

MAR 16 2009

K083763

1 of 4

SECTION 5.0

510(k) Summary

SUBMITTER:

R4 Vascular, Inc.
7550 Meridian Circle
Suite 150
Maple Grove, MN 55369

ESTABLISHMENT REGISTRATION NUMBER:

3006242715

CONTACT:

Laurie Lewandowski
Director, Quality and Regulatory Affairs
Telephone: 612-770-4038 cell
Telephone: 763-494-8400
Fax: 763-494-8484
Email: lalew@r4vascular.com

DATE PREPARED:

December 16, 2008

NAME OF MEDICAL DEVICE:

Proprietary Name: *Zeus™ CT PICC*
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC), single and double lumen

DEVICE CLASSIFICATION:

Classification Panel: General Hospital
Regulatory Class: Class II
Product Code: LJS
Regulation Number: 21 CFR 880.5970

PREDICATE DEVICES:

Proprietary Name: V-Cath (Polyurethane) Power PICC (Power-V)
Common/Usual Name: Peripherally Inserted Central Catheter (PICC), single and double lumen

Proprietary Name: Tyco Palindrome Emerald
Regulation Name: Chronic Hemodialysis Catheter
Common/Usual Name: Catheter, Hemodialysis, Apheresis, Intravascular

Device Description:

The r4 Vascular, Inc. *Zeus™ CT PICC* is a family of peripherally inserted central venous catheters designed to perform infusion, intravenous therapy, blood sampling, power injection of contrast media studies and central venous pressure monitoring. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each *Zeus™ CT PICC* has a kink resistant reverse tapered catheter design. The *Zeus™ CT PICC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *Zeus™ CT PICC* product line has catheters in 4 Fr and 5 Fr single lumen and 5 Fr and 6 Fr dual lumen.

The *Zeus™ CT PICC* is similar to HDC's V-Cath (Polyurethane) Power PICC (Power-V), with the addition of a Biomimetic Coating that is similar in performance to the Tyco Palindrome Emerald.

Intended Use / Indication for Use:

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

Technological Comparison to Predicate Devices:

The technological characteristics of the *Zeus™ CT PICC* are substantially equivalent to the predicates, HDC's V-Cath (Polyurethane) Power PICC (Power-V) and Tyco Palindrome Emerald in terms of intended use, application, user population, basic design, performance and labeling.

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates.

Does the new device have the same indication statements? Yes.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Not in all regards. The principles of operations and basic design are the same as the predicate devices. The main change in design is the addition of the biomimetic coating to the catheter.

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There is precedence in the market for coated catheters, Tyco Palindrome Emerald and their predicates.

Could the new characteristics affect safety or effectiveness? Yes. The changes may affect safety and effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

Yes. Testing was based on FDA guidance documents and recognized standards to evaluate the devices' performance.

- The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.
- ISO 10555-1:1997 Sterile, Single-use Intravascular Catheters, General requirements;
- ISO 594 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part 1: General requirements
- AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 10993 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing

Sterilization requirements of ISO 11135:2007, *Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization*.

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*. Test profiles for externally communicating, blood-contacting, long-term devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Performance testing was generated in accordance with the above referenced guidance document and standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrate that the *Zeus™ CT PICC* with biomimetic coating met the performance criteria of safety and effectiveness test performed and based on the FDA's decision tree is substantially equivalent to the noted predicate devices.

CONCLUSION

The *Zeus™ CT PICC* met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the *Zeus™ CT PICC* is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate devices: HDC V-Cath (Polyurethane) Power PICC (Power-V) and Tyco Palindrome Emerald.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 16 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Laurie Lewandowski
Director, Quality and Regulatory Affairs
R4 Vascular, Incorporated
7550 Meridian Circle North
Suite 150
Maple Grove, Minnesota 55369

Re: K083763
Trade/Device Name: Zeus CT PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 16, 2008
Received: December 18, 2008

Dear Ms. Lewandowski:

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.

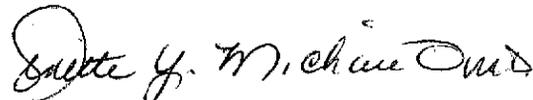
Page 2 – Ms. Lewandowski

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4.0

Indications for Use

510(k) Number (if known): K083763

Device Name: Zeus CT PICC

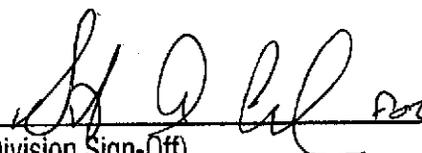
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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510(k) Number: K083763



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 24 2009

Food and Drug Administration
9200 Corporate Boulevard
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Dear Ms. Lewandowski:

This letter corrects our substantially equivalent letter of March 16, 2009.

