U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K052257 - 290 pages
COMPANY:	VASCULAR SOLUTIONS, INC. (VASCSOLU)
PRODUCT:	CATHETER, PERCUTANEOUS (DQY)
SUMMARY:	Product: VASCULAR SOLUTIONS TWIN-PASS DUAL ACCESS CATHETER
DATE REQUESTED:	Mar 21, 2016
DATE PRINTED:	Mar 21, 2016
Note:	Printed

K052257

Appendix E: Summary of Safety and Effectiveness

NOV 23 2005

Common/Usual Name: Intravascular Catheter

Product Trade Name: Twin-Pass™ Dual Access Catheter

Classification Name: Unclassified
Product Code: DQY

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369
USA

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4200 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:
The Twin-Pass Dual Access Catheter is a 3F O.D. catheter that has two lumens—a short distal lumen and a second full length lumen—each of which are compatible with a 0.014" standard guide wire. The Twin-Pass catheter has a working length of 135cm and contains positioning markers at 95 and 105cm which provide a visual indication of the relative positions of Twin Pass and the end of a standard 105cm guide catheter. Two radiopaque marker bands at the end of each wire lumen provide for a radiographic means of locating the position of each lumen. The softer, distal end of the catheter is coated with a hydrophilic coating to assist passage through the guide catheter and vessels while the proximal end of the catheter contains a strain relief and a standard luer hub. A 126cm stiffening mandrel is included which provides support and pushability to the Twin-Pass.

Intended Use:
The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Summary of Non-Clinical Testing:
Testing conducted included assessments of the design verification of the Twin-Pass Dual Access Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Twin-Pass Dual Access Catheter for its intended use.

Summary of Clinical Testing:
No clinical evaluations of this product have been conducted.

Predicate Device:
The Twin-Pass Dual Access Catheter is similar in intended use and function to the Lumend Percutaneous Catheter, the Quick-Cross Catheter, and the Dual Lumen Catheter.

Conclusions:
The Twin-Pass Dual Access Catheter is substantially equivalent to the Lumend Percutaneous Catheter, the Quick-Cross Catheter, and the Dual Lumen Catheter. The testing performed confirms that the Twin-Pass Dual Access Catheter will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2005

Vascular Solutions, Inc.
c/o Ms. Sara L. Coon
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K052257
Twin-Pass™ Dual Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: September 30, 2005
Received: October 3, 2005

Dear Ms. Coon:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

II. Indications For Use Statement

510(k) Number: K052257

Device Name: Vascular Solutions Twin-Pass Dual Access Catheter

Indications for Use:

The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052257

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 3 2005

Vascular Solutions, Inc.
c/o Ms. Sara L. Coon
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K052257
Twin-Pass™ Dual Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: September 30, 2005
Received: October 3, 2005

Dear Ms. Coon:

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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volanes

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

Enclosure

II. Indications For Use Statement

510(k) Number: K052257

Device Name: Vascular Solutions Twin-Pass Dual Access Catheter

Indications for Use:

The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052257

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2005

Ms. Sara L. Coon
Sr. Regulatory Affairs Associate
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Re: K052257
Trade Name: Twin-Pass Dual Access Catheter
Dated: August 17, 2005
Received: August 18, 2005

Dear Ms. Coon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information.

1. Please provide additional information to clarify and indicate the following items in the Appendix F engineering drawing:

   a. (b)(4) [redacted]
   b.
   c.
   d.

2. In the manufacturing overview, you state that a (b)(4) [redacted] the [redacted].

3. There is a tapered section before the entrance to the exchange lumen in the Twin-Pass catheter. Please provide evidence to show that the (b)(4) [redacted].

4. You state that non-sterile Pronto V3 catheters are coated by (b)(4) [redacted]

5. In the results of your coefficient of friction (COF) test, (b)(4) [redacted]

6. You stated that the coated catheters were [redacted] (b)(4)

7. You state that biocompatibility testing was done [redacted] (b)(4)

8. You state that biocompatibility testing of the hydrophilic coating was (b)(4) [redacted] testing and [redacted]

9. Please clarify if the device is intended for use in the cerebral vasculature. If not, please add this contraindication to the instructions for use. Alternatively pleas provide information to support this clinical use.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

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You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of this letter, please contact Shang W. Hwang, Ph.D. at (301) 443-8243. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Ms. Sara L. Coon
Sr. Regulatory Affairs Associate
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Re: K052257
Trade Name: Twin-Pass Dual Access Catheter
Dated: August 17, 2005
Received: August 18, 2005

Dear Ms. Coon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information.

1. Please provide additional information to clarify and indicate the following items in the Appendix F engineering drawing:

   a. (b)(4) [redacted]
   b.
   c.
   d.

2. In the manufacturing overview, you state that a reflow process is used to create the (b)(4) [redacted]

3. There is a tapered section before the entrance to the exchange lumen in the Twin-Pass catheter. Please provide evidence to show (b)(4) [redacted]

4. You state that non-sterile Pronto V3 catheters are coated (b)(4) [redacted]

5. In the results of your coefficient of friction (COF) test, the COF for (b)(4) [redacted]

6. You stated that the coated catheters were accelerated aged for (b)(4) before the COF test. However, (b)(4) [redacted]

7. You state that b(b)(4) testing was done using (b)(4) [redacted]

8. You state that (b)(4) testing (b)(4) [redacted]

9. Please clarify if the device is intended for use in the cerebral vasculature. If not, please add this contraindication to the instructions for use. Alternatively pleas provide information to support this clinical use.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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Rockville, Maryland 20850

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Sincerely yours,

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

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

Prepared by:SWHwang:myb:09/16/05
Final:myb:09/23/05

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
40	Kwang	9/23/05						

U.S. GPO 1986-169-089

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 18, 2005

VASCULAR SOLUTIONS, INC.
6464 SYCAMORE COURT
MINNEAPOLIS, MN 55369
ATTN: SARA L. COON

510(k) Number: K052257
Received: 18-AUG-2005
Product: VASCULAR SOLUTIONS
TWIN-PASS DUAL
ACCESS CATHETER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K052257

Vascular SOLUTIONS

August 17, 2005

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: 510(k) Premarket Notification
Twin-Pass™ Dual Access 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, Vascular Solutions hereby submits the attached Premarket Notification.

Vascular Solutions, qualified as a small business, has submitted under separate cover, the user fee relevant to this submission. A copy of the User Fee Cover Sheet is provided Appendix A.

This Premarket Notification, provided in duplicate, contains trade secrets and confidential commercial information that should be protected in accordance with 21 CFR 20. Vascular Solutions hereby authorizes FDA to communicate via e-mail, fax or telephone if any questions or additional information is required regarding this submission.

Sincerely,

Sara L. Coon

Sara L. Coon
Sr. Regulatory Affairs Associate
scoon@vascularsolutions.com
(763) 656-4399 phone
(763) 656-4253 fax

VASCULAR SOLUTIONS, INC.
6464 Sycamore Court • Minneapolis, Minnesota 55369
PHONE: 763/656-4300 • FAX: 763/656-4250 • www.vascularsolutions.com

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Table of Contents

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List of Appendices

I. Truthful and Accurate Statement

I certify that, in my capacity as Senior Regulatory Affairs Associate of Vascular Solution, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Sara L. Coon
Signature

Sara L. Coon
Name

08/17/05
Date

II. Indications For Use Statement

510(k) Number: _____

Device Name: Vascular Solutions Twin-Pass Dual Access Catheter

Indications for Use:

The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

III. Trade or Proprietary Name

The trade or proprietary name of this device is the Vascular Solutions Twin-Pass™ Dual Access Catheter.

IV. Establishment Registration

The establishment registration number for Vascular Solutions, Inc. is 2134812.

V. Classification

The predicate devices identified for this submission are product code DQY (percutaneous catheter) under regulation 870.1250 and are class II medical devices. The Twin-Pass Dual Access Catheter is for short-term use, with product code DQY and is a class II medical device.

VI. Performance Standards

No performance standards have been developed under Section 514 of the Act for this product type.

VII. Product Labeling

The proposed instructions for use manual, describing the device, its intended use and the directions for use are enclosed in Appendix B. The draft sterile package labels are included in Appendix C.

VIII. Predicate Devices

The predicate devices for the Twin-Pass Dual Access Catheter are the Lumend Percutaneous Catheter (K011562), the Spectranetics Quick-Cross Catheter (K033678), and the Endologix Dual Lumen Catheter (K991601). Literature describing these devices is located in Appendix D.

IX. Summary of Safety and Effectiveness

A summary of safety and effectiveness is included in Appendix E, pursuant to Section 12, of the Safe Medical Devices Act of 1990.

X. Purpose of 510(k)

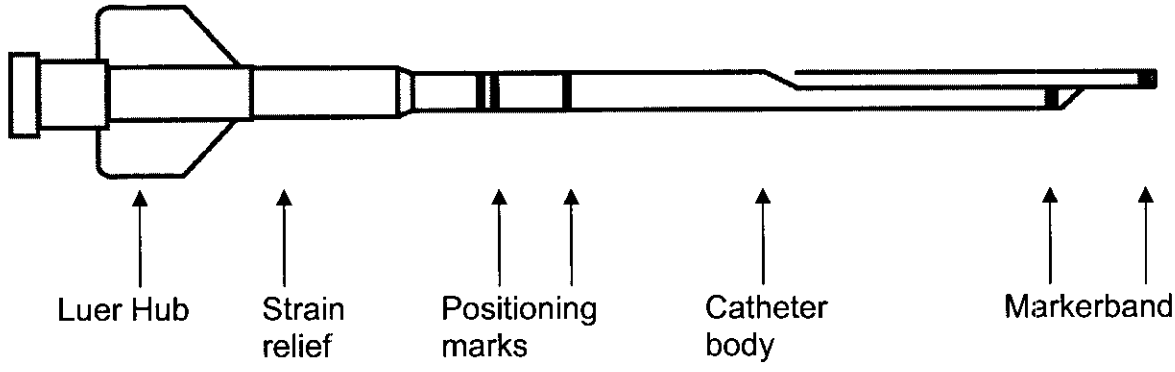
The purpose of this 510(k) is to notify FDA of a new device that is intended for use in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

XI. Device Description

A. General description

The Twin-Pass Dual Access Catheter is a 3F O.D. catheter that has two lumens—a short distal lumen and a second full length lumen—each of which are compatible with a 0.014" standard guide wire. The Twin-Pass catheter has a working length of 135cm and contains positioning markers at 95 and 105cm which provide a visual indication of the relative positions of Twin Pass and the end of a standard 105cm guide catheter. Two radiopaque marker bands at the end of each wire lumen provide for a radiographic means of locating the position of each lumen. The softer, distal end of the catheter is coated with a hydrophilic coating to assist passage through the guide catheter and vessels while the proximal end of the catheter contains a strain relief and a standard luer hub. A 126cm stiffening mandrel is included which provides support and pushability to the Twin-Pass. An engineering drawing is provided in Appendix F.

Figure 1: schematic diagram of Twin-Pass Dual Access Catheter - not to scale



B. Materials

The catheter is constructed of standard materials used in similar medical devices as described in table 1 (next page).

Table 1: List of Materials

Component	Material description
Catheter	
Luer hub	Polycarbonate
Adhesive	Urethane/Acrylate UV Cure Adhesive
Strain relief	Polyolefin
Full length lumen Inner layer Outer layer (proximal to distal)	 Polyimide with PTFE lining Pebax (Graduated from 72 to 55 durometer with blue colorant and $BaSO_4$)
Positioning marks	Pebax 72 durometer (with white colorant)
Rail lumen Inner layer Outer layer	 Polyimide with PTFE lining Pebax (55 durometer with blue colorant and $BaSO_4$)
Markerbands	Platinum/Iridium (90% / 10%)
Adhesive	Ethyl cyanoacrylate
Hydrophillic Coating	Hydromer Polyurethane Base (2-TS-96) and Polyurethane/polyvinylpyrollidone (3-TS-12)
Stiffening Mandrel	
Wire	304 stainless steel
Adhesive	Urethane/Acrylate UV Cure Adhesive
Luer Cap	Polystyrene

C. Mechanism of Action

The Twin-Pass catheter is designed to assist the placement of a second guide wire in the event that the procedure requires positioning more than one guidewire. During use, the short distal wire lumen of the Twin-Pass catheter is advanced beyond the guide catheter over the existing guide wire allowing the physician to preserve the position of the first guide wire while the second wire is advanced through the full length lumen. The second guide wire is advanced after the stiffening mandrel is removed from Twin pass. Once both wires have been positioned, Twin Pass is removed and the desired interventional devices may be delivered to the treatment location.

Based on the research of Burszotta, *et.al.*[1], it is anticipated that the following medical procedures could be performed using a second wire.

- Treatment of bifurcated lesions in order to maintain access to the side branches and to protect their integrity.
- Placement proximally to stent struts as a position marker for stent deployment in ostial regions.
- Reduction of balloon slippage during angioplasty for in-stent restenosis.
- Insufficient back-up of the guiding catheter.
- Stenting lesions located in vessels with proximal tortuosities/angulations.

[1] Burzotta F, Trani C, *et. al. Use of a second buddy wire during percutaneous coronary interventions: a simple solution for some challenging situations.* J Invasive Cardiol. 2005 Mar;17(3):171-4.

- Stenting of lesions located distally in the vessel.
- Facilitation on the positioning of distal protection devices.
- Stenting of a lesion distally located from a previously implanted stent of from a coronary segment with both calcification and sharp bend.
- PCI on coronary arteries with anomalous origin.

XII. Manufacturing Overview

Manufacturing operations are summarized in the manufacturing flowchart below. These operations are conducted as part of the manufacturing process for the Twin-Pass Dual Access Catheter. Product packaging occurs in a class 100,000 controlled environment.

Figure 2: Manufacturing Process Flowchart

(b)(4)

[redacted]

A. Reflow Process (thermo-bond formation)

Reflow processing (or thermo-bonding) is used to create the extraction lumen and the guidewire lumen and later join these two lumens together. In general, the inner lumen of the of the subassembly is placed over a mandrel and then the outer layer material (Pebax) is positioned over the lumen. (b)(4)

[redacted]

(b)(4) [redacted]

B. UV Cure Adhesive Bonding Process

Bonded components are assembled with a bead of adhesive on the outer diameter of the internal component. The components are assembled with a twisting motion to disperse the adhesive and cured per a validated process using (b)(4) [redacted]

C. Hydrophilic Coating Process

Non-sterile Pronto V3 catheters are coated by Hydromer, Inc. at their Somerville, New Jersey facility using their proprietary hydrophilic coating and process. This two-part coating, consisting of a primer (2-TS-96) and coating (3-TS-12), has been used on many other medical devices, including guidewires and introducer sheaths used in cardiovascular system. The coated catheters are returned to Vascular Solutions, where they are packaged and sterilized.

D. Packaging

The Twin-Pass Dual Access Catheter will be packaged in an HDPE coil (same as used for the Pronto catheter (K032763) only shorter in length) inside a poly/Tyvek pouch. A sterile barrier is provided by a 100 G Nylon/10# LDPE/0.002 HDPE and uncoated Tyvek Pouch. This is the same pouch material used for the sterile barrier of the Vascular Solutions, Inc. D-Stat flowable hemostat (approved in PMA P990037/S008) and will be sealed using the same equipment and process parameters. The device is provided sterile and is intended for single use only.

E. Sterilization

The Twin-Pass Dual Access Catheter will be terminally sterilized using ethylene oxide gas in a process designed to provide a Sterility Assurance Level (SAL) of 10^{-6} according to an established and validated sterilization process, which is in compliance with BS EN 556 "Sterilization of Medical Devices—Requirements (SAL) for medical devices labeled sterile". The cycle has been be validated according to BS EN 550 "Sterilization of Medical Devices—Validation and Routine control of Ethylene Oxide Sterilization, Method C: Half cycle method".

When a routine cycle is completed, product is shipped to Vascular Solutions along with a per-run and lot-specific cycle exposure report. The product is not released until a review of evidence demonstrates that:

- (b)(4) [redacted]
;

66

- (b)(4)

EO Residuals

(b)(4)

Non-pyrogenic

Non-pyrogenicity of the devices will be verified on each lot of product using the (b)(4)

XIII. Design Verification Testing and Evaluation

VSI performs testing on all products to ensure safety and effectiveness of the device for its intended use.

A. Physical Specifications

All testing was conducted on finished product that was manufactured, packaged and sterilized according to standard operating procedures developed for the Twin-Pass Dual Access Catheter. (b)(4)

(b)(4)

1. Insertion /removal with guide catheter and guidewire through tortuosity fixture

Specification:

a) (b)(4)

b)

c)

Protocol:

(b)(4)

(b)(4)

Results:

Time period	Number of Samples	Number of Samples that Passed Testing	Comments
Baseline units	(b)(4)		
6-month aged units			

Conclusions:

The Twin-Pass Dual Access Catheter meets the requirements for guidewire passage, guide catheter passage and tortuous pathway testing at baseline and 6-months aging.

2. Bend radius

Specification:

The catheter shafts should have a minimum bend radius of (b)(4)

Protocol:

The shaft of each catheter was bent in two locations (b)(4)

Results:

Time period	Number of Samples	Number of Samples that Passed Testing	Comments
Baseline units	(b)(4)		
6-month aged units			

Conclusions:

The Twin-Pass Dual Access Catheter meets the requirements for bend radius at baseline and 6-months aging.

3. Markerband presence

Specification:

(b)(4)

Protocol:

(b)(4) [redacted]

Results:

A single catheter containing radiopaque markers was examined and both markerbands were visible.

Conclusions:

The Twin-Pass Dual Access Catheter meets the requirements for presence of a radiopaque markerbands.

4. Slide easily through guide catheter

Specification:

(b)(4) [redacted]

Protocol:

(b)(4) [redacted]

Results:

(b)(4)

COF	Baseline (lb-f/lb)	Aged Samples (lb-f/lb)
Mean	(b)(4)	
Minimum		
Maximum		
Std. dev.		

Conclusions:

The application of the Hydromer coating onto the Twin-Pass Dual Access Catheter results (b)(4)

5. Hub to shaft adhesive bond integrity

Specification:

(b)(4)

Protocol:

(b)(4)

Results:

	Baseline Hub to Shaft Bond (lbs.)	6-month aging Hub to Shaft Bond (lbs.)
Specification	(b)(4)	
Sample size (n)		
Average		
Std deviation		
Minimum		
Maximum		

Conclusions:

The Twin-Pass Dual Access Catheter meets the requirements for hub to shaft bond strength.

6. Catheter shaft strength

Specification:

(b)(4)

Protocol:

(b)(4)

Results:

	Baseline shaft strength (lbs.)	6-month shaft strength (lbs.)
Specification	(b)(4)	
Sample size (n)		
Average		
Std deviation		
Minimum		
Maximum		

Conclusions:

(b)(4)

7. Stiffening mandrel adhesive bond strength

Specification:

(b)(4)

Protocol:

(b)(4)

Results:

	Baseline - Stiffening Mandrel Bond Strength (lbs.)	6-months - Stiffening Mandrel Bond Strength (lbs.)
Specification	(b)(4)	
Sample size (n)		
Average		
Std deviation		
Minimum		
Maximum		

Conclusions:

The stiffening mandrel meets the requirements for bond strength with all mandrels exhibiting (b)(4) [redacted]

8. Stiffening mandrel removal force

Specification:

(b)(4) [redacted]

Protocol:

(b)(4) [redacted]

Results:

	Baseline - Stiffening Mandrel Removal (lbs.)	6-month aging - Stiffening Mandrel Removal (lbs.)
Specification	(b)(4) [redacted]	
Sample size (n)		
Average		
Std deviation		
Minimum		
Maximum		

Conclusions:

(b)(4) [redacted]

9. Leakage under pressure

Specification:

(b)(4) [redacted]

Protocol:

(b)(4) [redacted]

Results:

Time period	Number of Samples	Number of Samples that Passed Testing	Comments
Baseline units	(b)(4)		
6-month aged units			

Conclusions:

(b)(4)

B. Clinical Testing

(b)(4)

.

C. Biocompatibility

(b)(4)

Table 2: Twin-Pass Dual Access Catheter Biocompatibility Results Summary

Test Method (ISO method)	Article Tested	Acceptance Criteria	Results	Conclusion
Hemolysis/direct contact/rabbit blood (ISO 10093-4:2002)	(b)(4)			
MEM Elution Cytotoxicity ISO 10993-5:1999				
Rabbit pyrogen/material mediated ISO 10993-11				
Lee and White clotting time/ human blood ISO 10993-4:2002				
Systemic injection/2 extracts ISO 10993-11:1993				
Intracutaneous injection/ 2exctracts ISO 10993-10:2002				
Kligman Maximization / 2 extracts /30 animals/historical (+) controls ISO 10993-10:2002				
In vitro hemocompatibility ISO 10993-4:2002				
Prothrombin Time (PT) – ISO 10993-4:2002				
Hemolysis /Extract/ Rabbit Blood – ISO 10993-4:2002				

D. Shelf Life

Package and Product Integrity

(b)(4)

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(b)(4)
[redacted]

Package and Product Shelf-Life

(b)(4)
[redacted]

XIV. Equivalence

The Twin-Pass Catheter is considered to be substantially equivalent to the Lumend Percutaneous Catheter (K011562), the Quick-Cross Catheter (K033678), and the Dual Lumen Catheter (K991601). As can be seen in Table 3 (next page), the indications for use selected for the Twin-Pass dual access catheter are a combination of the indications for use of the predicates. In addition, the products are covered by the same regulation, are made of similar materials, have similar sizes and have similar features.

The data submitted in the following section demonstrates that the Twin-Pass Dual Access Catheter is a safe and effective means delivering supporting steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Table 3: Table of Equivalence

Characteristic	Twin-Pass Dual Access Catheter	Lumend Percutaneous Catheter	Spectranetics Quick-Cross™ Support Catheter	Endologix Dual Lumen Catheter
510(k) number	Proposed Device	K011562	K033678	K991601
Product Code	DQY	DQY	DQY	DQY
Regulation	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Indications for use	to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.	to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.	... for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	for use during a two guidewire procedure
body material	(b)(4)	catheter: stainless steel braid, Pebax, Nylon 12 Hub: polycarbonate	unknown	catheter: Pebax Hub: polycarbonate Markerband: gold
lubricious coating		coated	hydrophilic coating (distal 40 cm)	none
Catheter type		guide catheter	intravascular catheter	guide catheter
Catheter size (French)		4 Fr shaft 2.81 Fr tip	3 Fr shaft tapering to 1.9 Fr tip	9 Fr
Catheter Length		135 cm	135 cm	90 cm
Number of lumens		1 lumen	1 lumen	2 lumens
Guidewire size		unknown	0.014"	0.035"
radiopaque markers		radiopaque tip	3 markers	1 marker
Biocompatibility		unknown	unknown	unknown
Sterilization Method		Radiation	Ethylene Oxide	Ethylene Oxide

Appendix A: User Fee Cover Sheet

  Mailed 7/19/05

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. 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. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

VASCULAR SOLUTIONS INC
6464 SYCAMORE COURT
MINNEAPOLIS MN 55369
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Sara Coon
2.1 E-MAIL ADDRESS
scoon@vascularsolutions.com
2.2 TELEPHONE NUMBER (Include Area code)
763-656-4399
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
NO DATA

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/dc/mdufma

elect an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 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)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD058028

5. 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, parents, and partner firms
[ ] This biologics application is submitted under secion 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

6. 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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)
04-Apr-2005

Form FDA 3601 (08/2003)

Close

Print Cover sheet

Appendix B: Instructions For Use

Document number, 42-0445-01

Twin-Pass™

Dual Access Catheter

DRAFT

Vascular SOLUTIONS

Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: 763-656-4300
Fax: 763-656-4250
www.vascularsolutions.com

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International Symbols Glossary

	CONT	MARKER	Latex		Manufacturer
International Symbols Glossary	Contents of package	Radiopaque Marker	Latex Free	Keep Dry	Manufactured by Vascular Solutions, Inc.

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TWIN-PASS™ Dual Access Catheter Model 5210
Instructions For Use

USA CAUTION

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

CAUTION

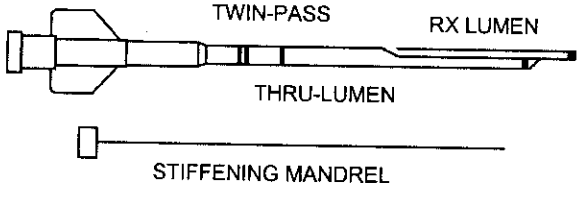
The TWIN-PASS dual access catheter should be used by physicians with adequate training in the use of the device.

DEVICE DESCRIPTION

The TWIN-PASS dual access catheter is a hydrophilically coated, dual lumen catheter designed for use in the arterial vasculature. The catheter provides support for 0.014" / 0.36mm guidewires during interventional procedures, and the dual lumen design allows for the delivery of a second guidewire into distal vasculature while leaving the initial guidewire in place.

The TWIN-PASS catheter comes pre-loaded with a stiffening mandrel in the thru-lumen to provide support and pushability during catheter insertion.

The TWIN-PASS catheter is compatible with guidewires and guide catheters with the following dimensions:



TWIN-PASS Model	Max. Guidewire Diameter	Min. Guide Catheter I.D.
5210	0.014" / 0.36mm	0.055" / 1.40mm

The TWIN-PASS catheter has a radiopaque marker band located approximately 1mm proximal to the distal tip and a second radiopaque marker band located at the thru-lumen exit port 10mm proximal to the distal tip. There are also two sets of white positioning marks located at 95cm (single mark) and 105cm (double marks) from the distal tip. The proximal end of the catheter incorporates a strain relief and a luer-lock entry port for flushing.

INDICATIONS

The TWIN-PASS catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

CONTRAINDICATIONS

Pressure injections.

WARNINGS

Do not advance the TWIN-PASS catheter without a guidewire in place through the RX lumen. Advancement of the catheter without a guidewire in the RX lumen may result in intimal damage, arterial dissection, or perforation.

The TWIN-PASS catheter is supplied sterile for single use only. Do not reuse, reshape or re-sterilize the device. Re-sterilization or reshaping may change the physical characteristics of the material and should not be attempted.

