CrossBoss Catheter	Asahi Corsair Microcatheter	Threader Micro-Dilatation Catheter	Threader is a dilatation catheter, like Emerge. "Micro" emphasizes the single small balloon size.
Manufacturer	Boston Scientific	Boston Scientific	Asahi Intecc Co., Ltd	Boston Scientific	N/A
Common Name	PTCA Dilatation Catheter	Percutaneous Catheter	Microcatheter	PTCA Dilatation Catheter	Threader is the same as Emerge.
Classification Name	PTCA Catheter	Percutaneous Catheter	Percutaneous Catheter	PTCA Catheter	Threader is the same as Emerge.
Classification	Class II	Class II	Class II	Class II	All are the same.
Regulation No.	21 CFR 870.5100	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.5100	Same as Emerge.
Product Code	LOX	DQY	DQY	LOX	Same as Emerge.
Intended Use	Emerge is intended for dilatation of stenosis in coronary arteries or bypass grafts.	The CrossBoss Catheter is intended for use with a guidewire to access discrete regions of the coronary and peripheral vasculature.	Corsair is a hybrid catheter, intended to allow access to complex lesions.	Threader is intended for dilatation of stenosis in coronary arteries or bypass grafts.	Intended use for Threader is the same as for Emerge.
Intended Use/ Indications for Use Statements on DFU	The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis).	--	--	The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.	The first indication statement for Threader is the same as for Emerge. CrossBoss and Corsair do not have similar statements.

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Predicate Device CrossBoss (K102725)	Predicate Device Corsair (K083127)	Proposed Device Threader	Discussion
	--	When used as part of the system consisting of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire, the CrossBoss Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.	The Asahi Corsair Microcatheter is intended to provide support to facilitate the placement of Guide wires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another.	The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.	The second Threader indication statement is similar to that of Corsair, but is only for coronary use. Threader guidewire exchange is applicable only to the OTW platform. This indication is different from the CrossBoss intraluminal CTO indication.
	--	--	The Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures.	The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.	The third Threader indication statement is similar to that of Corsair, but is only for coronary use, and only for hand-injection (lower pressures), as supported by test data.

A comparison of the product features that are important for the facilitation of guidewire exchange is provided in **Table 3**.

Table 3: Comparison of Technology/Product Features to Support Substantial Equivalence for Guidewire Indication

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Predicate Device CrossBoss (K102725)	Predicate Device Corsair (K083127)	Proposed Device Threader	Discussion
Guidewire Lumen Length	148 cm	140 cm	155 cm	155 cm	Corsair is available in both 135 and 150 cm lengths. Guidewire lumen length is approximately 5 cm longer than effective length when accounting for guidewire lumen located under the strain relief (~155 cm lumen length for a 150 cm effective length).
Guidewire Lumen Inner Diameter (ID)	(b) (4) Proximal, (b) (4) Distal	(b) (4) Proximal, (b) Distal	(b) Proximal, (b) Distal	(b) (4) Proximal, (b) (4) Distal	Guidewire lumen inner diameters are similar for Threader and Corsair. All devices are compatible with standard size guidewires.
Guidewire Lumen Surface	(b) (4)	Bare stainless steel coil	(b) (4)	(b) (4)	The low friction characteristics of (b) (4) promote a high level of wire mobility and wire exchange even when used in tortuous anatomy.

(b) (4)

To further support the Threader guidewire indication statements, BSC's Medical Director, (b) (6) has provided the following information regarding the use of PTCA balloon catheters to facilitate complex PCI (percutaneous coronary intervention), including the placement and exchange of guidewires:

- The overarching goal of complex PCI is to establish a rail across the lesion to support the delivery of more definitive therapy, typically a stent. Many factors are involved in determining a lesion's complexity. Some of the more commonly encountered factors are the degree of stenosis (particularly for 'super-tight', calcified or chronically occluded lesions), tortuosity, angulation, and distal location in the vasculature. As wire placement is a critical factor for success in any PCI, many techniques have been developed to facilitate wire placement to support an intervention.

- Crossing a complex lesion focuses considerable attention to the guidewire. The manipulation needed to cross a lesion can often lead to guidewire failures such as tip damage or shaft kinking. In other instances the guidewire used to cross the lesion may not be the appropriate wire to serve as a support for the ongoing intervention (due to wire robustness, wire length, etc.). In these cases the guidewire must be exchanged for another to successfully complete the case. A

distinct advantage of using an OTW system to approach a complex lesion is the ability to easily exchange a guidewire through the catheter lumen. This technique has been frequently utilized since the advent of PCI and to this day has not been replaced by any other method to exchange a guidewire without losing 'purchased' position in a vessel. There are no suitable alternatives, such as placing a wire adjacent to the balloon/wire system already in place, because the exact position of the exchanged wire (intimal or sub-intimal) can only be guaranteed if the wire is directly exchanged. This fact is often challenged with MR systems which require that the balloon catheter be completely removed and the vessel re-wired de novo if a wire exchange is performed. Although tools are available to facilitate balloon catheter exchange during a PCI (e.g., wire extensions, magnets, MR), the same do not exist for guidewires.

- Another factor to consider when crossing a lesion is the degree of control the operator has to steer the guidewire. When crossing a complex stenosis the exact position of the guidewire tip is crucial. Moreover, forces are often necessary to be applied to the wire that could likely deform the wire, either by bending it along the shaft thus disrupting critical tip position (as seen in lesions with proximal tortuosity or significant angulation) or the guidewire tip can be damaged if the soft "floppy" segment is pushed against an unyielding [often calcified] lesion. In these settings a common practice is to 'protect' the wire position by using a balloon catheter to provide support for the wire such that all linear or rotational forces applied to the wire can be transmitted directly to the wire tip/lesion interface. Crossing forces that are not attainable with a wire alone can be achieved by using the wire tip with catheter support method ('spearing').

In addition, testing supporting the guidewire indication, as recommended in the PTCA Guidance, was provided in Section 15 and Section 16 of the original Threader 510(k) submission.

Considering the above justification, BSC believes there is sufficient scientific rationale for the inclusion of the guidewire indication, without the need for clinical testing.

15) Additionally, the Emerge predicate device underwent a clinical trial. Your submission does not discuss an additional clinical study to demonstrate substantial equivalence. Please provide a discussion/justification regarding why you believe a clinical study is not necessary or reference an approved IDE for this device and provide the clinical data.

BSC Response:

A clinical study was required by FDA for the predicate Emerge 1.20 mm balloon catheter because it was a novel balloon size that was not previously marketed by BSC (which is stated in the PTCA guidance as a reason for needing a clinical study). Since the Threader balloon is the same size as the Emerge 1.20 mm predicate, it is no longer a novel balloon size. Therefore, a clinical study is not deemed appropriate as there are no new questions of safety and effectiveness associated with the matrix. BSC views the changes to Threader as providing an incremental performance enhancement to

pushability, which is testable on the bench and which does not lead to any new claim. The additional indication statements with respect to guidewire support and exchange are also readily supportable via analysis and non-clinical testing.

Scientific Justification for Balloon Size Substantial Equivalence:

- The Threader balloon is the same size as a currently-marketed PTCA balloon catheter (predicate Emerge).
- The Threader catheter is the same basic design and uses the same mode of action as the predicate Emerge catheter.
- The majority of the Threader components, materials, and manufacturing processes are the same as the Emerge predicate.
- The Threader device will be used in the same types of PCI procedures, in the same group of patients, and in the same manner as the Emerge predicate.
- Construction, materials, method of manufacture, usage (types of procedures) are substantially equivalent for Threader and Emerge
- Incremental performance enhancements to known performance attributes (pushability) are readily assessed via non-clinical testing.

Given these similarities between Threader and Emerge, BSC believes clinical testing is not needed to support the substantial equivalence of Threader to Emerge.

15) Lastly, you have not discussed the lack of a predicate indicated for hand-injection of contrast media.

BSC Response:

The new Threader OTW indication statement for hand-injection of contrast media is intended to allow visualization of small channels and distal vessels using very small injections of contrast media. Since the Threader device is designed for complex cases that often require extended procedure times and increased exposure of the patient to contrast media, the ability to deliver small targeted injections is desirable. The inclusion of this statement seems to be supported by specific recommended testing in FDA's PTCA Guidance. The additional predicate being added (Asahi Corsair Microcatheter, K083127, cleared February 3, 2009) has a contrast injection indication in addition to the guidewire indication statements, so it serves as a predicate for both new indication statements (see **Table 2**).

In addition, specific features of Threader and Corsair that are important to the delivery of contrast media are compared in **Table 4**.

Table 4: Comparison of Technology/Product Features to Support Substantial Equivalence for Contrast Indication

Attribute	Predicate Device Emerge 1.20 mm (K130391)	Predicate Device CrossBoss (K102725)	Predicate Device Corsair (K083127)	Proposed Device Threader	Discussion
Guidewire Lumen Length	148 cm	140 cm	155 cm	155 cm	Corsair is available in both 135 and 150 cm lengths. Guidewire lumen length is approximately 5 cm longer than effective length for both Threader and Corsair (~155 cm for a 150 cm effective length).
Guidewire Lumen Inner Diameter (ID)	(b) (4) Proximal	(b) (4) Proximal	(b) Proxima	(b) (4) Proximal	The proximal ID (which is similar for Threader and Corsair) comprises the vast majority of the guidewire lumen ID and therefore governs the flow rate achievable for a given injection pressure. The distal ID (listed in Table 3) only occurs in a very short section of the tip in both Threader and Corsair, and therefore has minimal impact on the fluid flow.
Luer Fitting	Industry Standard Luer	Industry Standard Luer	Industry Standard Luer	Industry Standard Luer	All devices have industry standard connections.

Scientific Justification for Hand-Injection Indication:

- Corsair predicate with contrast injection (power injection) indication has been added.
- An indication for hand-injection of contrast media is being requested for Threader OTW. Since the pressures that can be developed by hand are considerably lower (typically less than 100 psi) than those generated by power injection equipment (typically greater than 300 psi), and the wire lumen dimensions of the Threader OTW device are more restrictive to fluid flow than the predicate device, the maximum injection flow rate and exit velocity of the contrast media will remain at safe levels.
- Testing supporting the contrast injection indication, as recommended in the PTCA Guidance, was provided in Section 15 and Section 16 of the original Threader 510(k) submission. This testing supports the ability of the Threader OTW catheter to withstand hand injection pressures as well as provide a contrast media flow rate that is useful for visualization of small distal vessels.

Considering the above justification, BSC believes there is sufficient scientific rationale for the inclusion of the contrast media indication, without the need for clinical testing.

23c) Sterilization: The submission states that Threader catheters will meet the ethylene oxide (EO) and ethylene chlorohydrin (ECH) residual limits as specified in EN ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. However, the actual maximum residuals from your residual testing were not provided.

BSC Response:

The Threader catheters meet the ethylene oxide (EO) and ethylene chlorohydrin (ECH) residual limits as specified in EN ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals. The allowable residual limits are expressed as Average Daily Dose (ADD) in units of mg/day. The maximum levels of EO and ECH sterilant residuals remaining on the devices, and the allowable limits, are provided in **Table 5**.

Table 5: Ethylene Oxide Sterilization Residuals and Allowable Limits

Device Version	Ethylene Oxide (EO), mg/day		Ethylene Chlorohydrin (ECH), mg/day	
	Maximum Level Measured	Allowable Limit	Maximum Level Measured	Allowable Limit
Monorail	(b)	≤ 4	(b)	≤ 9
Over-The-Wire	(b)	≤ 4	(b)	≤ 9

37a) Performance Data: You have not provided raw data for your performance tests as recommended in the PTCA Guidance Document (Section VII-B). Please provide raw data test sheets for all test reports.

BSC Response:

The PTCA Guidance document recommends that raw data be included in appendices or made available for review upon request. BSC believes that stating that raw data sheets are available upon request (in Section 15.1 of the submission) satisfies the guidance recommendation. However, based on FDA's review of the acceptance checklist, the raw data sheets are provided at this time in **Attachment 4**.

39a/b) Animal Studies: Reports did not include "A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification." The reports also did not include "The signed and dated reports of each of the individual scientists or other professionals involved in the study."

BSC Response:

The animal studies included in the Threader submission were not intended to be conducted in accordance with Good Laboratory Practice (GLP) regulations (21 CFR Part 58). Study compliance and data integrity were supported by governing SOPs and processes at the external testing facilities and within BSC, as described in Section 16 of the Threader 510(k) submission.

The requested information on the animal test systems used in the studies is provided in **Table 6**.

Table 6: Test Systems Used in Threader Animal Studies

Test System	Study 13-120N	Study 09-042N	Study 08-111N S8	Study 09-054N
Number of Animals	(	(	(	(
Sex	Female	Male or Female	Male or Female	Male or Female
Body Weight Range	40 – 60 kg	40 – 55 kg	35 – 65 kg	35 – 65 kg*
Source of Supply	CRO-approved vender	CRO-approved vender	CRO-approved vender	CRO-approved vender
Species, Strain, Substrain	Domestic swine (sus scrofa)	Domestic swine (sus scrofa)	Domestic swine (sus scrofa)	Domestic swine (sus scrofa)
Age	Age appropriate for required weight	Age appropriate for required weight	Age appropriate for required weight	Age appropriate for required weight
Procedure Used for ID	Ear tags	Ear tags	Ear tags	Ear tags

* The actual body weight range was 62.0 to 66.0 kg. The limited increase in weight range would have no impact on device assessments or on study outcomes.

To address the requirement to provide signed and dated reports of the individual scientists or other professionals involved in the studies, the raw data collection forms from the animal studies are provided in **Attachment 5**.

Attachments	
1	Standards Data Report Forms
2	Updated 510(k) Section 2: 510(k) Summary
3	Updated 510(k) Section 7: Executive Summary
4	Raw Data Sheets
5	Animal Study Data Sheets

Attachment 1

Standards Data Report Forms

Forms are included for the following standards:

Number	Title
EN 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
EN ISO 10993-7:2008/ AC:2009	Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals
AAMI ST72	Bacterial Endotoxin – Test methodologies, routine monitoring and alternatives to batch testing
USP <85>	Bacterial Endotoxins Test
USP <161>	Transfusion and Infusion Assemblies and Similar Medical Devices
EN ISO 10993-1:2009 +AC 2010	Biological evaluation of medical devices – Part 1: Evaluation & Testing within a Risk Management process
EN ISO 10993-4:2009	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2009	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
USP <661>	Containers-Plastics
USP <788>	Particulate Matter in Injections
EN ISO 10555-1:2009	Sterile, single-use intravascular catheters – Part 1: General Requirements

Form Approved: OMB No. 0910 0120; Expiration Date: 12/31/13

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]

EN ISO 11135-1:2007 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-331	
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: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11135-1:2007 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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❖ 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.

Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-7:2008/AC:2009 Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-335	
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.	☐	☒
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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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-7:2008/AC:2009 Biological evaluation of medical devices – Part 7: Ethylene Oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ST72 Bacterial Endotoxin - Test methodologies, routine monitoring and alternatives to batch testing (2011)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-369	
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]?	☐	☐
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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?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ST72 Bacterial Endotoxin - Test methodologies, routine monitoring and alternatives to batch testing (2011)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP <85> Bacterial Endotoxins Test (2012)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-368	
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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP <85> Bacterial Endotoxins Test (2012)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

USP <161> Transfusion and Infusion Assemblies and Similar Medical Devices (2012)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-370	
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: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP <161> Transfusion and Infusion Assemblies and Similar Medical Devices (2012)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-1:2009+AC2010 Biological evaluation of medical devices – Part 1: Evaluation & Testing within a Risk Manag...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
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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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: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation...

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-1:2009+AC2010 Biological evaluation of medical devices – Part 1: Evaluation & Testing within a Risk Manag...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Form Approved: OMB No. 0910 0120; Expiration Date: 12/31/13

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]

EN ISO 10993-4:2009 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-4:2009 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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.

Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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]

EN ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-173	
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]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
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Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-11:2009 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
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?	☐	☒
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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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10993-11:2009 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-198	
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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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

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STANDARD TITLE [1]

USP <661> Containers-Plastics (2010)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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.	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP <661> Containers-Plastics (2010)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections		☒ 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

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SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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Public reporting burden for this collection of information is estimated to average 1 hour 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:

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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]

USP <788> Particulate Matter in Injections (2010)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP <788> Particulate Matter in Injections (2010)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Method 1	Light Obscuration Particle Count Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Method 1 used for sample preparation and test method used, but limits in Method 1 (Evaluation) were not applied.