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This letter will allow you to continue 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital

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Enclosure

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

Page 10

Section 4.0

Indications for Use

510(k) Number (if known): K083763

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510(k) Premarket Notification Submission: Zeus™ CT PICC

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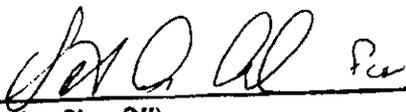
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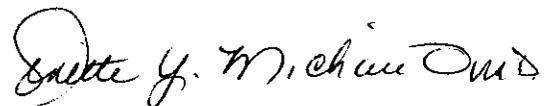
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Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

Section 4.0

Indications for Use

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Device Name: Zeus CT PICC

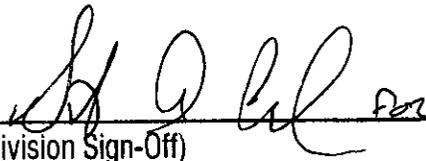
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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083763



Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 18, 2008

R4 VASCULAR, INC.
7550 MERIDIAN CIR. N
MAPLE GROVE, MINNESOTA 55369
UNITED STATES
ATTN: LAURIE LEWANDOWSKI

510k Number: K083763

Received: 12/18/2008

Product: ZEUS CT PICC 4 FR, 5 FR, SINGL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.**

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 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/ndufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007” (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

K083763

December 16, 2008

Food and Drug Administration
Center for Devices and Radiological health
510(K) Document mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC

DEC 18 2008

Received

Re: 510(K) Notification -- Traditional - r4 Vascular, Inc., Zeus CT PICC

Dear Document Control Staff:

Pursuant to the requirements of Section 510(K) of the Food, Drug and Cosmetic Act, notification is made of the objective of r4 Vascular, Inc. to market the following:
r4 Vascular, Inc. Zeus™ CT PICC.

NAME OF MEDICAL DEVICE:

Proprietary Name: *Zeus CT PICC*
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC), single and double lumen

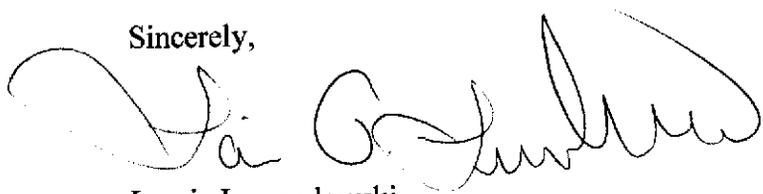
DEVICE CLASSIFICATION:

Classification Panel: General Hospital
Regulatory Class: Class II
Product Code: LJS
Regulation Number: 21 CFR 880.5970

We consider the contents of this 510(k) to be confidential commercial information and request that it be considered as such by the FDA.

Thank you in advance for the consideration of this application. Please address all correspondence and questions regarding this submission to me at the address noted below, by email at lalew@r4vascular.com; by telephone at 612-770-4038 (cell) or 763-494-8400 (office) or fax at 743-494-8484. Please feel free to contact me personally at any time.

Sincerely,



Laurie Lewandowski
Director, Regulatory Affairs and QA
R4 Vascular, Inc.
7550 Meridian Circle North
Suite 150
Maple Grove, MN 55369

K17

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

**Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s**

<http://www.fda.gov/cdrh/ode/guidance/1567.html>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	Pg. 2		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	Pg. 3		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Pg. 9		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	Pg. 10		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	Pg. 11		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	Pg. 15		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html	Pg. 16		
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html .	Pg. 17		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html . FDA Standards program www.fda.gov/cdrh/stdsprog.html . Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html	Pg. 18		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Pg. 19		

Rev. 5/30/07

Title	Related Information	Present	Inadequate	N/A
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Pg 23		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	Pg 39		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	Pg 42		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	Pg 43		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	Pg 46		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	Pg 51		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	Pg 52		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Pg 53		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Pg 94		
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf	Pg 99		
Kit Certification	Device Advice http://www.fda.gov/cdrh/devadvice/314c.html	Pg 28		

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20.0 Performance Testing – Clinical	99
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Attachment 3 – Predicate Labeling	
Attachment 4 – Sterilization Validation	
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Attachment 6 – Tray Sealing Operational Qualification	
Attachment 7 – Accelerated Aging & Packaging Validation Protocol	
Attachment 8 – Form 3654 for ISO/AAMI/ANSI 10993	
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Attachment 13 – (b)(4) Study	