The TWIN-PASS catheter has not been tested for pressure injections. If a 0.014" / 0.36mm guidewire cannot be passed through the catheter, do not attempt to resolve the blockage by flushing the catheter *in vivo*. Catheter rupture and arterial injury could result. Identify and resolve the cause of the blockage or replace the catheter with a new one.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.

COMPLICATIONS

As with all catheterization procedures, complications may occur when using the TWIN-PASS catheter. These may include:

- local or systemic infection
- intimal disruption
- arterial dissection
- perforation and vessel rupture
- arterial thrombosis
- distal embolization of blood clots and plaque
- Myocardial Infarction
- arterial spasm
- catheter fracture with tip separation and distal embolization

PRECAUTIONS

The TWIN-PASS catheter deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

Do not use the TWIN-PASS catheter if the packaging has been damaged.

Inspect the catheter prior to use for any bends or kinks. Do not use a damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur.

Care should be taken not to crush the catheter. Excessive tightening of a hemostatic valve onto the catheter shaft may result in damage to the guidewire lumen and difficulty while inserting the catheter or guidewires.

Both catheter lumens should be flushed with sterile, heparinized saline prior to use.

Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.

Exercise care while handling the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

When the catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the TWIN-PASS catheter. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

Each TWIN-PASS dual access catheter includes the following components:

- Single-use disposable catheter
- Stiffening mandrel
- Dispenser coil with flushing luer

Other materials required but not provided are:

- Guiding catheter with an I.D. of at least 0.055" / 1.40mm fitted with a rotating hemostatic valve (RHV) (Tuohy-Borst type)
- 0.014" / 0.36mm guidewires
- 10ml syringe (for flushing the dispenser coil and the catheter lumen)
- Sterile heparinized saline (for system flushing)

PREPARATIONS FOR USE

1. Carefully inspect the TWIN-PASS catheter packaging and components for damage prior to use. Utilizing sterile technique, remove the TWIN-PASS catheter dispenser coil from its packaging and transfer it to the sterile field.

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2. Remove the stiffening mandrel from the catheter. DO NOT DISCARD.
3. Attach a 10ml syringe filled with sterile heparinized saline to the luer-lock guidewire entry port of the TWIN-PASS catheter and thoroughly flush the catheter.
4. Attach a 10ml syringe filled with sterile heparinized saline to the flushing luer on the dispensing coil and completely flush the coil to activate the hydrophilic coating on the TWIN-PASS catheter.
5. Insert the stiffening mandrel through the luer-lock and into the TWIN-PASS catheter and lock it in place.
6. Remove the TWIN-PASS catheter from the dispensing coil and inspect for any bends or kinks.
7. Remove the packaging mandrel from the rapid exchange lumen of the TWIN-PASS catheter while under sterile saline.

DEPLOYMENT PROCEDURE

The following TWIN-PASS catheter deployment steps assume a standard PTCA protocol using the following items: a guiding catheter, an inserted 0.014" guidewire, a 300cm x 0.014" wire to be delivered, and a rotating hemostatic valve (RHV) (Touhy-Borst type).

As with any interventional procedure, proper anticoagulation and anti-platelet therapy should be administered prior to beginning.

Note: Familiarity with traditional long and short guidewire exchange techniques is required for successful deployment of the TWIN-PASS catheter and the delivery of a second guidewire.

TWIN-PASS DEPLOYMENT STEPS

1. Backload the rapid exchange segment of the TWIN-PASS catheter onto the proximal end of the 0.014" / 0.36mm guidewire that is already in place in the distal vasculature.

   WARNING: Do not advance the TWIN-PASS catheter without a guidewire in place through the RX lumen. Advancement of the catheter without a guidewire in the RX lumen may result in intimal damage, arterial dissection, or perforation.
2. Carefully advance the catheter until both marker bands are visible in the desired distal vascular space.

   WARNING: Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.
3. Slowly remove the stiffening mandrel.
4. Insert the desired exchange length guidewire into the luer-lock of the TWIN-PASS catheter. Advance the guidewire until it exits the thru-lumen into the distal vascular space.
5. Fix both guidewires using standard guidewire exchange techniques and carefully withdraw the TWIN-PASS catheter until the distal tip exits the hemostatic valve and both wires can be secured.

When not in use during this procedure, wipe the TWIN-PASS catheter with a sterile gauze pad saturated with heparinized saline, flush the thru-lumen well, reload the stiffening mandrel into the thru-lumen, and store in the dispensing tube in a saline bath.

PACKAGING & STORAGE

The TWIN-PASS has been sterilized with ethylene oxide.

Store in a cool, dry place.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the TWIN-PASS catheter is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the TWIN-PASS catheter. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.

PATENTS AND TRADEMARKS

International and U.S. patents pending.

Twin-Pass™ is a trademark of Vascular Solutions, Inc.

See the International Symbols Glossary on page 3.

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Vascular SOLUTIONS

Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369 USA
Tel: 763-656-4300
Fax: 763-656-4250
www.vascularsolutions.com

Appendix C: Draft Package Labels

Twin-Pass™

Dual Access Catheter

Vascular SOLUTIONS

DRAFT

REF 5200
3F/.014"

LOT XXXXXXX YYYYYYY

Vascular SOLUTIONS

+M20652000Z

Twin-Pass

REF 5200
3F/.014"

+$$YYYYXXXXXXXZ5

USA CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

CAUTION
The Twin-Pass Dual Access Catheter procedure should be performed by physicians with adequate training in the use of the device.

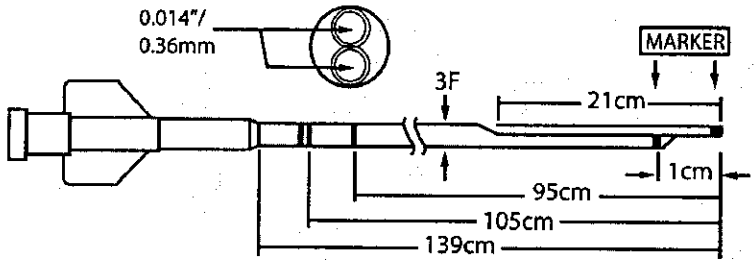
Latex

CONT

1x

1x

STERILE EO



Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Office: (763) 656-4300
Customer Service:
US: (888) 240-6001
Germany: +49 234 9712 731

Vascular SOLUTIONS

Label Content #1-0484 r01

Twin-Pass™

Dual Access Catheter

REF 5200
3F/.014"

Vascular SOLUTIONS

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Appendix D: Predicate Device Literature

Lumend Percutaneous Catheter, K011562

Quick-Cross Support Catheter, K033678

Dual Lumen Catheter, K991601

The following pages have been redacted from Lumend 510(k) number K011562.

DEFINITION OF SYMBOLS ON LABEL

Sterile R	Sterilized with gamma radiation
LOT	Lot number
2	Single use only
	Read instructions prior to use
	Date of Manufacture
	Expiration Date
REF	Model Number

LuMend™

Percutaneous Coronary Catheter

INSTRUCTIONS FOR USE

LIMITED WARRANTY

LuMend, Inc. warrants that reasonable care has been used in the manufacture of this device. There is no express or implied warranty, including fitness for a particular purpose, on this LuMend product. The description or specifications are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. LuMend is not responsible for any direct, incidental, special, or consequential loss, damage, or expense based on any defect, failure, or malfunction of this product, other than as expressly provided by mandatory provisions of applicable law. No person has the authority to bind LuMend to any representation or warranty except as indicated in this Limited Warranty.

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

LuMend

Manufactured by:

LuMend, Inc.
400 Chesapeake Drive
Redwood City, CA 94063 USA

Toll Free: 877.458.6363
Telephone: 650.364.1400
Fax: 650.556.9968
www.LuMend.com

Percutaneous Coronary Catheter

DESCRIPTION

The LuMend Percutaneous Coronary Catheter is a sterile, single-use, disposable device intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.

LuMend Percutaneous Coronary Catheter consists of:

- a torqueable shaft which terminates distally into a small curved, flexible radiopaque tip,
- a guide wire lumen contained within the catheter shaft, and
- a proximal luer connector

OPERATION

The LuMend Percutaneous Coronary Catheter curved distal tip is flexible and straightens easily to allow tracking over a guide wire. The catheter may be tracked over a guide wire which has already been advanced to the target site, or the guide wire may be pre-loaded in the catheter and both devices advanced to the chosen site via standard interventional procedures. When advancing the catheter forward or backward through the vasculature, the distal tip should always be tracked over the guide wire. The distal tip of the catheter is advanced until it reaches the distal end of the guide wire. The guide wire may be retracted into the device, allowing the curved tip of the catheter to reform. Using fluoroscopic guidance, the curved tip of the catheter is directed as desired and the guide wire is advanced to access the desired vasculature. After the guide wire has been placed, the catheter is retracted leaving the guide wire placed to facilitate the use of therapeutic devices.

CONTENTS

One (1) Percutaneous Coronary Catheter. See package labeling for model and size.

INDICATIONS FOR USE

The LuMend Percutaneous Coronary Catheter is intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.

CONTRAINDICATIONS

The device is not intended for use in the cerebral or peripheral vasculature.

WARNINGS

- *The safety and effectiveness of this device have not been established.*
- Single use only. Do not resterilize, autoclave, or reuse. This may result in impaired performance and could cause patient injury and/or the communication of infectious diseases from one patient to another.
- Do not use this device to cross a lesion within a stent.

PRECAUTIONS

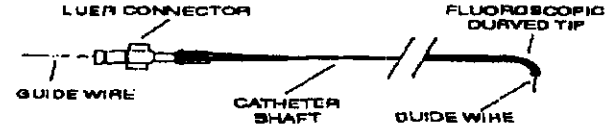
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- This catheter should only be used by physicians trained in coronary percutaneous interventional techniques in a fully equipped catheterization laboratory.
- Do not use without completely reading and understanding this document.
- Store in a cool, dark, dry place. Do not use if package is opened or damaged. Use by the last day of the month of the "Use By" date on the package.
- Inspect the catheter for functionality, integrity, size, and shape prior to use to ensure that it is undamaged and suitable for the specific procedure.
- Manipulation of the catheter, advancement of the guide wire out of the fluoroscopic curved distal tip, and withdrawal of the catheter should always be performed under high-quality fluoroscopic guidance
- Torquing the catheter excessively may cause damage to the product. Withdraw the catheter should it become kinked.
- Do not rotate the catheter more than 3 times without noting a response at the distal tip as verified by fluoroscopy.
- If strong resistance is felt during manipulation, determine the cause of the resistance before proceeding further. If the cause cannot be determined, withdraw the catheter.
- Do not expose the catheter to organic solvents (e.g., alcohol).
- Excessive bending or kinking of the catheter may affect performance.

ADVERSE EFFECTS

This product is designed for use by physicians trained in and familiar with percutaneous coronary interventional techniques. Possible complications include, but are not limited to, the following:

- vessel dissection, perforation, or injury
- vascular thrombosis
- embolism
- puncture site hemorrhage or hematoma
- pyrogenic reaction
- sepsis or infection
- allergic reaction to contrast medium
- pain and tenderness at the insertion site

DIRECTIONS FOR USE



The guide wire is advanced out of the curved tip.

1. Inspect the catheter package before opening. Do not use if package is opened or damaged.
2. Use sterile technique to carefully remove the catheter from the packaging. Inspect the catheter to ensure the catheter exhibits no signs of damage.
3. Remove the curved stylet from the distal end of the catheter and discard.
4. Flush the catheter with heparinized saline through the proximal luer connector.
5. Wipe the catheter with heparinized saline or submerge in heparinized saline to hydrate the hydrophilic coating just prior to use.
- ***Advancement and manipulation of the catheter, advancement of the guide wire out of the fluoroscopic curved distal tip, and withdrawal of the catheter should always be performed under high-quality fluoroscopic guidance.***
6. Introduce the LuMend Percutaneous Coronary catheter over a guide wire, which has been advanced to the appropriate vascular site. If a guide wire is not in place in the patient, load the guide wire into the catheter and introduce both into the patient using standard interventional methods. When advanced or retracted, the distal end of the catheter must always be tracked over the guide wire.
7. Advance the distal tip of the LuMend Percutaneous Coronary Catheter over the guide wire to the desired vascular site. Retract the guidewire to allow the distal curve of the catheter to reform.
8. Using fluoroscopic guidance, (multiple, orthogonal views may be utilized) align the exit port of the fluoroscopic curved tip to re-direct the guide wire as desired.
9. Advance the guide wire through the exit port of the fluoroscopic curved tip to access the desired vascular site.
- ***Monitor guide wire advancement/retraction using fluoroscopic guidance.***
10. While maintaining the guide wire's access in the vascular site, fully retract the catheter completely.
11. Proceed with elective therapies.

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PRT00XXX-A

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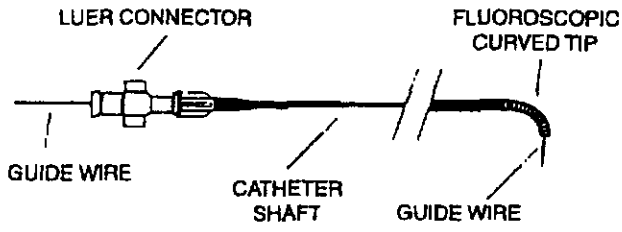
 91

LuMend™

Percutaneous Coronary Catheter

REF SSU24135



Pouch Label

2.81F	4.0F	[illegible] cm	2 mm
[illegible] OD	Shaft Diameter	[illegible] Length	Tip Length

Contents: 1 unit

Date of Manufacturing: XXXX-XX

Use By: XXXX-XX

LOT XXXX

STERILE R

Min 25 kGy

Do not use if package is opened or damaged.

Read package insert before using.

Single use only. Do not resterilize.

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

Made in USA.
US and International Patents Pending.
Store in a cool, dark, dry place.

Manufactured by:
LuMend, Inc.
400 Chesapeake Drive
Redwood City, CA 94063 USA
877.458.6363 toll-free
650.364.1400
650.556.9968 fax

PRT00XXX Rev A

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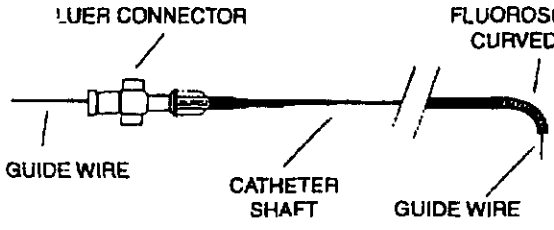
 92

2.81F Tip OD | 4.0F Shaft Diameter | 135 cm Shaft Length | 2 mm Tip Length
REF SSU24135
LuMend

LuMend

Percutaneous Coronary Catheter

REF SSU24135



Box Label

2.81F	4.0F	135 cm	2 mm
Tip OD	Shaft Diameter	Shaft Length	Tip Length

Contents: 1 unit

Date of Manufacturing: **XXXX-XX**

Use By: **XXXX-XX**

LOT **XXXX**

STERILE R

Min 25 kGy

Do not use if package is opened or damaged.

Read package insert before using.

Single use only. Do not resterilize.

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

Made in USA.
US and International Patents Pending.
Store in a cool, dark, dry place

Manufactured by:
LuMend, Inc.
400 Chesapeake Drive
Redwood City, CA 94063 USA
877.458.6363 toll-free
650.364.1400
650.556.9968 fax

PRT00XXX Rev A

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93

510(k) Number (if known): TBD

Device Name: LuMend Percutaneous Catheter

Indications For Use:

The LuMend Percutaneous Catheter is intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

SUMMARY

6.1 Substantial Equivalence Rationale

The LuMend Percutaneous Catheter is substantially equivalent to a combination of Class II Percutaneous Coronary Guide / Support Catheters (74 DQY 870.1250) as follows:

Predicate Device	510(k) Number	Key Elements that are Substantially Equivalent:
ILT 0.014" Catheter Model C114NI2 IntraLuminal Therapeutics, Inc.	K001992	*ILT Indication for use*: intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the [coronary] vasculature
Zuma Guide Catheters Medtronic, Inc.	K000677	*Other Indication for use*: designed to provide a pathway through which therapeutic and diagnostic devices are introduced.
Viking Optima Guiding Catheter Guidant Corp.	K001435	*Mechanism of Action:* Guide wire and interventional device support and direction within the coronary vasculature and facilitation of placement of interventional devices.
Brite Tip™ Guiding Catheters Cordis / J&J	K992673	*Construction:* Standard medical grade metallic and polymeric catheter compounds including Polycarbonate handles, Stainless Steel braid, PEBAX of varying durometer and Grilamid.
Wiseguide™ Cyber Triguide Boston Scientific/SCIMED	K981788	*Instructions for use:* conventional interventional techniques.

The LuMend Percutaneous Catheter is used in conjunction with a steerable guide wire or other interventional catheters in the same manner as the predicate devices cited above to facilitate device placement within selected regions of the coronary vasculature. Each of these devices are intended to allow access and placement of conventional guide wires and / or other therapeutic devices.

The range of sizes, lengths and diameters of the LuMend Guide Catheter are entirely consistent with the predicates cited. The table in the next subsection (6.2) summarizes and compares the salient characteristics of these devices.

An FDA 510(k) "Substantial Equivalence" Decision-Making Process flow chart is included with a proposed rational following the table in section 6.3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2002

Mr. Michael A. Daniel
Regulatory and Clinical Affairs
LuMend, Inc.
400 Chesapeake Drive
Redwood City, CA 94063

Re: K011562
LeMend Percuataneous Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II
Product Code: DQY
Dated: October 18, 2001
Received: October 18, 2001

Dear Mr. Daniel:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): ~~TBD~~ K011562

Device Name: LuMend Percutaneous Catheter

Indications For Use:

The LuMend Percutaneous Catheter is intended to be used in conjunction with a steerable guide wire in order to access discreet regions of the coronary vasculature. It may be used to facilitate placement of guide wires and other interventional devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011562

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K033678

FEB 2 3 2004

Premarket Notification 510(k) Summary

Submitted By:
Michael J. Ryan
RA Manager
Spectranetics Corporation
96 Talamine Court
Colorado Springs, CO 80907
Signature and Date: Michael J. Ryan 21 Nov 03

Device Trade Name:	Spectranetics Quick-Cross Support Catheter.
Common Name:	Intravascular Catheter
Classification Name:	Percutaneous Catheter, CFR 870.1250

Device Description: The Spectranetics Quick-Cross Support Catheters are intravascular catheters, available in seven (7) models:

518-032	0.014" diameter catheter,	135cm length
518-033	0.018" diameter catheter	90 cm length
518-034	0.018" diameter catheter	135 cm length
518-035	0.018" diameter catheter	150 cm length
518-036	0.035" diameter catheter	90 cm length
518-037	0.035" diameter catheter	135 cm length
518-038	0.035" diameter catheter	150 cm length

Model number 518-032 has a shaft of varying stiffness with a proximal shaft diameter of 3.0 Fr. tapering to a distal shaft diameter of 1.9 Fr.

Model numbers 518-033, 518-034, and 518-035 have a shaft of varying stiffness with a proximal shaft diameter of 3.4 Fr. tapering to a distal shaft diameter of 2.2 Fr.

Model numbers 518-036, 518-037, and 518-038 have a shaft of varying stiffness with a proximal shaft diameter of 4.8 Fr. tapering to a distal shaft diameter of 3.7 Fr.

	All models have three (3) radiopaque markers located at their tapered distal tip. A standard female luer is placed on the proximal end of each model. The distal 40 cm of each model is coated with a lubricious, hydrophilic coating. Predicate devices of this type with similar intended uses have been classified into Class II.
Indications for Use:	The Spectranetics Quick-Cross Support Catheters are designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.
Substantial Equivalence:	This product is substantially equivalent in design, composition, function, and intended use to the Spectranetics Support Catheters, 510(k) K991059 and K022138.
Technological Characteristics & Nonclinical Testing Summary:	The Spectranetics Quick-Cross Support Catheters are similar in design, construction, indications, target population, risk analysis, performance and materials to the predicate devices, the Spectranetics 0.014" and 0.018" Support Catheters, K991059, and the Spectranetics 0.035" Support Catheter, K022138. Spectranetics New Production Introduction procedure has been used in concert with the Quality System Regulations for the introduction of the Quick Cross Support Catheter. The design validation protocols and risk analysis addressed all known aspects of the device including tensile strength, functionality, visibility, flow rate, sterility, and biocompatibility. Testing performed for the Spectranetics Support Catheter provides reasonable assurance that the device will perform in a safe and effective manner when used as indicated
	The Spectranetics Quick-Cross Support Catheters are similar in the indications for use as the Spectranetics Support Catheters K991059 and K022138.
Conclusions:	The results of the bench testing demonstrate that the Spectranetics Quick-Cross Support Catheters are substantially equivalent to the predicate devices and they will perform in a safe and effective manner when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2004

Spectranetics Corporation
c/o Mr. Michael J. Ryan
Regulatory Affairs Manager
96 Talamine Court
Colorado Springs, CO 80907

Re: K033678
Spectranetics Quick-Cross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: November 21, 2003
Received: November 25, 2003

Dear Mr. Ryan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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): K033678

Device Name: Spectranetics Quick-Cross Support Catheter

Indications For Use:

The Spectranetics Quick-Cross Support Catheters are a guidewire exchange and infusion device designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devic
510(k) Number K033678

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Spectranetics *Quick-Cross*™ Support^2 Catheters

Instructions for Use

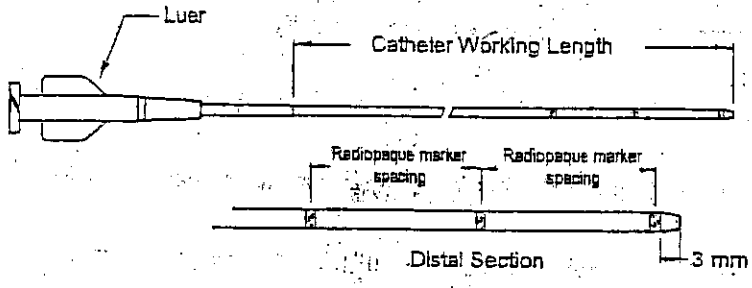
Description

The Spectranetics Quick-Cross™ Support^2 Catheters are intravascular catheters, available in 7 models. Model 518-032 is a 0.014 inch guidewire compatible, 3.0 French (Fr.) outside diameter catheter. Models 518-033, 518-034, and 518-035 are a 0.018 inch guidewire compatible, 3.4 Fr. outer diameter catheter. Models 518-036, 518-037, and 518-038 are a 0.035 inch guidewire compatible, 4.8 Fr. outer diameter catheter. All models have 3 radiopaque markers spaced equally along the distal shaft to aid in estimating geometry within the vascular system. The distal radiopaque marker is positioned within 3 mm of the distal catheter tip. A standard female luer is placed on the proximal end of each model. The distal 40 cm of each catheter model is coated with a lubricious, hydrophilic coating.

Model number 518-032 has a shaft of varying stiffness with a proximal shaft diameter of 3.0 Fr. tapering to a distal shaft diameter of 1.9 Fr.

Model numbers 518-033, 518-034, and 518-035 have a shaft of varying stiffness with a proximal shaft diameter of 3.4 Fr. tapering to a distal shaft diameter of 2.2 Fr.

Model numbers 518-036, 518-037, and 518-038 have a shaft of varying stiffness with a proximal shaft diameter of 4.8 Fr. tapering to a distal shaft diameter of 3.7 Fr.



Specifications

	518-032	518-033	518-034	518-035	518-036	518-037	518-038
Maximum guidewire, inch	0.014	0.018	0.018	0.018	0.035	0.035	0.035
Catheter Working Length, cm	135	90	135	150	90	135	150
Minimum guidewire length, cm	180	150	180	180	150	180	180
Radiopaque marker spacing, mm	15	15	15	15	50	50	50
Proximal Shaft diameter, inch	0.039	0.044	0.044	0.044	0.063	0.063	0.063
Distal Shaft diameter, inch	0.025	0.029	0.029	0.029	0.048	0.048	0.048
Tip outside diameter, inch	0.021	0.025	0.025	0.025	0.041	0.041	0.041
Tip inside diameter, inch	0.016	0.020	0.020	0.020	0.037	0.037	0.037
Minimum Guide Catheter, Fr.	6	6	6	6	6	6	6
Minimum Introducer Sheath, Fr.	5	5	5	5	5	5	5

Notes

The Spectranetics Quick-Cross™ Support^2 Catheters have been sterilized using Ethylene Oxide and are supplied STERILE. The devices are designated and designed for SINGLE USE ONLY and must not be resterilized and/or reused.

Store in a cool, dry place. Protect from direct sunlight and high temperature *(greater than 60°C or 140°F)*.

The sterility of the product is guaranteed only if the package is unopened and undamaged. Before use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter if its "Use Before Date," found on package labeling, has been passed.

Before use, examine carefully for defects, all of the equipment to be used. Do not use any equipment if it is damaged.

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially bio-hazardous materials.

Indications for Use

The Spectranetics Quick-Cross™ Support^2 Catheters are guide wire exchange and infusion devices designed for use in the vascular system. The catheters are intended to support a guidewire during access of vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Directions for Use

Note: Follow instructions for use for all equipment to be used with the Quick-Cross™ Support^2 catheters. For example, guiding catheters, introducer sheaths, and guidewires.

1. Preparation: Using sterile technique, open the sterile package. Gently remove the protective hoop with the catheter from the pouch. Fill a sterile standard luer-lock syringe with sterile saline. Before removing the catheter from the hoop, connect the syringe to the catheter proximal luer fitting, flush the catheter and allow the saline to fill the hoop. Set catheter in hoop aside until ready for use.
2. Insertion: Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the catheter over an appropriate sized guidewire (see specifications) using standard technique.
3. Advancement: Use fluoroscopic guidance when advancing the catheter to the desired location within the vasculature.
4. Removal: Gently withdraw the catheter using standard technique, being careful to maintain guidewire position if the guidewire is to remain in place.
5. Infusion: To perform infusion, withdraw the guidewire and reference the chart below. Note: Do not exceed 300 psi inlet infusion pressure.