DESCRIPTION

JUSTIFICATION
USP limits (particle counts in injections) do not apply to device. Testing was for characterization only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Method 2	Microscopic Particle Count Test	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Method 2 not used

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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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN ISO 10555-1:2009 Sterile, single-use intravascular catheters - Part 1: General Requirements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10555-1:2009 Sterile, single-use intravascular catheters - Part 1: General Requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 5, 6	Requirements, Designation of Nominal Size, Info Supplied by Manufacturer	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Full compliance of all sections except as noted below.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4, 4.6, 4.7	Requirements	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Partial compliance with these sections.

DESCRIPTION
4.4 Surface, 4.6 Peak Tensile Force. 4.7 Freedom from Leakage

JUSTIFICATION
4.4 Inspection done at arm's length rather than at 2.5x mag., cleanliness controlled through SOPs. 4.6 Specs based on peak max. force rather than force at break. 4.7 Leakage tested per repeat inflation bench test and per EN 1707:1996 luer standard.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.9, 4.10, 4.11	Requirements	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Testing not completed

DESCRIPTION
4.9 Flowrate, 4.10 Power Injection, 4.11 Side Holes

JUSTIFICATION
Sections not applicable. Flowrate and power injection are not specified for Threader. Threader design does not have side holes.

* 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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Attachment 2

Updated 510(k) Section 2: 510(k) Summary

The updated section is attached.

Section 2 510(k) Summary

The 510(k) Summary follows this page.

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Cardiovascular Division One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222		
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-494-1522 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com		
Date Prepared	January 27, 2014		
Proprietary Name(s)	Threader™ Monorail™ Micro-Dilatation Catheter Threader™ Over-The-Wire Micro-Dilatation Catheter		
Common Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter		
Product Code	LOX		
Classification	Class II, 21 CFR Part 870.5100		
Predicate Devices	Emerge™ PTCA Dilatation Catheter (1.20 mm)	K130391	July 10, 2013
	CrossBoss™ Catheter	K102725	May 10, 2011
	Coyote™ PTA Balloon Dilatation Catheter	K111295	May 31, 2011
	Asahi Corsair Microcatheter	K083127	February 3, 2009
Device Description	The Boston Scientific Threader™ Micro-Dilatation Catheter is a sterile, single-use, intravascular medical device. The catheter consists of a shaft with a semi-compliant balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter (1.2 mm) and length (12 mm) at recommended pressures. The Threader™ Micro-Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. There is a single radiopaque marker band located in the center of the balloon body to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance.		
Intended Use of Device	The Threader™ Micro-Dilatation Catheter is intended for dilatation of stenosis in coronary arteries or bypass grafts.		

Indications for Use

The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Comparison of Technological Characteristics

The Threader™ Micro-Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices: Emerge™ PTCA Dilatation Catheter (1.20 mm), K130391 (cleared July 10, 2013); CrossBoss™ Catheter, K102725 (cleared May 10, 2011); Coyote™ PTA Dilatation Catheter, K111295 (cleared May 31, 2011); and Asahi Corsair Microcatheter, K083127 (cleared February 3, 2009).

Performance Data

The Threader™ Micro-Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. 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 testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following biocompatibility and chemical characterization tests were completed on the Threader™ Micro-Dilatation Catheter:

Cytotoxicity	Hemolysis (Direct Contact & Extract)
Sensitization	Complement Activation
Intracutaneous Reactivity	Coagulation
Acute Systemic Toxicity	In Vitro Hemocompatibility
Materials Mediated Pyrogenicity	USP Physicochemical

The following in-vitro performance tests were completed on the Threader™ Micro-Dilatation Catheter:

Effective Length	Catheter Bond Strength
Shaft Inner and Outer Diameter	Tip Pull Test
Balloon Crossing Profile	Flexibility and Kink
Balloon Preparation, Deployment, and Retraction	Torque Strength
Withdrawal into a Guide Catheter	Radiopacity
Balloon Rated Burst Pressure	Coating Integrity
Balloon Fatigue (Repeat Inflations)	Particulate Evaluation
Balloon Compliance	Catheter Body Burst Pressure
Balloon Inflation/Deflation Time	Contrast Media Flow Rate

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Threader™ Micro-Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.

Attachment 3

Updated 510(k) Section 7: Executive Summary

The updated section is attached.

Section 7 Executive Summary

Common or Usual Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter	
Trade Name(s)	Threader™ Monorail™ Micro-Dilatation Catheter Threader™ Over-The-Wire Micro-Dilatation Catheter	
Product Code	LOX	
Classification of Device	PTCA catheters are Class II devices according to 21 CFR 870.5100.	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-494-1522 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device. However, this notification has followed the recommendations in the FDA guidance, *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010.	
Establishment Registration Numbers	**Owner / Operator:**	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760
	Manufacturing Facilities:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facility:	Boston Scientific – Coventry 8 Industrial Drive Coventry, Rhode Island, 02816

Section 7 Executive Summary

Predicate Devices	Emerge™ PTCA Dilatation Catheter (1.20 mm) K130391 Cleared July 10, 2013 CrossBoss™ Catheter K102725 Cleared May 10, 2011 Coyote™ PTA Balloon Dilatation Catheter K111295 Cleared May 31, 2011 Asahi Corsair Microcatheter K083127 Cleared February 3, 2009
Intended Use	The Threader Micro-Dilatation Catheter is intended for dilatation of stenosis in coronary arteries or bypass grafts.
Indications for Use	The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion. The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another. The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.
Comparison of Required Technological Characteristics	The Threader Micro-Dilatation Catheter incorporates substantially equivalent device materials and design, fundamental technology, manufacturing processes, sterilization process, and intended use as those featured in the primary predicate device, Emerge PTCA Dilatation Catheter (1.20 mm). Asahi Corsair Microcatheter is included as a predicate to support the guidewire and contrast media injection indication statements. CrossBoss Catheter is included as a predicate to support substantial equivalence of the stainless steel coil construction used in the shaft of the Threader catheter. Coyote PTA Balloon Dilatation Catheter is included as a predicate because Threader uses the same packaging as Coyote. A more detailed comparison of the device to the predicates is provided in **Section 9, Substantial Equivalence Discussion**.

Section 7 Executive Summary

Summary of Non-Clinical Testing	Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. 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, safety and performance testing, the Threader Micro-Dilatation Catheter is appropriate for the intended uses and is considered to be substantially equivalent to the predicates.

Attachment 4

Raw Data Sheets

Raw data sheets are included in the following order, supporting the referenced sections of the original 510(k) Notification:

Section	Content of Data Sheets	No. of Pages
T=0 (Nominal Testing)		
15.3.2	Outer Diameter	2
15.3.4	Balloon Crossing Profile	2
15.3.5	DDR and Deflated Balloon Profile	3
15.3.6	Balloon Withdrawal into a Guide Catheter	5
15.3.7	Rated Burst Pressure	4
15.3.8	Balloon Fatigue (Repeat Inflation)	3
15.3.9	Balloon Compliance (Sizing)	2
15.3.10	Balloon Deflation and Inflation Time	3
15.3.11	Catheter Bond Strength	14
15.3.12	Tip Bond Tensile	3
15.3.13	Flexibility and Kink	2
15.3.14	Torque Strength	2
15.3.16	Coating Integrity	2
15.3.17	Particulates	66
15.3.18	Catheter Burst Pressure	1
15.3.20	Kissing Balloon Force	2
15.3.21	Kissing Balloon Dye Flow	4
T=3-Month AA (Aged Testing)		
15.4.2	Outer Diameter	2
15.4.4	Balloon Crossing Profile	2
15.4.5	DDR and Deflated Balloon Profile	3
15.4.6	Balloon Withdrawal into a Guide Catheter	4
15.4.7	Rated Burst Pressure	8
15.4.8	Balloon Fatigue (Repeat Inflation)	2
15.4.9	Balloon Compliance (Sizing)	4
15.4.10	Balloon Deflation and Inflation Time	2
15.4.11	Catheter Bond Strength	23
15.4.12	Tip Bond Tensile	6
15.4.13	Flexibility and Kink	2
15.4.14	Torque Strength	2
15.4.15	Coating Integrity	2
15.4.16	Particulates	44
15.4.17	Catheter Burst Pressure	1
Packaging Verification		
15.5	Packaging Integrity and User Interface (Nominal and Aged)	22

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Boston Scientific

Cardiovascular
One Scimed Place
Maple Grove, MN 55311-1566
763.494.1700 Tel
www.bostonscientific.com

January 29, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K134031
Response to RTA Hold
Threader™ Micro-Dilatation Catheter

Dear Sir or Madam:

Boston Scientific Corporation (BSC) submits the enclosed information as Additional Information for 510(k) Premarket Notification K134031 for the Threader™ Micro-Dilatation Catheter. This submission provides a response to the missing elements identified in FDA's Refuse to Accept (RTA) checklist, sent on January 13, 2014.

This information is submitted in duplicate in accordance with the regulation 21 CFR 807.90(c). Per FDA's guidance issued on December 31, 2012 entitled *eCopy Program for Medical Device Submissions*, one electronic copy is submitted in lieu of a paper copy. The eCopy is an exact duplicate of the paper copy.

This submission contains trade secret and confidential information that, in accordance with 21 CFR 807.95 and 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.

Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
763-494-2222 (fax)
vicky.hagens@bsci.com

Boston Scientific

Additional Information for 510(k) Notification
K134031
Threader™ Micro-Dilatation Catheter

Response to RTA Hold
(January 13, 2014)

Volume 2 of 2

Submitted by:
Boston Scientific Corporation
One Scimed Place
Maple Grove MN 55311

January 29, 2014

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K134031/S002

Boston Scientific

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One Scimed Place
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June 16, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
JUN 17 2014
Received

RE: K134031
Response to AI Hold Letter
Threader™ Micro-Dilatation Catheter

Dear Sir or Madam:

Boston Scientific Corporation (BSC) submits the enclosed information as Additional Information for 510(k) Premarket Notification K134031 for the Threader™ Micro-Dilatation Catheter. This submission provides a response to all of the deficiencies identified in FDA's AI Hold Letter, sent on March 27, 2014.

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Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
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763-494-2222 (fax)
vicky.hagens@bsci.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
6/16/2014		K134031/S___

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Boston Scientific Corporation	2134265		
Division Name *(if applicable)*	Phone Number *(including area code)*		
Interventional Cardiology	(763) 494-1522		
Street Address	FAX Number *(including area code)*		
One Scimed Place	(763) 494-2222		
City	State / Province	ZIP/Postal Code	Country
Maple Grove	MN	55311	USA
Contact Name			
Vicky L. Hagens			
Contact Title	Contact E-mail Address		
Principal Regulatory Affairs Specialist	vicky.hagens@bsci.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Graphics (301) 443-2454 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify):*
  Response to AI hold letter

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	H74939189xx120	2	H74939191xx120	3	H749M2000A0	4	H74939185xxxxx
5	H74939186xxxxx	6	CSW150-26N	7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K130391	1	Emerge™ PTCA Dilatation Catheter	1	Boston Scientific Corporation
2	K102725	2	CrossBoss™ Catheter	2	Boston Scientific Corporation
3	K111295	3	Coyote™ PTA Balloon Dilatation Catheter	3	Boston Scientific Corporation
4	K083127	4	Asahi Corsair Microcatheter	4	Asahi Intecc Co., Ltd.
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Threader™ Monorail Micro-Dilatation Catheter	1	H7493926912120
2	Threader™ Over-The-Wire Micro-Dilatation Catheter	2	H7493927012120
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K134031	2 Q140451	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
LOX

C.F.R. Section *(if applicable)*
21 CFR Part 870.5100

Classification Panel
Cardiovascular Devices

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.
The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.
The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name Boston Scientific Corporation		Establishment Registration Number 2134265	
Division Name *(if applicable)* Interventional Cardiology		Phone Number *(including area code)* (763) 494-1700	
Street Address Two Scimed Place		FAX Number *(including area code)* ( )	
City Maple Grove		State / Province MN	ZIP/Postal Code 55311 / Country USA
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City		State / Province	ZIP/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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 control

Boston Scientific

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June 16, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K134031
Response to AI Hold Letter
Threader™ Micro-Dilatation Catheter

Dear Sir or Madam:

Boston Scientific Corporation (BSC) submits the enclosed information as Additional Information for 510(k) Premarket Notification K134031 for the Threader™ Micro-Dilatation Catheter. This submission provides a response to all of the deficiencies identified in FDA's AI Hold Letter, sent on March 27, 2014.

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Please contact the undersigned, or Rebeka Stoltman (763-494-1231), if additional information is required.

Sincerely,

Vicky L. Hagens
Principal Regulatory Affairs Specialist
Boston Scientific Corporation
763-494-1522 (telephone)
763-494-2222 (fax)
vicky.hagens@bsci.com

Boston Scientific

Additional Information for 510(k) Notification
K134031
Threader™ Micro-Dilatation Catheter

Response to AI Hold Letter
(March 27, 2014)

Volume 1 of 1

Submitted by:
Boston Scientific Corporation
One Scimed Place
Maple Grove MN 55311

June 16, 2014

For ease of review, the deficiencies noted in FDA's letter of March 27, 2014 are reproduced in **bold**. Boston Scientific Corporation's response is provided in normal font below the question.

Indications for Use

1. **FDA believes that the design and proposed indications for use for the Threader Micro-Dilatation Catheter shows that the actual intended clinical use of your device is for the treatment of chronic total occlusions (CTOs). Your specification of another predicate device (Cross Boss catheter, K102725) with similar design features (incorporation of a stainless steel (b) (4) reinforce the shaft) supports this intention since the Cross Boss is specifically indicated for the treatment of CTOs. Although the proposed Instructions for Use for the Threader Micro-Dilatation Catheter do not specifically mention the term "chronic total occlusion," FDA believes that there is a reasonable likelihood that your device will be used for an intended use not identified in the proposed labeling. As indicated in our response to your (b) (4) email inquiry to FDA, in which you asked what the "clinical requirements" would be to obtain a CTO indication for the (b) (4) PTCA Dilatation Catheter, FDA believes that clinical data should be provided to support this intended use. We recommend that you utilize the pre-submission process to further discuss these concerns.**

BSC Response:

BSC used the pre-submission process to discuss these concerns with FDA. Submission Issue Meeting Request (b) (4) was submitted to FDA on (b) (4) and a meeting was held at FDA on (b) (4) during which BSC and FDA discussed the issues. The discussion and outcome of that meeting was documented in meeting minutes, submitted by BSC (b) (3) (B)

During the meeting on April 30, 2014, FDA (b) (4) (b) (4) as a possible option to address the concerns. In an e-mail to FDA on (b) (4) BSC agreed (b) (4) and proposed wording related to CTO usage (below) to be added to the Threader Directions for Use (DFU). In an e-mail reply on (b) (4) FDA agreed consider the approach and the proposed wording.

Therefore, to address FDA's concerns regarding possible CTO usage, the following additional bullet has been added to the Precautions section of the DFU:

- *The safety and effectiveness of the Threader Micro-Dilatation Catheter have not been established for the treatment of chronic total occlusions. The risk of adverse events is likely to be higher when treating such lesions. Physicians should be aware of this increased risk and the limitations of the available scientific evidence. Additional data from clinical studies and analyses of the treatment of chronic total occlusions are expected and should be considered in making treatment decisions as data becomes available.*

The redlined Threader DFU is provided in **Attachment 1**, and the clean Threader DFU is provided in **Attachment 2**.

BSC anticipates that additional changes to the DFU may be requested by FDA during the remaining review time. In this case, following clearance of the 510(k), BSC may elect to initially launch the Threader product in the US market with an electronic DFU, and change to the multi-language paper DFU once the product is launched globally.

Labeling

2. Please provide a red-lined copy of the Emerge 1.20 PTCA Catheter Directions for Use (DFU), as cleared under the predicate 510(k), with all differences between the Emerge 1.20 PTCA Catheter and the Threader Micro-Dilatation Catheter noted.

BSC Response:

A copy of the predicate Emerge PTCA Dilatation Catheter (1.20 mm) Directions for Use (DFU), with the changes between Emerge and Threader red-lined, is provided in **Attachment 3**.