Form Approved OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) R4 VASCULAR INC 7550 Meridian Cir. N. Maple Grove MN 55369 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Laurie Lewandowski <i>Laurie Lewandowski</i> 2.1 E-MAIL ADDRESS lalew@r4vascular.com 2.2 TELEPHONE NUMBER (include Area code) 763-494 8400 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
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/oc/mdufma) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD090008		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		02-Dec-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

FDA CDRH DMC

SECTION 2.0

DEC 18 2008

Cover Sheet

Received

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Date of Submission	
User Fee Payment ID Number (b)(4)		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION			
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-HDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
		Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input type="checkbox"/> No (if Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name r4 Vascular, Inc.		Establishment Registration Number (if known) 3006242715	
Division Name (if applicable)		Phone Number (including area code) (763) 494-8400 (cell 612-770-4038)	
Street Address 7550 Meridian Cir. N.		FAX Number (including area code) (763) 494-8484	
City Maple Grove	State / Province MN	ZIP/Postal Code 55369	Country USA
Contact Name Laurie Lewandowski			
Contact Title Director, Quality and Regulatory Affairs		Contact E-mail Address lalew@r4Vascular.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name		Phone Number (including area code) ()	
Division Name (if applicable)		FAX Number (including area code) ()	
Street Address		State / Province	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

FORM FDA 3514 (9/07)

PAGE 1 OF 5 PAGES

FD-3514 (Rev. 4-11-00) 100-01

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:	<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address				
<input type="checkbox"/> Other Reason (specify):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Reponse to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed						Summary of, or statement concerning, safety and effectiveness information	
1	LJS	2		3		4	
5		6		7		8	
						<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
Information on devices to which substantial equivalence is claimed (if known)							
	510(k) Number		Trade or Proprietary or Model Name				Manufacturer
1	K071875	1	V Cath Poly PICC Power V	1			HDC
2	K060509	2	Palindrome Emerald	2			Tyco
3		3		3			
4		4		4			
5		5		5			
6		6		6			
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification							
Percutaneous Implant, long-term intravascular catheter							
	Trade or Proprietary or Model Name for This Device					Model Number	
1	Zeus™ CT PICC 4 Fr Single Lumen					1 71045040, 71045041	
2	Zeus™ CT PICC 5 Fr Single Lumen					2 71046040, 71046041	
3	Zeus™ CT PICC 5 Fr Dual Lumen					3 72055540, 72055541	
4	Zeus™ CT PICC 6 Fr Dual Lumen					4 72066040, 72066041	
5						5	
FDA document numbers of all prior related submissions (regardless of outcome)							
1	2	3	4	5	6	7	8
7	8	9	10	11	12		
Data Included in Submission							
<input checked="" type="checkbox"/> Laboratory Testing <input checked="" type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials							
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code	C.F.R. Section (if applicable)			Device Class			
LJS	part 880.5797			<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified			
Classification Panel							
General Hospital							
Indications (from labeling)							
The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.							

r4 Vascular, Inc.

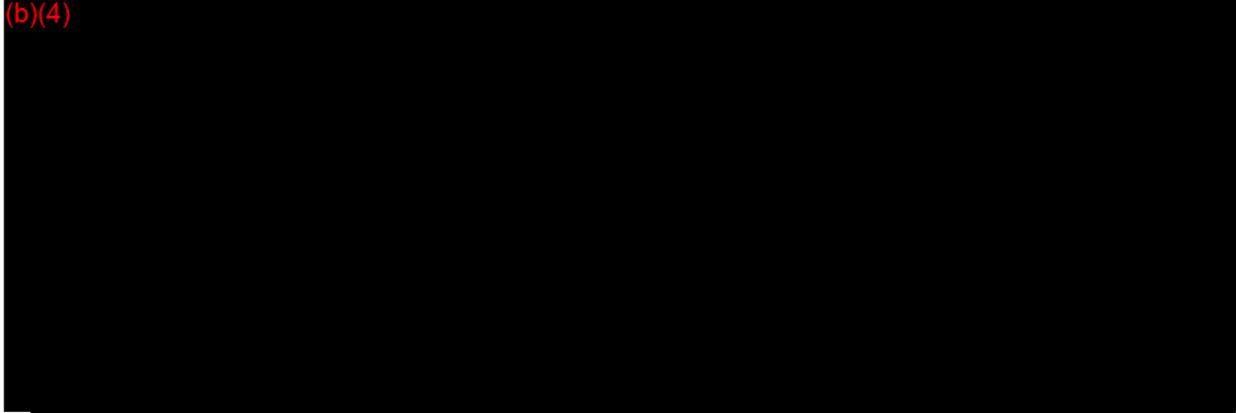
510(k) Premarket Notification Submission: Zeus™ CT PICC