Quick-Cross™ Infusion Flow Rates (ml/second) at 150 and 300 psi Injection Pressures for Saline and Contrast Solutions

			Sterile Saline		Contrast*	
Model	Size	Length	150 psi	300 psi	150 psi	300 psi
518-032	0.014	135	1.1	1.6	0.4	1.0
518-033	0.018	90	2.0	2.9	0.8	1.6
518-034	0.018	135	1.8	2.5	0.7	1.2
518-035	0.018	150	1.7	2.4	0.6	1.2
518-036	0.035	90	6.8	10.0	4.2	7.2
518-037	0.035	135	5.6	8.5	3.4	6.1
518-038	0.035	150	5.4	8.0	3.2	5.5

* 75/25 Optiray 320 contrast / Sterile Saline mix

Warnings/Precautions:

- Maximum recommended infusion pressure is 300 psi.
- The catheter is designed and intended for intravascular use only.
- This catheter is designed and intended for one time use only. Do not re-sterilize and/or reuse.

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- Careful inspection before use should verify that the catheter has not been damaged in shipment and that its condition is suitable for the procedure.
- The catheter should not be advanced through an area of resistance unless the source of resistance is identified by fluoroscopy and appropriate steps are taken to reduce or remove the obstruction.
- Catheter manipulation should only occur under fluoroscopy.
- The catheter should not be advanced into a vessel having a diameter smaller than the catheter outer diameter.
- Only use guidewires of the recommended diameter and length.
- If the catheter is used for infusion, reference the table of flow rates and ensure infusion pressure does not exceed the recommendations.
- This catheter should only be used by physicians qualified to perform percutaneous, vascular interventions.
- Avoid introducing air or any other gas through the catheter into the vascular system.

Adverse Effects:

Vascular catheterization and/or vascular interventions may result in complications including but not limited to:

- Vessel dissection, perforation, rupture or total occlusion
- Unstable angina
- Embolism
- Hypo/hypertension
- Acute myocardial infarction
- Arrhythmia, including ventricular fibrillation
- Death

Disclaimer:

Spectranetics offers an exclusive limited warranty on this product. Spectranetics warrants that this product will perform as specified in the Instructions for Use for the period of time up to the product's "Use before" date.

Spectranetics *Quick-Cross*™ Support^2 Katheter

Gebrauchsanleitung

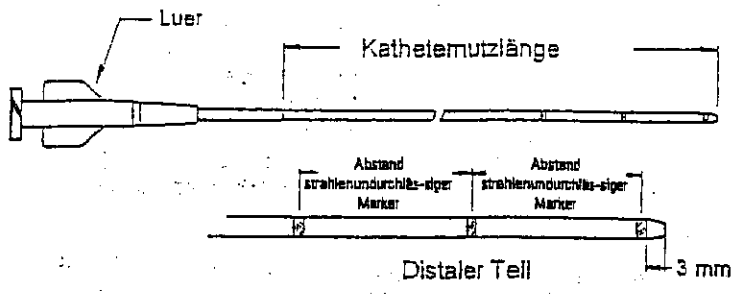
Beschreibung

Die Quick-Cross™ Support^2 Katheter von Spectranetics sind Gefäßkatheter, die in 7 Ausführungen erhältlich sind. Modell 518-032 hat einen Katheteraußendurchmesser von 3,0 French (Fr.), der mit einem 0,014 Zoll Führungsdraht kompatibel ist. Die Modelle 518-033, 518-034 und 518-035 haben einen Katheteraußendurchmesser von 3,4 Fr., der mit einem 0,018 Zoll Führungsdraht kompatibel ist. Die Modelle 518-036, 518-037 und 518-038 haben einen Katheteraußendurchmesser von 4,8 Fr., der mit einem 0,035 Zoll Führungsdraht kompatibel ist. Alle Modelle haben 3 strahlenundurchlässige Marker, die in gleichmäßigen Abständen an dem distalen Schaft angeordnet sind, um geometrische Schätzungen im Gefäßsystem zu erleichtern. Der distale strahlenundurchlässige Marker ist 3 mm von der distalen Katheterspitze entfernt positioniert. Ein standardmäßiger aufnehmender Luer ist am proximalen Ende jedes Modells positioniert. Die distalen 40 cm jedes Kathetermodells sind mit einer glatten hydrophilen Beschichtung überzogen.

Das Modell Nummer 518-032 hat einen Schaft mit variierender Steifheit mit einem proximalen Schaftdurchmesser von 3,0 Fr., der sich zu einem distalen Schaftdurchmesser von 1,9 Fr. verjüngt.

Die Modelle Nummer 518-033, 518-034 und 518-035 haben einen Schaft mit variierender Steifheit mit einem proximalen Schaftdurchmesser von 3,4 Fr., der sich zu einem distalen Schaftdurchmesser von 2,2 Fr. verjüngt.

Die Modelle Nummer 518-036, 518-037 und 518-038 haben einen Schaft mit variierender Steifheit mit einem proximalen Schaftdurchmesser von 4,8 Fr., der sich zu einem distalen Schaftdurchmesser von 3,7 Fr. verjüngt.



Spezifikationen

	518-032	518-033	518-034	518-035	518-036	518-037	518-038
Maximaler Führungsdraht, Zoll	0,014	0,018	0,018	0,018	0,035	0,035	0,035
Katheter-Nutzlänge, cm	135	90	135	150	90	135	150
Minimale Führungsdrahtlänge, cm	180	150	180	180	150	180	180
Abstand strahlenundurchlässiger Marker, mm	15	15	15	15	50	50	50
Proximaler Schaftdurchmesser, Zoll	0,039	0,044	0,044	0,044	0,063	0,063	0,063
Distaler Schaftdurchmesser, Zoll	0,025	0,029	0,029	0,029	0,048	0,048	0,048
Spitzenaußendurchmesser, Zoll	0,021	0,025	0,025	0,025	0,041	0,041	0,041
Spitzeninnendurchmesser, Zoll	0,016	0,020	0,020	0,020	0,037	0,037	0,037
Minimaler Führungskatheter, Fr.	6	6	6	6	6	6	6
Minimale Einführhülle, Fr.	5	5	5	5	5	5	5

Hinweise

Die Quick-Cross™ Support² Katheter von Spectranetics sind unter Verwendung von Ethylenoxid sterilisiert worden und werden STERIL geliefert. Die Geräte sind NUR ZUM EINMALIGEN GEBRAUCH bestimmt und konstruiert und dürfen nicht resterilisiert und/oder wieder verwendet werden.

An einem kühlen, trockenen Ort lagern. Vor direktem Sonnenlicht schützen und keinen hohen Temperaturen *(über 60°C oder 140°F)* aussetzen.

Die Sterilität dieses Produkts ist nur dann gewährleistet, wenn die Verpackung nicht geöffnet und nicht beschädigt ist. Vor dem Gebrauch muss die sterile Verpackung genau überprüft werden, um sicher zu gehen, dass die Versiegelung unversehrt ist. Der Katheter darf nicht verwendet werden, wenn die Verpackung beschädigt ist. Der Katheter darf nicht verwendet werden, wenn das „Verfallsdatum", das Sie auf der Verpackungsbeschriftung finden, überschritten wurde.

Vor der Verwendung müssen Sie alle Geräte, die verwendet werden sollen, einer genauen Überprüfung auf Defekte unterziehen. Es dürfen keine beschädigten Geräte verwendet werden.

Nach der Verwendung müssen alle Geräte entsprechend den speziellen geltenden Vorschriften für Krankenhausabfall und potenziell biogefährliche Stoffe entsorgt werden.

Indikationen

Die Quick-Cross™ Support² Katheter von Spectranetics sind Geräte mit austauschbarem Führungsdraht und zur Infusion, die zur Anwendung im Gefäßsystem bestimmt sind. Die Katheter sind dafür bestimmt, einen Führungsdraht während des Zugangs zum Gefäßsystem zu stützen, gestatten den Austausch von Führungsdrähten und bieten einen Kanal für die Verabreichung von Kochsalzlösungen oder Kontrastmitteln zur Diagnose.

Gebrauchsanweisung

Hinweis: Befolgen Sie die Gebrauchsanweisungen für alle Geräte, die mit den Quick-Cross™ Support² Kathetern verwendet werden sollen. Dazu gehören z.B. Führungskatheter, Einführhüllen und Führungsdrähte.

1. Vorbereitung: Öffnen Sie die sterile Verpackung unter Einhaltung steriler Praktiken. Entnehmen Sie dem Beutel vorsichtig den Schutzring mit dem Katheter. Füllen Sie eine standardmäßige Spritze mit Luer-Verschluss mit steriler Kochsalzlösung. Verbinden Sie die Spritze mit dem proximalen Luer-Anschlussstück, spülen Sie den Katheter durch und warten Sie, bis der Ring sich mit Kochsalzlösung gefüllt hat, bevor Sie den Katheter aus dem Ring nehmen. Legen Sie den Katheter in dem Ring beiseite, bis er einsatzbereit ist.
2. Einführen: Führen Sie den Katheter durch einen bereits vorher eingeführten Führungskatheter angemessener Größe bzw. eine Einführhülle über einen Führungsdraht der entsprechenden Größe (siehe Spezifikationen) unter Anwendung standardmäßiger Verfahren ein.
3. Vorwärtsbewegen: Überwachen Sie das Vorwärtsbewegen des Katheters an die gewünschte Stelle im Gefäßsystem durch Fluoroskopie.
4. Entfernen: Ziehen Sie den Katheter unter Befolgung standardmäßiger Verfahren vorsichtig heraus, und achten Sie dabei darauf, die Position des Führungsdrahtes beizubehalten, wenn der Führungsdraht in seiner Position verbleiben soll.
6. Infusion: Zur Vornahme einer Infusion ziehen Sie den Führungsdraht heraus und folgen Sie der unten stehenden Tabelle. Hinweis: Der Druck bei Eintritt der Infusion darf 300 psi nicht übersteigen.

Quick-Cross™ Infusionsflussraten (ml/Sekunde) bei Injektionsdrücken von 150 und 300 psi für Kochsalz- und Kontrastmittellösungen

Modell	Größe	Länge	Sterile Kochsalzlösung		Kontrastmittel*	
			150 psi	300 psi	150 psi	300 psi
518-032	0,014	135	1,1	1,6	0,4	1,0
518-033	0,018	90	2,0	2,9	0,8	1,6
518-034	0,018	135	1,8	2,5	0,7	1,2
518-035	0,018	150	1,7	2,4	0,6	1,2
518-036	0,035	90	6,8	10,0	4,2	7,2
518-037	0,035	135	5,6	8,5	3,4	6,1
518-038	0,035	150	5,4	8,0	3,2	5,5

* 75/25 Optiray 320 Kontrastmittel / Sterile Kochsalzlösungsmischung

Warnhinweise//Vorsichtsmaßnahmen:

- Der maximale empfohlene Infusionsdruck beträgt 300 psi.
- Der Katheter ist nur zum intravaskulären Gebrauch bestimmt und geeignet.
- Dieser Katheter ist nur zum einmaligen Gebrauch bestimmt und geeignet. Nicht resterilisieren und/oder wieder verwenden.
- Bei einer sorgfältigen Überprüfung vor der Verwendung muss sichergestellt werden, dass der Katheter beim Versand nicht beschädigt wurde und dass sein Zustand für den Eingriff geeignet ist.
- Der Katheter sollte nicht durch einen Bereich vorwärts bewegt werden, der Widerstand bietet, sofern die Ursache des Widerstandes nicht durch Fluoroskopie identifizien wird und entsprechende Maßnahmen zur Verkleinerung oder Entfernung des Hindernisses ergriffen werden.
- Der Katheter sollte nur unter Fluoroskopie betätigt werden.
- Der Katheter sollte nicht in ein Gefäß hinein geführt werden, dessen Durchmesser kleiner als der Außendurchmesser des Katheters ist.
- Verwenden Sie nur Führungsdrähte mit empfohlenem Durchmesser und Länge.
- Wird der Katheter zur Infusion verwendet, muss die Tabelle mit Angabe der Flussraten befolgt und sicher gestellt werden, dass der Infusionsdruck die empfohlenen Werte nicht übersteigt.
- Dieser Katheter sollte ausschließlich von Ärzten verwendet werden, die in der Durchführung perkutaner, vaskulärer Gefäßeingriffe entsprechend geschult sind.
- Vermeiden Sie das Eindringen von Luft bzw. jeglichen anderen Gases durch den Katheter in das Gefäßsystem.

Unerwünschte Nebenwirkungen:

Eine Gefäßkatheterisierung und/oder vaskuläre Eingriffe können zu Komplikationen, u.a. zu den nachstehend aufgeführten Komplikationen führen:

- Dissektion von Gefäßen, Perforation, Ruptur oder vollständige Okklusion
- Instabile Angina
- Embolie
- Niedriger Blutdruck/Bluthochdruck
- Akuter Myokardinfarkt
- Arrhythmie, einschließlich Kammerflimmern
- Tod

Verzichterklärung:

Spectranetics bietet eine ausschließliche beschränkte Gewährleistung für dieses Produkt an. Spectranetics gewährleistet, dass dieses Produkt wie in der Gebrauchsanweisung angegeben für den Zeitraum bis zum „Verfallsdatum" des Produkts funktionsfähig ist.

Cateteri *Quick-Cross*™ Support^2 Spectranetics

Istruzioni per l'uso

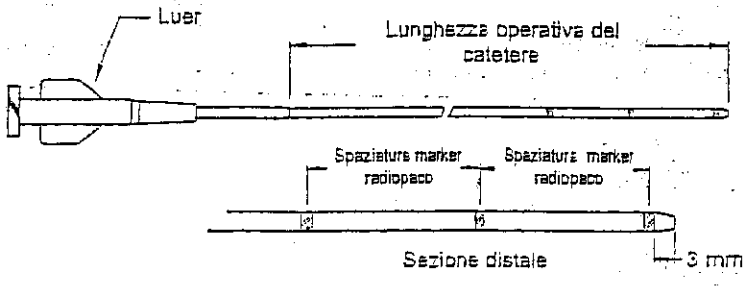
Descrizione

I cateteri Quick-Cross™ Support^2 Spectranetics sono di tipo intravascolare, disponibili in 7 modelli. Il modello 518-032 è un catetere compatibile con filo guida da 0,014", diametro esterno da 3,0 Fr. I modelli 518-033, 518-034 e 518-035 sono cateteri compatibili con filo guida da 0,018" e diametro esterno da 3,4 Fr. I modelli 518-036, 518-037 e 518-038 sono cateteri compatibili con filo guida da 0,035" e un diametro esterno da 4,8 Fr. Tutti i modelli sono dotati di 3 marker radiopachi, distanziati in modo uniforme lungo l'asse distale, in modo da agevolare la valutazione della geometria del sistema vascolare. Il marker radiopaco distale è posizionato entro 3 mm dalla punta del catetere distale. Un luer femmina standard è collocato sull'estremità prossimale di ciascun modello. I 40 cm distali di ciascun modello di catetere sono ricoperti da un rivestimento idrofilo lubrificato.

Il modello numero 518-032 è dotato di un asse a rigidità variabile con un diametro prossimale di circa 3,0 Fr, che si restringe fino ad un diametro dell'asse distale pari a 1,9 Fr.

I modelli nn. 518-033, 518-034 e 518-035 sono dotati di asse a rigidità variabile con un diametro prossimale di circa 3,4 Fr, che si restringe fino ad un diametro dell'asse distale pari a 2,2 Fr.

I modelli nn. 518-036, 518-037 e 518-038 sono dotati di asse a rigidità variabile con un diametro prossimale di circa 4,8 Fr, che si restringe fino ad un diametro dell'asse distale pari a 3,7 Fr.



Specifiche tecniche

	518-032	518-033	518-034	518-035	518-036	518-037	518-038
Lunghezza massima filo guida, in pollici	0,014	0,018	0,018	0,018	0,035	0,035	0,035
Lunghezza operativa catetere, in cm	135	90	135	150	90	135	150
Lunghezza minima filo guida, in cm	180	150	180	180	150	180	180
Spaziatura marker radiopaco, in mm	15	15	15	15	50	50	50
Diametro asse prossimale, in pollici	0,039	0,044	0,044	0,044	0,063	0,063	0,063
Diametro asse distale, in pollici	0,025	0,029	0,029	0,029	0,048	0,048	0,048
Punta diametro esterno, in pollici	0,021	0,025	0,025	0,025	0,041	0,041	0,041
Punta diametro interno, in pollici	0,016	0,020	0,020	0,020	0,037	0,037	0,037
Lunghezza minima catetere guida, in Fr	6	6	6	6	6	6	6
Misura minima guaina per introduzione catetere, in Fr	5	5	5	5	5	5	5

Note

I cateteri Spectranetics Quick-Cross™ Support^2 sono sterilizzati con ossido di etilene e vengono forniti in confezione STERILE. I dispositivi sono ideati e progettati ESCLUSIVAMENTE PER ESSERE UTILIZZATI UNA SOLA VOLTA e non devono essere risterilizzati e/o riutilizzati.

Conservare in luogo fresco e asciutto. Evitare l'esposizione alla luce solare diretta ed alle temperature elevate *(superiori a 60 °C o 140 °F)*.

Le condizioni sterili del prodotto vengono garantite solo se la confezione non è aperta o danneggiata. Prima dell'uso, ispezionare visualmente la confezione sterile per verificare l'integrità dei sigilli. Non utilizzare il catetere se la confezione è stata danneggiata. Non utilizzare il catetere se la "Data di scadenza" indicata sulla confezione è trascorsa.

Prima dell'uso, esaminare attentamente l'intera apparecchiatura da usare, per rilevare la presenza di eventuali difetti. Non utilizzare l'apparecchiatura se danneggiata.

Dopo l'uso, eliminare l'intera apparecchiatura, in conformità con le normative specifiche applicabili in materia di rifiuti ospedalieri e materiali a potenziale rischio biologico.

Indicazioni per l'uso

I cateteri Spectranetics Quick-Cross™ Support^2 consistono in dispositivi per lo scambio di filo guida e l'infusione, realizzati per l'uso nel sistema vascolare. I cateteri sono realizzati al fine di supportare un filo guida nel corso dell'accesso ai vasi, consentire lo scambio di fili guida e fornire un condotto per il rilascio di soluzioni saline o di agenti di contrasto diagnostici.

Istruzioni per l'uso

Nota: seguire le istruzioni per l'uso per l'intera apparecchiatura da utilizzarsi con i cateteri Quick-Cross™ Support^2, ad esempio, cateteri guida, guaine di introduzione e fili guida.

1. Preparazione: utilizzando tecniche sterili, aprire la confezione sterile. Rimuovere delicatamente l'anello protettivo con il catetere dalla sacca. Riempire una siringa sterile luer-lock con una soluzione fisiologica sterile. Prima di rimuovere il catetere dall'anello, collegare la siringa al raccordo luer prossimale del catetere, sciacquare il catetere e consentire alla soluzione fisiologica di riempire l'anello. Mettere il catetere da parte nell'anello fino al momento dell'uso.
2. Inserimento: con un catetere guida inserito in precedenza e dalle dimensioni appropriate, oppure con una guaina per introduzione, inserire il catetere su un filo guida dalle dimensioni appropriate (fare riferimento alle specifiche), utilizzando la tecnica standard.
3. Avanzamento: utilizzare una guida fluoroscopica quando si fa avanzare il catetere verso la posizione desiderata all'interno del vaso.
4. Rimozione: ritirare delicatamente il catetere utilizzando la tecnica standard, e facendo attenzione a mantenere il filo guida in posizione, se deve rimanere in posizione.

7. Infusione: per eseguire l'infusione, ritirare il filo guida e fare riferimento alla tabella riportata di seguito. Nota: non superare una pressione massima di infusione in ingresso di 300 psi.

Velocità di flusso infusione Quick-Cross™ (ml/secondo) a una pressione di iniezione per soluzioni fisiologiche o di contrasto pari a 150 e 300 psi

			Soluzione fisiologica		Contrasto*	
Modello	Dimensioni	Lunghezza	150 psi	300 psi	150 psi	300 psi
518-032	0,014	135	1,1	1,6	0,4	1,0
518-033	0,018	90	2,0	2,9	0,8	1,6
518-034	0,018	135	1,8	2,5	0,7	1,2
518-035	0,018	150	1,7	2,4	0,6	1,2
518-036	0,035	90	6,8	10,0	4,2	7,2
518-037	0,035	135	5,6	8,5	3,4	6,1
518-038	0,035	150	5,4	8,0	3,2	5,5

* 75/25 Optiray 320 per contrasto / Mix soluzione fisiologica sterile

Avvertenze/Precauzioni:

- La massima pressione di infusione raccomandata è 300 psi.
- Il catetere è ideato e realizzato per esclusivo uso intravascolare.
- Il catetere è ideato e realizzato esclusivamente per essere utilizzato una sola volta. Non risterilizzare e/o riutilizzare.
- È necessaria un'accurata ispezione prima dell'uso per verificare che il catetere non sia stato danneggiato durante la spedizione e che le sue condizioni siano idonee per la procedura.
- Non fare avanzare il catetere in un'area di resistenza, salvo il caso in cui l'origine della resistenza sia identificata mediante fluoroscopia, e vengano adottate le misure appropriate per ridurre o rimuovere l'ostruzione.
- Il catetere deve essere manipolato solo in fluoroscopia.
- Non fare avanzare il catetere in un vaso, se questo presenta un diametro inferiore a quello esterno del catetere.
- Utilizzare solo fili guida di diametro e lunghezza raccomandati.
- Se il catetere viene utilizzato per infusione, fare riferimento alla tabella delle velocità di flusso e verificare che la pressione di infusione non superi i limiti raccomandati.
- Questo catetere deve essere utilizzato esclusivamente da personale medico qualificato per eseguire interventi vascolari percutanei.
- Evitare di introdurre aria o qualsiasi altro gas nel sistema vascolare attraverso il catetere.

Effetti indesiderati:

La cateterizzazione vascolare e/o gli interventi vascolari possono generare complicazioni che includono, e non si limitano a:

- dissezione, perforazione, rottura od occlusione vascolare completa
- angina instabile
- embolia
- ipo/ipertensione
- infarto acuto del miocardio
- aritmia con fibrillazione ventricolare
- morte

Dichiarazione di limitazione di responsabilità:

Spectranetics offre una garanzia esclusiva limitata su questo prodotto. Spectranetics garantisce che le prestazioni del prodotto saranno conformi a quanto specificato nelle Istruzioni per l'uso per il periodo precedente la "Data di scadenza" indicata sulla confezione.

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

Catéteres Support² *Quick-Cross*™ de Spectranetics

Instrucciones de uso

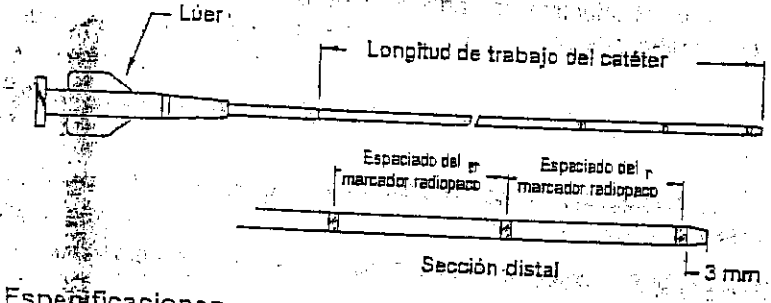
Descripción

Los catéteres Support² Quick-Cross™ de Spectranetics son catéteres intravasculares, disponibles en 7 modelos diferentes. El modelo 518-032 es un catéter de 3,0 French (Fr.) de diámetro exterior, compatible con una guía de 0,014 pulgadas. Los modelos 518-033, 518-034 y 518-035 son catéteres de 3,4 Fr de diámetro exterior, compatibles con guías de 0,018 pulgadas. Los modelos 518-036, 518-037 y 518-038 son catéteres de 4,8 Fr. de diámetro exterior compatibles con guías de 0,035 pulgadas. Todos los modelos tienen 3 marcadores radiopacos equidistantes a lo largo del eje distal que sirven para estimar la geometría dentro del sistema vascular. El marcador radiopaco distal está situado a menos de 3 mm de la punta distal del catéter. El extremo proximal de cada modelo de catéter lleva un conector lúer hembra estándar. Los 40 cm distales de cada uno de los modelos de catéter está recubierto con una capa hidrofílica lubricante.

El modelo número 518-032 tiene un eje de rigidez variable con un diámetro proximal de 3,0 Fr. en disminución hasta un diámetro distal de 1,9 Fr.

Los modelos números 518-033, 518-034 y 518-035 tienen un eje de rigidez variable con un diámetro proximal de 3,4 Fr. en disminución hasta un diámetro distal de 2,2 Fr.

Los modelos números 518-036, 518-037 y 518-038 tienen un eje de rigidez variable con un diámetro proximal de 4,8 Fr. en disminución hasta un diámetro distal de 3,7 Fr.



Especificaciones

	518-032	518-033	518-034	518-035	518-036	518-037	518-038
Guía máxima, pulg.	0,014	0,018	0,018	0,018	0,035	0,035	0,035
Longitud de trabajo del catéter, cm	135	90	135	150	90	135	150
Longitud mínima de la guía, cm	180	150	180	180	150	180	180
Espaciado de los marcadores radiopacos, mm	15	15	15	15	50	50	50
Diámetro del eje proximal, pulg.	0,039	0,044	0,044	0,044	0,063	0,063	0,063
Diámetro del eje distal, pulg.	0,025	0,029	0,029	0,029	0,048	0,048	0,048
Diámetro exterior de la punta, pulg.	0,021	0,025	0,025	0,025	0,041	0,041	0,041
Diámetro interior de la punta, pulg.	0,016	0,020	0,020	0,020	0,037	0,037	0,037
Catéter guía mínimo, Fr.	6	6	6	6	6	6	6
Vaina introductora mínima, Fr.	5	5	5	5	5	5	5

Notas

Los catéteres Support² Quick-Cross™ de Spectranetics han sido esterilizados con óxido de etileno y se suministran ESTÉRILES. Los dispositivos están indicados y diseñados para UN ÚNICO USO y no deben reesterilizarse ni utilizarse por segunda vez.

Conserve este producto en un lugar fresco y seco, al resguardo de la luz directa del sol y de las temperaturas altas *(más de 60 °C o 140 °F)*.

La esterilidad del producto está garantizada únicamente si el envase está cerrado y en buen estado. Antes de utilizar el producto, examine visualmente el envase estéril para asegurarse de que los sellos estén intactos. No

utilice el catéter si la integridad del envase está comprometida. No utilice el catéter si la "fecha de caducidad" que figura en la etiqueta del envase ha vencido.