3. The subject device is referred to as the Threader Monorail and Over-the-Wire Micro-Dilatation Catheter. Please explain what design aspect of this device makes it a "Micro-Dilatation" catheter with respect to device metrics and size specifications.

BSC Response:

The Threader device has the following design aspects that set it apart from other "workhorse" POBA catheters:

- The Threader crossing profile (b) (4) will be the smallest on the US market. The crossing profile for the 1.2 mm diameter Emerge catheter is (b) (4)
- The Threader product matrix only includes the smallest 1.2 mm balloon size, which is targeted for small diameter vasculatures. By comparison, the Emerge product matrix includes balloon diameters from 1.2 to 4.0 mm.

As a result of these design aspects, BSC wishes to differentiate the Threader device from similar workhorse devices by using the "micro" designation.

4. The Device Description section of the DFU states, "...the inner lumen permits the use of guidewires ≤ 0.014 in (0.36 mm) to facilitate advancement of the catheter to the stenosis or through a previously placed stent prior to dilatation...The catheter's tip is tapered to facilitate advancement of the catheter to the stenosis or through a previously placed stent prior to dilatation." These descriptions in the DFU appear to describe the use of the device to treat in-stent restenosis. However, Section 15.3 (Design Verification Testing) clarifies, "device not intended for In-Stent Restenosis (ISR) or stent expansion." The Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters recommends, "For balloons that have not been cleared for the treatment of ISR, labeling should advise the safety and effectiveness of this use have not been established, for example: The safety and effectiveness of this PTCA balloon catheter for the treatment of ISR has not been established. For balloons that have not been cleared for stent expansion, the labeling should address the exclusion of that indication from the intended use, for example: This balloon is not intended for the expansion or delivery of a stent." Please address this discrepancy. Please provide red-line and clean versions of your DFU for any changes made.

BSC Response:

The Device Description in the Emerge predicate stated:

> *"...the inner lumen permits the use of guidewires ≤ 0.014 in (0.36 mm) to facilitate advancement of the catheter to and through the stenosis or stent to be dilated . . . The catheter's tip is tapered to facilitate advancement of the catheter to and through the stenosis or stent."*

BSC recognized that the Emerge product matrix contains larger balloon catheters that are indicated for post-delivery expansion of balloon-expandable stents (while Threader does not). As such, the Threader Device Description was modified from the Emerge description as follows:

> *"...the inner lumen permits the use of guidewires ≤ 0.014 in (0.36 mm) to facilitate advancement of the catheter to ~~and through~~ the stenosis or through a previously placed stent ~~to be dilated~~ prior to dilatation . . . The catheter's tip is tapered to facilitate advancement of the catheter to ~~and through~~ the stenosis or through a previously placed stent prior to dilatation."*

This re-wording of the description was meant to convey that Threader is not used for post-delivery expansion of balloon-expandable stents, but that it might be necessary to deliver the device distally of a previously-placed stent in order to reach a lesion to be treated. It was not meant to convey that Threader is intended to be used to treat in-stent restenosis. The third bullet under Precautions on the Threader DFU contains the precaution against in-stent restenosis, as recommended in the PTCA guidance.

BSC acknowledges the confusion the re-worded description may cause and proposes to remove the mention of stents altogether in the statements:

> *"...the inner lumen permits the use of guidewires ≤ 0.014 in (0.36 mm) to facilitate advancement of the catheter to the stenosis ~~or through a previously placed stent prior to dilatation~~ . . . The catheter's tip is tapered to facilitate advancement of the catheter to the stenosis ~~or through a previously placed stent prior to dilatation~~."*

The final version of the statements in the Threader DFU would then be:

> *"...the inner lumen permits the use of guidewires ≤ 0.014 in (0.36 mm) to facilitate advancement of the catheter to the stenosis . . . The catheter's tip is tapered to facilitate advancement of the catheter to the stenosis."*

In addition, the following additional bullet has been added to the Precautions section of the DFU, as recommended in the PTCA guidance.

- *This balloon is not intended for the expansion or delivery of a stent.*

The redlined Threader DFU is provided in **Attachment 1**, and the clean Threader DFU is provided in **Attachment 2**.

Animal Studies

5. You provided a non-GLP test protocol, test report, and attachments in Supplement 1 with data sheets for each non-GLP study. Please note that FDA is not obliged to accept non-GLP studies for marketing or research submissions, but in the interest of reducing burden, we will attempt to determine whether the information provided is sufficient for a regulatory decision. Key information was either missing or insufficiently described in this submission to enable a decision as to the authenticity and completeness of the study information, or the rationale for certain study design features that may impact FDA's decision processes. Please answer the following questions about the non-GLP studies:

a. Please state what test sites "IMM" and "RTC" stand for.

BSC Response:

(b) (4) [redacted] These test sites are described in Section 16.2 (page 16-9) of the Threader 510(k) Notification.

b. Please state how, in the absence of a GLP audit, it is known that the information you provided is representative of all of the data you collected for the referenced tests and is not a subset of data selected to best illustrate acceptance criteria agreement.

BSC Response:

BSC processes and quality procedures require that all data collected from the preclinical studies related to Design Validation and Labelling of the Threader device or of related devices (if data are leveraged) be provided in this submission. This includes the protocol, all signed raw data sheets, and technical reports.

The three studies that evaluated the radiopacity of the marker band on the NC Quantum Apex PTCA catheter (09-42N, 08-111N-S8 and 09-045N) were reviewed previously under the Emerge predicate submissions (K113220 and K130391). No additions or subtractions have been made to the data since the prior submissions.

Study 13-120N was conducted to support Design Validation and product labeling of the Threader device and evaluate the intended needs and primary operating functions of the device in an acute (in-vivo) animal study. This was a non-GLP animal study, and was not intended to be conducted in full accordance with the United States Food and Drug Administration (FDA) Good Laboratory Practice Regulations, 21 CFR Part 58. In place of GLP compliance, data integrity was supported by governing SOPs and processes at the external testing facility and within BSC, as follows:

The local test facility is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) and licensed by the USDA. A written protocol was reviewed and approved by the test facility Institutional Animal Care and Use Committees (IACUC) prior to conducting the study. The study was conducted in accordance with protocols and standard operating procedures (SOPs) of the test facility.

Test devices were production-equivalent units, built to print specifications by trained operators using controlled production processes and qualified equipment, and assigned unique identification numbers. Test device manufacturing data and traceable identity numbers were recorded on shop floor paperwork and stored by Boston Scientific in the Design History File. Test device identification numbers were recorded on study datasheets.

Study conduct was monitored for adherence to the protocol, and changes were documented by amendments and deviations. Data were recorded on protocol specific datasheets, were reviewed and signed by the clinical investigators who performed the evaluations, and copies of the raw data were provided in the submission (K134031/ S001, Attachment 5) along with the protocol and report (K134031, Appendix 16).

c. You provided Study 13-120N to provide the bulk of recent information on the finished device performance assessment. In this study, if the test article was representative of the finished device, please explain why radiopacity was not a part of the assessment criteria.

BSC Response:

The test articles used in study 13-120N were representative of the finished device. Marker band radiopacity was not assessed in study 13-120N because BSC leveraged data from previous animal studies using the NC Quantum Apex and the Emerge Catheters, which have substantially equivalent marker bands when compared to the Threader device.

As described in Section 16.2 of the Threader 510(k), the materials used in the radiopaque marker bands for Threader are identical to those used on the Emerge and NC Quantum Apex commercial devices. The wall thickness of the Threader marker band is the same as the wall thickness of the marker bands used on Emerge and NC Quantum Apex. The Threader marker band has a slightly smaller inner and outer diameter in order to match the smaller inner shaft component on Threader. To compensate, the length of the Threader marker band is slightly longer. These dimensional differences result in a (b) (4) in marker band mass for Threader compared to Emerge and NC Quantum Apex, which will only improve marker band visibility. Therefore, no additional marker band radiopacity assessments on the finished version of the Threader device were required to show substantial equivalence.

d. In a GLP study, the test site management generally appoints a study director. FDA reviews considerable information and reports from the (b) (4) test site and the report you provided is unlike any report we are accustomed to reviewing from (b) (4) Additionally, the report lacks detailed methodology and signatures that are usual and ordinary for this test site. Specifically, while you list (b) (6) as the PI for the study, the test protocol and report you provided for Study 13-120N does not list a study director and the reports are not signed. Please state who the study director was and what qualifications in study directorship they possessed to run this study.

BSC Response:

As a non-GLP study, a study report authored by (b) (4) was not requested, and internal BSC report (90899336, Appendix 16-A2 of the 510(k)) presented all of the data and study results of the devices that were evaluated. Internal BSC reports are approved and maintained in an electronic data system, and therefore do not have hard-copy signatures.

A Study Director was assigned by (b) (4) management to write and sign the protocol, and to assure approval of the protocol by the Institutional Animal Use and Care Committee, adherence to the approved protocol, compliance with facility standard operating procedures, and appropriate animal use.

(b) (6) was assigned the institutional role of the Study Director. He has over two years' experience serving as a study director in both non-GLP and GLP studies at the test facility, and has completed all required training to the test facility standard operating procedures, regulations in the conduct of non-clinical studies, and appropriate research animal use.

e. Please state the rationale for why you believe a single investigator and only (b) (4) device simulations in (b) (4) was deemed sufficient to address the performance of this device in study 13-120N. In your explanation, please state how bias was addressed.

BSC Response:

(b) (4) Threader MR and (b) (4) Threader OTW catheters were assessed in (b) (4) in study 13-120N. One back up animal was available, but wasn't used. Because the Threader devices are substantially equivalent to predicate devices such as Emerge and Apex balloon catheters, and the clinical use patterns and environment are well understood, BSC considered a single evaluator performing (b) (4) observations of each device type as adequate to establish end-user needs and demonstrate compliance with the Design and Usability Validation Plan (90849468) for the devices.

The investigator, (b) (6), has extensive experience performing percutaneous coronary interventions in complex lesions. (b) (6) had no vested interest in the success of the Threader catheters and maintained objectivity in rating the test devices over the course of the study.

Performance Testing

6. In Section 15.5, Table 15-101 (Catheter Removal Force from Carrier Tube) noted in a footer that, (b) (4) " Please discuss the finding that a Threader MR device, (b) (4) Please explain how this demonstrates that the device is undergoing appropriate quality controls and meets the tensile strength requirements.

BSC Response:

As a result of an investigation this event was found to be an isolated incident.

Throughout the production process, there are several inspections which a unit with a (b) (4) would not pass. The inspections include visual, tactile and functional leak tests. These in-process inspections were reviewed and found to be appropriate. The processes and equipment used to produce and inspect Threader devices are equivalent to those used to manufacture and inspect other Boston Scientific POBA devices. It could not be determined how this one unit was able to get through the inspection processes.

The investigation also included an assessment of the test equipment, equipment run program, carrier tube, product mandrel and test device. No assignable cause was determined as a result of these examinations. Attempts were also made to recreate this failure but were unsuccessful.

Additionally, over the course of design verification testing, approximately (b) (4) Threader MR catheters were manually removed from carrier tubes without incident (no other instances of (b) (4) Successful tensile strength test results at T=0, 3-month accelerated, and 25-month accelerated time points demonstrate the MR device (b) (4) meet strength requirements, as shown in **Table 1**.

Table 1: Threader MR Catheter Shaft Strength

Time Point	Size (mm)/ Platform	Unit of Measure	Spec	Ave	n
T=0	1.2 x 12 MR	lbf	(b) (4)		
		N			
3 month AA	1.2 x 12 MR	lbf			
		N			
25 month AA	1.2 x 12 MR	lbf			
		N			

In summary, based on the evidence above it has been determined that this incident was an isolated event. The investigation demonstrates that the device is undergoing appropriate quality controls and meets the tensile strength requirements.

7. Section 15.3.5 (Balloon Preparation, Deployment, and Retraction) notes, "A design change was implemented to (b) (4) (b) (4) and the design change was proven to be effective in reducing the rate of (b) (4) Similar issues were noted subsequent to Balloon Fatigue testing (at time zero and shelf life). Please provide evidence demonstrating that the design change was proven to be effective, as described.

BSC Response:

The effectiveness of the (b) (4) design change has been confirmed through in-process inspections and finished device testing.

An in-process inspection monitors the visual appearance of the (b) (4) after the (b) (4) process. (b) (4) (b) (4) no longer evident after the (b) (4) change, as seen in **Figure 1** and **Figure 2**.

(b)(4)Design

(b)(4)Design

Additionally, at the in-process final inspection, the rate of (b) (4) (b) (4) was reduced (b) (4) as seen in **Table 2**. All devices undergo this final inspection and all leaking units are scrapped.

Table 2: (b) (4) Detected During Final Inspection

Product	(b) (4) Version	No. of Units Inspected at Final Review	No. of Units with (b) (4) at Final Review	(b) (4) Percentage
Threader	Before Design Change (b) (4)	(b)	(b	(b) (4)
Threader	After Design Change (b) (4)	(b)	(b	(b) (4)

Finally, design verification testing was conducted on (b) units (following the (b) (4) design change), in which the units were inflated to RBP (14 atm). None of these (b) units had (b) (4) s. The Threader design validation testing (animal study 13-120N) also was conducted on units manufactured after the (b) (4) design change, and there were no (b) (4) issues.

8. Please clarify whether any bench testing acceptance criteria set for the Emerge predicate device were changed for the subject Threader device. For any changes, please provide a justification.

BSC Response:

Table 3 shows the differences in bench testing acceptance criteria for Emerge 1.20 (predicate) and Threader. The columns in the table labeled "Sect." refer to the section numbers of the individual tests in the 510(k) Notifications (K130391 for Emerge 1.20 and K134031 for Threader).

The Threader product specifications for safety and efficacy were based on the predicate, Emerge 1.20. Justifications for differences in acceptance criteria between Emerge and Threader are noted in the table.

Threader has some additional testing (not included for Emerge) as a result of new indication statements. Those additional tests are also included in the table.

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

(b)(4)Testing

9. Section 15.3.16 (Coating Integrity) states, "For the 1.2 mm models, which are not indicated for post dilatation, the balloon catheter is inflated to RBP [rated burst pressure] inside tubing sized to the deployed diameter." Similarly, particulate testing only included inflation to RBP. However, the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters recommends, "Catheters should be tracked through a tortuous path fixture...and then expanded...to the maximum labeled diameter described in the Instructions for Use prior to visual inspection." The RBP is 14 atm and the maximum labeled diameter is 16 atm. As this evaluation is also assessing the coating integrity and particulate generation of the coated balloon, only inflating to the RBP may not be appropriately representative of the worst case. Please provide a sound justification for only inflating the subject device to RBP. Alternately please repeat Particulate and/or Coating Integrity testing with inflation to the maximum labeled diameter.

BSC Response:

Upon consideration of deficiency No. 9 and No. 10, BSC has elected to update the Threader labeling. In the updated labeling the maximum labeled diameter is the diameter at the RBP of 14 atm. As a result, the coating integrity and particulate testing has been conducted with inflation to the maximum labeled diameter.

The redlined Threader DFU is provided in **Attachment 1**, and the clean Threader DFU is provided in **Attachment 2**.

The proposed Threader pouch, carton, and compliance labels were provided in the Threader 510(k) in Appendices 10-A1, 10-A3, and 10-A5, respectively. Updated Threader pouch, carton, and compliance labels (with inflation pressures up to 14 atm, rather than 16 atm) are provided in **Attachments 5**, **6**, and **7**.

10. It appears that the acceptance criteria for the Balloon Rated Burst Pressure (RBP) test have changed from time-zero testing to shelf-life testing. At shelf-life, there is no longer a requirement for the balloon to meet (b) (4) Additionally, you have not assessed whether the Threader device met the 14 atm shelf-life specification (b) (4) as you did at time-zero. Please address the following:

a. The Class II Special Controls Guidance Document for Certain PTCA Catheters recommends in the Balloon Compliance section, "The compliance chart may include pressures up to (but not exceeding) 25% above the RBP, if you provide data and statistics demonstrating that 99% of the balloons will not fail at the listed pressure with 95% confidence." You have not provided data and statistics supporting the decision to label the device for inflations up to 16 atm. To support this, please repeat shelf-life testing with the same specifications used for your time-zero testing. Alternatively, please revise your labeling to only list inflation pressures up to the RBP of 14 atm.