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

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

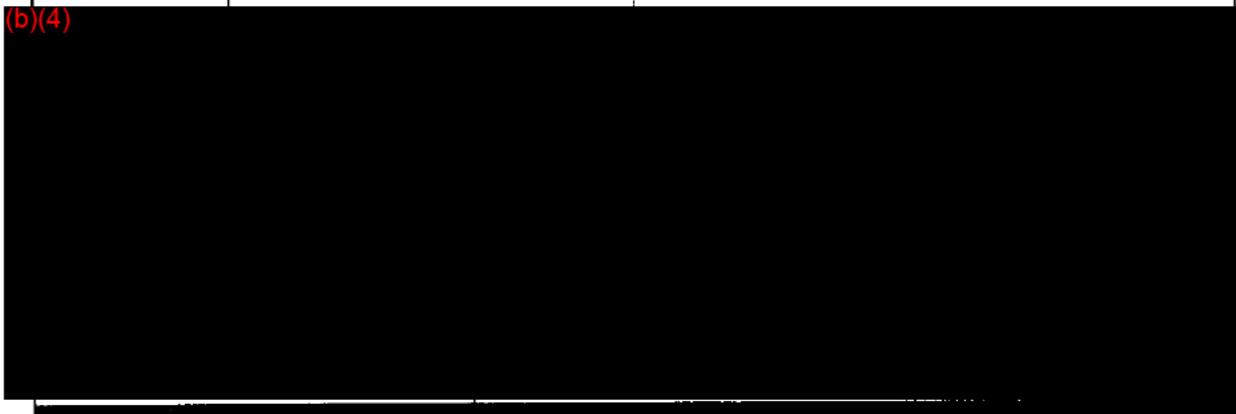
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
--	--	--	---

(b)(4)



<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Repackager / Relabeler
--	--	---	--

(b)(4)



<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
--	--	--	---

(b)(4)



r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. 10555-1	Standards Organization ISO	Standards Title Sterile, Single-use Intravascular Catheters, General requirements	Version 10555-1:1995/ Amend 1:1999, 2-04	Date 05/21/2007
2	Standards No. 594-1	Standards Organization ISO	Standards Title Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part 1: General requirements	Version 1986	Date 10/31/2005
3	Standards No. 11135-1	Standards Organization AAMI / ANS /ISO	Standards Title Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization	Version 2007	Date 07/31/2008
4	Standards No. 10993	Standards Organization ISO	Standards Title Biological Evaluation of Medical Devices Part-1: Evaluation and Testing	Version Sections 3-2003, 5-1999, 11-2006	Date 09/12/2007
5	Standards No. 10993	Standards Organization ISO	Standards Title Biological Evaluation of Medical Devices Part-1: Evaluation and Testing	Version 6-2007, 10-2002,	Date 07/31/2008
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850</p> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control</i></p>					

r4 Vascular, Inc.

Page 8

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

SECTION 3.0

Cover Letter

December 16, 2008

Food and Drug Administration
Center for Devices and Radiological health
510(K) Document mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CT

DEC 18 2008

Received

Re: 510(K) Notification – Traditional - r4 Vascular, Inc., Zeus CT PICC

Dear Document Control Staff:

Pursuant to the requirements of Section 510(K) of the Food, Drug and Cosmetic Act, notification is made of the objective of r4 Vascular, Inc. to market the following:
r4 Vascular, Inc. Zeus™ CT PICC.

NAME OF MEDICAL DEVICE:

Proprietary Name: *Zeus CT PICC*
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC), single and double lumen

DEVICE CLASSIFICATION:

Classification Panel: General Hospital
Regulatory Class: Class II
Product Code: LJS
Regulation Number: 21 CFR 880.5970

We consider the contents of this 510(k) to be confidential commercial information and request that it be considered as such by the FDA.

Thank you in advance for the consideration of this application. Please address all correspondence and questions regarding this submission to me at the address noted below, by email at lalew@r4vascular.com; by telephone at 612-770-4038 (cell) or 763-494-8400 (office) or fax at 743-494-8484. Please feel free to contact me personally at any time.

Sincerely,



Laurie Lewandowski
Director, Regulatory Affairs and QA
R4 Vascular, Inc.
7550 Meridian Circle North
Suite 150
Maple Grove, MN 55369

r4 Vascular, Inc.