Antes de utilizar el producto, examine cuidadosamente todo el equipo que se va a utilizar para ver si presenta defectos. No utilice un equipo si está dañado.

Una vez utilizado, deseche todo el equipo de acuerdo con los requisitos específicos aplicables referentes a materiales de desecho y a materiales que representen potencialmente un peligro biológico.

Indicaciones de uso

Los catéteres Support^2 Quick-Cross™ de Spectranetics son dispositivos de infusión y de cambio de guías, diseñados para utilizarse en el sistema vascular. Los catéteres están concebidos para apoyar una guía durante el acceso a la vasculatura, permitir el cambio de guías, y para proporcionar un conducto para el suministro de soluciones salinas o medios de contraste para diagnóstico.

Modo de empleo

Nota: Siga las instrucciones de uso para todo el equipo que se vaya a utilizar con los catéteres Support^2 Quick-Cross™. Por ejemplo, catéteres guía, vainas introductoras y guías.

1. Preparación: mediante una técnica estéril, abra el envase estéril. Extraiga suavemente el aro protector con el catéter de la bolsa. Llene una jeringa lúer-lock estéril estándar con solución salina estéril. Antes de separar el catéter del aro, conecte la jeringa al acople lúer proximal del catéter, irrigue el catéter y espere a que la solución salina llene el aro. Deje el catéter en el aro a un lado hasta que vaya a utilizarlo.
2. Inserción: a través de un catéter guía o vaina introductora del tamaño adecuado, previamente inserto, introduzca el catéter sobre una guía del tamaño adecuado (véase las especificaciones) con ayuda de una técnica estándar.
3. Avance: bajo visualización fluoroscópica, avance el catéter hasta el lugar deseado dentro de la vasculatura.
4. Extracción: extraiga suavemente el catéter mediante una técnica estándar, con cuidado de mantener la posición de la guía si ésta debe dejarse colocada en su lugar.
8. Infusión: para realizar la infusión, extraiga la guía y consulte la tabla a continuación. Nota: la presión de infusión de entrada no debe ser superior a 300 psi.

Velocidades del flujo de infusión (ml/segundo) de Quick-Cross™ a presiones de inyección de 150 y 300 psi para soluciones salinas y de contraste

			Salina estéril		Contraste*	
Modelo	Tamaño	Longitud	150 psi	300 psi	150 psi	300 psi
518-032	0,014	135	1,1	1,6	0,4	1,0
518-033	0,018	90	2,0	2,9	0,8	1,6
518-034	0,018	135	1,8	2,5	0,7	1,2
518-035	0,018	150	1,7	2,4	0,6	1,2
518-036	0,035	90	6,8	10,0	4,2	7,2
518-037	0,035	135	5,6	8,5	3,4	6,1
518-038	0,035	150	5,4	8,0	3,2	5,5

* mezcla del 75/25 de contraste Optiray 320 / solución salina estéril

Advertencias y precauciones:

- La presión de infusión máxima recomendada es 300 psi.
- El catéter está diseñado e indicado para uso intravascular solamente.
- Este catéter está diseñado e indicado para utilizarse una sola vez. No lo reesterilice ni lo vuelva a utilizar.

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

- Inspeccione el catéter detenidamente antes de utilizarlo para verificar que no ha sufrido daños durante el envío y que su estado es adecuado para el procedimiento.
- El catéter no debe avanzarse por una zona de resistencia a menos que se identifique la causa de la resistencia mediante fluoroscopia y se tomen las medidas pertinentes para reducir o eliminar la obstrucción.
- El catéter únicamente debe manipularse bajo fluoroscopia.
- El catéter no deberá avanzarse en un vaso que tenga un diámetro menor que el diámetro exterior del catéter.
- Utilice únicamente guías del diámetro y la longitud recomendados.
- Si el catéter se utiliza para infusión, consulte la tabla de velocidades de flujo y asegúrese de que la presión de infusión no exceda las recomendaciones.
- Este catéter sólo debe ser utilizado por médicos cualificados para realizar intervenciones vasculares por vía percutánea.
- No introduzca aire ni otro tipo de gas a través del catéter en el sistema vascular.

Efectos adversos:
El cateterismo vascular y/o las intervenciones vasculares pueden conllevar, entre otras, las siguientes complicaciones:

- Disección, perforación, rotura u oclusión total del vaso
- Angina inestable
- Embolia
- hipo- o hipertensión
- Infarto agudo de miocardio
- Arritmia, incluyendo fibrilación ventricular
- Muerte

Exoneración de responsabilidad:
Spectranetics ofrece una garantía limitada exclusiva para este producto. Spectranetics garantiza que este producto funcionará según lo especificado en las Instrucciones de uso durante el período de tiempo hasta la "fecha de caducidad" del producto.

Cathéters Support² *Quick-Cross*™ Spectranetics

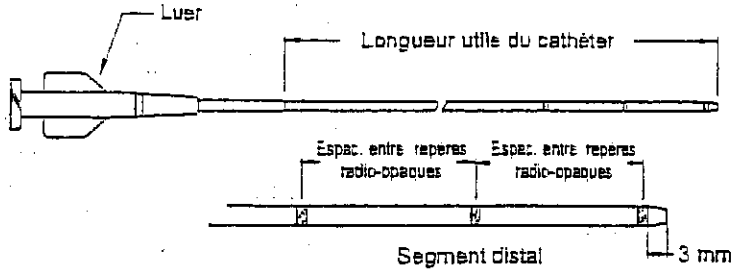
Mode d'emploi

Description
Les cathéters Support² Quick-Cross™ Spectranetics sont des cathéters intravasculaires, disponibles en 7 modèles. Le modèle 518-032 est un cathéter de diamètre externe de 3,0 Fr., compatible avec un guide de 0,014 pouce. Les modèles 518-033, 518-034 et 518-035 sont des cathéters de diamètre externe de 3,4 Fr., compatibles avec des guides de 0,018 pouce. Les modèles 518-036, 518-037 et 518-038 sont des cathéters de diamètre externe de 4,8 Fr., compatibles avec des guides de 0,035 pouce. Tous les modèles portent trois marqueurs radio-opaques également espacés le long de la tige distale pour aider à estimer la géométrie à l'intérieur du système vasculaire. Le marqueur radio-opaque distal est positionné à 3 mm de l'extrémité distale du cathéter. L'extrémité proximale de chaque modèle comporte un raccord luer femelle standard. Le segment distal de 40 cm de chaque modèle de cathéter est enduit d'un revêtement hydrophile lubrifiant.

Le numéro de modèle 518-032 possède une tige de rigidité variable présentant un diamètre proximal de 3 Fr. décroissant à 1,9 Fr. sur son segment distal.

Les numéros de modèle 518-033, 518-034 et 518-035 possèdent une tige de rigidité variable présentant un diamètre proximal de 3,4 Fr. décroissant à 2,2 Fr. sur son segment distal.

Les numéros de modèle 518-036, 518-037 et 518-038 possèdent une tige de rigidité variable présentant un diamètre proximal de 4,8 Fr. décroissant à 3,7 Fr. sur son segment distal.



Caractéristiques

	518-032	518-033	518-034	518-035	518-036	518-037	518-038
Diamètre max. du guide, po.	0,014	0,018	0,018	0,018	0,035	0,035	0,035
Longueur utile du cathéter, cm	135	90	135	150	90	135	150
Longueur min. du guide, cm	180	150	180	180	150	180	180
Esp. entre marq. radio-op., mm	15	15	15	15	50	50	50
Diam. de la tige proximale, po.	0,039	0,044	0,044	0,044	0,063	0,063	0,063
Diam. de la tige distale, po.	0,025	0,029	0,029	0,029	0,048	0,048	0,048
D. E. de l'extrémité, po.	0,021	0,025	0,025	0,025	0,041	0,041	0,041
D. I. de l'extrémité, po.	0,016	0,020	0,020	0,020	0,037	0,037	0,037
Diam. min. du cathéter guide, Fr.	6	6	6	6	6	6	6
Diam. min. de la gaine d'intro., Fr.	5	5	5	5	5	5	5

Remarques

Les cathéters Support^2 Quick-Cross™ Spectranetics ont été stérilisés à l'oxyde d'éthylène et sont fournis STÉRILES. Ils sont conçus et destinés exclusivement à un USAGE UNIQUE et ne doivent pas être restérilisés ni réutilisés.

Conserver dans un endroit frais et sec. Protéger de la lumière directe du soleil et des températures élevées *(supérieures à 60 °C)*.

La stérilité du produit n'est garantie que si l'emballage n'a pas été ouvert ou endommagé. Examiner l'emballage avant l'utilisation pour s'assurer que les témoins de stérilité sont intacts. Ne pas utiliser le cathéter si l'emballage a été endommagé. Ne pas utiliser le cathéter si sa date de péremption (Utiliser avant le) indiquée sur son emballage est dépassée.

Vérifier soigneusement avant l'utilisation que tout le matériel à utiliser ne présente aucun défaut. Ne pas utiliser du matériel endommagé.

Après l'utilisation, jeter tout le matériel conformément aux exigences particulières en vigueur se rapportant aux déchets hospitaliers et aux matières présentant des risques biologiques.

Indications

Les cathéters Support^2 Quick-Cross™ Spectranetics sont des dispositifs de perfusion et d'échange sur guide conçus pour être utilisés dans le système vasculaire. Les cathéters ont pour but de soutenir un guide lors d'un abord intravasculaire, de permettre un échange sur guide et de fournir une voie d'administration de sérum physiologique ou de produits de contraste à des fins diagnostiques.

Mode d'emploi

Remarque : Observer le mode d'emploi de tout le matériel à utiliser avec les cathéters Support^2 Quick-Cross™, tel que les cathéters guides, les gaines d'introduction et les guides.

1. Préparation : Ouvrir l'emballage stérile en respectant les règles d'asepsie. Retirer délicatement le moule de protection et le cathéter de la pochette. Remplir une seringue luer lock standard stérile de sérum physiologique stérile. Avant de retirer le cathéter du moule, fixer la seringue au raccord luer proximal du cathéter, rincer le cathéter et laisser le sérum physiologique remplir le moule. Mettre le cathéter dans le moule de côté jusqu'à son utilisation.

2. Insertion : Introduire le cathéter sur un guide de diamètre approprié (consulter les caractéristiques) par une gaine d'introduction ou un cathéter guide de diamètre approprié préalablement inséré en recourant à la technique habituelle.
3. Progression : Avancer le cathéter sous contrôle radioscopique jusqu'au site vasculaire voulu.
4. Retrait : Retirer doucement le cathéter par la technique habituelle, en veillant à maintenir la position du guide si celui-ci doit rester en place.
9. Perfusion : Pour réaliser une perfusion, retirer le guide et consulter le tableau ci-dessous. Remarque : Ne pas dépasser une pression de perfusion de 20 bars.

Débits de perfusion par cathéters Quick-Cross™ (ml/seconde) à des pressions d'injection de sérum physiologique et de produits de contraste entre 10 et 20 bars

			Sérum physiologique stérile		Produit de contraste*	
Modèle	Diamètre	Longueur	10 bars	20 bars	10 bars	20 bars
518-032	0,014	135	1,1	1,6	0,4	1,0
518-033	0,018	90	2,0	2,9	0,8	1,6
518-034	0,018	135	1,8	2,5	0,7	1,2
518-035	0,018	150	1,7	2,4	0,6	1,2
518-036	0,035	90	6,8	10,0	4,2	7,2
518-037	0,035	135	5,6	8,5	3,4	6,1
518-038	0,035	150	5,4	8,0	3,2	5,5

* Mélange à 75-25 de produit de contraste Optiray 320 et de sérum physiologique stérile

Avertissements et mises en garde :

- La pression de perfusion maximum recommandée est de 20 bars.
- Le cathéter est conçu et destiné à être utilisé uniquement pour un abord intravasculaire.
- Ce cathéter est exclusivement réservé à un usage unique. **Ne pas restériliser ni réutiliser.**
- Examiner soigneusement le cathéter avant son utilisation pour s'assurer qu'il n'a pas été endommagé en cours d'expédition et qu'il est en état d'être utilisé.
- Ne pas forcer le cathéter dans une zone de résistance sans avoir préalablement identifié la source de résistance sous radioscopie et pris les mesures nécessaires pour réduire ou éliminer l'obstruction.
- Ne manipuler le cathéter que sous radioscopie.
- Ne pas faire avancer le cathéter dans un vaisseau dont le diamètre est plus petit que le diamètre externe du cathéter.
- Utiliser uniquement les guides de diamètre et de longueur recommandés.
- Si le cathéter est utilisé pour une perfusion, consulter le tableau de débit et s'assurer que la pression de perfusion ne dépasse pas les recommandations.
- Ce cathéter ne doit être utilisé que par des praticiens habilités à réaliser des interventions vasculaires percutanées.
- Éviter d'introduire de l'air ou des gaz dans le système vasculaire par le cathéter.

Effets indésirables :

Parmi les complications possibles associées au cathétérisme et aux interventions vasculaires, on citera :

- Dissection, perforation, rupture ou occlusion vasculaire totale

- Angor instable
- Embolie
- Hypo/hypertension
- Infarctus aigu du myocarde
- Arythmie, y compris une fibrillation ventriculaire
- Décès

Clause limitative de garantie :
Spectranetics offre ce dispositif sous garantie limitée exclusive. Spectranetics garantit que ce dispositif fonctionnera ainsi que le spécifie le mode d'emploi pendant la période de temps précédant sa date de péremption.

Spectranetics *Quick-Cross*™ Support²-katetrar

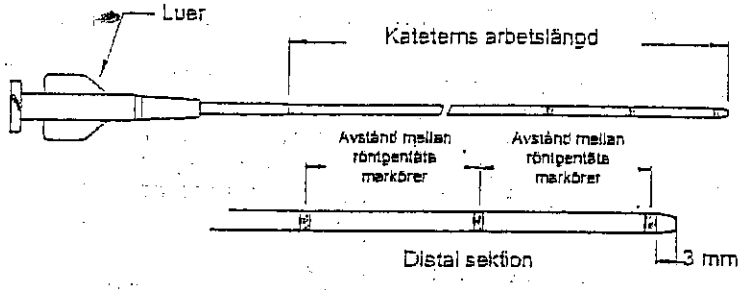
Bruksanvisning

Beskrivning
Spectranetics Quick-Cross™ Support²-katetrar utgör intravaskulära katetrar som tillhandahålls i 7 modeller. Modell 518-032 är en 0,014-tums ledarkompatibel kateter med 3,0 Fr. ytterdiameter. Modell 518-033, 518-034 och 518-035 är en 0,018-tums ledarkompatibel kateter med 3,4 Fr. ytterdiameter. Modell 518-036, 518-037 och 518-038 är en 0,035-tums ledarkompatibel kateter med 4,8 Fr. ytterdiameter. Alla modellerna uppvisar 3 röntgentäta markörer på inbördes lika avstånd längs det distala skaftet. Dessa används för att underlätta beräkning av kärlsystemets geometri. Den distala röntgentäta markören sitter inom 3 mm från den distala kateterspetsen. En standardhonkoppling med luerlås placeras på proximal ände av respektive modell. Varje katetermodells distala 40 cm har försetts med en glatt, hydrofil beläggning.

Modell nummer 518-032 har ett skaft av varierande styvhet med en proximal skaftdiameter på 3,0 Fr. som avsmalnar till en distal skaftdiameter på 1,9 Fr.

Modell nummer 518-033, 518-034 och 518-035 har ett skaft av varierande styvhet med en proximal skaftdiameter på 3,4 Fr. som avsmalnar till en distal skaftdiameter på 2,2 Fr.

Modell nummer 518-036, 518-037 och 518-038 har ett skaft av varierande styvhet med en proximal



skaftdiameter på 4,8 Fr. som avsmalnar till en distal skaftdiameter på 3,7 Fr.

Specifikationer

	518-032	518-033	518-034	518-035	518-036	518-037	518-038
Maximal ledare, tum	0,014	0,018	0,018	0,018	0,035	0,035	0,035
Kateterns arbetslängd, cm	135	90	135	150	90	135	150
Min. ledarelängd, cm	180	150	180	180	150	180	180
Avstånd mellan röntgentät markör, mm	15	15	15	15	50	50	50
Proximal skaftdiameter, tum	0,039	0,044	0,044	0,044	0,063	0,063	0,063
Distal skaftdiameter, tum	0,025	0,029	0,029	0,029	0,048	0,048	0,048
Spetsens ytterdiameter, tum	0,021	0,025	0,025	0,025	0,041	0,041	0,041
Spetsens innerdiameter, tum	0,016	0,020	0,020	0,020	0,037	0,037	0,037
Min. styrkateter, Fr.	6	6	6	6	6	6	6
Min. introducerskida, Fr.	5	5	5	5	5	5	5

Anteckningar

Spectranetics Quick-Cross™ Support²-katetrar har steriliserats med etylenoxid och levereras STERILA. Enheterna är betecknade med och avsedda ENDAST FÖR ENGÅNGSBRUK och får inte resteriliseras och/eller återanvändas.

Förvaras svalt och torrt. Skyddas från att utsättas för direkt solljus och höga temperaturer *(högre än 60 °C eller 140 °F)*.

Produktens sterilitet garanteras endast om förpackningen är oöppnad och oskadad. Före användning, inspektera den sterila förpackningen och se till att förseglingarna är obrutna. Katetern får inte användas om förpackningens sterilitet har komprometterats. Katetern får inte användas efter det "Används före" datum som anges på förpackningsetiketten.

Undersök all utrustning som ska användas för eventuella brister och defekter, före användning. Använd inte någon utrustning som är skadad.

Kassera all utrustning efter användning, i enlighet med gällande specifika krav beträffande sjukhusavfall och potentiellt biologiskt riskavfall.

Indikationer

Spectranetics Quick-Cross™ Support²-katetrar utgör utrustning för ledarutbyte och infusion vid användning i kärlsystemet. Katetrarna är avsedda att stödja en ledare vid tillträde till kärlsystemet, möjliggöra utbyte av ledare samt skapa en tillförselväg för koksaltlösningar eller diagnostiska kontrastmedel.

Anvisningar

OBS! Följ bruksanvisningarna till all utrustning som ska användas med Quick-Cross™ Support² katetrar. Till exempel styrkatetrar, introducerskidor och ledare.

1. Förberedelse: Öppna den sterila förpackningen med hjälp av steril teknik. Ta försiktigt ut skyddsringen med kateter ur påsen. Fyll en steril, Luerlås-försedd spruta av standardtyp med steril koksaltlösning. Anslut sprutan till kateterns proximala Luerpassning, spola katetern och låt ringen fyllas med koksaltsaltlösning innan katetern avlägsnas ur ringen. Lägg katetern i ringen åt sidan, tills den ska tas i bruk.

2. Införing: Genom en tidigare införd, lämpligt dimensionerad styrkateter eller introducerskida, ska katetern föras in över en lämpligt dimensionerad ledare (se specifikationerna) med användning av vedertagna metoder.

3. Framskjutandet: För fram katetern under fluoroskopi till önskat läge i vaskulaturen.

4. Avlägsnande: Använd standardteknik och dra försiktigt tillbaka katetern. Var försiktig och behåll ledarens läge om den ska förbli på sin plats.

10. Infusion: Infundera genom att dra tillbaka ledaren under hänvisning till diagrammet nedan. OBS! Överskrid inte ett ingående infusionstryck på 300 psi.

Quick-Cross™ Infusionsflödeshastighet (ml/second) vid injiceringstryck på 150 och 300 psi för salt- och kontrastlösningar

			Steril saltlösning		Kontrast*	
Modell	Storlek	Längd	150 psi	300 psi	150 psi	300 psi
518-032	0,014	135	1,1	1,6	0,4	1,0
518-033	0,018	90	2,0	2,9	0,8	1,6
518-034	0,018	135	1,8	2,5	0,7	1,2
518-035	0,018	150	1,7	2,4	0,6	1,2
518-036	0,035	90	6,8	10,0	4,2	7,2
518-037	0,035	135	5,6	8,5	3,4	6,1
518-038	0,035	150	5,4	8,0	3,2	5,5

* 75/25 Optiray 320 blandning av kontrast- / steril saltlösning

Varningar/försiktighetsåtgärder:

- Högsta rekommenderade infusionstryck är 300 psi.
- Katetern är endast utformad och avsedd för intravaskulärt bruk.
- Katetern är endast utformad och avsedd för engångsbruk. Får ej resteriliseras och/eller återanvändas.
- Vid omsorgsfull inspektion före användning ska det bekräftas att katetern inte har skadats vid transporten och att den är i lämpligt skick för proceduren.
- Katetern ska inte skjutas fram genom ett område som uppbjuder motstånd om inte upphovet till detta motstånd har identifierats genom fluoroskopi och lämpliga åtgärder vidtagits för att minska eller avlägsna hindret.
- Katetermanipulation får endast förekomma under fluoroskopi.
- Katetern ska inte föras fram i ett kärl som har en diameter som är mindre än katetems ytterdiameter.
- Använd endast ledare av rekommenderad diameter och längd.
- Om katetern används för infusion, måste tabellen med flödeshastigheter beaktas och infusionstrycket får inte överskrida det rekommenderade.
- Denna kateter får endast användas av läkare med behörighet att utföra perkutana, vaskulära interventioner.
- Undvik att föra in luft eller annan gas genom katetern och in i kärlsystemet.

Biverkningar:
Vaskulär kateterisering och/eller vaskulära interventioner kan resultera i komplikationer, bland annat:

- Kärldissektion, perforering, ruptur eller total ocklusion
- Instabil angina
- Emboli
- Lågt/högt blodtryck
- Akut myokardinfarkt
- Arrytmi, inklusive ventrikelflimmer
- Dödsfall

Friskrivning:
Spectranetics erbjuder en exklusiv begränsad garanti för denna produkt. Spectranetics garanterar att denna produkt fungerar enligt specifikationerna i denna bruksanvisning för den tidsperiod som avser produktens "Används före:"-datum.

Spectranetics

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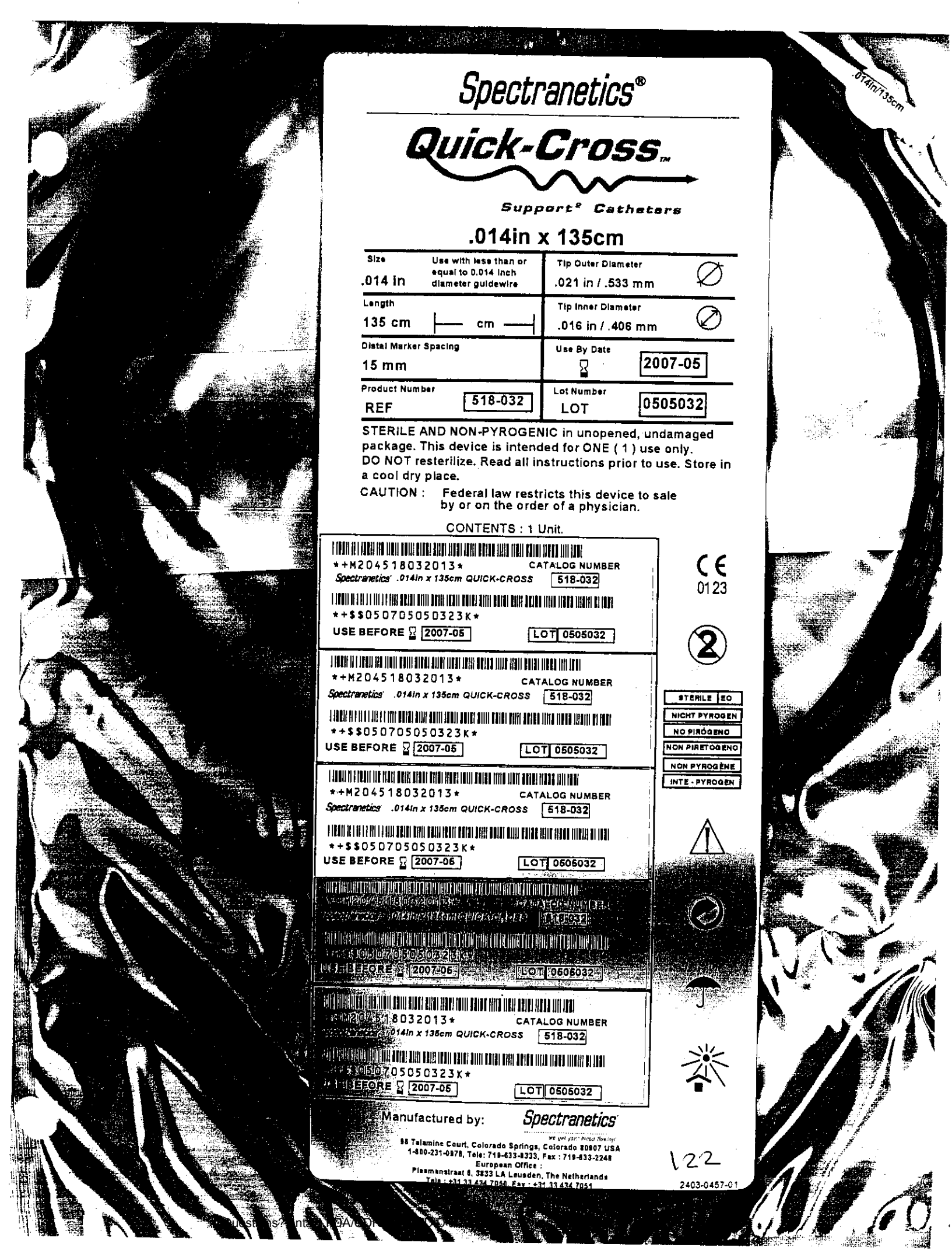

Spectranetics®

Quick-Cross™

Support² Catheters

.014in x 135cm

Size: .014 in — Use with less than or equal to 0.014 inch diameter guidewire	Tip Outer Diameter: .021 in / .533 mm
Length: 135 cm — cm	Tip Inner Diameter: .016 in / .406 mm
Distal Marker Spacing: 15 mm	Use By Date: 2007-05
Product Number: REF 518-032	Lot Number: LOT 0505032

STERILE AND NON-PYROGENIC in unopened, undamaged package. This device is intended for ONE (1) use only. DO NOT resterilize. Read all instructions prior to use. Store in a cool dry place.