BSC Response:

Upon consideration of deficiency No. 9 and No. 10, BSC has elected to update the Threader labeling. In the updated labeling, the maximum inflation pressure is the RBP of 14 atm.

The redlined Threader DFU is provided in **Attachment 1**, and the clean Threader DFU is provided in **Attachment 2**.

The proposed Threader pouch, carton, and compliance labels were provided in the Threader 510(k) in Appendices 10-A1, 10-A3, and 10-A5, respectively. Updated Threader pouch, carton, and compliance labels (with inflation pressures up to 14 atm, rather than 16 atm) are provided in **Attachments 5**, **6**, and **7**.

b. At shelf-life, you have not described the confidence and reliability of your RBP results. Please demonstrate that "the rated burst pressure (RBP) is the pressure at which 99.9% of the balloons can survive with 95% confidence," at shelf-life as well as at time-zero. If you cannot demonstrate this at shelf-life, please revise your RBP claim.

BSC Response:

Due to specific aging requirements of shelf-life studies, BSC executes different protocols for the design verification of un-aged and aged product. Mechanical accelerated aging is a method to approximate the effects of aging by subjecting the product to conditions (beyond normal exposure) in order to expedite the typical chemical reaction associated with the product. Therefore, sampling criteria for time points associated with accelerated aging studies are considered using less restrictive reliability levels (than nominal design verification).

In addition, the mechanical accelerated aging protocol stacks environmental conditioning (thermal cycling and distribution conditioning) with accelerated aging conditioning. Therefore, mechanical accelerated aging testing is considered challenge testing and is tested to challenge acceptance criteria (which is defined per BSC Corp WI SUD Design Verification, 90744436).

The overall purpose of this testing is to demonstrate that no material degradation has occurred and that the device meets product specification requirements. As such, sampling plans for shelf-life testing are designed with the intent of recognizing shifts in performance.

As reported in the design verification report for rated burst pressure (90892157, summarized in Section 15.3.7 of submission K134031), time-zero testing met the acceptance criteria of 99.9% conformance at a 95% confidence level.

Therefore, time-zero testing demonstrates that the device meets the acceptance criteria that "rated burst pressure (RBP) is the pressure at which 99.9% of balloons can survive with 95% confidence" as recommended in the FDA Guidance for Industry and FDA Staff "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters," September 8, 2010. Additionally, shelf-life testing has confirmed performance is not impacted by aging.

c. (b) (4) failure modes were noted during your shelf-life RBP testing and are less common than longitudinal and pin-hole failure modes. However, these failure modes did not occur at time-zero. New failure modes may be indicative of a deterioration resulting from device aging. Please discuss these failure modes results and explain why they do not raise safety concerns.

BSC Response:

The failure modes for Threader RBP time-zero testing were all recorded as (b) (4) but, by comparison, the predicate Emerge 1.20 testing had very few (b) (4) failures, as seen in **Table 4**.

Table 4: Threader and Emerge 1.20 RBP Failure Modes

Failure Modes	Threader Testing		Emerge 1.20 Testing	
	T=0	T=3 mo AA	T=0	T=36 mo AA
(b) (4)				

All four failure mode types are seen in small balloons and none of the failure modes is unacceptable for the 1.20 balloon because the fully-inflated outer diameter of the balloon can still be withdrawn into a 5F (0.056" ID) guide.

As a result of FDA's question, BSC reviewed the data sheets and re-inspected the devices for the two units recorded as having (b) (4)

modes to further characterize the mode of failure. These two devices (which were both OTW units) can be seen in **Figures 4** and **5**, respectively.

Figure 4: Device with (b) (4) **Failure Mode**

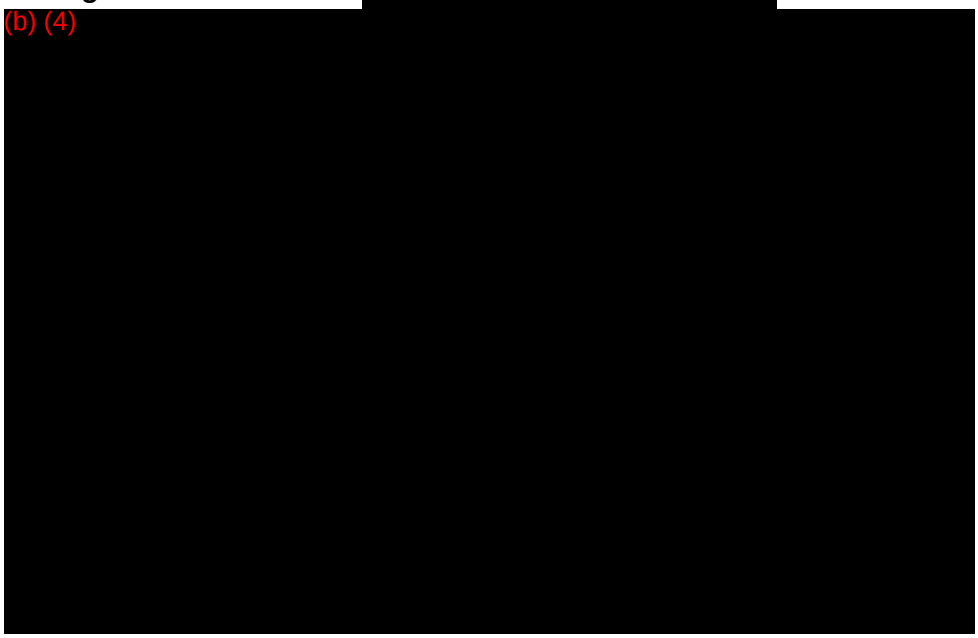
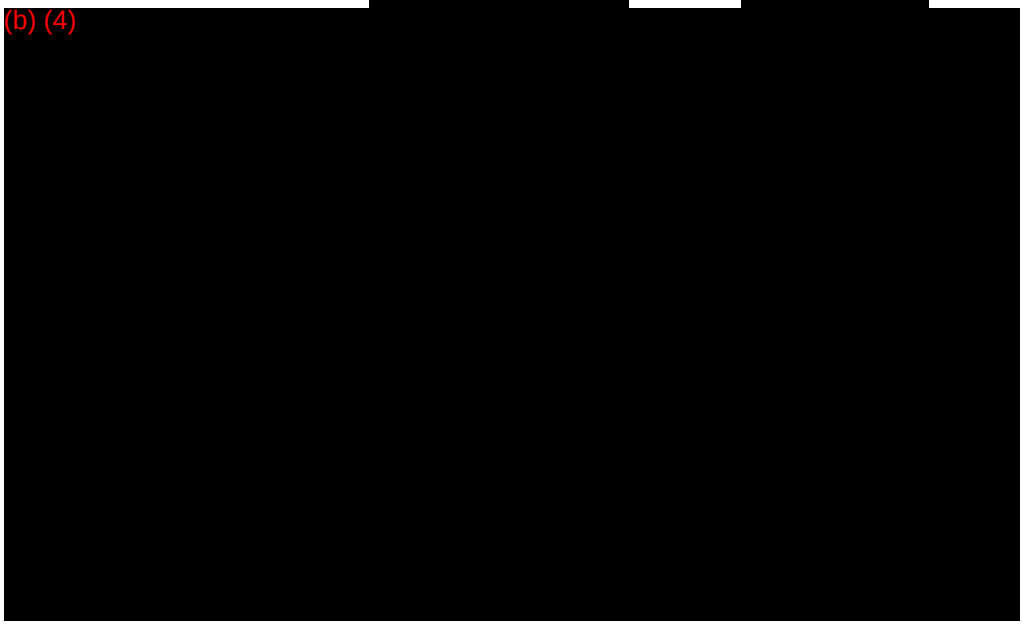


Figure 5: Device with (b) (4) **Failure** (b) (4) **Region**



Re-inspection of these shelf-life failure modes showed the failures are consistent with the failures of the balloons at time-zero. The first unit was found to not be a typical full (b) (4) but rather a (b) (4), as seen in **Figure 4**. The second unit (**Figure 5**) was found to have a failure in the (b) (4) region, but again the size resembled that of a (b) (4).

Images of the two units show there was no separation of the devices, and the identified failure modes represent a conservative description of the actual failure modes. Therefore, it is not believed that these failures present a safety concern, nor do they represent evidence of deterioration.

In addition, the average rated burst pressure (RBP) for all OTW devices after 3-month accelerated aging was (b) (4) psi (and ranged from (b) (4) psi). The time-zero average RBP of OTW devices was (b) (4) psi (and ranged from (b) (4) psi). BSC does not conclude that the shelf-life results are indicative of deterioration since the average and range of both groups are similar.

11. The Class II Special Controls Guidance Document for Certain PTCA Catheters recommends in the Balloon Fatigue section, "that you record all failure modes, and that your results demonstrate that 90% of the balloons will survive the test with at least 95% confidence." However, it appears that you have changed your sample selection rationale for your shelf-life testing of Balloon Fatigue. Please demonstrate that your shelf-life results for this test have met the confidence/reliability recommendations from the special controls guidance document.

BSC Response:

Please see the BSC response to Question 10b for BSC's approach to shelf-life testing, as it applies to the balloon fatigue testing as well as to the RBP testing.

As summarized in Section 15.3.8 of the submission (K134031), time-zero balloon fatigue (repeat inflation) testing demonstrates that the device meets the acceptance criteria of 20 inflations to RBP in which 90% of the balloons will survive at a 95% confidence level. Additionally, shelf-life testing has confirmed performance is not impacted by aging.

12. At shelf-life for the Flexibility and Kink test, all distal parts of the Monorail (MR) variant kinked compared to no kinks at time-zero. Furthermore, you indicated in the Protocol Deviations section that one unit was so damaged by this Kink test that it was unable to complete the subsequent (b) (4) testing. It appears that at least one device failed your acceptance criterion of device functionality subsequent to kink, and the devices performed notably worse at shelf-life. Please demonstrate the ability "to withstand flexural forces that are typical of clinical use," without "device failure or vessel damage," as recommended in the Class II Special Controls Guidance Document for Certain PTCA Catheters.

BSC Response:

The midshaft region of the MR catheter is tested for flex and kink using the following test sequence steps.

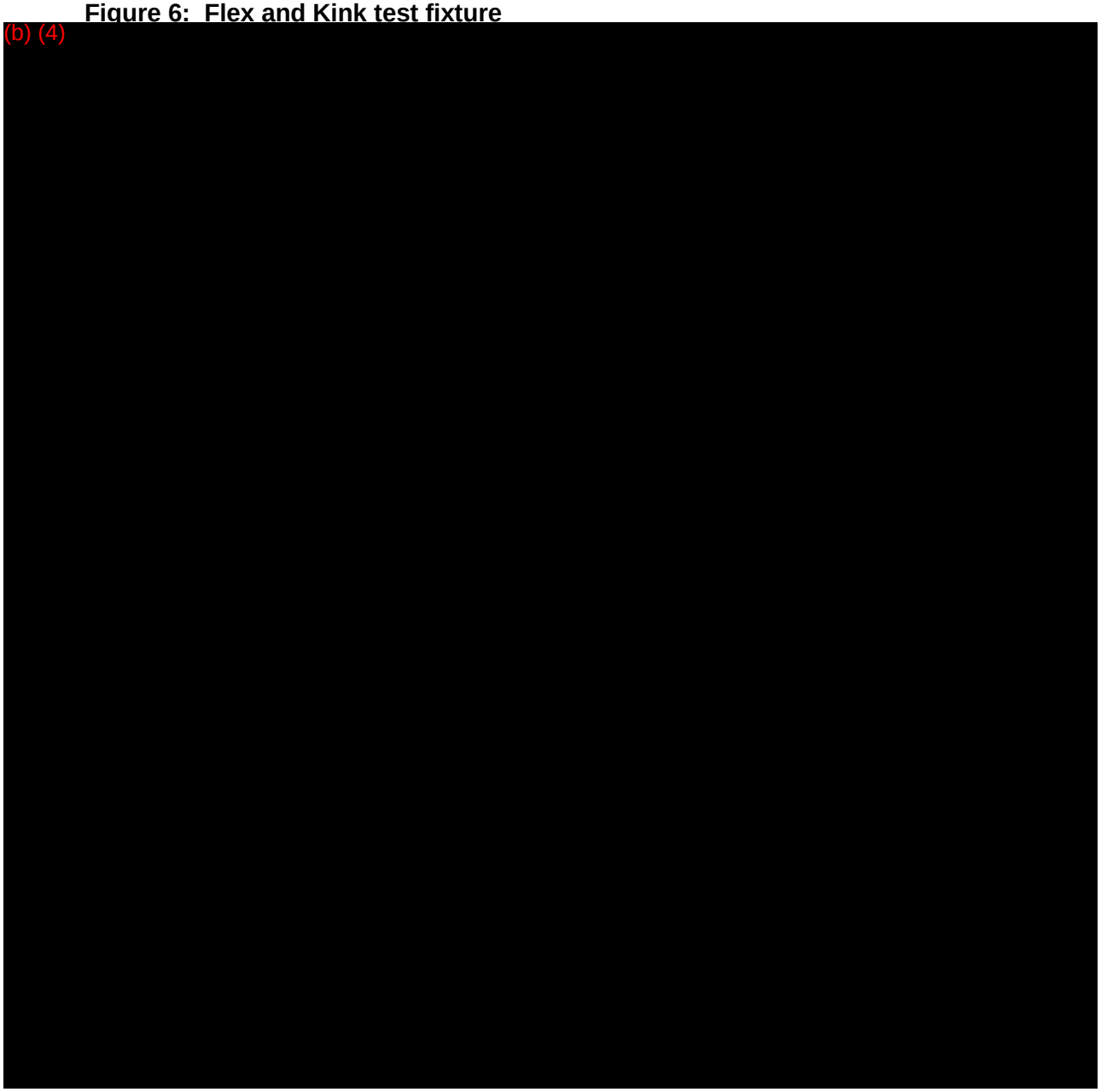
1. Tactile inspection
2. Wrap midshaft around the mandrel radius
3. Tactile inspections
    a. NOTE: The portion of the catheter which is secured to the fixture is not subject to inspection as damage may occur when fixing the unit to the conditioning plate (see fixture in **Figure 6**)
4. Tactile Inspection = Pass – move to next smallest mandrel radius
5. Tactile Inspection = Fail – record the mandrel radius at which the unit failed on the data sheet
    a. Units which fail tactile assessment are subject to lumen integrity assessment

On MR devices there is no wire lumen from the port bond proximal to the manifold, therefore guidewire movement cannot be used to determine if the inflation lumen is compromised by a kink, as is done with the use length portion of the MR catheter and the OTW device. Instead the lumen is assessed using (b) (4)

The unit in question was being tested for the midshaft section of the MR catheter and failed the tactile inspection after radius 4 (out of 5). As the unit was being prepared for a lumen integrity assessment a leak was noticed. A small hole was discovered in the device that lined up with the holding bar on the kink fixture. The failure to assess the lumen integrity was the result of damage imparted by the testing method fixturing and not the result of wrapping the device around mandrel radii (flex and kink testing).

Figure 6: Flex and Kink test fixture

(b) (4)



Damage imparted by the testing method is an anticipated scenario noted in the test method. However, the test method and protocol did not specify that a unit damaged by the test fixture should be replaced. Because of the fixture-induced damage, the final result for this unit was not determined.

Flex and kink testing has subsequently been completed on 25-month accelerated aged MR units and all midshaft sections passed the tactile inspection after all mandrel radii sizes (see **Table 5**).

Table 5: Threader Flexibility and Kink Results (25-month Accelerated Aged Units)

Lot Number/ Model	n	Pre-Test		Post-Radius 2		Post-Radius 3		Post-Radius 4		Post-Radius 5	
		Tactile Test	G/W Mvt.	Tactile Test	G/W Mvt.	Tactile Test	G/W Mvt.	Tactile Test	G/W Mvt.	Tactile Test	G/W Mvt.
16222844 (OTW)	(b	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16200988[1] (MR)	(b)	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
16200988[2] (MR)	(b	Pass	N/A	Pass	N/A	Pass	N/A	Pass	N/A	Pass	N/A

[1] Kink testing of Use Length portion of MR device
[2] Kink testing of Midshaft portion of MR device

Since no kinks were detected after wrapping the devices around all the mandrel radii, lumen integrity assessments (b) (4) were not conducted. The 25-month results demonstrate that the Threader devices meet the flexibility and kink test requirement.

Attachments	
1	Threader DFU, showing additional red-line changes
2	Threader DFU, clean copy with all changes incorporated
3	Emerge DFU, showing changes from Emerge to Threader as red-lines
4	Threader Proximal Balloon Bond Tensile Specification (Technical Report 90903276)
5	Threader Pouch Labels (updated with change to RPB)
6	Threader Carton Labels (updated with change to RPB)
7	Threader Compliance Labels (updated with change to RPB)

Threader™

M O N O R A I L ™

O V E R - T H E - W I R E

Micro-Dilatation Catheter

R_X 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. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

Boston Scientific Threader Over-The-Wire Micro-Dilatation Catheter and Threader Monorail Micro-Dilatation Catheter. The generic name of the device is Over-The-Wire Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter/Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

The Threader Over-The-Wire (OTW) and Threader Monorail (MR) Micro-Dilatation Catheters, from Boston Scientific, are Over-The-Wire and rapid exchange catheters, respectively, with a semi-compliant balloon near the distal tip. The Threader OTW and Threader MR catheters are offered in a 1.2 x 12 mm configuration. The distal section of both catheters (and the proximal section of the OTW catheter) is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 in (0.36 mm) to facilitate advancement of the catheter to the stenosis ~~or through a previously placed stent prior to dilatation~~.

The proximal section of the rapid exchange catheter is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The PowerCoil™ technology makes up the mid-shaft and distal section which consists of a polymer-sheathed stainless steel coil. The OTW catheter has a dual luer port hub: one for inflation/deflation of the balloon, the other for guidewire lumen access. The PowerCoil technology makes up the proximal shaft of the

OTW catheter which consists of a polymer-sheathed stainless steel coil. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the catheter prior to use. The catheter's tip is tapered to facilitate advancement of the catheter to the stenosis ~~or through a previously placed stent prior to dilatation~~. The shafts have ZGlide™ (hydrophilic) coating. For MR, the distal 22 cm of the device including the balloon and tip are coated with ZGlide. For OTW, the distal 60 cm of the device including the balloon and tip are coated with ZGlide. In addition, both MR and OTW devices have Xtra™ (hydrophobic) coating applied to the tip and balloon.

The effective length of both the OTW and MR devices is 150 cm. Marks on the proximal portion of the catheter shaft indicate the imminent exit of the balloon catheter tip out of the guide catheter (mark present at 90 cm and at 100 cm).

A radiopaque marker band, in conjunction with fluoroscopy, aids in the placement of the catheter's balloon segment. The Threader Micro-Dilatation Catheter has one radiopaque marker band located in the center of the balloon body. A CLIPIT™ Hypotube Clip is provided with the Threader Monorail Micro-Dilatation Catheter to aid in handling the catheter.

Contents

One (1) Threader (Monorail or Over-The-Wire) Micro-Dilatation Catheter

One (1) CLIPIT Hypotube Clip (Threader Monorail Micro-Dilatation Catheter Only)

INTENDED USE / INDICATIONS FOR USE

The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion.

The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

CONTRAINDICATIONS

The Threader Micro-Dilatation~~Guide~~ Catheter is contraindicated for use in:

- Unprotected left main coronary artery disease.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
- Use prior to the "use by" date as indicated on the label.

- Use extreme caution and careful judgment in patients for whom anticoagulation is contraindicated.
- Use extreme caution and careful judgment in patients who have reaction to contrast agents that cannot be adequately pre-medicated.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be performed.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate, or be less than, the diameter of the vessel just proximal and distal to the stenosis.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the balloon rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure.
- Use of a pressure monitoring device is recommended to prevent over or under pressurization.
- If difficulty is experienced during balloon inflation, do not continue; remove the catheter.
- Before withdrawing the balloon catheter, visually confirm complete balloon deflation by fluoroscopy.
- Balloon catheter retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the treated vessel and/or the vascular access site. Complications can include but are not limited to bleeding, hematoma, pseudoaneurysm or dissection.

PRECAUTIONS

- The compatibility of the device has not been evaluated for the delivery of materials (e.g., alcohol or nitroglycerine, stem cells, etc.) through the guidewire lumen, other than those required for normal use.
- The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.
- This balloon is not intended for the expansion or delivery of a stent.
- The safety and effectiveness of the Threader Micro-Dilatation Catheter have not been established for the treatment of chronic total occlusions. The risk of adverse events is likely to be higher when treating such lesions. Physicians should be aware of this increased risk and the limitations of the available scientific evidence. Additional data from clinical studies

and analyses of the treatment of chronic total occlusions are expected and should be considered in making treatment decisions as data becomes available.

- Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Caution should be taken not to overtighten a hemostatic adapter around the catheter shaft as lumen constriction may occur, possibly affecting inflation/deflation of the balloon.
- Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
- Care should be taken to control the position of the guide catheter tip during manipulation of the balloon catheter.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.
- Do not expand the balloon if it is not properly positioned in the vessel.
- In the case of simultaneous use of two Threader™ balloon catheters in one guide catheter, care should be taken when introducing, rotating, and removing guidewires and balloon catheters to avoid entanglement.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) that may be associated with the use of a Micro-Dilatation Catheter include, but are not limited to, the following:

- abrupt closure
- acute myocardial infarction
- angina or unstable angina
- arrhythmia, including ventricular fibrillation
- arteriovenous fistula
- cardiac tamponade/pericardial effusion
- cardiogenic shock
- cerebrovascular accident/stroke
- coronary aneurysm
- coronary artery bypass graft surgery
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury, possibly requiring surgical repair or intervention
- death
- drug reactions, including allergic reaction to contrast medium
- embolism
- hemodynamic compromise
- hemorrhage or hematoma
- hypo/hypertension
- infection
- minor vessel spasm
- myocardial ischemia

- pseudoaneurysm (at vascular access site)
- pyrogenic reaction
- renal failure
- respiratory insufficiency
- restenosis of the dilated vessel
- side branch occlusion
- slow flow/no reflow
- target vessel re-intervention
- thrombosis
- total occlusion of the coronary artery or bypass graft
- transient ischemic attack
- vasovagal reaction
- volume overload

HOW SUPPLIED
- Non-pyrogenic.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE
Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

One or more of each of the following materials are required for PTCA but not supplied with the Threader Over-The-Wire or Threader Monorail Micro-Dilatation Catheter.

Description
- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set (for femoral approach only)
- Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.066 in (1.68 mm) (Threader Over-The-Wire Micro-Dilatation Catheter)
- Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.056 in (1.42 mm) (Threader Monorail Micro-Dilatation Catheter)
- Contrast medium
- Sterile saline or heparinized normal sterile saline
- Inflation device with manometer
- ≤0.014 in (0.36 mm) x 300 cm guidewire(s) (Threader Over-The-Wire Micro-Dilatation Catheter)
- ≤0.014 in (0.36 mm) x 185 cm guidewire(s) (Threader Monorail Micro-Dilatation Catheter)
- 10, 12 or 20 ml (cc) luer-lock syringe
- Hemostatic adapter
- Three-way stopcock
- Guidewire torqueing device

Inspection Prior to Use

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended. Do not use if sterile package is damaged.

Note: Do not continue to use the catheter if damage occurs or sterility is compromised during use.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air using only the contrast medium.

Catheter Selection

The inflation diameter of the balloon catheter must not exceed the diameter of the coronary artery proximal and distal to the stenosis.

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon ~~catheter~~ (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For Threader Over-The-Wire Micro-Dilatation Catheters, the mandrel will slide off with the balloon catheter protector. For Threader Monorail Micro-Dilatation Catheters, remove the mandrel distally after removing the balloon protector.

Caution: If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the catheter and replace with another.

3. The Threader Monorail Micro-Dilatation Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body.

Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

4. Prepare the catheter for purging. Fill a luer lock syringe or inflation device with appropriate balloon catheter inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile saline). **Do not use air or any gaseous medium to inflate the balloon catheter.**
5. Connect a three-way stopcock to the port fitting on the catheter. Flush through the stopcock taking care to ensure that the balloon cannot be inflated. Connect syringe or inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread

causing subsequent leakage and use care when connecting the catheter to avoid damage (e.g., shaft kink).

6. Hold the syringe or inflation device with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger or open stopcock to air.
7. Remove the syringe or inflation device and evacuate all air from the barrel.
8. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If bubbles persist, check luer connections. If bubbles still persist, inflate the balloon to verify that there are no leaks present prior to insertion. Do not use the balloon catheter if there are any leaks.
9. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointing upwards.
10. Disconnect the syringe used in preparation. Verify that a meniscus of contrast medium is evident in both the balloon catheter port and the inflation device connection to ensure a fluid to fluid connection. Adding a drop of inflation medium to the port may be necessary. Securely couple the inflation device to the balloon catheter port of the catheter.
11. Open the stopcock to the catheter and leave on neutral.

Insertion Procedure

1. Guidewire Lumen Flush.

   A. For the Threader Monorail Micro-Dilatation Catheter, flush the guidewire lumen of the catheter with sterile saline through the distal tip of the catheter.

   B. For the Threader Over-The-Wire Micro-Dilatation Catheter, flush the guidewire lumen of the catheter with sterile saline through the guidewire port of the catheter hub.

   C. Check for bends, kinks and other damage. Do not use if any defects are noted.

2. Catheter Advancement

   A. Prepare the vascular access site according to standard practice.

   B. Maintain neutral pressure on the inflation device attached to the catheter.

   C. Insert a guidewire through the hemostatic adapter following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.

   D. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then position the distal wire in the desired location.

   E. Backload the distal tip of the catheter onto the guidewire ensuring that the guidewire exits the midsection opening in the Threader Monorail Micro-Dilatation Catheter or the wire port of the Threader Over-The-Wire Micro-Dilatation Catheter manifold. When loading or exchanging the catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

F. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the balloon catheter.

G. Carefully advance the catheter through the hemostatic adapter while the balloon is fully deflated. If unusual resistance is felt, do not advance the catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

H. Advance the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis to be dilated. Use the center radiopaque marker band as a reference point. Balloon inflation should not be undertaken if the balloon is not properly positioned within the stenosis.

I. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that contrast media is needed, withdraw the guidewire and hand-inject contrast media through the catheter hub with a syringe.

J. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that an alternative guidewire is needed, remove the guidewire while holding the hub of the Over-The-Wire Micro-Dilatation Catheter in place. Once the guidewire has been removed from the patient, an alternative guidewire can be introduced into the hub of the Over-The-Wire Micro-Dilatation Catheter and advanced to the distal tip of the catheter.

K. Simultaneous use of two balloon catheters in a guide catheter (Kissing Balloon): Bench ~~and preclinical~~ testing has shown that one Threader Monorail Micro-Dilatation C~~c~~atheter and one 3.25 x 20 mm (or smaller) Emerge Monorail PTCA Dilatation ~~balloon c~~Catheter can be inserted simultaneously into a 6F (minimum 0.070 in ID) guide catheter and one Threader Over-The-Wire Micro-Dilatation Catheter and one 3.25 x 20 mm (or smaller) Emerge Over-The-Wire PTCA Dilatation Catheter can be inserted into an 8F (minimum 0.088 in ID) guide catheter with acceptable compatibility. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical study. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.

3. Catheter Inflation

A. Inflate the balloon slowly to the appropriate pressure to perform PTCA. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to the balloon compliance table or chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA, deflate the balloon by pulling negative pressure on the inflation device until the balloon is fully deflated. Bench testing has demonstrated that the deflation times range from 2 to 5 seconds.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon expansion should be used to properly judge the optimum expanded balloon diameter as compared to the proximal and distal coronary artery diameter(s). Repeat inflation of balloon until the desired result is achieved.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (Threader Over-The-Wire Micro-Dilatation Catheter) or step 6 – Catheter Exchange Procedure (Threader Monorail Micro-Dilatation Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery has not abruptly occluded. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the hemostatic adapter.

C. The Threader Monorail Micro-Dilatation Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to the catheter being inserted in the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

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5. Catheter Exchange Procedure (Threader Over-The-Wire Micro-Dilatation Catheter)

The Threader Over-The-Wire Micro-Dilatation Catheter typically requires two operators to exchange. To perform a catheter exchange, execute the following steps:

A. Loosen the hemostatic adapter.

B. The primary operator holds the hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. While maintaining guidewire position, withdraw the deflated catheter until the catheter tip exits the hemostatic adapter.

D. Close the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the stenosis.

E. Prepare the next device and load onto the guidewire as described in step 2.

F. Continue the procedure.

6. Catheter Exchange Procedure (Threader Monorail Micro-Dilatation Catheter)

The Threader Monorail Micro-Dilatation Catheter has been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

A. Loosen the hemostatic adapter.

B. Hold the guidewire and hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. Maintain the guidewire position in the coronary artery by holding the guidewire stationary. Begin pulling the deflated catheter out of the guide catheter while maintaining the guidewire position under fluoroscopy.

D. Withdraw the catheter until the opening in the guidewire lumen is reached (approximately 25 cm proximal to the balloon catheter tip).

E. While maintaining guidewire position, carefully slide the flexible, distal portion of the catheter out of the hemostatic adapter, and tighten the hemostatic adapter onto the guidewire to hold it securely in place. Completely remove the catheter from the guidewire while maintaining guidewire position.

F. Prepare the next device and load onto the guidewire as described in step 2.

G. Continue the procedure.

Typical Threader Micro-Dilatation Catheter Balloon Compliance

Pressure		Balloon size is listed as mm (nominal = 6.0 atm) *Rated Burst Pressure. DO NOT EXCEED.
atm	kPa	1.2 mm
3.0	304	1.06
4.0	405	1.11
5.0	507	1.15
6.0 (nominal)	608	1.18
7.0	709	1.21
8.0	811	1.23
9.0	912	1.24
10.0	1013	1.26
11.0	1115	1.27
12.0	1216	1.28
13.0	1317	1.29
14.0*	1419	1.30

Note: Over inflation may result in burst of the balloon or shaft.

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Pressure		Balloon size is listed as mm (nominal = 6.0 atm) *Rated Burst Pressure. DO NOT EXCEED.
atm	kPa	1.2 mm
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10.0	1013	1.26
11.0	1115	1.27
12.0	1216	1.28
13.0	1317	1.29
14.0*	1419	1.30
15.0	1520	1.31
16.0	1621	1.33

Note: Over inflation may result in burst of the balloon or shaft.

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
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência



Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização



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EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.



Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante legal

LOT

Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto



Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável



Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano



For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.



Do Not Resterilize
No resterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize



Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

GW R

Recommended Guidewire
Guía recomendada
Guide recommandé
Empfohlener Führungsdraht
Filoguida consigliato
Aanbevolen voerdraad
Fio-guia Recomendado

GC R

Recommended Guide Catheter
Catéter guía recomendado
Cathéter guide recommandé
Empfohlener Führungskatheter
Catetere guida consigliato
Aanbevolen geleidekatheter
Cateter-guia Recomendado

STERILE EO

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesterliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

CL R

Includes CLIPIT™ Hypotube Clip
Incluye pinza de hipotubo CLIPIT™
Inclut un clip de l'hypotube CLIPIT™
Enthält CLIPIT™ Hypotube-Klemme
Include clip per ipotubo CLIPIT™
Bevat CLIPIT™-hypotubeclip
Inclui o Clipe para Hipotubo CLIPIT™

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Do not use if package is damaged.

Recyclable Package

CE 0344

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Threader™

M O N O R A I L ™

O V E R - T H E - W I R E

Micro-Dilatation Catheter

R_X ONLY

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Boston Scientific Threader Over-The-Wire Micro-Dilatation Catheter and Threader Monorail Micro-Dilatation Catheter. The generic name of the device is Over-The-Wire Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter/Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

The Threader Over-The-Wire (OTW) and Threader Monorail (MR) Micro-Dilatation Catheters, from Boston Scientific, are Over-The-Wire and rapid exchange catheters, respectively, with a semi-compliant balloon near the distal tip. The Threader OTW and Threader MR catheters are offered in a 1.2 x 12 mm configuration. The distal section of both catheters (and the proximal section of the OTW catheter) is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 in (0.36 mm) to facilitate advancement of the catheter to the stenosis.