CAUTION : Federal law restricts this device to sale by or on the order of a physician.

CONTENTS : 1 Unit.

+M204518032013 CATALOG NUMBER

Spectranetics .014in x 135cm QUICK-CROSS 518-032

+$$050705050323K

USE BEFORE 2007-05 LOT 0505032

+M204518032013 CATALOG NUMBER

Spectranetics .014in x 135cm QUICK-CROSS 518-032

+$$050705050323K

USE BEFORE 2007-05 LOT 0505032

+M204518032013 CATALOG NUMBER

Spectranetics .014in x 135cm QUICK-CROSS 518-032

+$$050705050323K

USE BEFORE 2007-06 LOT 0505032

CATALOG NUMBER 518-032

2007-06 LOT 0505032

CATALOG NUMBER

.014in x 135cm QUICK-CROSS 518-032

050705050323K*

BEFORE 2007-05 LOT 0505032

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STERILE EO

NICHT PYROGEN

NO PIRÓGENO

NON PIRETOGENO

NON PYROGÈNE

INTE - PYROGEN

Manufactured by: Spectranetics

we get your blood flowing!

9965 Talamine Court, Colorado Springs, Colorado 80907 USA
1-800-231-9978, Tele: 719-633-8333, Fax : 719-633-2248
European Office :
Plasmanstraat 6, 3833 LA Leusden, The Netherlands
Tele : +31 33 434 7050, Fax : +31 33 434 7051

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2403-0457-01

CLiRpath®
Cool Laser Revascularization for Peripheral Artery Therapy

***NEW!* 2nd Generation Enhancements based directly from physician feedback**

Quick-Cross® Support^2 Catheters

Access and Cross Tortuous Vasculature and Lesions

- **Three distal radiopaque markers** specifically spaced for improved assessment of vessel and lesion:
  - **Length** – allowing for most appropriate selection of stent length
  - **Geometry** – improved visibility and gauging of bends and angles based on known relationships of points
- **Low profile** for accessing and crossing small vessels and CTOs
- **Shapeable tip** for easy modification to access narrow take-offs
- **Variable stiffness** profile allows for excellent shaft force transmission to tip
- **Spectraglide® Plus coating** reduces sheath friction during access
- **Atraumatic tip** enables smooth passage through tight and tortuous anatomy
- **Non-latex** for peace-of-mind with latex sensitive patients

The only support catheter available with multiple distal markers for improved assessment of lesion and vessel LENGTH and GEOMETRY!

Multiple Radiopaque Markers: A .035" Quick-Cross in a right SFA being utilized for guidewire support

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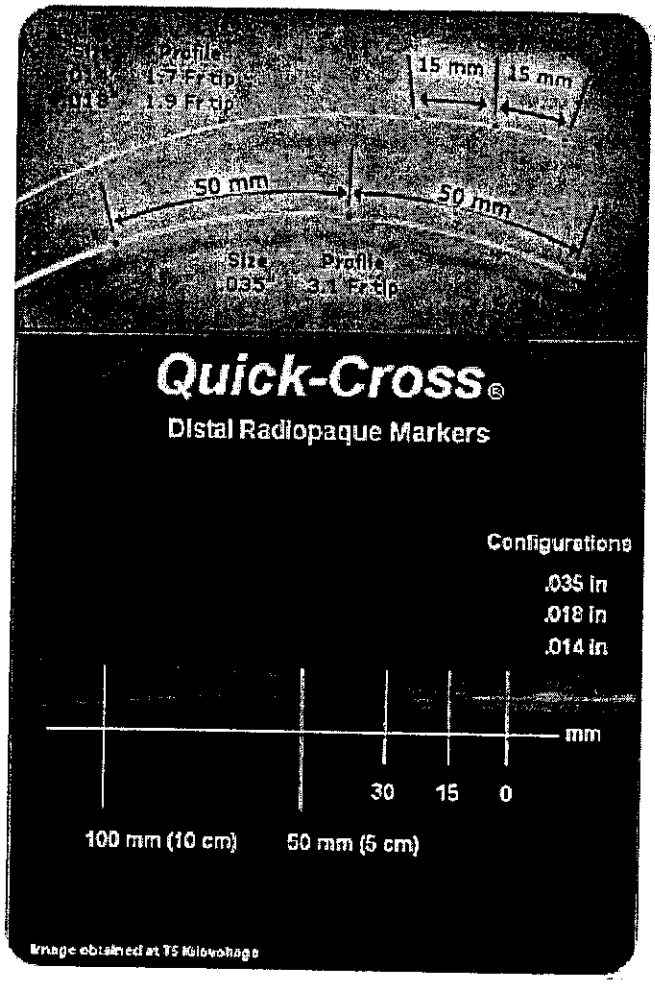

length. Distal markers are spaced 50mm apart.
Angiogram courtesy of Dr. M. A. Khan, Medical Center Plano, Plano, TX.

Assessing Lesion Length: A. The multiple radiopaque markers of a .014" Quick-Cross in a degenerated SVG being used to determine lesion length for proper DES placement. **B.** Same vessel and Quick-Cross catheter during contrast injection.
Angiograms courtesy of Dr. Philip Morales, Medical Center Plano, Plano, TX.

Click on angiograms to enlarge.

Quick-Cross® Support^2 Catheter Product Specifications

	.014"	.018"	.035"
Catheter Working Lengths		**Model Number**	
90 cm	—	518-033	518-036
135 cm	518-032	518-034	518-037
150 cm	—	518-035	518-038
Specifications			
Maximum Guidewire Diameter	0.014 inch	0.018 inch	0.035 inch
Distal Radiopaque Marker Spacing	15 mm	15 mm	50 mm
Proximal Shaft Outer Diameter	0.039 inch (3.0 Fr)	0.044 inch (3.4 Fr)	0.063 inch (4.8 Fr)
Distal Shaft Outer Diameter	0.025 inch (1.9 Fr)	0.029 inch (2.2 Fr)	0.048 inch (3.7 Fr)
Tip Outer Diameter	0.021 inch (1.7 Fr)	0.025 inch (1.9 Fr)	0.041 inch (3.1 Fr)

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Spectranetics
we get your blood flowing®

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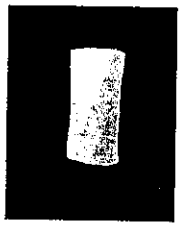
The Powerlink® System

Model #	Description	Proximal Diameter	Distal Diameter	Total Stent Length	Bifurcated Limb Length	Delivery System Outer Diameter
		All measurements in mm unless otherwise noted				
Bifurcated Devices						
28-16-155BL	Infrarenal Bifurcated Stent Graft	28	16	155	55	21 Fr
28-16-135BL	Infrarenal Bifurcated Stent Graft	28	16	135	55	21 Fr
28-16-140BL	Infrarenal Bifurcated Stent Graft	28	16	140	40	21 Fr
25-16-155BL	Infrarenal Bifurcated Stent Graft	25	16	155	55	21 Fr
25-16-135BL	Infrarenal Bifurcated Stent Graft	25	16	135	55	21 Fr
25-16-140BL	Infrarenal Bifurcated Stent Graft	25	16	140	40	21 Fr



Infrarenal Cuffs						
28-28-75L	Infrarenal Proximal Cuff	28	28	75		19 Fr
28-28-55L	Infrarenal Proximal Cuff	28	28	55		19 Fr
25-25-75L	Infrarenal Proximal Cuff	25	25	75		19 Fr
25-25-55L	Infrarenal Proximal Cuff	25	25	55		19 Fr

Limb Extensions						
20-20-55L	Limb Extension	20	20	55		17 Fr
16-16-88L	Limb Extension	16	16	88		17 Fr
16-16-55L	Limb Extension	16	16	55		17 Fr

Ancillary Products	
DL-35-90	Dual Lumen Catheter (90 cm total length)
HLS-1012.5	12.5 Fr Tear-Away Sheath (packaged and sold in boxes of 5 each)

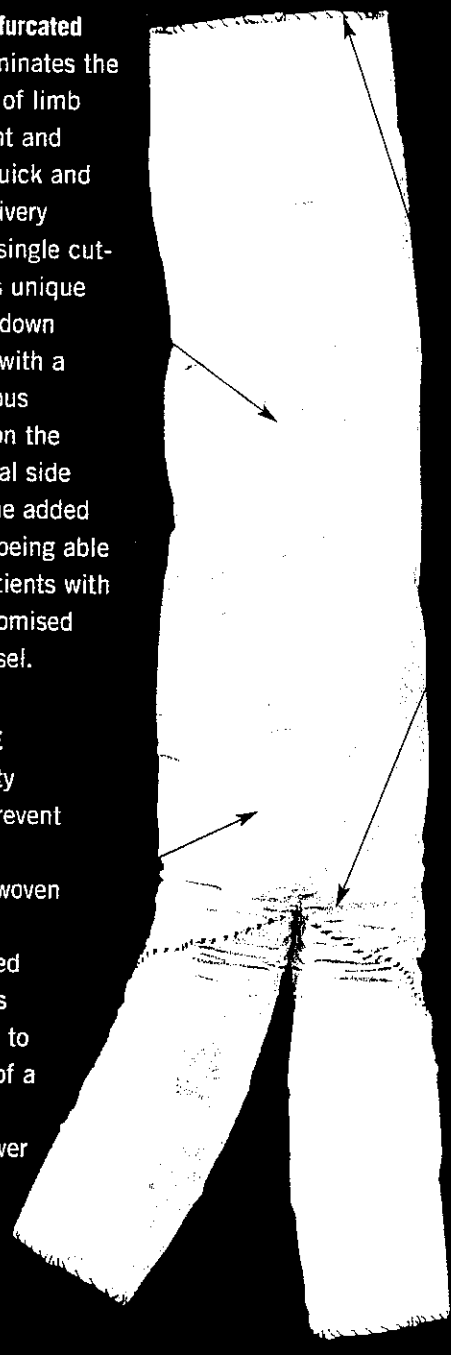
ENDOLOGIX

13900 Alton Parkway, Suite 122, Irvine, CA 92618 USA
Telephone: 949.595.7200
Customer Service: 800.983.2284 • Fax: 949.830.4463
Email: customerservice@endologix.com • www.endologix.com

The Powerlink® System for Abdominal Aortic Aneurysms

Unibody-Bifurcated Design eliminates the possibility of limb detachment and provides quick and simple delivery through a single cut-down. This unique single cut-down combined with a percutaneous approach on the contralateral side provides the added benefit of being able to treat patients with one compromised access vessel.

Proprietary ePTFE has a low-porosity formulation to prevent contrast "blush" associated with woven grafts, while it's strong, thin-walled design minimizes fabric "pleating" to allow treatment of a broader range of anatomy with fewer graft sizes.



Single-wire Construction provides proven durability and contributes to column strength.

Long Main Body mimics native aortic anatomy and provides good column strength to inhibit late migration.

Fully Supported to reduce risk of limb kinking and thrombosis.

ENDOLOGIX

The Powerlink System is the endovascular graft of choice for its ease of delivery, durability, and solid clinical results.

The following pages have been copied from the referenced redacted 510(k).

DUAL LUMEN CATHETER*
(Peel Away Guidewire Introducer)
INSTRUCTIONS FOR USE
FOR SINGLE USE ONLY

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

PRODUCT DESCRIPTION OF SYSTEM

The Dual Lumen Catheter is designed to allow for the insertion of two guidewires into a single vessel, preventing them from crossing or entangling, and then allowing them to separately advance to different vessels. The Dual Lumen Catheter consists of two lumens: one lumen allows the guidewire to advance along its length, and the second lumen allows separation and release of the second guidewire via two skives located 35cm apart and peeling along its length. A radiopaque marker is located at the proximal skive to aid in positioning of the catheter. The Dual Lumen Catheter is available to fit into an introducer catheter with an outer diameter of 9F, and has a working length of 90cm. The proximal end of the catheter consists of a female luer connector.

INTENDED USE

The Dual Lumen Catheter is intended for use during a two guidewire procedure.

CONTRAINDICATIONS

The Dual Lumen Catheter is contraindicated in patients in which radiographic contrast or imaging agents are contraindicated.

POTENTIAL COMPLICATIONS

Potential complications with this procedure may include, but are not limited to:

Vessel perforation	Vessel dissection
Hematoma at site of entry	Wound infection

***Patent Pending**
Endologix, Inc.
20 Fairbanks, Suite #173, Irvine, CA 92618
(949) 830-9433

PRECAUTIONS

1. The Dual Lumen Catheter shall be used only by physicians trained in vascular surgery, interventional radiology, or interventional cardiology.

2. The Dual Lumen Catheter should be handled with care to avoid excessive bending or kinking of the catheter, which may result in an inability to properly advance the guidewires.

3. To avoid insertion difficulties or tissue injury, never advance this device without the use of fluoroscopic guidance.

4. The Dual Lumen Catheter is not intended to be used to infuse radiographic contrast agents.

READ ALL INSTRUCTIONS THOROUGHLY BEFORE USE. THE DUAL LUMEN CATHETER IS NOW READY FOR USE

INSTRUCTIONS FOR USE

1. Perform standard procedure to access vessel.

2. Flush lumen.

3. Advance a 0.035" guidewire to the desired location for the Dual Lumen Catheter placement.

4. Advance the Dual Lumen Catheter over this guidewire via the inner reinforced catheter lumen.

5. Advance the Dual Lumen Catheter so that the radiopaque marker (located at the proximal skive of the outer catheter lumen), is in the desired location.

6. Remove the guidewire.

7. Insert the first guidewire through the inner reinforced catheter lumen.

8. Insert the second guidewire into the distal skive until it exits the proximal skive. This will keep the two guidewires separated.

9. To remove the second guidewire, retract the inner reinforced catheter lumen, and the guidewire will separate as the outer catheter lumen peels away.

WARNING: CATHETER ADVANCEMENT SHOULD BE PERFORMED UNDER FLUOROSCOPIC GUIDANCE. DO NOT USE EXCESSIVE FORCE TO ADVANCE OR WITHDRAW THE CATHETER WHEN RESISTANCE IS ENCOUNTERED.

THE DUAL LUMEN CATHETER IS DESIGNED FOR SINGLE USE ONLY. DO NOT REUSE.

STORAGE

Store the Dual Lumen Catheter in a cool, dry place.

PRODUCT INFORMATION DISCLAIMER

ENDOLOGIX MEDICAL DEVICES ARE SOLD "AS IS" CONDITION. THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE DEVICES IS WITH THE BUYER. ENDOLOGIX DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, WITH RESPECT TO THE DEVICE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ENDOLOGIX SHALL NOT BE LIABLE TO ANY PERSON FOR ANY MEDICAL EXPENSES OR ANY DIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF ANY DEVICE, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND ENDOLOGIX TO ANY WARRANTY WITH RESPECT TO ITS MEDICAL DEVICES.

STERILIZATION

The Dual Lumen Catheter is a single use item and shipped sterile. Do not reuse. Sterile/Non-pyrogenic only if the package is not opened, damaged or broken. Do not re-sterilize.

REPACKAGING INSTRUCTIONS

In the event the device must be returned for any reason, return the Dual Lumen Catheter into its original package and shipping box. Contact Customer Service at (949) 830-9433, to receive a return authorization number prior to the return shipment.

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SYMBOLOGY LEGEND

SYMBOL	DESCRIPTION
	Product expiration date.
LOT	Lot number or work order number for the product.
STERILE EO	Method of sterility is Ethylene Oxide.
	See instructions for use for warnings, precautions and general instructions.
	Device is intended for use one time only. Do not reuse or re-sterilize.
CE 0123	CE Mark symbol with Notified Body registration number (TUV Product Services).
SN	Serial Number of the device.

EU AUTHORIZED REPRESENTATIVE

AGORA Technologie GmbH
P.O. Box 1117 D-79577 / Schloss
Str. 2 D79585 Steinen, Germany
Tel: (49) 7627-3193
Fax: (49) 7627-8541

Part Number C00078 Rev. XB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

K991601

OCT 28 1999

Ms. Karen U. Salinas
Vice President, RA/CA/QA
Endologix, Inc.
20 Fairbanks, Ste. 173
Irvine, CA 92618

Re: K991601
Trade Name: Dual Lumen Catheter
Regulatory Class: II
Product Code: DQY
Dated: September 2, 1999
Received: September 7, 1999

Dear Ms. Salinas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the *Quality System Regulation (QS) for Medical Devices: General* regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation

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you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

510(k) number (if known): K991601

Device Name: **Dual Lumen Catheter**

Indications for Use:

For use during a two guidewire procedure

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

for Spirstein

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991601

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ENDOLOGIX

Endologix, Inc.
20 Fairbanks, Suite #173
Irvine, CA USA 92618
(949) 830-9433 Fax (949) 830-4463

MODEL # : *DL-35-90* **DESCRIPTION:** *Dual Lumen Catheter*

SPECS : *Working Length - 90 cm*
Max. Wire OD - .035"
Fits into 9FR ID Introducer

CONTENTS : One (1) Dual Lumen Catheter

WARNING : Single use only. Contents are sterile and non-pyrogenic if the package is unopened or undamaged. DO NOT RESTERILIZE.

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

INTENDED USE : For use during a two-guidewire procedure.

LOT NO. : Wyy-#### **STERILE UNTIL:** YYYY-MM

Part Number F00026 Rev. XA

ENDOLOGIX

Endologix, Inc.
20 Fairbanks, Suite #173
Irvine, CA USA 92618
(949) 830-9433 Fax (949) 830-4463

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Part Number F00026 Rev. XA

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20 Fairbanks, Suite #173
Irvine, CA USA 92618
(949) 830-9433 Fax (949) 830-4463

MODEL # : *DL-35-90* **DESCRIPTION:** *Dual Lumen Catheter*

SPECS : *Working Length - 90 cm* vs 100
Max. Wire OD - .035"
Fits into 9FR ID Introducer vs 10F

CONTENTS : One (1) Dual Lumen Catheter

WARNING : Single use only. Contents are sterile and non-pyrogenic if the package is unopened or undamaged. DO NOT RESTERILIZE.

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

INTENDED USE : For use during a two-guidewire procedure.

LOT NO. : Wyy-#### **STERILE UNTIL:** YYYY-MM

Part Number F00026 Rev. XA

ENDOLOGIX

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Irvine, CA USA 92618
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Part Number F00026 Rev. XA

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LOT NO. : Wyy-#### **STERILE UNTIL:** YYYY-MM

Part Number F00026 Rev. XA

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SUBSTANTIAL EQUIVALENCE COMPARISON CHART

Teleflex Cook Quinton Instr.

PARAMETER				
Product Code	74 DYB/74 DQY	74 DYB	74 DYB/74 DQY	74 DYB
Classification Section	870.1340/870.1250	870.1340	870.1340/870.1250	870.1340
Classification Name	Catheter Introducer/Percutaneous Catheter	Catheter Introducer	Catheter Introducer/Percutaneous Catheter	Catheter Introducer
510(k) Reference Number	Not Applicable (N/A)	#K860307	#K895044/#K914856	#K844693
Intended Use	Introducer/Guidewire Catheter	Introducer Catheter	Introducer/Guidewire Catheter	Introducer Catheter
Design Technology	Peel away sheath and guidewire catheter	Peel away sheath	Guidewire catheter	Peel away sheath
Placement	Cardiovascular access	Cardiovascular access	Cardiovascular access	Cardiovascular access
Outer Diameter	9F	4F to 18F	5F to 18F	Unknown
Working Length	35cm	~ 15cm	7cm to 85cm	Unknown
Main Components	Catheter Connector Radiopaque Marker	Catheter Connector Pull Tabs	Catheter Connector Radiopaque Band/Catheter Pull Tabs	Unknown
Main Materials	Pebax Polycarbonate Gold	Fluorinated Ethylene Propylene Polyethylene Barium Sulfate Polypropylene Other materials unknown	Teflon Fluorinated Ethylene Propylene Other materials unknown	Unknown
How Supplied	Disposable/ single use/ sterile	Disposable/ single use/ sterile	Disposable/ single use/ sterile	Disposable/ single use/ sterile

Appendix D: Predicate Device Literature

Lumend Percutaneous Catheter, K011562

Quick-Cross Support Catheter, K033678

Dual Lumen Catheter, K991601

Appendix E: Summary of Safety and Effectiveness

Common/Usual Name: Intravascular Catheter

Product Trade Name: Twin-Pass™ Dual Access Catheter

Classification Name: Unclassified
Product Code: DQY

Manufacturer: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, Minnesota 55369
USA

Establishment Registration: 2134812

Contact: Sara L. Coon
Senior Regulatory Affairs Associate
(763) 656-4300 phone
(763) 656-4200 fax

Performance Standards: No performance standards have been developed under section 514 for this device.

Device Description:
The Twin-Pass Dual Access Catheter is a 3F O.D. catheter that has two lumens—a short distal lumen and a second full length lumen—each of which are compatible with a 0.014" standard guide wire. The Twin-Pass catheter has a working length of 135cm and contains positioning markers at 95 and 105cm which provide a visual indication of the relative positions of Twin Pass and the end of a standard 105cm guide catheter. Two radiopaque marker bands at the end of each wire lumen provide for a radiographic means of locating the position of each lumen. The softer, distal end of the catheter is coated with a hydrophilic coating to assist passage through the guide catheter and vessels while the proximal end of the catheter contains a strain relief and a standard luer hub. A 126cm stiffening mandrel is included which provides support and pushability to the Twin-Pass.

Intended Use:
The Twin-Pass Dual Access Catheter is to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

Summary of Non-Clinical Testing:
Testing conducted included assessments of the design verification of the Twin-Pass Dual Access Catheter along with biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Twin-Pass Dual Access Catheter for its intended use.

Summary of Clinical Testing:
No clinical evaluations of this product have been conducted.

Predicate Device:
The Twin-Pass Dual Access Catheter is similar in intended use and function to the Lumend Percutaneous Catheter, the Quick-Cross Catheter, and the Dual Lumen Catheter.

Conclusions:
The Twin-Pass Dual Access Catheter is substantially equivalent to the Lumend Percutaneous Catheter, the Quick-Cross Catheter, and the Dual Lumen Catheter. The testing performed confirms that the Twin-Pass Dual Access Catheter will perform as intended.

Appendix F: Engineering Prints

(b)(4) Schematic drawing

(b)(4) Schematic drawing

Appendix G: Biocompatibility Testing Report

SR 1267

Non-Clinical Study Protocol:

Biocompatibility Evaluation of Pronto V3, Skyway and Sidekick Catheters

(b)(4) Testing

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

6. STUDY DESIGN

(b)(4) Testing

[redacted]

The following table lists the components required to manufacture the Pronto V3, Skyway and Sidekick catheters including the material description.