The proximal section of the rapid exchange catheter is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The PowerCoil™ technology makes up the mid-shaft and distal section which consists of a polymer-sheathed stainless steel coil. The OTW catheter has a dual luer port hub: one for inflation/deflation of the balloon, the other for guidewire lumen access. The PowerCoil technology makes up the proximal shaft of the OTW catheter which consists of a polymer-sheathed stainless steel coil. The balloon is designed

to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the catheter prior to use. The catheter's tip is tapered to facilitate advancement of the catheter to the stenosis. The shafts have ZGlide™ (hydrophilic) coating. For MR, the distal 22 cm of the device including the balloon and tip are coated with ZGlide. For OTW, the distal 60 cm of the device including the balloon and tip are coated with ZGlide. In addition, both MR and OTW devices have Xtra™ (hydrophobic) coating applied to the tip and balloon.

The effective length of both the OTW and MR devices is 150 cm. Marks on the proximal portion of the catheter shaft indicate the imminent exit of the balloon catheter tip out of the guide catheter (mark present at 90 cm and at 100 cm).

A radiopaque marker band, in conjunction with fluoroscopy, aids in the placement of the catheter's balloon segment. The Threader Micro-Dilatation Catheter has one radiopaque marker band located in the center of the balloon body. A CLIPIT™ Hypotube Clip is provided with the Threader Monorail Micro-Dilatation Catheter to aid in handling the catheter.

Contents

One (1) Threader (Monorail or Over-The-Wire) Micro-Dilatation Catheter

One (1) CLIPIT Hypotube Clip (Threader Monorail Micro-Dilatation Catheter Only)

INTENDED USE / INDICATIONS FOR USE

The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion.

The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

CONTRAINDICATIONS

The Threader Micro-Dilatation Catheter is contraindicated for use in:

- Unprotected left main coronary artery disease.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
- Use prior to the "use by" date as indicated on the label.
- Use extreme caution and careful judgment in patients for whom anticoagulation is contraindicated.

- Use extreme caution and careful judgment in patients who have reaction to contrast agents that cannot be adequately pre-medicated.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be performed.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate, or be less than, the diameter of the vessel just proximal and distal to the stenosis.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the balloon rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure.
- Use of a pressure monitoring device is recommended to prevent over or under pressurization.
- If difficulty is experienced during balloon inflation, do not continue; remove the catheter.
- Before withdrawing the balloon catheter, visually confirm complete balloon deflation by fluoroscopy.
- Balloon catheter retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the treated vessel and/or the vascular access site. Complications can include but are not limited to bleeding, hematoma, pseudoaneurysm or dissection.

PRECAUTIONS

- The compatibility of the device has not been evaluated for the delivery of materials (e.g., alcohol or nitroglycerine, stem cells, etc.) through the guidewire lumen, other than those required for normal use.
- The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.
- This balloon is not intended for the expansion or delivery of a stent.
- The safety and effectiveness of the Threader Micro-Dilatation Catheter have not been established for the treatment of chronic total occlusions. The risk of adverse events is likely to be higher when treating such lesions. Physicians should be aware of this increased risk and the limitations of the available scientific evidence. Additional data from clinical studies and analyses of the treatment of chronic total occlusions are expected and should be considered in making treatment decisions as data becomes available.

- Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Caution should be taken not to overtighten a hemostatic adapter around the catheter shaft as lumen constriction may occur, possibly affecting inflation/deflation of the balloon.
- Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
- Care should be taken to control the position of the guide catheter tip during manipulation of the balloon catheter.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.
- Do not expand the balloon if it is not properly positioned in the vessel.
- In the case of simultaneous use of two Threader™ balloon catheters in one guide catheter, care should be taken when introducing, rotating, and removing guidewires and balloon catheters to avoid entanglement.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) that may be associated with the use of a Micro-Dilatation Catheter include, but are not limited to, the following:

- abrupt closure
- acute myocardial infarction
- angina or unstable angina
- arrhythmia, including ventricular fibrillation
- arteriovenous fistula
- cardiac tamponade/pericardial effusion
- cardiogenic shock
- cerebrovascular accident/stroke
- coronary aneurysm
- coronary artery bypass graft surgery
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury, possibly requiring surgical repair or intervention
- death
- drug reactions, including allergic reaction to contrast medium
- embolism
- hemodynamic compromise
- hemorrhage or hematoma
- hypo/hypertension
- infection
- minor vessel spasm
- myocardial ischemia
- pseudoaneurysm (at vascular access site)
- pyrogenic reaction

- renal failure
- respiratory insufficiency
- restenosis of the dilated vessel
- side branch occlusion
- slow flow/no reflow
- target vessel re-intervention
- thrombosis
- total occlusion of the coronary artery or bypass graft
- transient ischemic attack
- vasovagal reaction
- volume overload

HOW SUPPLIED

- Non-pyrogenic.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

One or more of each of the following materials are required for PTCA but not supplied with the Threader Over-The-Wire or Threader Monorail Micro-Dilatation Catheter.

Description

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set (for femoral approach only)
- Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.066 in (1.68 mm) (Threader Over-The-Wire Micro-Dilatation Catheter)
- Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.056 in (1.42 mm) (Threader Monorail Micro-Dilatation Catheter)
- Contrast medium
- Sterile saline or heparinized normal sterile saline
- Inflation device with manometer
- ≤0.014 in (0.36 mm) x 300 cm guidewire(s) (Threader Over-The-Wire Micro-Dilatation Catheter)
- ≤0.014 in (0.36 mm) x 185 cm guidewire(s) (Threader Monorail Micro-Dilatation Catheter)
- 10, 12 or 20 ml (cc) luer-lock syringe
- Hemostatic adapter
- Three-way stopcock
- Guidewire torqueing device

Inspection Prior to Use

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended. Do not use if sterile package is damaged.

Note: Do not continue to use the catheter if damage occurs or sterility is compromised during use.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air using only the contrast medium.

Catheter Selection

The inflation diameter of the balloon catheter must not exceed the diameter of the coronary artery proximal and distal to the stenosis.

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For Threader Over-The-Wire Micro-Dilatation Catheters, the mandrel will slide off with the balloon catheter protector. For Threader Monorail Micro-Dilatation Catheters, remove the mandrel distally after removing the balloon protector.

Caution: If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the catheter and replace with another.

3. The Threader Monorail Micro-Dilatation Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body.

Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

4. Prepare the catheter for purging. Fill a luer lock syringe or inflation device with appropriate balloon catheter inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile saline). **Do not use air or any gaseous medium to inflate the balloon catheter.**
5. Connect a three-way stopcock to the port fitting on the catheter. Flush through the stopcock taking care to ensure that the balloon cannot be inflated. Connect syringe or inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread

causing subsequent leakage and use care when connecting the catheter to avoid damage (e.g., shaft kink).

6. Hold the syringe or inflation device with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger or open stopcock to air.
7. Remove the syringe or inflation device and evacuate all air from the barrel.
8. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If bubbles persist, check luer connections. If bubbles still persist, inflate the balloon to verify that there are no leaks present prior to insertion. Do not use the balloon catheter if there are any leaks.
9. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointing upwards.
10. Disconnect the syringe used in preparation. Verify that a meniscus of contrast medium is evident in both the balloon catheter port and the inflation device connection to ensure a fluid to fluid connection. Adding a drop of inflation medium to the port may be necessary. Securely couple the inflation device to the balloon catheter port of the catheter.
11. Open the stopcock to the catheter and leave on neutral.

Insertion Procedure

1. Guidewire Lumen Flush.

   A. For the Threader Monorail Micro-Dilatation Catheter, flush the guidewire lumen of the catheter with sterile saline through the distal tip of the catheter.

   B. For the Threader Over-The-Wire Micro-Dilatation Catheter, flush the guidewire lumen of the catheter with sterile saline through the guidewire port of the catheter hub.

   C. Check for bends, kinks and other damage. Do not use if any defects are noted.

2. Catheter Advancement

   A. Prepare the vascular access site according to standard practice.

   B. Maintain neutral pressure on the inflation device attached to the catheter.

   C. Insert a guidewire through the hemostatic adapter following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.

   D. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then position the distal wire in the desired location.

   E. Backload the distal tip of the catheter onto the guidewire ensuring that the guidewire exits the midsection opening in the Threader Monorail Micro-Dilatation Catheter or the wire port of the Threader Over-The-Wire Micro-Dilatation Catheter manifold. When loading or exchanging the catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

F. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the balloon catheter.

G. Carefully advance the catheter through the hemostatic adapter while the balloon is fully deflated. If unusual resistance is felt, do not advance the catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

H. Advance the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis to be dilated. Use the center radiopaque marker band as a reference point. Balloon inflation should not be undertaken if the balloon is not properly positioned within the stenosis.

I. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that contrast media is needed, withdraw the guidewire and hand-inject contrast media through the catheter hub with a syringe.

J. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that an alternative guidewire is needed, remove the guidewire while holding the hub of the Over-The-Wire Micro-Dilatation Catheter in place. Once the guidewire has been removed from the patient, an alternative guidewire can be introduced into the hub of the Over-The-Wire Micro-Dilatation Catheter and advanced to the distal tip of the catheter.

K. Simultaneous use of two balloon catheters in a guide catheter (Kissing Balloon): Bench testing has shown that one Threader Monorail Micro-Dilatation Catheter and one 3.25 x 20 mm (or smaller) Emerge Monorail PTCA Dilatation Catheter can be inserted simultaneously into a 6F (minimum 0.070 in ID) guide catheter and one Threader Over-The-Wire Micro-Dilatation Catheter and one 3.25 x 20 mm (or smaller) Emerge Over-The-Wire PTCA Dilatation Catheter can be inserted into an 8F (minimum 0.088 in ID) guide catheter with acceptable compatibility. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical study. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.

3. Catheter Inflation

A. Inflate the balloon slowly to the appropriate pressure to perform PTCA. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to the balloon compliance table or chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA, deflate the balloon by pulling negative pressure on the inflation device until the balloon is fully deflated. Bench testing has demonstrated that the deflation times range from 2 to 5 seconds.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon expansion should be used to properly judge the optimum expanded balloon diameter as compared to the proximal and distal coronary artery diameter(s). Repeat inflation of balloon until the desired result is achieved.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (Threader Over-The-Wire Micro-Dilatation Catheter) or step 6 – Catheter Exchange Procedure (Threader Monorail Micro-Dilatation Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery has not abruptly occluded. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the hemostatic adapter.

C. The Threader Monorail Micro-Dilatation Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to the catheter being inserted in the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

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5. Catheter Exchange Procedure (Threader Over-The-Wire Micro-Dilatation Catheter)

The Threader Over-The-Wire Micro-Dilatation Catheter typically requires two operators to exchange. To perform a catheter exchange, execute the following steps:

A. Loosen the hemostatic adapter.

B. The primary operator holds the hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. While maintaining guidewire position, withdraw the deflated catheter until the catheter tip exits the hemostatic adapter.

D. Close the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the stenosis.

E. Prepare the next device and load onto the guidewire as described in step 2.

F. Continue the procedure.

6. Catheter Exchange Procedure (Threader Monorail Micro-Dilatation Catheter)

The Threader Monorail Micro-Dilatation Catheter has been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

A. Loosen the hemostatic adapter.

B. Hold the guidewire and hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. Maintain the guidewire position in the coronary artery by holding the guidewire stationary. Begin pulling the deflated catheter out of the guide catheter while maintaining the guidewire position under fluoroscopy.

D. Withdraw the catheter until the opening in the guidewire lumen is reached (approximately 25 cm proximal to the balloon catheter tip).

E. While maintaining guidewire position, carefully slide the flexible, distal portion of the catheter out of the hemostatic adapter, and tighten the hemostatic adapter onto the guidewire to hold it securely in place. Completely remove the catheter from the guidewire while maintaining guidewire position.

F. Prepare the next device and load onto the guidewire as described in step 2.

G. Continue the procedure.

Typical Threader Micro-Dilatation Catheter Balloon Compliance

Pressure		Balloon size is listed as mm (nominal = 6.0 atm) *Rated Burst Pressure. DO NOT EXCEED.
atm	kPa	1.2 mm
3.0	304	1.06
4.0	405	1.11
5.0	507	1.15
6.0 (nominal)	608	1.18
7.0	709	1.21
8.0	811	1.23
9.0	912	1.24
10.0	1013	1.26
11.0	1115	1.27
12.0	1216	1.28
13.0	1317	1.29
14.0*	1419	1.30

Note: Over inflation may result in burst of the balloon or shaft.

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
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência



Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização



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EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.



Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante legal

LOT

Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto



Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável



Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano



For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.



Do Not Resterilize
No resterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize



Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

GW R

Recommended Guidewire
Guía recomendada
Guide recommandé
Empfohlener Führungsdraht
Filoguida consigliato
Aanbevolen voerdraad
Fio-guia Recomendado

GC R

Recommended Guide Catheter
Catéter guía recomendado
Cathéter guide recommandé
Empfohlener Führungskatheter
Catetere guida consigliato
Aanbevolen geleidekatheter
Cateter-guia Recomendado

STERILE EO

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesterliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

CL R

Includes CLIPIT™ Hypotube Clip
Incluye pinza de hipotubo CLIPIT™
Inclut un clip de l'hypotube CLIPIT™
Enthält CLIPIT™ Hypotube-Klemme
Include clip per ipotubo CLIPIT™
Bevat CLIPIT™-hypotubeclip
Inclui o Clipe para Hipotubo CLIPIT™

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Do not use if package is damaged.

Recyclable Package

CE 0344

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ThreaderEmerge™

MONORAIL™

OVER-THE-WIRE

Micro-PTCA Dilatation Catheter

R_X 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. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

Boston Scientific ThreaderEmerge Over-The-Wire Micro-PTCA Dilatation Catheter and ThreaderEmerge Monorail Micro-PTCA Dilatation Catheter. The generic name of the device is Over-The-Wire Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter/Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

The ThreaderEmerge Over-The-Wire (OTW) and ThreaderEmerge Monorail (MR) Micro-Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheters, from Boston Scientific, are Over-The-Wire and rapid exchange catheters, respectively, with a semi-compliant balloon near the distal tip. The Threader OTW and Threader MR catheters are offered in a 1.2 x 12 mm configuration. The distal section of both catheters (and the proximal section of the OTW catheter) is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 in (0.36 mm) to facilitate advancement of the catheter to and through the stenosis or through a previously placed stent to be dilatedprior to dilatation.

The proximal section of the rapid exchange catheter is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The PowerCoil™ technology makes up the mid-shaft and distal section which consists of a polymer-sheathed stainless steel coil. The OTW catheter has a dual luer port hub: one for inflation/deflation of the balloon, the

other for guidewire lumen access. The PowerCoil technology makes up the proximal shaft of the OTW catheter which consists of a polymer-sheathed stainless steel coil. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the catheter prior to use. The catheter's tip is tapered to facilitate advancement of the catheter to ~~and through~~ the stenosis or through a previously placed stent prior to dilatation. ~~In addition to the standard design, the 1.20 mm and 1.50 mm catheters are offered in "Push" models that provide different performance characteristics.~~ The~~All~~ shafts have ZGlide™ (hydrophilic) coating. For MR, the distal 22 cm of the device including the balloon and tip are coated with ZGlide ~~is located from the guidewire port to just proximal of the proximal balloon waist~~. For OTW, the distal 60 cm of the device including the balloon and tip are coated with ZGlide ~~is located from distal of the proximal marks to just proximal of the proximal balloon waist~~. In addition, both MR and OTW devices~~All balloons~~ have Xtra™ (hydrophobic) coating applied to the tip and balloon~~and some balloons have ZGlide applied from the distal tip to just proximal of the balloon, per Table 1~~.

Table 1. Emerge Balloon Coatings

Balloon Diameter	Balloon Length: 8 mm	12 mm	15 mm	20 mm	30 mm
1.20 mm					
1.20 mm Push					
1.50 mm					
1.50 mm Push					
2.00 mm					
2.25 mm	Xtra Only			ZGlide and Xtra	
2.50 mm					
2.75 mm					
3.00 mm					
3.25 mm					
3.50 mm					
3.75 mm					
4.00 mm					

The effective length of both the OTW and MR devices is 150 cm ~~is 143 cm and the rapid exchange catheter is 144 cm~~. Marks on the proximal portion of the catheter shaft indicate the imminent exit of the balloon catheter tip out of the guide catheter (mark present~~one~~ at 90 cm and ~~two~~ at 100 cm).

A rRadiopaque marker bands, in conjunction with fluoroscopy, aids in the placement of the catheter's balloon segment. The Threader has1.20 mm and 1.50 mm models have one radiopaque marker band located in the center of the balloon body, while all other models have two radiopaque marker bands. A CLIPIT® Hypotube Clip is provided with the ThreaderEmerge Monorail Micro-PTCADilatation Catheter to aid in handling of the catheter.

Contents

Quantity Material

One (1) ThreaderEmerge (Monorail or Over-The-Wire) Micro-PTCA Dilatation Catheter

One (1) CLIPIT Hypotube Clip (Threader Monorail Micro-Dilatation Catheter Oonly)

INTENDED USE / INDICATIONS FOR USE

The Threader Micro-Dilatation CathetersEmerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated foras pre-dilatation ofcatheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-4.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Note: Bench testing was conducted with Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters and marketed Boston Scientific balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design. All stents should be deployed in accordance with the manufacturer's indications and instructions for use.

CONTRAINDICATIONS

The Threader Guide Catheter is contraindicated for use in:

- Unprotected left main coronary artery disease.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

General Warnings

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
- Use prior to the "use by" date as indicated on the label.
- Use extreme caution and careful judgment in patients for whom anticoagulation is contra~~not~~ indicated.
- Use extreme caution and careful judgment in patients who have ~~severe~~ reaction to contrast agents that cannot be adequately pre-medicated.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be ~~quickly~~ performed ~~in the event of a potentially injurious or life-threatening complication~~.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate, or be less than, the diameter of the vessel just proximal and distal to the stenosis.

~~Use the balloon catheter prior to the "Use By" date specified on the package.~~

~~**Catheter Handling**~~

- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

~~**Catheter Placement and Removal**~~

- When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated ~~under vacuum~~. If resistance is felt during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the balloon rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure.
- Use of a pressure monitoring device is recommended to prevent over or under pressurization.
- If difficulty is experienced during balloon inflation, do not continue; remove the catheter.
- Before withdrawing the balloon catheter, visually confirm complete balloon deflation by fluoroscopy.
- Balloon catheter retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the treated vessel and/or the vascular access site. Complications can include but are not limited to bleeding, hematoma, ~~or~~ pseudoaneurysm or dissection.

PRECAUTIONS

~~**General Precautions**~~

- The compatibility of the device has not been evaluated for the delivery of materials (e.g., ~~drugs,~~ alcohol or nitroglycerine, ~~or~~ stem cells, etc.) through the guidewire lumen, other than those required for normal use.

- The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.

~~**Catheter Handling**~~

- Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Caution should be taken not to overtighten a hemostatic adapter around the catheter shaft as lumen constriction may occur, possibly affecting inflation/deflation of the balloon.

~~**Catheter Placement**~~

- Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
- Care should be taken to control the position of the guide catheter tip during manipulation of the balloon catheter.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.
- Do not expand the balloon if it is not properly positioned in the vessel.
- ~~Models not specified within step J of the Insertion Procedure have not been evaluated for simultaneous use of two balloon catheters in a guide catheter.~~
- In the case of simultaneous use of two Threader~~Emerge~~™ balloon catheters in one guide catheter, care should be taken when introducing, rotating~~torquing~~, and removing guide~~-~~wires and balloon catheters to avoid entanglement.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) that may be associated with the use of a Micro-~~PTCA~~ Dilatation Catheter include, but are not limited to, the following:

- abrupt closure
- acute myocardial infarction
- angina or unstable angina
- arrhythmia, including ventricular fibrillation
- arteriovenous fistula
- cardiac tamponade/pericardial effusion
- cardiogenic shock
- cerebrovascular accident/stroke
- coronary aneurysm
- coronary artery bypass graft surgery
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury, possibly requiring surgical repair or intervention
- death

- drug reactions, including allergic reaction to contrast medium
- embolism
- hemodynamic compromise
- hemorrhage or hematoma
- hypo/hypertension
- infection
- minor vessel spasm~~trauma~~
- myocardial ischemia
- ~~percutaneous re-intervention~~
- pseudoaneurysm (at vascular access site ~~of catheter insertion~~)
- pyrogenic reaction
- renal failure
- respiratory insufficiency
- restenosis of the dilated vessel
- side branch occlusion
- slow flow/no reflow
- target vessel re-intervention
- thrombosis
- total occlusion of the coronary artery or bypass graft
- transient ischemic attack
- vasovagal reaction~~s~~
- ~~ventricular irritability/dysfunction~~
- ~~vessel trauma requiring surgical repair or intervention~~
- volume overload

~~**OVERVIEW OF CLINICAL STUDY**~~

~~**EMERGE Clinical Study**~~

~~Potential adverse events (in alphabetical order) that may be associated with the use of a PTCA Dilatation Catheter include, but are not limited to, the following:~~

~~**Study Purpose**~~

~~The objective of the EMERGE study was to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter when used to initially treat the stenotic portion of coronary arteries or bypass grafts.~~

~~**Study Design**~~

~~The EMERGE study was a prospective, open label, multi center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter in subjects with stenotic coronary arteries or bypass grafts during percutaneous coronary intervention (PCI).~~

~~Sixty (60) subjects were treated at 3 US sites with the Emerge 1.20 mm PTCA Dilatation Catheter to pre-dilate coronary arteries or bypass grafts during their index procedure. All subjects were to be screened according to the protocol inclusion and exclusion criteria and were followed through hospital discharge.~~

The primary endpoint was device procedural success consisting of successful delivery, inflation, deflation and withdrawal of the study balloon; no evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline related to the study balloon; final TIMI flow grade of 3 at the conclusion of the PCI procedure.

The secondary clinical endpoints measured through hospital discharge included in hospital MACE (cardiac and non-cardiac death, MI and TVR); in hospital stent thrombosis within the target vessel; clinically significant arrhythmias requiring intervention.

Subjects were followed through hospital discharge.

Demographics

A total of 60 subjects with 67 target lesions were enrolled in the study at 3 US sites. The subject population was predominantly male (71.7%) and Caucasian (95.0%) with an average age of 61 years. Most subjects had a history of medically treated hyperlipidemia (85.0%) and hypertension (93.3%) with a history of PCI (61.7%), myocardial infarction (23.3%) and coronary bypass surgery (18.3%). Medically treated diabetic subjects accounted for 35% of the subject population, of which 16.7% were insulin requiring.

Baseline Lesion Characteristics

A total of 67 target lesions were treated in the study, of which 97% (65/67) were located in native coronary arteries and 3.0% (2/67) in bypass graft. The average reference vessel diameter was 2.6 ± 0.5 mm, average minimum lumen diameter was 0.7 ± 0.4 mm, average diameter stenosis was 73.0% ± 12.6%, and average lesion length was 15.5 ± 14.7 mm. Total occlusion was observed in 10.4% (7/67) of target lesions.

Very severe stenosis was the primary lesion characteristic in 40.0% (4/10) of all Push devices used in the trial. Pushability was the primary physician preference in 60.0% (6/10) of all Push devices used in the trial. Preference of the Standard model was given mainly for tortuosity 20.4% (11/54), calcification 20.4% (11/54) and very severe stenosis 27.8% (15/54) lesion characteristics. Deliverability was the primary physician preference in 51.9% (28/54) followed by Pushability in 27.8% (15/54) of all Standard devices used in the trial.

Primary Endpoint (Device Procedural Success)

As illustrated in **Table 2**, 98.3% (59/60) of subjects and 98.5% (66/67) of lesions achieved device procedural success, including successful delivery, inflation, deflation and withdrawal of the Emerge 1.20 mm PTCA Dilatation Catheter. Device procedural failure was observed in 1.7% (1/60) of subjects and 1.5% (1/67) of lesions and was related to unsuccessful delivery (i.e. failure to cross a lesion) of the study device. No procedural complications were observed in the intent to treat subject population. This included no vessel perforation, no flow limiting dissection, and no reduction in TIMI flow from baseline. Furthermore, 100% (60/60) of subjects and 100% (67/67) of lesions had a final TIMI flow grade of 3 at the conclusion of the PCI procedure.

Table 2. Primary Endpoint Outcomes

	EMERGE Subjects (N=60)	EMERGE Lesions (N=67)
Device Procedural Success	98.3% (59/60)	98.5% (66/67)
Device Procedural Failure	1.7% (1/60)	1.5% (1/67)
Failure of delivery, inflation/deflation and withdrawal	1.7% (1/60)	1.5% (1/67)
Vessel perforation, flow limiting disection or reduction in TIMI flow	0.0% (0/60)	0.0% (0/67)
Failure of final TIMI flow	0.0% (0/60)	0.0% (0/67)

Numbers are % (Count/Sample Size), and based on number of subjects and lesions with site reported data.

~~**Secondary Clinical Endpoint (Safety Events)**~~

~~As illustrated in **Table 3**, the in-hospital major adverse cardiac events were observed in 6.7% (4/60) of the subjects. The non-Q wave MI rate was 6.7% (4/60), characterized by elevation of post-procedure creatine kinase-myoglobin band (CK-MB) levels to >3.0 times upper limit of normal (ULN). The Q-wave MI rate was 0% (0/60). The all-cause death and TVR rates were 0% (0/60). The in-hospital stent thrombosis rate, per Academic Research Consortium (ARC), was 0% (0/60). No clinically significant arrhythmias requiring intervention were observed in this study.~~

Table 3. Secondary Endpoint Outcomes

	EMERGE Subjects (N=60)
In-hospital MACE	6.7% (4/60)
All Death or MI	6.7% (4/60)
All Death	0.0% (0/60)
MI	6.7% (4/60)
Q-Wave MI	0.0% (0/60)
Non-Q-Wave MI	6.7% (4/60)
TVR, Overall	0.0% (0/60)
TVR, PCI	0.0% (0/60)
TVR, CABG	0.0% (0/60)
TLR, Overall	0.0% (0/60)
TLR, PCI	0.0% (0/60)
TLR, CABG	0.0% (0/60)
TVR Remote, Overall	0.0% (0/60)
TVR Remote, PCI	0.0% (0/60)
TVR Remote, CABG	0.0% (0/60)
In-hospital ARC Stent Thrombosis	0.0% (0/60)
In-hospital Clinical Significant Arrhythmias	0.0% (0/60)

Numbers are % (Count/Sample Size), and based on number of subjects with site reported and CEC adjudicated data.

~~**Conclusion**~~

~~The results of the EMERGE™ study support the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter and its intended use as a pre-dilatation catheter in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).~~

HOW SUPPLIED

- Non-pyrogenic.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS ~~FOR USE~~

One or more of each of the following materials are required for PTCA but not supplied with the Threader~~Emerge~~ Over-The-Wire or Threader~~Emerge~~ Monorail Micro-~~PTCA~~ Dilatation Catheter.

Description

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set (for femoral approach only)
- ~~Femoral or brachial g~~Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.066 in (1.68 mm) (Threader~~Emerge~~ Over-The-Wire Micro-~~PTCA~~ Dilatation Catheter)
- ~~Femoral or brachial g~~Guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.056 in (1.42 mm) (Threader~~Emerge~~ Monorail Micro-Dilatation~~PTCA~~ Catheter)
- ~~Vial of c~~Contrast medium
- Sterile saline or heparinized normal sterile saline
- Inflation device with manometer
- ~~Emerge Over-The-Wire PTCA Dilatation Catheter(s)~~
- ~~Emerge Monorail PTCA Dilatation Catheter(s)~~
- ≤0.014 in (0.36 mm) x 300 cm guidewire(s) (Threader~~Emerge~~ Over-The-Wire Micro-Dilatation~~PTCA~~ Catheter)
- ≤0.014 in (0.36 mm) x 185 cm guidewire(s) (Threader~~Emerge~~ Monorail Micro-Dilatation~~PTCA~~ Catheter)
- 10, 12 or 20 ml (cc) luer-lock syringe
- Hemostatic adapter
- Three-way stopcock
- ~~CLIPIT® Clip (Emerge Monorail PTCA Catheter only)~~
- Guidewire t~~T~~orqueing device

Inspection Prior to Use

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended. Do not use if sterile package is damaged.

Note: Do not continue to use the catheter if damage occurs or sterility is compromised during use.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air using only the contrast medium.

Catheter Selection

The inflation diameter of the balloon catheter must not exceed the diameter of the coronary artery proximal and distal to the stenosis. ~~If the stenosis cannot be crossed with the desired catheter,~~

~~use a smaller diameter catheter to pre-dilate the stenosis to facilitate passage of a more appropriately sized catheter.~~

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon catheter (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For Threader~~Emerge~~ Over-The-Wire Micro-Dilatation~~PTCA~~ Catheters, the mandrel will slide off with the balloon catheter protector. For Threader~~Emerge~~ Monorail Micro-Dilatation~~PTCA~~ Catheters, remove the mandrel distally after removing the balloon protector.

Caution: If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the catheter and replace with another.

3. The Threader~~Emerge~~ Monorail Micro-Dilatation~~PTCA~~ Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body.

Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

4. Prepare the catheter for purging. Fill a luer lock syringe or inflation device with appropriate balloon catheter inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile saline). **Do not use air or any gaseous medium to inflate the balloon catheter.**
5. Connect a three-way stopcock to the port fitting on the catheter. Flush through the stopcock taking care to ensure that the balloon cannot be inflated. Connect syringe or inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread causing subsequent leakage and use care when connecting the catheter to avoid damage (e.g., shaft kink).
6. Hold the syringe or inflation device with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger or open stopcock to air.
7. Remove the syringe or inflation device and evacuate all air from the barrel.
8. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If bubbles persist, check luer connections. If bubbles still persist, inflate the balloon to verify that there are no leaks present prior to insertion. Do not use the balloon catheter if there are any leaks.
9. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointing upwards.

10. Disconnect the syringe used in preparation. Verify that a meniscus of contrast medium is evident in both the balloon catheter port and the inflation device connection to ensure a fluid to fluid connection. Adding a drop of inflation medium to the port may be necessary. Securely couple the inflation device to the balloon catheter port of the catheter.
11. Open the stopcock to the catheter and leave on neutral.

Insertion Procedure

1. Guidewire Lumen Flush.

A. For the Threader~~Emerge~~ Monorail Micro-Dilatation~~PTCA~~ Catheter~~s~~, flush the guidewire lumen of the catheter with sterile saline through the distal tip of the catheter.

B. For the Threader~~Emerge~~ Over-The-Wire Micro-Dilatation~~PTCA~~ Catheter~~s~~, flush the guidewire lumen of the catheter with sterile saline through the guidewire port of the catheter hub.

C. Check for bends, kinks and other damage. Do not use if any defects are noted.

2. Catheter Advancement

A. Prepare the vascular access site according to standard practice.

B. Maintain neutral pressure on the inflation device attached to the catheter.

C. Insert a guidewire through the hemostatic adapter following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.

D. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then position the distal wire in the desired location~~across the stenosis or stent~~.

E. Backload the distal tip of the catheter onto the guidewire ensuring that the guidewire exits the midsection opening in the Threader~~Emerge~~ Monorail Micro-Dilatation~~PTCA~~ Catheter or the wire port of the Threader~~Emerge~~ Over-The-Wire Micro-Dilatation~~PTCA~~ Catheter manifold. When loading or exchanging the catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

F. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the balloon catheter.

G. Carefully advance the catheter through the hemostatic adapter while the balloon is fully deflated. If unusual resistance is felt, do not advance the catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

Note: To avoid kinking, advance the catheter slowly, in small increments, until the proximal end of the guidewire emerges from the catheter.

H. Connect the side port of the guide catheter hemostatic adapter to the proximal pressure recording/infusion line or manifold assembly, which permits proximal pressure recording or infusion through the guide catheter.

I.H. Advance the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis or stent to be dilated. Use the center radiopaque marker bands as a reference point. The outside edges of the marker bands indicate the balloon shoulders on the 2.00-4.00 mm models; the 1.20-1.50 mm models have a single central marker band. Balloon inflation should not be undertaken if the balloon is not properly positioned within the stenosis or stent.

I. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that contrast media is needed, withdraw the guidewire and hand-inject contrast media through the catheter hub with a syringe.