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

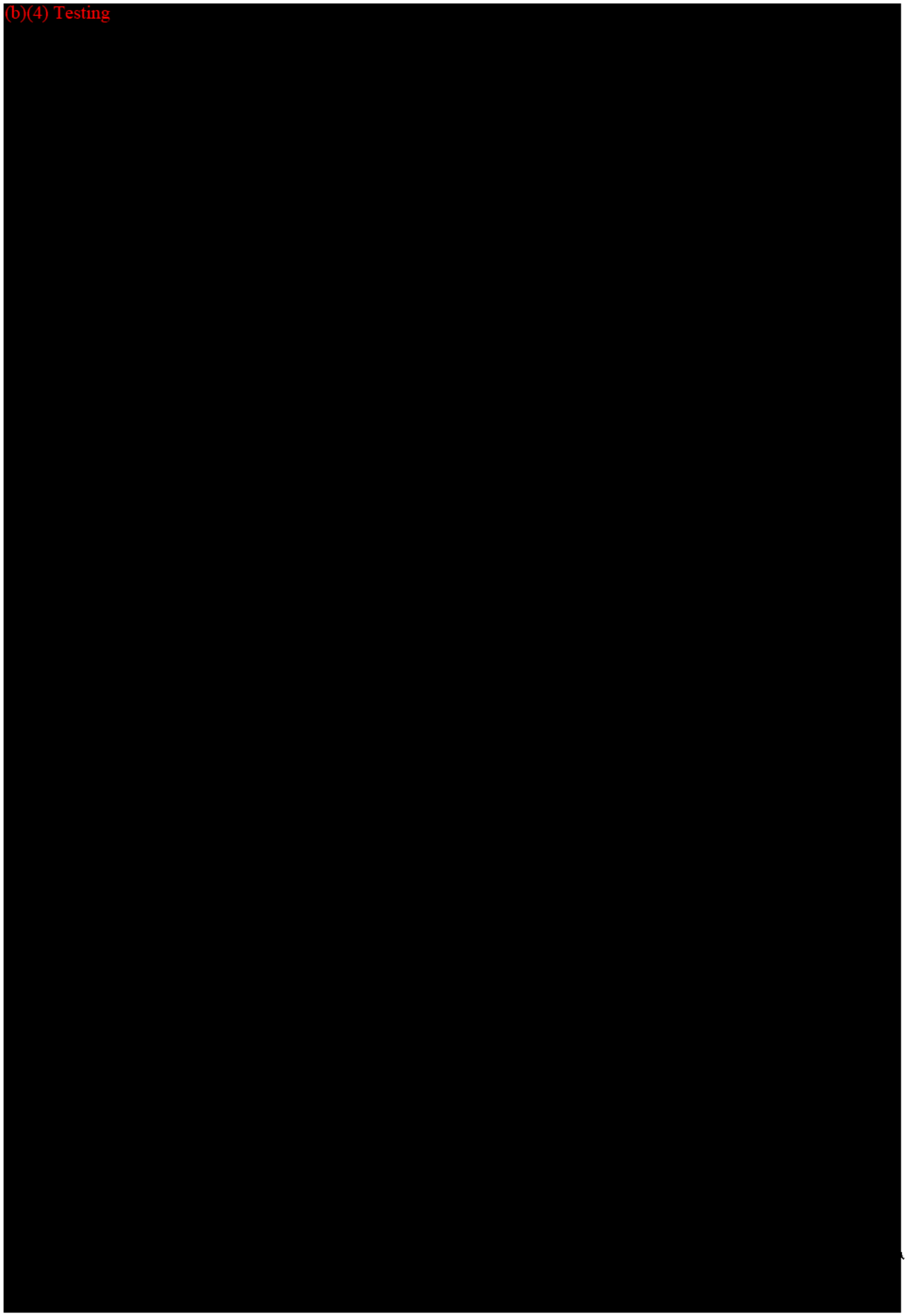
The following table lists the sample requirements for each test:

(b)(4) Testing

[redacted]

6.2. Study Test System

(b)(4) Testing



(b)(4) Testing

[redacted]

Appendix G: Biocompatibility Testing Report

SR 1267

9 Omk
5/25/05

Non-Clinical Study Report:

Biocompatibility Evaluation of Pronto V3, Skyway and Twin-Pass Catheters

(b)(4) Testing

[redacted]

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-- Contents --

1. INTRODUCTION & STUDY PURPOSE

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

5. STUDY PROTOCOL DESCRIPTION

(b)(4) Testing

[redacted]

6. ASSESSMENT OF STUDY RESULTS

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

(b)(4) Testing

[redacted]

8. ATTACHMENTS

(b)(4) Testing

Attachment 1:
Materials Identification Table
(1 Page)

TABLE A

Material matrix for the Biocompatibility test-catheter used in SR1267

VSI Part Number	Description	Material	Where used
20-0666	(b)(4) Testing		
21-0388-01			
21-0398, 21-0381			
21-0397, 21-0391			
51-0326			
20-0450-05			
21-0396			
21-0396			
21-0396, 21-0380			
21-0396			
21-0396			
21-0396			
21-0390-TAB			
20-0646 and 20-0645			
0059			
21-0383			
20-0653			
0159-01			
0160			
31-0308			
20-0643			
20-0492			
20-0494			

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Attachment 2:

(b)(4) Testing

[redacted]

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

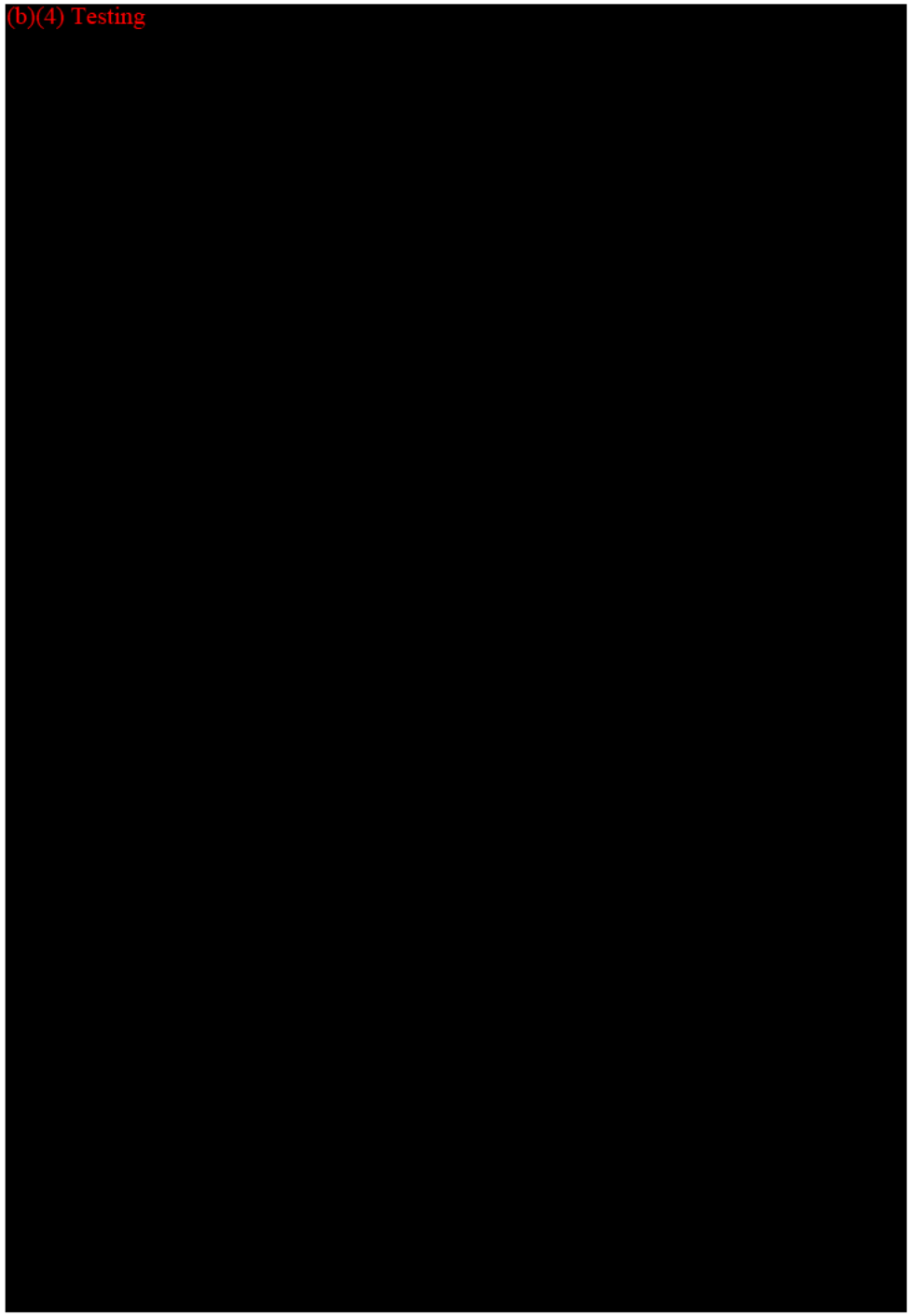
[redacted]

Attachment 4:

(b)(4) Final Report: 05-0798-G3

Intracutaneous Injection Test ISO

(14 Pages)


(b)(4) Testing

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A0

(b)(4) Testing [redacted]

STUDY SUMMARY

(b)(4) Testing [redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

[redacted]

Attachment 5:
(b)(4) Final Report: 05-0798-G4
Systemic Injection Test - ISO
(12 Pages)

(b)(4) Testing

[redacted]

MANAGEMENT OF THE STUDY

(b)(4) Testing

[redacted]

TABLE OF CONTENTS

STUDY SUMMARY

(b)(4) Testing

(b)(4) Testing

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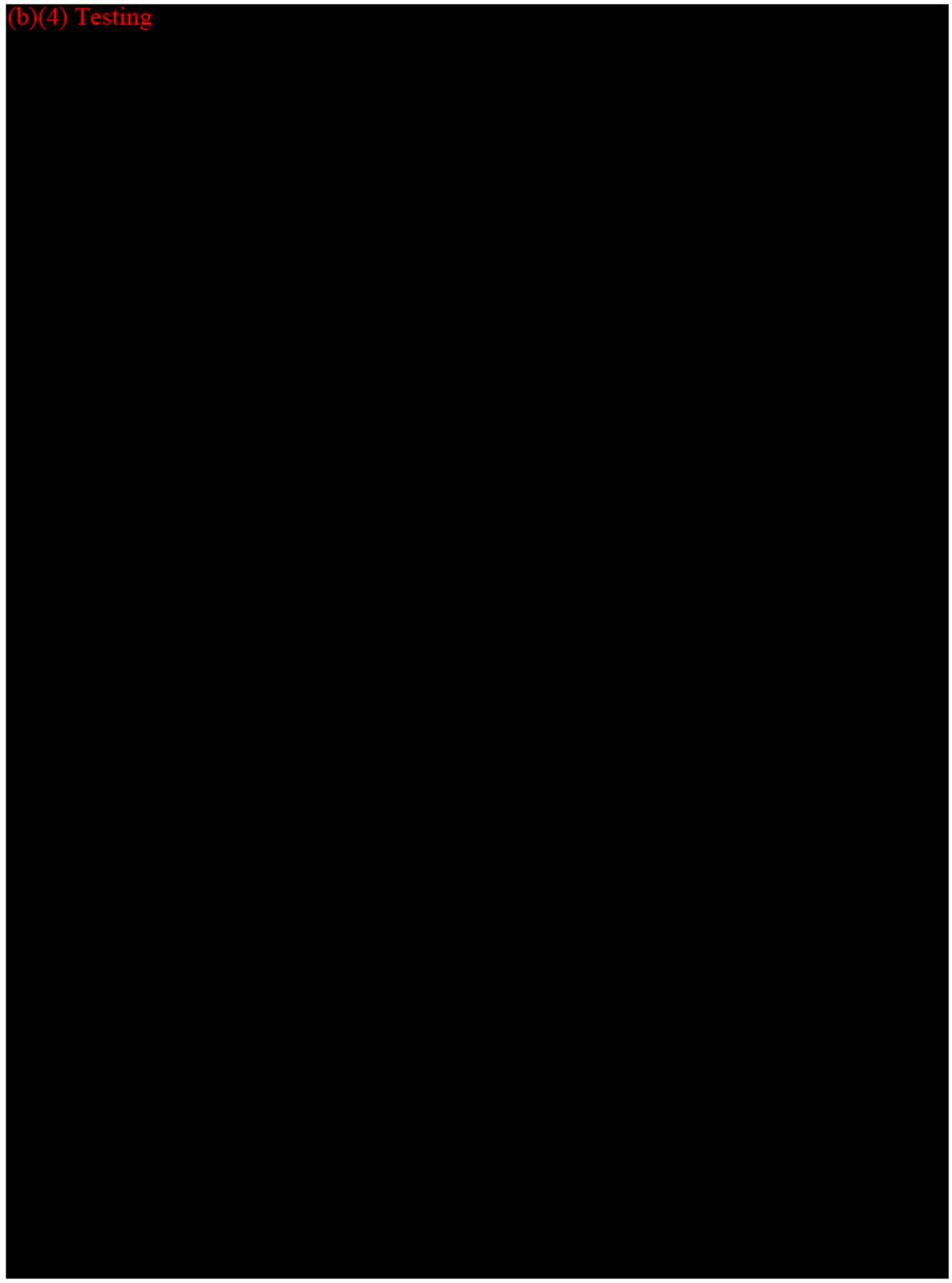
(b)(4) Testing

[redacted]

Attachment 6:
(b)(4) Final Report: 05-0798-G5
Rabbit Pyrogen Test (Material Mediated) - ISO
(12 Pages)

(b)(4) Testing



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STUDY SUMMARY

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

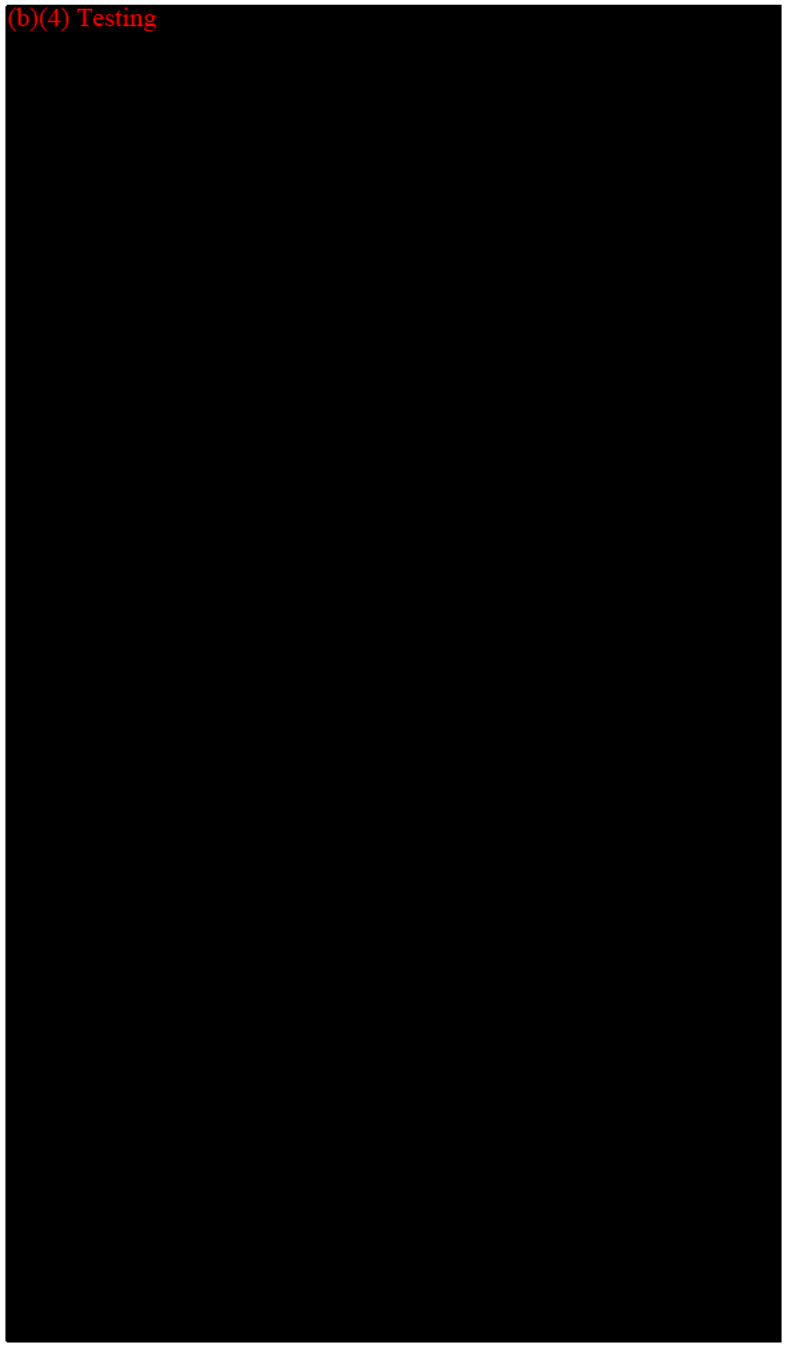
[redacted]

Attachment 7:

(b)(4) Testing Final Report: 05-0798-G6

Hemolysis Direct– (b)(4) Testing

(10 Pages)



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(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

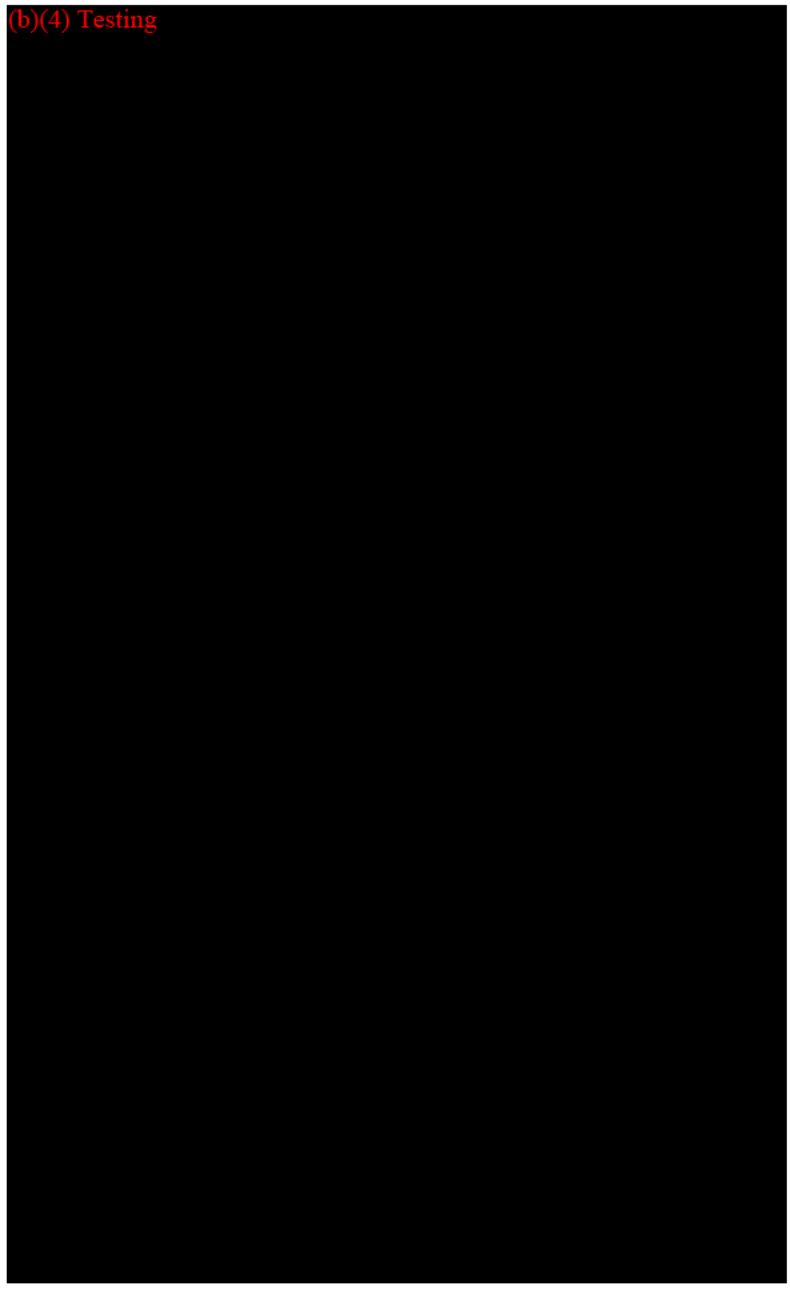
[redacted]

Attachment 8:

(b)(4) Final Report: 05-0798-G7

Hemolysis Extract– [redacted] (b)(4) Testi

(11 Pages)



(b)(4) Testing

[redacted]

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STUDY SUMMARY

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

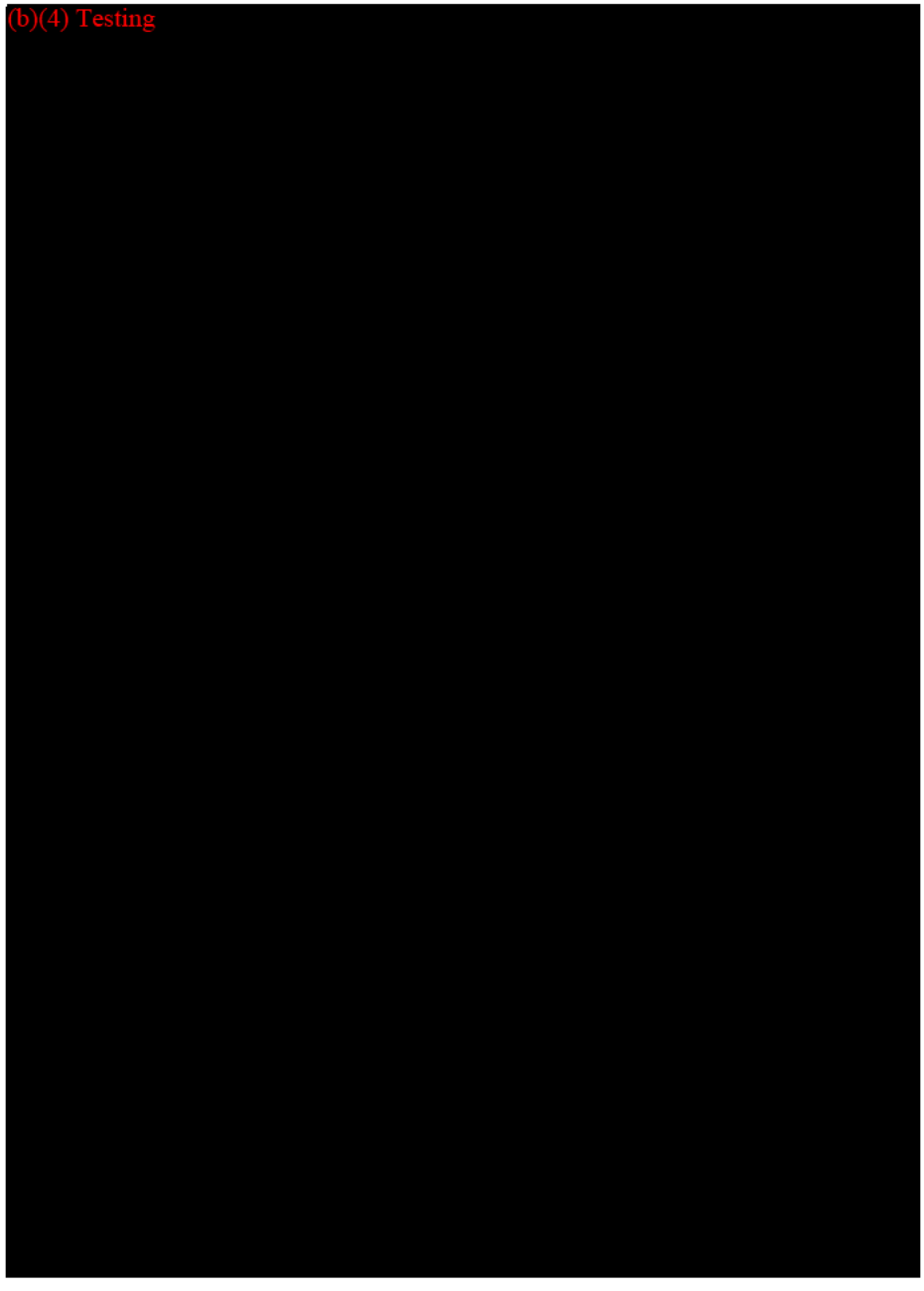
(b)(4) Testing

[redacted]

Attachment 9:
(b)(4) Final Report: 05-0798-G8
Prothrombin Time Assay - ISO
(11 Pages)

252

(b)(4) Testing



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(b)(4) Testing

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(b)(4) Testing

[redacted]

Attachment 10:
(b)(4) Final Report: 05-0798-G9
Lee-White Coagulation Test - ISO
(9 Pages)

(b)(4) Testing

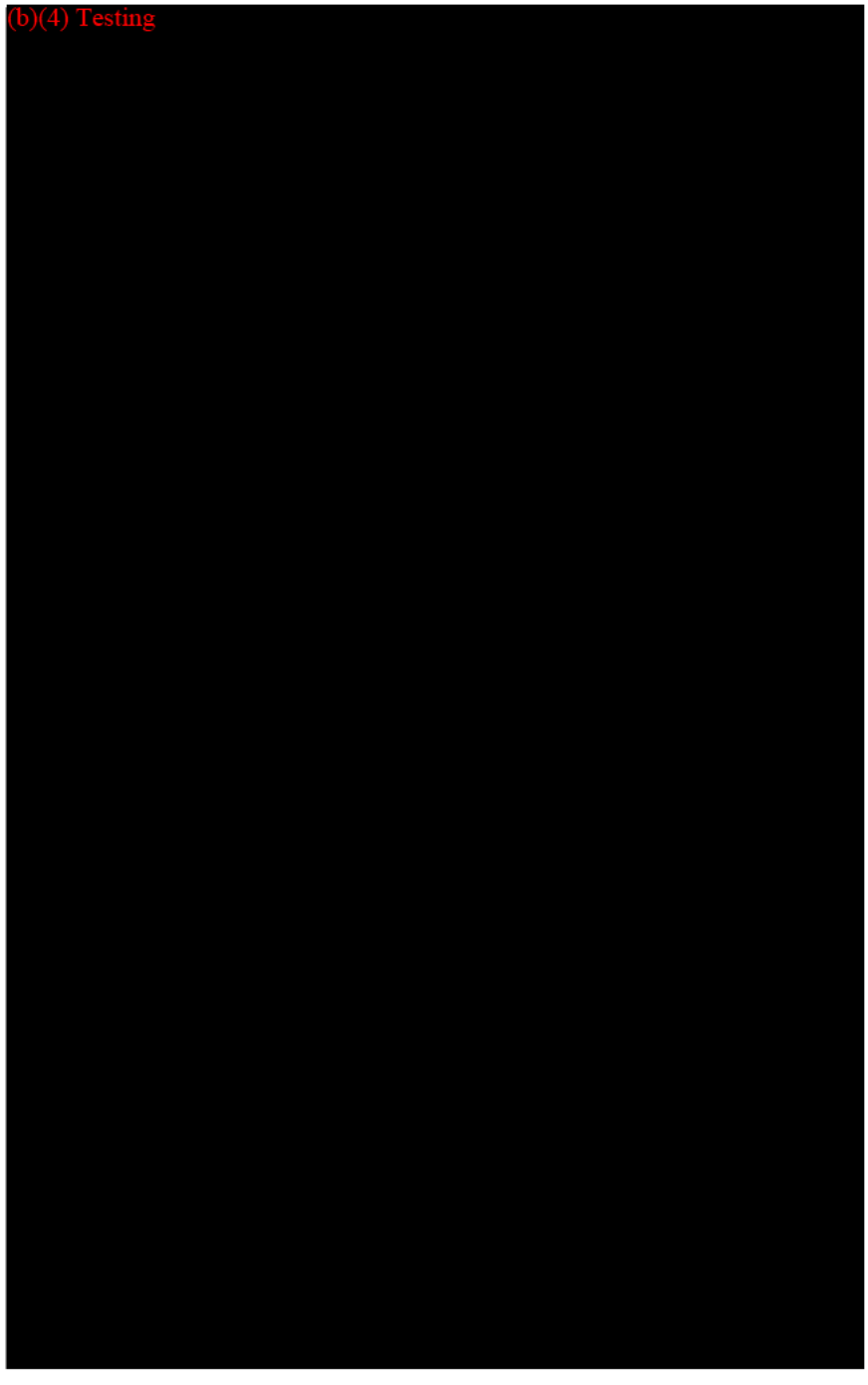

TABLE OF CONTENTS

(b)(4) Testing [redacted]

STUDY SUMMARY

(b)(4) Testing [redacted]

(b)(4) Testing

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

[redacted]

Attachment 11:

(b)(4) Final Report: 05-0798-G10

In Vitro Hemocompatibility Assay - ISO

(11 Pages)

(b)(4) Testing

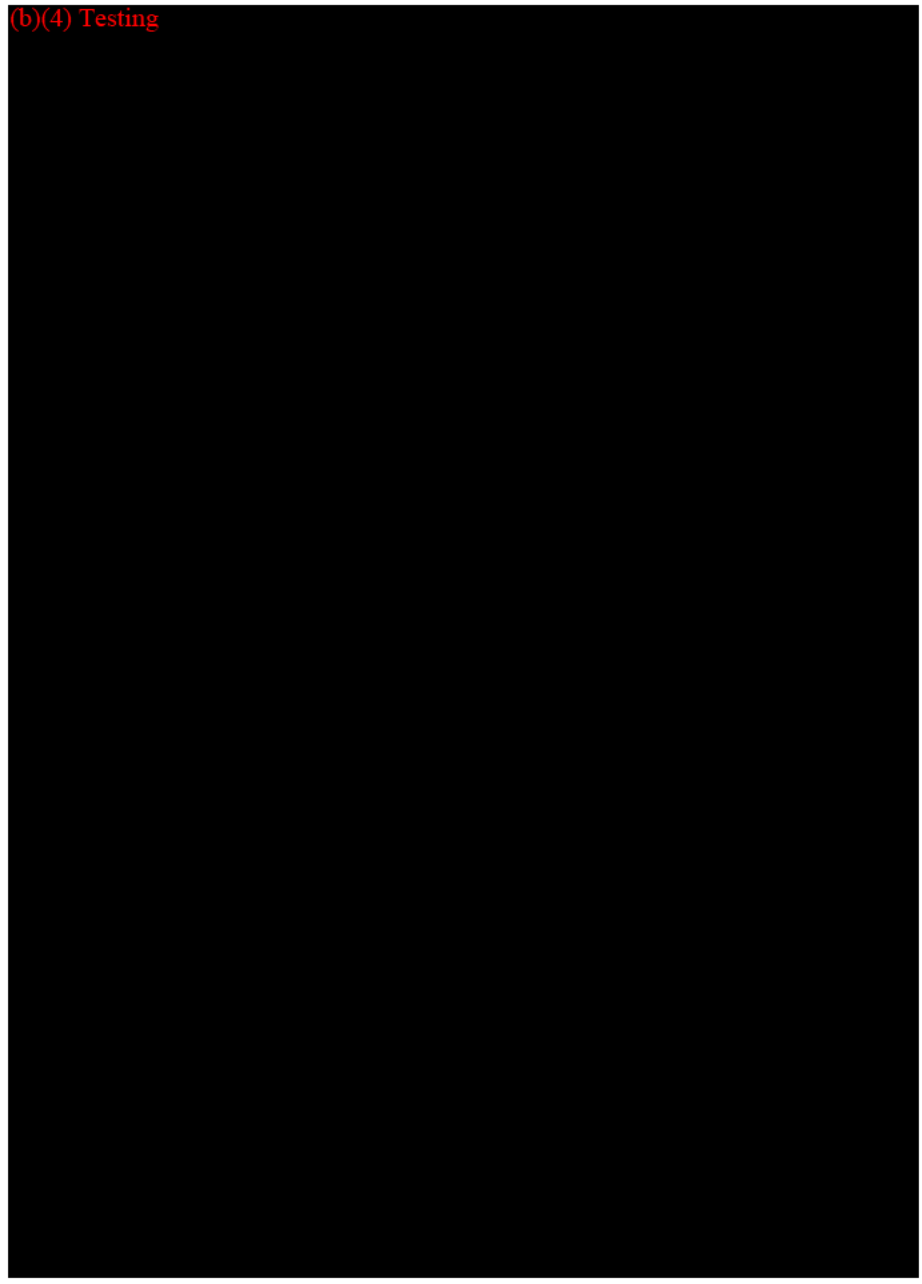

TABLE OF CONTENTS

(b)(4) Testing

[redacted]

STUDY SUMMARY

(b)(4) Testing

[redacted]

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Shang W Hwang

Subject: 510(k) Number K052257/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: DQY II 870.1250

Additional Product Code(s) with panel (optional):

Review: Ashley B Boone (Branch Chief) ICDS (Branch Code) 11/18/05 (Date)

Final Review: Bruce R. Vechinski for BDZ (Division Director) 11/22/05 (Date)

Revised:4/2/03

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 052257

Reviewer: Shang W Hwang

Division/Branch: DCD / ICDB

Device Name: Twin-Pass Dual Access Catheter

Product To Which Compared (510(K) Number If Known): Lumend Percutaneous Catheter (K011562)

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	(✓) → X		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

MEMO

DATE : 11-15-05

FROM : Shang W. Hwang, PhD., Pharmacologist, ICDG/DCD, HFZ-450

SUBJECT : Document Number: K052257/S01
Company Name: Vascular Solutions, Inc.
Contact: Sara L. Coon
Device Name: Vascular Solutions Twin-Pass Dual Access Catheter

TO : THE RECORD

This510 K amendment is submitted by Vascular Solutions, Inc. in response to FDA letter of September 26, 2005. The subject device is the Twin-Pass Dual Access Catheter. The responses from the sponsor are as follows:

1) Response 1:

(b)(4) Deficiencies-Comments

[redacted]

2) Response 2:

(b)(4) Deficiencies-Comments

[redacted]

3) Response 3:

(b)(4) Deficiencies-Comments

4) Response 4:

(b)(4) Deficiencies-Comments

5) Response 5:

(b)(4) Deficiencies-Comments

6) Response 6:

(b)(4) Deficiencies-Comments

7) Response 7:

(b)(4) Deficiencies-Comments

(b)(4) Deficiencies-Comments

[redacted]

8) Response 8:

(b)(4) Deficiencies-Comments

[redacted]

9) Response 9:

(b)(4) Deficiencies-Comments

[redacted]

The above responses are acceptable.

The Twin-Pass Dual Access Catheter is a 3F O.D. catheter that has two lumens--a short distal lumen and a second full length lumen--each of which are compatible with a 0.014" standard guide wire. The Twin-Pass catheter has a working length of 135cm and contains positioning markers at 95 and 105cm which provide a visual indication of the relative positions of Twin Pass and the end of a standard 105cm guide catheter. Two radiopaque marker bands at the end of each wire lumen provide for a radiographic means of locating the position of each lumen. The softer, distal end of the catheter is coated with a hydrophilic coating (the primer (2-TS-96) consists of Hydromer polyurethane base and the coating (3-TS-12) consists of polyurethane/polyvinylpyrollidone), while the proximal end of the catheter contains a strain relief and a standard luer hub. A 126cm stiffening mandrel is included which provides support and pushability to the Twin-Pass Catheter..

The Twin-Pass catheter is designed to assist the placement of a second guide wire in the event that the procedure requires positioning more than one guidewire. During use, the short distal wire lumen of the Twin-Pass catheter is advanced beyond the guide catheter over the existing guide wire allowing the physician to preserve the position of the first guide wire while the second wire is advanced through the full length lumen. The second guide wire is advanced after the stiffening mandrel is removed from Twin pass. Once both wires have been positioned, Twin Pass is removed and the desired interventional devices may be delivered to the treatment location.

The predicate devices for the Twin-Pass Dual Access Catheter are the Lumend Percutaneous Catheter (K011562), the Spectranetics Quick-Cross Catheter (K033678), and the Endologix Dual Lumen Catheter (K991601). These claims are supported in a comparison table included in the original 510(k) application.

The Twin-Pass Dual Access catheter is constructed of materials used in similar medical devices as described in table1 below:

Table 1: List of Materials

Component	Material Description
Catheter	
Luer hub	Polycarbonate
Adhesive	Urethane/Acrylate UV Cure Adhesive
Strain relief	Polyolefin
Full length lumen Inner layer Outer layer (proximal to distal)	 Polyimide with PTFE lining Pebax (Graduated from 72 to 55 durometer with blue colorant and BaS04)
Positioning marks	Pebax 72 durometer (with white colorant)
Rail Lumen Inner layer Outer layer	 Polyimide with PTFE lining Pebax (55 durometer with blue colorant and BaS04)
Markerbands	Platinum/Iridium (90% / 10%)
Adhesive	Ethyl cyanoacrylate
Hydrophillic Coating	Hydromer Polyurethane Base (2-TS-96) and Polyurethane/polyvinylpyrollidone (3-TS-12)
Stiffening Material	
Wire	304 stainless steel
Adhesive	Urethane/Acrylate UV Cure Adhesive
Luer Cap	Polystyrene

Reflow processing (or thermo-bonding) is used to create two lumens and later join these two lumens together.

Bonded components (b)(4) [redacted].

Non-sterile Twin-Pass catheters are coated (b)(4) [redacted].

The Twin-Pass Dual Access Catheter will be packaged in an HDPE coil inside a poly/Tyvek pouch. The device is provided sterile and is intended for single use only.

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The Twin-Pass Dual Access Catheter will be sterilized using ethylene oxide gas in a process designed to provide a Sterility Assurance Level (SAL) of 10^{-6} . The cycle has been be validated according to BS EN 550 "Sterilization of Medical Devices-Validation and Routine control of Ethylene Oxide Sterilization, Method C: Half cycle method".

Non-pyrogenicity of the devices will be verified on (b)(4) [redacted].

Non-clinical testing conducted included assessments of the design verification of the Twin-Pass Dual Access Catheter along with biocompatibility assessments, which confirmed the suitability of the Twin-Pass Dual Access Catheter for its intended use.

All testing was conducted on finished product that was manufactured, packaged and sterilized according to standard operating procedures developed for the Twin-Pass Dual Access Catheter. All samples were sterilized two times prior to testing. Testing performed verifies the Twin-Pass Dual Access Catheter meets the required specifications.

Additional product samples were also built and accelerated aged to represent 6-months shelf-life. Aged samples were tested for the same critical parameters as the original units. Testing performed verifies the Twin-Pass Dual Access Catheter continues to meet the required specifications at 6 months.

The following bench tests were performed to meet pre-specified criteria:

1. (b)(4) [redacted]
2. (b)(4) [redacted]
3. [redacted]

4. Slide easily through guide catheter
   Specification:
   The distal segment must have a lubricious coating.
   Protocol:
(b)(4) [redacted]

5. Hub to shaft adhesive bond integrity
   Specification:
(b)(4) [redacted]

6. Catheter shaft strength
(b)(4) [redacted]

7. Stiffening mandrel adhesive bond strength
   Specification:
(b)(4) [redacted]

8. Stiffening mandrel removal force
   Specification:
(b)(4) [redacted]

9. Leakage under pressure
   Specification:
(b)(4) [redacted]

The biocompatibility of the Twin-Pass Dual Access Catheter has been completely assessed utilizing the appropriate methods (b)(4)

Testing conducted by (b)(4)

Table 2: Twin-Pass Dual Access Catheter Biocompatibility Results Summary

Test Method ISO method)	(b)(4)
Hemolysis/direct contact/rabbit blood ISO 10093-4:2002	
MEM Elution Cytotoxicity ISO 10993-5:1999	
Rabbit pyrogen/material mediated ISO 10993-11	
Lee and White clotting time/ human blood ISO 10993-4:2002	
Systemic injection/2 extracts ISO 10993-11:1993	
Intracutaneous injection/ 2exctracts ISO 10993-10:2002	
Kligman Maximization / 2 extracts /30 animals/historical (+) controls ISO 10993-10:2002	
In vitro hemocompatibility ISO 10993-4:2002	
Prothrombin Time (PT) - ISO 10993-4:2002	
Hemolysis /Extract/ Rabbit Blood - ISO 10993-4:2002	

No clinical testing was performed for the Twin-Pass Dual Access Catheter.

Since the primary purpose of the package is to maintain device sterility and integrity, the packaging is subjected to testing to a protocol that includes standardized shipping tests as described in ASTM D4169, "Standard Practice for Performance Testing of Shipping Containers and Systems". These packages are then subjected to dye penetration (ASTM F1929-98 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration = Product to be tested in substantial compliance with the requirements of this standard) and bubble emission (FPA SPMC 005-96 Flexible Packaging Association, Standard Test Method for Detection of Heat Seal Package Internal Pressurization by Bubble Emission) testing to ensure product integrity will be maintained. Product is visually examined to verify no damage has occurred during the shipping process.

(b)(4) [redacted]

Recommendation for Response:

__x__ SE

Shang W. Hwang

Signatory review:
I concur with SE recommendation.
D Kaiser 11/17/05

MEMO

DATE : 9-19-05

FROM : Shang W. Hwang, PhD., Pharmacologist, ICDG/DCD, HFZ-450

SUBJECT : Document Number: K052257
Company Name: Vascular Solutions, Inc.
Contact: Sara L. Coon
Device Name: Vascular Solutions Twin-Pass Dual Access Catheter

TO : THE RECORD

The 510 K is submitted by Vascular Solutions, Inc. for its Twin-Pass Dual Access Catheter. The Twin-Pass Dual Access Catheter has two lumens, a short distal lumen and a second full length lumen, each of which are compatible with a 0.014" standard guide wire. The Twin-Pass catheter has a working length of 135cm. The softer, distal end of the catheter is coated with a hydrophilic coating to assist passage through the guide catheter and vessels while the proximal end of the catheter contains a strain relief and a standard luer hub. A 126cm stiffening mandrel is included which provides support to the Twin-Pass catheter. After my initial review, I have the following questions for the sponsor:

1. Additional information is needed to clarify and show the following items in the Appendix F engineering drawing:

   (1) (b)(4) [redacted]
   (2)
   (3)
   (4)

2. In the manufacturing overview, you state (b)(4) [redacted].

3. There is a tapered section before the entrance to the exchange lumen in the twin-pass catheter. Please provide evidence to show (b)(4) [redacted].

53

4. You state that non-sterile Pronto V3 catheters are coated (b)(4) [redacted].

5. In the results of your coefficient of friction (b)(4) [redacted].

6. You stated that the coated catheters were accelerated (b)(4) [redacted].

7. You state that biocompatibility testing was done using (b)(4) [redacted].

8. You state that biocompatibility testing of the (b)(4) [redacted].

Recommendation for Response:

__x__ Additional information required

Shang W. Hwang

Shang W Hwang

signatory review:
I agree w/ the request for Additional Information. I think the sponsor should address if the device is intended for use in the cerebral vasculature also.

9/28/05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Shawn W Thrasher

Subject: 510(k) Number K052257

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices n/a

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

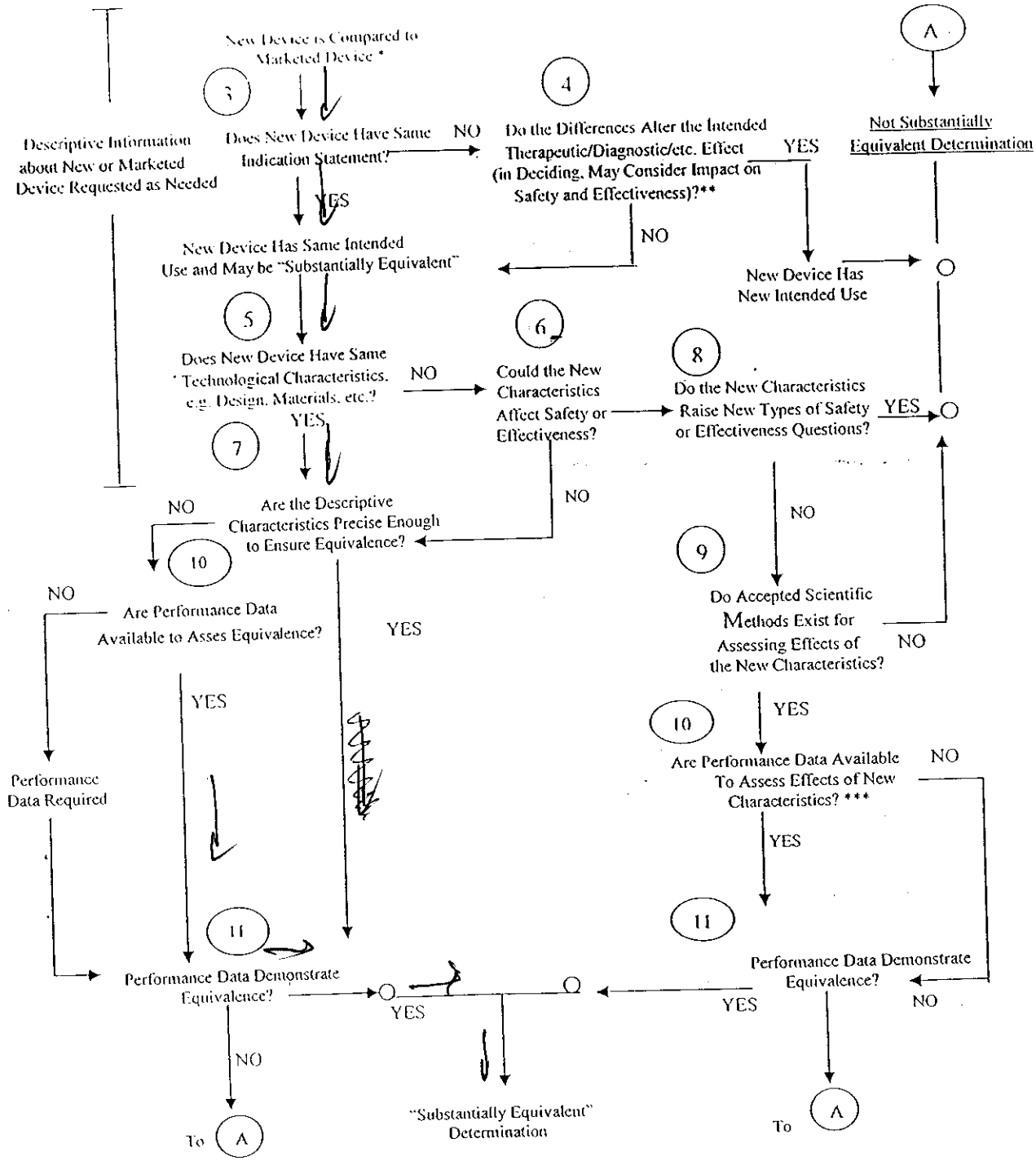
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: Ashley B. Boam (Branch Chief) CDB (Branch Code) 9/22/05 (Date)

Final Review: _____ (Division Director) (Date)

Revised:4/2/03

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 03, 2005

VASCULAR SOLUTIONS, INC.
6464 SYCAMORE COURT
MINNEAPOLIS, MN 55369
ATTN: SARA L. COON

510(k) Number: K052257
Product: VASCULAR
SOLUTIONS
TWIN-PASS DUAL
ACCESS CATHETER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.
On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/oivd/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K052257/S1

COPY

Vascular SOLUTIONS

September 30, 2005

Food and Drug Administration
CDRH, Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: **K052257, Amendment 1**
Response to letter dated Sep. 26, 2005

To Whom It May Concern:

Vascular Solutions Inc. (VSI) provides the attached information regarding the above referenced file. This information is being provided in response to the questions in letter dated Sep. 26, 2005.

For ease of review we have repeated the questions asked (in bold) and provided the response immediately following it.

1) **Please provide additional information to clarify and indicate the following items in the Appendix F engineering drawing:**

   a. **the length of the distal lumen (exchange lumen),**
   (b)(4) [redacted]

   b. **the outside diameter of the twin-pass catheter at B-B,**
   (b)(4) [redacted]

   c. **the outside diameter of the twin-pass catheter at C-C,**
   (b)(4) [redacted]

   d. **the outside and inside diameter of the twin-pass catheter at the tapered section before the entrance to the exchange lumen.**
   (b)(4) [redacted]

VASCULAR SOLUTIONS, INC.
6464 Sycamore Court • Minneapolis, Minnesota 55369
Phone: 763/656-4300 • FAX: 763/656-4301 • www.vascularsolutions.com

K 28

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2) In the manufacturing overview, you state that a reflow process is used to create the extraction lumen and the guidewire lumen, and later join these two lumens together. Please provide more detail on the (b)(4)

The reflow process is used in (b)(4)

The reflow process is performed at temperatures above (b)(4)

Reflow is used to (b)(4)

3) There is a tapered section before the entrance to the exchange lumen in the Twin-Pass catheter. Please provide evidence to show that the (b)(4)

The tapered section (b)(4)

4) You stated that non-sterile Pronto V3 catheters are coated by (b)(4)

The primer (2-TS-96) consists of (b)(4)

17

(b)(4)

The statement regarding application of coating (b)(4)

5) **In the results of your coefficient of friction** (b)(4)

The COF of 0.516 was tested (b)(4)

Uncoated test catheters were (b)(4) No other material differences existed.

6) **You stated that the coated catheters were** (b)(4)

The 12 month aged testing was performed on a (b)(4)

7) **You state that biocompatibility testing was done using samples representative of the** (b)(4)

(b)(4) [redacted]

Biocompatibility report SR1267 was performed per protocol ST1267. The (b)(4) [redacted]

8) **You state that biocompatibility testing** (b)(4) [redacted]

The coating is applied to the (b)(4) [redacted]

9) **Please clarify if the device is intended for use in the cerebral vasculature.** (b)(4) [redacted]

The device is not intended for use in the cerebral vasculature. A contraindication has been added to the IFU. An updated draft of the IFU is included as attachment #4 to the letter.

Please feel free to contact me again if you have any additional questions regarding this file.

Sincerely,

Sara L. Coon

Sara L. Coon
Sr. Regulatory Affairs Specialist

scoon@vascularsolutions.com
(763) 656-4399 phone
(763) 656-4250 fax

Vascular SOLUTIONS

September 30, 2005

Food and Drug Administration
CDRH, Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: **K052257, Amendment 1**
Response to letter dated Sep. 26, 2005

To Whom It May Concern:

Vascular Solutions Inc. (VSI) provides the attached information regarding the above referenced file. This information is being provided in response to the questions in letter dated Sep. 26, 2005.

For ease of review we have repeated the questions asked (in bold) and provided the response immediately following it.

1) **Please provide additional information to clarify and indicate the following items in the Appendix F engineering drawing:**

(b)(4) [redacted]

The diameters of the Twin-Pass catheter (b)(4) [redacted].

A revised print showing these dimensions is included as attachment #1 to the letter.

2) In the manufacturing overview, you state that a (b)(4) [redacted]

The reflow process is used in (b)(4) [redacted]

The reflow process is performed at temperatures (b)(4) [redacted]

Reflow is used to coat (b)(4) [redacted]

3) There is a tapered section before the entrance to the exchange lumen in the Twin-Pass catheter. Please provide evidence to show that the tapered sections (b)(4) [redacted]

The tapered section (b)(4) [redacted]

4) You stated that non-sterile Pronto V3 catheters are coated (b)(4) [redacted]

The primer (2-TS-96) consists of (b)(4) [redacted]

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considered proprietary. Additional product coated with the Hydromer coating include K052232-Pronto V3 Extraction Catheter and the list of products included in attachment #2 to this catheter.

The statement regarding application of coating to (b)(4) [redacted]."

5) In the results of your coefficient of friction (COF) (b)(4) [redacted].

The COF of 0.516 was tested (b)(4) [redacted]

Uncoated test catheters were (b)(4) [redacted]. No other material differences existed.

6) You stated that the coated catheters were (b)(4) [redacted]

The 12 month aged testing was performed on a (b)(4) [redacted].

7) You state that biocompatibility testing (b)(4) [redacted]

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[redacted] (b)(4)

Biocompatibility report SR1267 (b)(4) [redacted].

8) You state that biocompatibility testing (b)(4) [redacted]

The coating is applied to the (b)(4) [redacted].

9) Please clarify if the device is intended for use in the cerebral vasculature. (b)(4) [redacted]

The device is not intended for use in the cerebral vasculature. A contraindication has been added to the IFU. An updated draft of the IFU is included as attachment #4 to the letter.

Please feel free to contact me again if you have any additional questions regarding this file.

Sincerely,

Sara L. Coon

Sara L. Coon
Sr. Regulatory Affairs Specialist

scoon@vascularsolutions.com
(763) 656-4399 phone
(763) 656-4250 fax

Attachment 1

(b)(4) Schematic drawing

Attachment 2

(b)(4) [redacted]

FDA 510(k) list

The following devices are coated with Hydromer formulas and have been approved for sale by the FDA under Section 510 (k) of the Regulations:

K790387 **Dobbhoff [R] Enteric Feeding Tube with lubricant coating**, by Biosearch Medical Products Inc.

K790612 **Nutriflow Nasogastric Feeding Tube with Hydromer,** by Biosearch Medical Products Inc.

K801415 **Latex Foley Catheter (Hydromer Coated),** by G.D. Searle and Co.

K801558 **Enteric Feeding Tube with segmented flexible metal weight,** by Biosearch Medical Products Inc.

K813209 **Tracheobronchial Suction Catheter with Hydromer**, by: Hydromer Inc.

K810023 **Tracheobronchial Suction Catheter with Hydromer**, by Bard-Parker

K822875 **Pediatric Feeding Tube with Hydromer lubricant coating**, by Biosearch Medical Products Inc.

K821947 **Silicone Heart Pacemaker Leaders with Hydromer**, by Pacesetter Systems, Inc.

K823351 **Central Venous Catheter with Hydromer**, by Plasmetics, Inc.

K832416 **Axiom Hydromer Wound Drain**, by Axiom Medical, Inc.

K832064 **Venous Catheter**, by Cardiosearch, Inc.

K832808 **Ureteral Dilation Set**, by Van-Tec, Inc

K831868 **Dobbhoff [R] Feeding Tube with Hydromer lubricant**, by Biosearch Medical Products Inc.

K833293 **Leider Feeding Tube with lubricant coating**, by Biosearch Medical Products Inc.

K833621 **Entri Flex Enteric Feeding**, by Bioscarch Medical Products Inc.

(b)(4) [redacted]

FDA 510(k) list (continued)

The following devices are coated with Hydromer formulas and have been approved for sale by the FDA under Section 510 (k) of the Regulations:

K834268	**Islami Gastrointestinal Tube,** by Biosearch Medical Products Inc.
K841880	**Erythrocath Umbilical Catheter**, Cardiosearch, Inc.
K842133	**Erythrocath Double Lumen Central Venous Catheter**, by Cardiosearch, Inc.
K851160	**Van-Tec Guidewire with Hydromer Coating,** by Van-Tec, Inc.
K855150/A	**Hemorrhoid Treatment Device,** HPK International
K850074	**Esophageal pH Catheter**, by Biosearch Medical Products Inc.
K850664	**Endo-Tube,** by Biosearch Medical Products Inc.
K870556	**Van-Tec Suprapubic Balloon Catheter Set,** Van-Tec, Inc.
K870555	**Van-Tec Pediatric Suprapubic Catheter Set,** by Van-Tec, Inc.
K870695	**Van-Tec Urethal Dilation System**, by Van-Tec, Inc.
K870697	**Van-Tec One Step Ureteral Dilation Catheter,** by Van-Tec, Inc.
K873004	**Guiding Catheter**, by Mallinckrodt
K880100	**Cook Urological Wire Guide w/Hydromer Coating,** by Cook Urological
K901582	**Dobbhoff Biliary Stent Set,** by Biosearch Medical Products Inc.
K912129	**Dobbhoff Bipolar Hemostatic Probe**, by Biosearch Medical Products Inc.
K913073	**Dobbhoff Percutaneous Transhepatic Biliary Stent**, by Biosearch Medical Products Inc.
K913784	**Dobbhoff Single Pass PEG Kit**, by Biosearch Medical Products Inc.
K914482	**Stoma Measuring Device**, by Biosearch Medical Products Inc.