J. In the event, when using the Threader Over-The-Wire Micro-Dilatation Catheter, that an alternative guidewire is needed, remove the guidewire while holding the hub of the Over-The-Wire Micro-Dilatation Catheter in place. Once the guidewire has been removed from the patient, an alternative guidewire can be introduced into the hub of the Over-The-Wire Micro-Dilatation Catheter and advanced to the distal tip of the catheter.

J.K. Simultaneous uUse of tTwo bBalloon cCatheters in a gGuide cCatheter (Kissing Balloon): Bench and preclinical testing has shown that one Threader4.00 x 30 mm (or smaller) Monorail Micro-Dilatation balloon catheter and one 3.25 x 20 mm (or smaller) Emerge Monorail PTCA Dilatation balloon catheter can be inserted simultaneously into a 6F (minimum 0.070 in" ID) guide catheter and one Threader Over-The-Wire Micro-Dilatation Catheter and one two 3.25 x 20 mm 4.00 x 30 mm (or smaller) Emerge Over-The-Wire Dilatation balloon catheters can be inserted into an 8F (minimum 0.088 in" ID) guide catheter with acceptable compatibility. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical study. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.

3. Catheter Inflation

A. Inflate the balloon slowly to the appropriate pressure to perform PTCA or post-dilatation of a stent. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to Table 2 or to the balloon compliance table or chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA or post-dilatation of a stent, deflate the balloon by pulling negative pressure on the inflation device until the balloon is fully deflated. Bench testing has demonstrated that, on average, the deflation times range from 2 to 518 seconds, dependent upon balloon volume.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon expansion should be used to properly judge the optimum expanded balloon diameter as compared to the proximal and distal coronary artery diameter(s). Repeat inflation of balloon until the desired result is achieved.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (ThreaderEmerge™ Over-The-Wire Micro-DilatationPTCA Catheter) or step 6 – Catheter Exchange Procedure (ThreaderEmerge Monorail Micro-DilatationPTCA Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery has not abruptly occluded. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the knurled knob on the hemostatic adapter.

C. The ThreaderEmerge Monorail Micro-DilatationPTCA Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to the catheter being inserted in the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

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5. Catheter Exchange Procedure (ThreaderEmerge Over-The-Wire Micro-DilatationPTCA Catheter)

The ThreaderEmerge Over-The-Wire Micro-DilatationPTCA Catheters typically requires two operators to exchange. To perform a catheter exchange, execute the following steps:

A. Loosen the knurled knob on the hemostatic adapter.

B. The primary operator holds the hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. The secondary operator is positioned near the foot of the patient and should maintain the guidewire position in the coronary artery by holding the guidewire stationary and confirming guidewire position at all times under fluoroscopy while the primary operator begins pulling the catheter out of the guide catheter.

D.C. While maintaining guidewire position, wWithdraw the deflated catheter until the catheter tip exits the hemostatic adapter.

E.D. Close the knurled knob on the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the stenosis or stent.

F.E. Prepare the next device and load onto the guidewire as described in step 2catheter to be used as described in the Catheter Preparation section.

G.F. Back load the new catheter onto the guidewire as described under step 2 – Catheter Advancement – and cContinue the procedure.

6. Catheter Exchange Procedure (ThreaderEmerge Monorail Micro-DilatationPTCA Catheter)

The ThreaderEmerge Monorail Micro-DilatationPTCA Catheters hashave been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

A. Loosen the knurled knob on the hemostatic adapter.

B. Hold the guidewire and hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. Maintain the guidewire position in the coronary artery by holding the guidewire stationary. Begin pulling the deflated catheter out of the guide catheter while maintainingmonitoring the guidewire position under fluoroscopy.

D. Withdraw the deflated catheter until the opening in the guidewire lumen is reached (approximately 25 cm proximal to the balloon catheter tip).

E. While maintaining guidewire position, cCarefully slide the flexible, distal portion of the catheter out of the hemostatic adapter, and tighten the hemostatic adapterknurled knob onto the guidewire to hold it securely in place. Completely remove the catheter from the guidewire while maintaining guidewire position across the stenosis.

F. Prepare the next device and load onto the guidewire as described in step 2catheter to be used as described in the Catheter Preparation section.

G. Back load the new catheter onto the guidewire as described under step 2 – Catheter Advancement – and cContinue the procedure.

REFERENCES

The physician should consult current medical practice literature on PTCA, such as that published by the American College of Cardiology/American Heart Association.

Typical Threader Micro-Dilatation Catheter Balloon Compliance

Pressure		Balloon size is listed as mm (nominal = 6.0 atm) *Rated Burst Pressure. DO NOT EXCEED.
atm	kPa	1.2 mm
3.0	304	1.06
4.0	405	1.11
5.0	507	1.15
6.0 (nominal)	608	1.18
7.0	709	1.21
8.0	811	1.23
9.0	912	1.24
10.0	1013	1.26
11.0	1115	1.27
12.0	1216	1.28
13.0	1317	1.29
14.0*	1419	1.30
15.0	1520	1.31
16.0	1621	1.33

Note: Over inflation may result in burst of the balloon or shaft.

Table 4. Typical Emerge PTCA Dilatation Catheter Balloon Compliance

	Balloon Size										
Pressure atm (kPa)	1.20 mm	1.50 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm
3.0 (304)	1.09	1.39	1.86	2.06	2.28	2.53	2.76	3.01	3.19	3.45	3.66
4.0 (405)	1.13	1.45	1.93	2.14	2.37	2.61	2.85	3.10	3.30	3.58	3.80
5.0 (507)	1.16	1.48	1.99	2.20	2.44	2.68	2.93	3.18	3.39	3.67	3.88
6.0 (608) Nominal	1.20	1.52	2.03	2.26	2.50	2.75	3.00	3.26	3.46	3.75	3.96
7.0 (709)	1.23	1.55	2.07	2.31	2.55	2.81	3.06	3.33	3.52	3.81	4.04
8.0 (811)	1.26	1.58	2.10	2.34	2.59	2.85	3.11	3.37	3.57	3.86	4.09
9.0 (912)	1.28	1.60	2.13	2.38	2.62	2.88	3.15	3.41	3.61	3.90	4.14
10.0 (1013)	1.31	1.62	2.15	2.40	2.65	2.91	3.18	3.45	3.64	3.95	4.18
11.0 (1115)	1.33	1.64	2.18	2.42	2.67	2.94	3.21	3.48	3.68	3.98	4.22
12.0 (1216)	1.35	1.65	2.19	2.44	2.69	2.96	3.23	3.51	3.72**	4.02**	4.25**
13.0 (1317)	1.37	1.66	2.21	2.46	2.72	2.99	3.26	3.54	-	-	-
14.0 (1419)	1.39	1.68*	2.23**	2.48**	2.74**	3.02**	3.28**	3.57**	-	-	-
15.0 (1520)	1.41	-	-	-	-	-	-	-	-	-	-
16.0 (1621)	1.42	-	-	-	-	-	-	-	-	-	-
17 (1723)	1.43	-	-	-	-	-	-	-	-	-	-
18.0 (1824)	1.45*	-	-	-	-	-	-	-	-	-	-
19.0 (1925)	1.46	-	-	-	-	-	-	-	-	-	-
20.0 (2027)	1.48	-	-	-	-	-	-	-	-	-	-

* Rated Burst Pressure. Do not exceed.
** Rated Burst Pressure and Stent Rated Burst Pressure. Do not exceed.

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**.

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Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

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PO Box 332
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NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

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Scientific (Master Brand DFUTemplate 8.2677in x 11.6929in A4, 9010[illegible]18 AM) DFU, MB, Emerge, English, 90822295-01D

REF

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência



Consult instructions for use.
Consultar las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Raadpleeg instructies voor gebruik.
Consulte as Instruções de Utilização



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Contenido
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Conteúdo

EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.



Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabricante legal

LOT

Lot
Lote
Lot
Charge
Lotto
Partij
Lote

UPN

Product Number
Número del producto
Référence
Produktnummer
Codice prodotto
Productnummer
Número do Produto



Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável



Use By
Fecha de caducidad
Date limite d'utilisation
Verwendbar bis
Usare entro
Uiterste gebruiksdatum
Validade

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
Endereço do Patrocinador Australiano



For single use only. Do not reuse.
Para un solo uso. No reutilizar.
À usage unique. Ne pas réutiliser.
Für den einmaligen Gebrauch. Nicht wieder verwenden.
Exclusivamente monouso. Non riutilizzare.
Uitsluitend bestemd voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.



Do Not Resterilize
No reesterilizar
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize



Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

GW R

Recommended Guidewire
Guía recomendada
Guide recommandé
Empfohlener Führungsdraht
Filoguida consigliato
Aanbevolen voerdraad
Fio-guia Recomendado

GC R

Recommended Guide Catheter
Catéter guía recomendado
Cathéter guide recommandé
Empfohlener Führungskatheter
Catetere guida consigliato
Aanbevolen geleidekatheter
Cateter-guia Recomendado

STERILE EO

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l'oxyde d'éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesterliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

CL R

Includes CLIPIT™ Hypotube Clip
Incluye pinza de hipotubo CLIPIT™
Inclut un clip de l'hypotube CLIPIT™
Enthält CLIPIT™ Hypotube-Klemme
Include clip per ipotubo CLIPIT™
Bevat CLIPIT™-hypotubeclip
Inclui o Clipe para Hipotubo CLIPIT™

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USA
USA Customer Service 888-272-1001

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CE 0344

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(b)(4)Specification Technical Report

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Boston Scientific

1.2mm x 12mm

Threader™

MONORAIL™

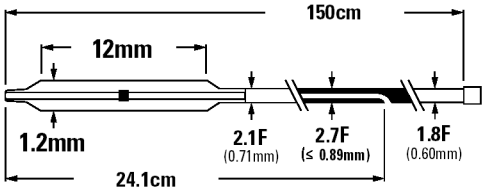
Micro-Dilatation Catheter

atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.

Contents (1)

CL (1) Includes CLIPIT™ Hypotube Clip



GW R 0.014in (≤ 0.36mm) Recommended Guidewire

GC R 5F (≥ 0.056in/1.42mm) Recommended Guide Catheter

REF Catalog No. 39269-1212

Use By 2000-12

UPN Product No. H7493926912120

LOT 12345678

STERILE EO Sterilized using ethylene oxide.

The current Instructions For Use are available on the web at www.bostonscientific.com/threader. The instructions are provided in Adobe Portable Document Format (PDF). If you have difficulties accessing documents or would prefer to receive a paper copy, please contact Boston Scientific Customer Service USA at 888-272-1001.

90244533-01

90939135-01A

Threader™
MONORAIL™
1.2mm x 12mm
REF 39269-1212
LOT 12345678

Threader™
MONORAIL™
1.2mm x 12mm
REF 39269-1212
LOT 12345678

+H7493926912120R

+$$8011200123456 78RM

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

Label Specification Part Number:90939135-01A

Boston Scientific

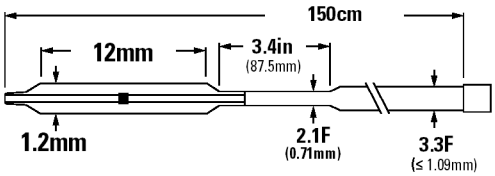
1.2mm x 12mm

Threader™

OVER-THE-WIRE

Micro-Dilatation Catheter

Contents (1)



atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.

GW R 0.014in (≤ 0.36mm) Recommended Guidewire

GC R 6F (≥ 0.066in/1.68mm) Recommended Guide Catheter

REF Catalog No. 39270-1212

Use By 2000-12

UPN Product No. H7493927012120

LOT 12345678

STERILE EO Sterilized using ethylene oxide.

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90244533-01

90939139-01A

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

Threader™
OVER-THE-WIRE
1.2mm x 12mm
REF 39270-1212
LOT 12345678

+H7493927012120J

+$$8011200123456 78JE

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

Label Specification Part Number:90939139-01A

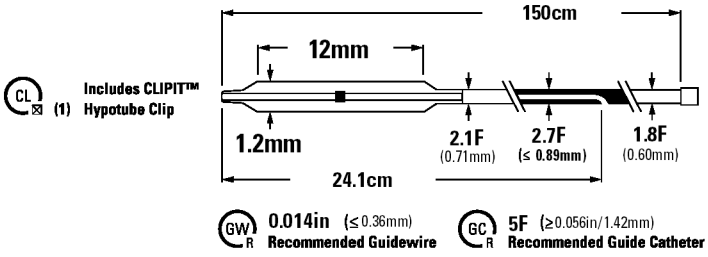
Threader™

MONORAIL™

Micro-Dilatation Catheter

1.2mm x 12mm

Contents (1)



atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.

The current Instructions For Use are available on the web at www.bostonscientific.com/threader. The instructions are provided in Adobe Portable Document Format (PDF). If you have difficulties accessing documents or would prefer to receive a paper copy, please contact Boston Scientific Customer Service USA at 888-272-1001.

REF Catalog No. **39269-1212**

Use By **2000-12**

Threader™ MONORAIL™ 1.2 mm 12 mm REF 39269-1212 2000-12

Threader™ MONORAIL™ 1.2 mm 12 mm

90244534-01

90939133-01A

Threader™ MONORAIL™ 1.2mm x 12mm REF 39269-1212 LOT 12345678

Threader™ MONORAIL™ 1.2mm x 12mm REF 39269-1212 LOT 12345678

Threader™ MONORAIL™ 1.2mm x 12mm REF 39269-1212 LOT 12345678

+H7493926912120R

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

+$$801120012345678RM

UPN Product No. **H7493926912120** LOT **12345678**

STERILE EO Sterilized using ethylene oxide.

Label Specification Part Number:90939133-01A

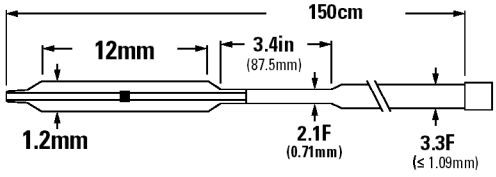
Threader™

OVER-THE-WIRE

Micro-Dilatation Catheter

1.2mm x 12mm

Contents (1)



atm - kPa Pressure		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.

GW R **0.014in** (≤ 0.36mm) **Recommended Guidewire**

GC R **6F** (≥ 0.066in/1.68mm) **Recommended Guide Catheter**

The current Instructions For Use are available on the web at www.bostonscientific.com/threader. The instructions are provided in Adobe Portable Document Format (PDF). If you have difficulties accessing documents or would prefer to receive a paper copy, please contact Boston Scientific Customer Service USA at 888-272-1001.

REF **Catalog No.** **39270-1212**

Use By **2000-12**

Threader™ OVER-THE-WIRE | 1.2 mm | 12 mm | REF 39270-1212 | 2000-12

Threader™ OVER-THE-WIRE 1.2 mm 12 mm

90244534-01

90939138-01A

Threader™ OVER-THE-WIRE 1.2mm x 12mm REF 39270-1212 LOT 12345678

Threader™ OVER-THE-WIRE 1.2mm x 12mm REF 39270-1212 LOT 12345678

Threader™ OVER-THE-WIRE 1.2mm x 12mm REF 39270-1212 LOT 12345678

+H7493927012120J

Made In USA
Two Scimed Place
Maple Grove, MN 55311 USA

+$$801120012345678JE

UPN **Product No.** **H7493927012120** LOT **12345678**

STERILE EO **Sterilized using ethylene oxide.**

Label Specification Part Number:90939138-01A

Threader™

MONORAIL™

Micro-Dilatation Catheter

atm - kPa PRESSURE		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.

90375893-01

90939128-01A

Label Specification Part Number:90939128-01A

Threader™

OVER-THE-WIRE

Micro-Dilatation Catheter

atm - kPa PRESSURE		1.2mm Balloon
3.0 - 304		1.06
4.0 - 405		1.11
5.0 - 507		1.15
6.0 - 608	NOMINAL	1.18
7.0 - 709		1.21
8.0 - 811		1.23
9.0 - 912		1.24
10.0 - 1013		1.26
11.0 - 1115		1.27
12.0 - 1216		1.28
13.0 - 1317		1.29
14.0 - 1419	RATED*	1.30

*Rated Burst Pressure. DO NOT EXCEED.

90375893-01

90939137-01A

Label Specification Part Number:90939137-01A