(b)(4) [redacted]

FDA 510(k) list (continued)

The following devices are coated with Hydromer formulas and have been approved for sale by the FDA under Section 510 (k) of the Regulations:

K923002	**Enteroclysis Tube**, by Biosearch Medical Products Inc.
K923474	**Low Profile Gastrostomy Device**, by Biosearch Medical Products Inc.
K922609	**ITC Catheters w/Hydromer**, by Interventional Therapeutics Corp.
K932295	**Non-Balloon Gastrostomy Kit**, by Biosearch Medical Products Inc.
K935045	**Biosearch Laparoscopic Gastrostomy Catheter**, by Biosearch Medical Products Inc.
K946249	**BARD Jejunal Feeding/gastric decompression Tube**, by C.R. Bard
K951260	**Urinary Intermittent Catheters with Hydromer coating**, by Biosearch Medical Products Inc.
K954300	**Argyle Neo-sert Hydrophilic Polyurethane Umbilica,** by Sherwood Medical Co.
K954429	**Kangaroo Entristar Skin-level Gastrostomy kit,** by Sherwood Medical Co.
K960677	**Kangaroo Jejunal Feeding System**, by Sherwood Medical Co.
K964780	**Director Guidewire #000560**, by C.R. Bard
K965146	**Flat Silicone closed Wound Drain**, by Axiom Medical, Inc.
K973057	**1.4 fr Mapcath Sensor Stylet**, Navion Biomedical Corp.
K984214	**Cordis Endovascular Temporary Occlusion Balloon Catheter**, by Cordis Endovascular Systems, Inc.
K990145	**Wilson-Cook Bipolar Probe**, by Wilson-Cook Medical
K991219	**C-flex Ureteral Stents**, by Applied Medical Resources
K993564	**Possis XMI-RX rheolytic thrombectomy Catheter**, by Possis Medical, Inc.
K993650	**Ureteral Access Sheath Set**, by Applied Medical Resources

(b)(4) [redacted]

FDA 510(k) list (continued)

The following devices are coated with Hydromer formulas and have been approved for sale by the FDA under Section 510 (k) of the Regulations:

K024010	**Dover Silver Hydrogel Coated Silicone Foley Catheter**, by Tyco Healthcare Group., Kendall Company div.
K022686	**Lap Surgical Systems Multiple Instrument Guide**, by LapSurgical Systems, Inc.
K023259	**Inhealth Soft Sleeve Colonoscope Splint, model CS**, by Helix Medical, Inc.
K030956	**Navigator Ureteral Access Sheath Set** , by Boston Scientific Corp.
K031916	**Galt Hydrophilic Guidewires** , by Galt Medical Corp.
K031357	**GUARDDOG OCCLUSION SYSTEM, GUIDEWIRE** , by Possis Medical, Inc.

(b)(4) [redacted]

Attachment 3

Non-Clinical Study Protocol:

Biocompatibility Evaluation of Pronto V3, Skyway and Sidekick Catheters

(b)(4)

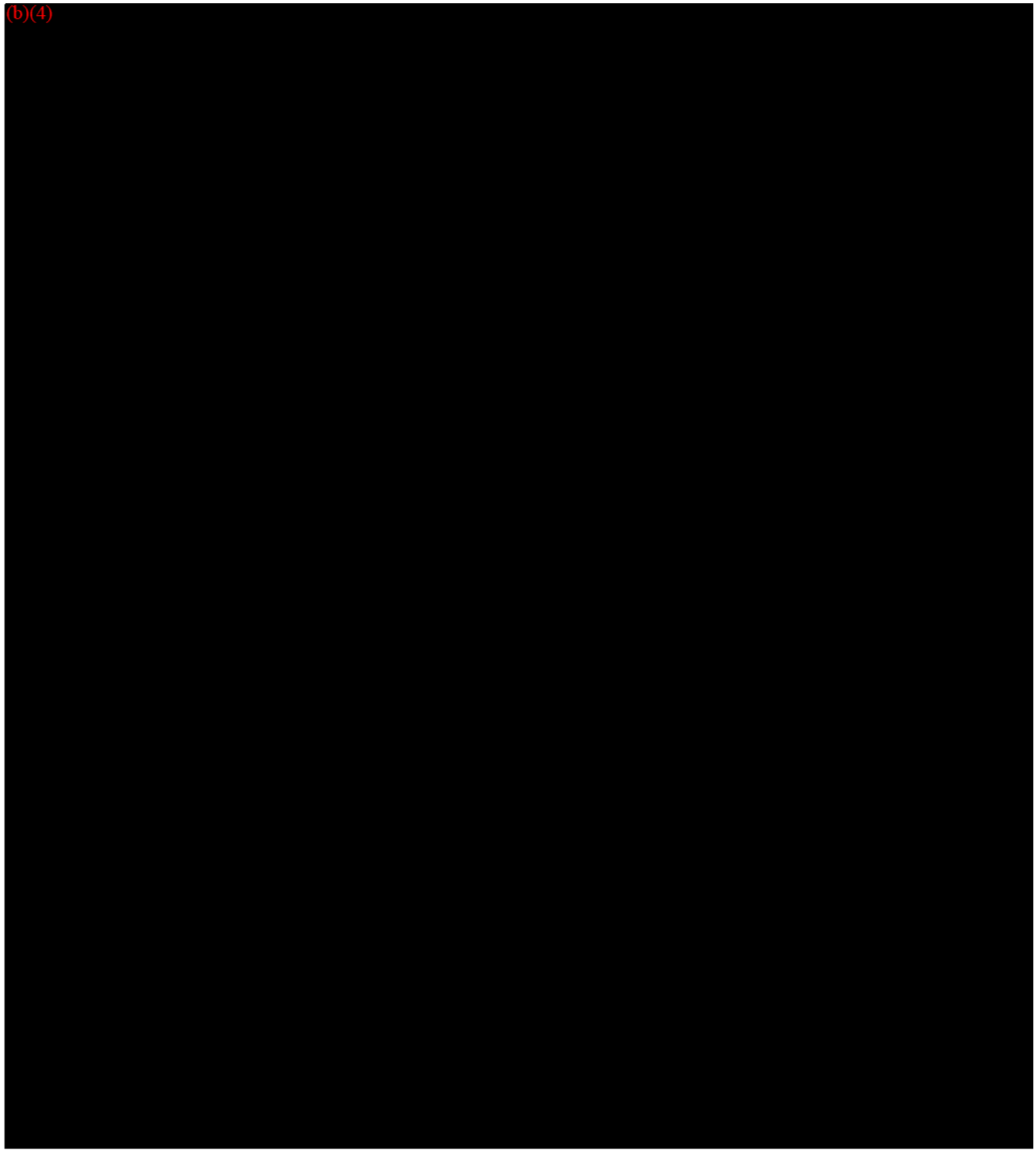
[redacted]

2. STUDY OBJECTIVES

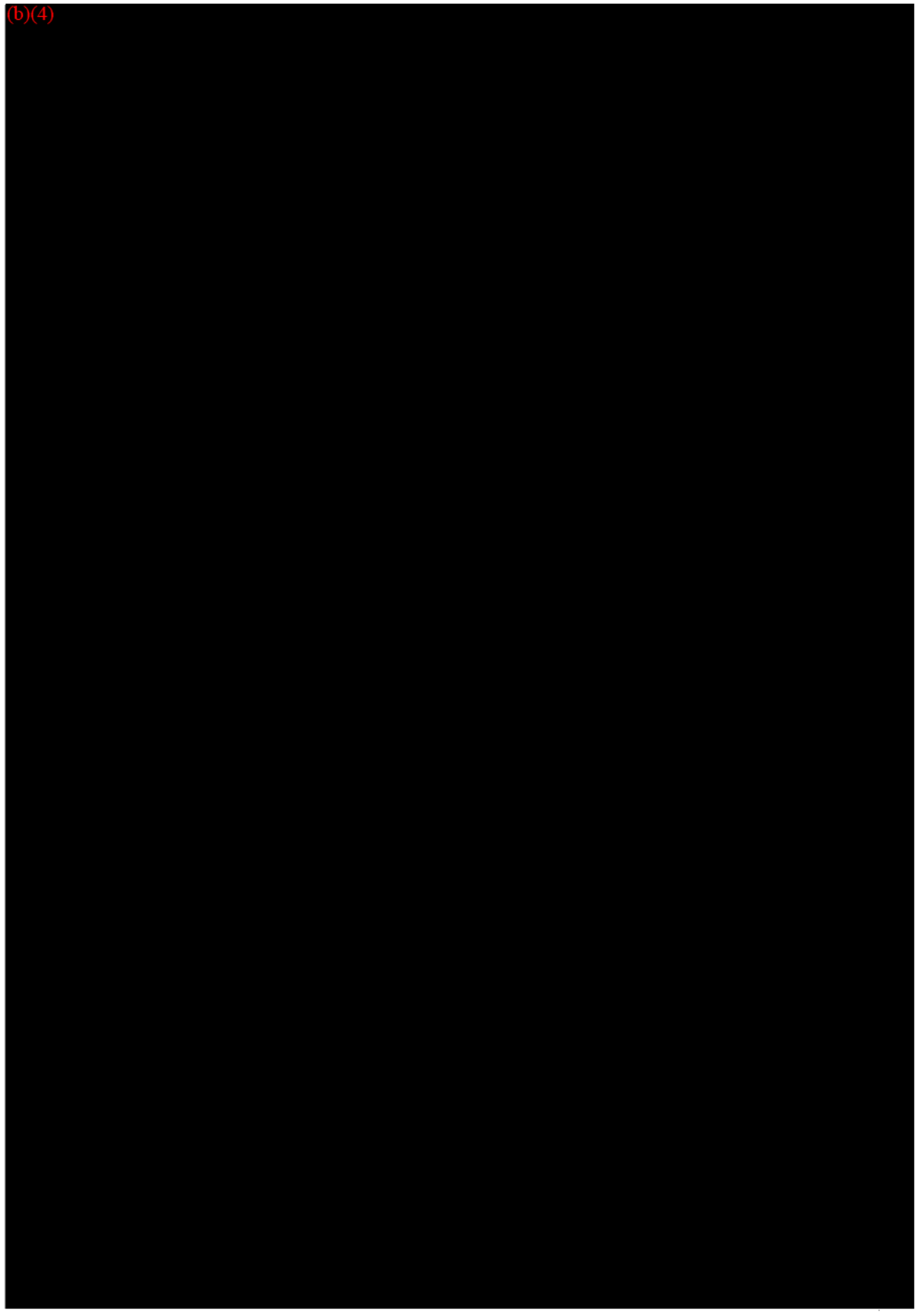
(b)(4)

[redacted]

(b)(4)



(b)(4)



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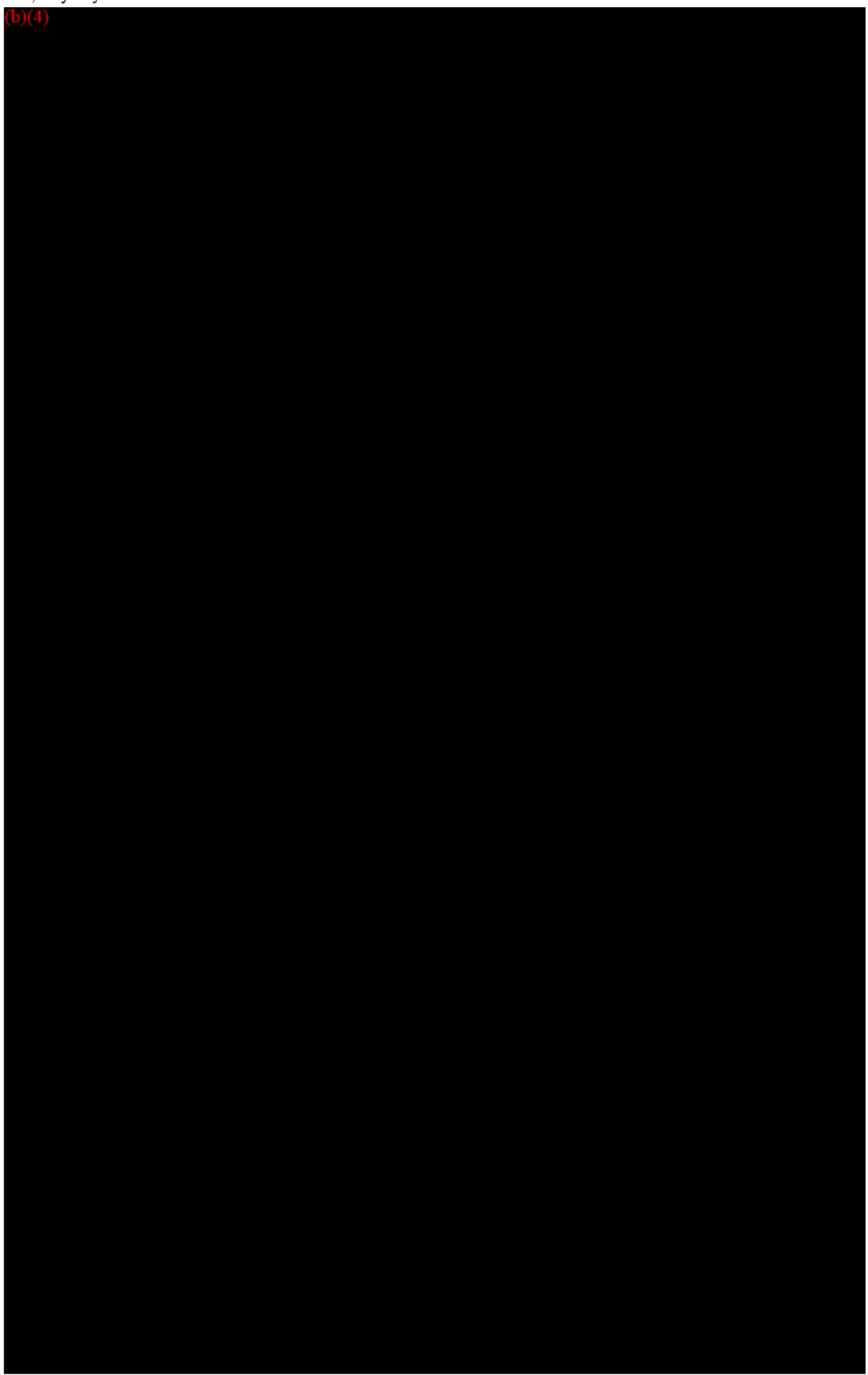
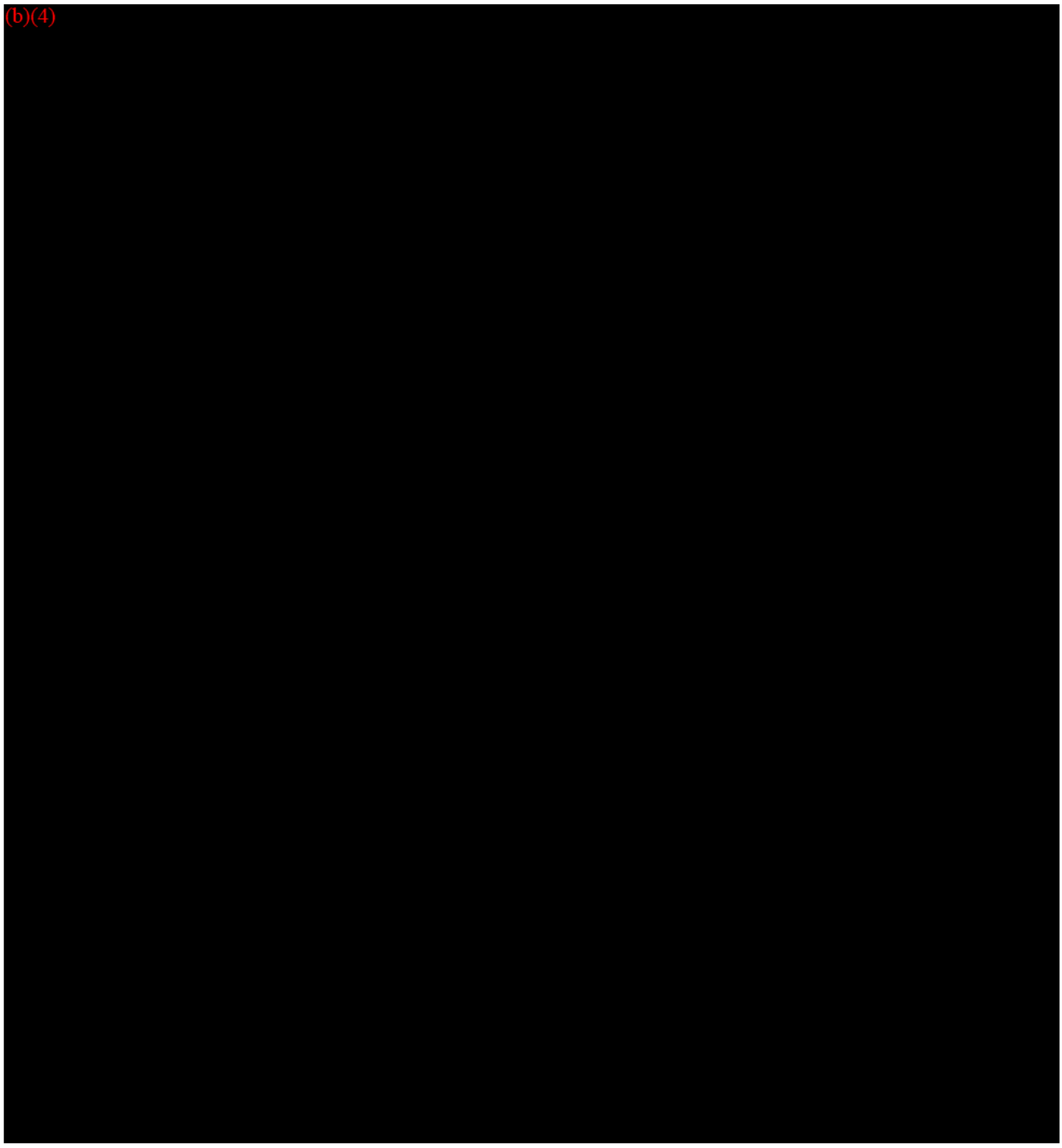


6.2. Study Test System

(b)(4)

7.

(b)(4)



Attachment 4

Twin-Pass™

Dual Access Catheter

DRAFT

Vascular SOLUTIONS

Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: 763-656-4300
Fax: 763-656-4250
www.vascularsolutions.com

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International Symbols Glossary

	CONT	MARKER	Latex		Manufacturer
International Symbols Glossary	Contents of package	Radiopaque Marker	Latex Free	Keep Dry	Manufactured by Vascular Solutions, Inc.

TWIN-PASS™ Dual Access Catheter Model 5210

Instructions For Use

USA CAUTION

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

CAUTION

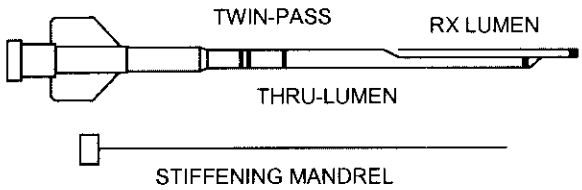
The TWIN-PASS dual access catheter should be used by physicians with adequate training in the use of the device.

DEVICE DESCRIPTION

The TWIN-PASS dual access catheter is a hydrophilically coated, dual lumen catheter designed for use in the arterial vasculature. The catheter provides support for 0.014" / 0.36mm guidewires during interventional procedures, and the dual lumen design allows for the delivery of a second guidewire into distal vasculature while leaving the initial guidewire in place.

The TWIN-PASS catheter comes pre-loaded with a stiffening mandrel in the thru-lumen to provide support and pushability during catheter insertion.

The TWIN-PASS catheter is compatible with guidewires and guide catheters with the following dimensions:



TWIN-PASS Model	Max. Guidewire Diameter	Min. Guide Catheter I.D.
5210	0.014" / 0.36mm	0.055" / 1.40mm

The TWIN-PASS catheter has a radiopaque marker band located approximately 1mm proximal to the distal tip and a second radiopaque marker band located at the thru-lumen exit port 10mm proximal to the distal tip. There are also two sets of white positioning marks located at 95cm (single mark) and 105cm (double marks) from the distal tip. The proximal end of the catheter incorporates a strain relief and a luer-lock entry port for flushing.

INDICATIONS

The TWIN-PASS catheter is intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature, to facilitate placement of guidewires and other interventional devices, and for use during two guidewire procedures.

CONTRAINDICATIONS

The Twin-Pass catheter is contraindicated for high pressure injections and for use in the cerebral vasculature.

WARNINGS

Do not advance the TWIN-PASS catheter without a guidewire in place through the RX lumen. Advancement of the catheter without a guidewire in the RX lumen may result in intimal damage, arterial dissection, or perforation.

The TWIN-PASS catheter is supplied sterile for single use only. Do not reuse, reshape or re-sterilize the device. Re-sterilization or reshaping may change the physical characteristics of the material and should not be attempted.

The TWIN-PASS catheter has not been tested for pressure injections. If a 0.014" / 0.36mm guidewire cannot be passed through the catheter, do not attempt to resolve the blockage by flushing the catheter *in vivo*. Catheter rupture and arterial injury could result. Identify and resolve the cause of the blockage or replace the catheter with a new one.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.

COMPLICATIONS

As with all catheterization procedures, complications may occur when using the TWIN-PASS catheter. These may include:

- local or systemic infection
- intimal disruption
- arterial dissection
- perforation and vessel rupture
- arterial thrombosis
- distal embolization of blood clots and plaque
- Myocardial Infarction
- arterial spasm
- catheter fracture with tip separation and distal embolization

PRECAUTIONS

The TWIN-PASS catheter deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

Do not use the TWIN-PASS catheter if the packaging has been damaged.

Inspect the catheter prior to use for any bends or kinks. Do not use a damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur.

Care should be taken not to crush the catheter. Excessive tightening of a hemostatic valve onto the catheter shaft may result in damage to the guidewire lumen and difficulty while inserting the catheter or guidewires.

Both catheter lumens should be flushed with sterile, heparinized saline prior to use.

Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized sterile solution should be considered.

Exercise care while handling the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

When the catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the TWIN-PASS catheter. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

Each TWIN-PASS dual access catheter includes the following components:

- Single-use disposable catheter
- Stiffening mandrel
- Dispenser coil with flushing luer

Other materials required but not provided are:

- Guiding catheter with an I.D. of at least 0.055" / 1.40mm fitted with a rotating hemostatic valve (RHV) (Tuohy-Borst type)
- 0.014" / 0.36mm guidewires
- 10ml syringe (for flushing the dispenser coil and the catheter lumen)
- Sterile heparinized saline (for system flushing)

PREPARATIONS FOR USE

1. Carefully inspect the TWIN-PASS catheter packaging and components for damage prior to use. Utilizing sterile technique, remove the TWIN-PASS catheter dispenser coil

from its packaging and transfer it to the sterile field.

2. Remove the stiffening mandrel from the catheter. DO NOT DISCARD.
3. Attach a 10ml syringe filled with sterile heparinized saline to the luer-lock guidewire entry port of the TWIN-PASS catheter and thoroughly flush the catheter.
4. Attach a 10ml syringe filled with sterile heparinized saline to the flushing luer on the dispensing coil and completely flush the coil to activate the hydrophilic coating on the TWIN-PASS catheter.
5. Insert the stiffening mandrel through the luer-lock and into the TWIN-PASS catheter and lock it in place.
6. Remove the TWIN-PASS catheter from the dispensing coil and inspect for any bends or kinks.
7. Remove the packaging mandrel from the rapid exchange lumen of the TWIN-PASS catheter while under sterile saline.

DEPLOYMENT PROCEDURE

The following TWIN-PASS catheter deployment steps assume a standard PTCA protocol using the following items: a guiding catheter, an inserted 0.014" guidewire, a 300cm x 0.014" wire to be delivered, and a rotating hemostatic valve (RHV) (Touhy-Borst type).

As with any interventional procedure, proper anticoagulation and anti-platelet therapy should be administered prior to beginning.

Note: Familiarity with traditional long and short guidewire exchange techniques is required for successful deployment of the TWIN-PASS catheter and the delivery of a second guidewire.

TWIN-PASS DEPLOYMENT STEPS

1. Backload the rapid exchange segment of the TWIN-PASS catheter onto the proximal end of the 0.014" / 0.36mm guidewire that is already in place in the distal vasculature.

   WARNING: Do not advance the TWIN-PASS catheter without a guidewire in place through the RX lumen. Advancement of the catheter without a guidewire in the RX lumen may result in intimal damage, arterial dissection, or perforation.
2. Carefully advance the catheter until both marker bands are visible in the desired distal vascular space.

   WARNING: Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.
3. Slowly remove the stiffening mandrel.
4. Insert the desired exchange length guidewire into the luer-lock of the TWIN-PASS catheter. Advance the guidewire until it exits the thru-lumen into the distal vascular space.
5. Fix both guidewires using standard guidewire exchange techniques and carefully withdraw the TWIN-PASS catheter until the distal tip exits the hemostatic valve and both wires can be secured.

When not in use during this procedure, wipe the TWIN-PASS catheter with a sterile gauze pad saturated with heparinized saline, flush the thru-lumen well, reload the stiffening mandrel into the thru-lumen, and store in the dispensing tube in a saline bath.

PACKAGING & STORAGE

The TWIN-PASS has been sterilized with ethylene oxide.

Store in a cool, dry place.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the TWIN-PASS catheter is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the TWIN-PASS catheter. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Vascular Solutions, Inc. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Vascular Solutions, Inc.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF VASCULAR SOLUTIONS, INC.

PATENTS AND TRADEMARKS

International and U.S. patents pending.

Twin-Pass™ is a trademark of Vascular Solutions, Inc.

See the International Symbols Glossary on page 3.

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