Page 10

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

SECTION 4.0

Indications For Use Statement

510(k) Number (if known): _____

Device Name: *Zeus CT PICC*

Indications For Use:

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

SECTION 5.0

510(k) Summary

SUBMITTER:

R4 Vascular, Inc.
7550 Meridian Circle
Suite 150
Maple Grove, MN 55369

ESTABLISHMENT REGISTRATION NUMBER:

3006242715

CONTACT:

Laurie Lewandowski
Director, Quality and Regulatory Affairs
Telephone: 612-770-4038 cell
Telephone: 763-494-8400
Fax: 763-494-8484
Email: lalew@r4vascular.com

DATE PREPARED:

December 16, 2008

NAME OF MEDICAL DEVICE:

Proprietary Name:	Zeus™ CT PICC
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single and double lumen

DEVICE CLASSIFICATION:

Classification Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	LJS
Regulation Number:	21 CFR 880.5970

PREDICATE DEVICES:

Proprietary Name:	V-Cath (Polyurethane) Power PICC (Power-V)
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC), single and double lumen

Proprietary Name:	Tyco Palindrome Emerald
Regulation Name:	Chronic Hemodialysis Catheter
Common/Usual Name:	Catheter, Hemodialysis, Apheresis, Intravascular

Device Description:

The r4 Vascular, Inc. *Zeus™ CT PICC* is a family of peripherally inserted central venous catheters designed to perform infusion, intravenous therapy, blood sampling, power injection of contrast media studies and central venous pressure monitoring. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each *Zeus™ CT PICC* has a kink resistant reverse tapered catheter design. The *Zeus™ CT PICC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *Zeus™ CT PICC* product line has catheters in 4 Fr and 5 Fr single lumen and 5 Fr and 6 Fr dual lumen.

The *Zeus™ CT PICC* is similar to HDC's V-Cath (Polyurethane) Power PICC (Power-V), with the addition of a Biomimetic Coating that is similar in performance to the Tyco Palindrome Emerald.

Intended Use / Indication for Use:

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

Technological Comparison to Predicate Devices:

The technological characteristics of the *Zeus™ CT PICC* are substantially equivalent to the predicates, HDC's V-Cath (Polyurethane) Power PICC (Power-V) and Tyco Palindrome Emerald in terms of intended use, application, user population, basic design, performance and labeling.

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates.

Does the new device have the same indication statements? Yes.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Not in all regards. The principles of operations and basic design are the same as the predicate devices. The main change in design is the addition of the biomimetic coating to the catheter.

There is precedence in the market for coated catheters, Tyco Palindrome Emerald and their predicates.

Could the new characteristics affect safety or effectiveness? Yes. The changes may affect safety and effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

Yes. Testing was based on FDA guidance documents and recognized standards to evaluate the devices' performance.

- The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95 was used to determine the appropriate methods for evaluating the device's performance.
- ISO 10555-1:1997 Sterile, Single-use Intravascular Catheters, General requirements;
- ISO 594 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part1: General requirements
- AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 10993 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing

Sterilization requirements of ISO 11135:2007, *Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization*.

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*. Test profiles for externally communicating, blood-contacting, long-term devices will be met.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Performance testing was generated in accordance with the above referenced guidance document and standards.

Do performance data demonstrate equivalence? Yes. Performance data gathered in design verification testing demonstrate that the *Zeus™ CT PICC* with biomimetic coating met the performance criteria of safety and effectiveness test performed and based on the FDA's decision tree is substantially equivalent to the noted predicate devices.

CONCLUSION

The *Zeus™ CT PICC* met all established acceptance criteria for performance testing and design verification testing. This testing demonstrated that the *Zeus™ CT PICC* is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate devices: HDC V-Cath (Polyurethane) Power PICC (Power-V) and Tyco Palindrome Emerald.

r4 Vascular, Inc.

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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

SECTION 6.0

3. Premarket Notification Truthful And Accurate Statement

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director, Quality and Regulatory Affairs, I believe to the best of my knowledge, that all data and information submitted in this 510(k) Premarket Notification Submission are truthful and accurate and that no material fact has been omitted.



Laurie Lewandowski

Director, Quality and Regulatory Affairs

r4 Vascular, Inc.

December 16, 2008

510(k) Number: _____

SECTION 7.0

Class III Summary and Certification

This section does not apply.

SECTION 8.0

Financial Certification or Disclosure Statement

This section does not apply.

SECTION 9.0

Declarations of Conformity and Summary Reports

This section does not apply.

SECTION 10.0

Executive Summary

10.1 Device Description:

The r4 Vascular, Inc. *Zeus™ CT PICC* is a family of peripherally inserted central venous catheters designed to perform infusion, intravenous therapy, blood sampling and also power injection for contrast media studies. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each *Zeus™ CT PICC* has a kink resistant, reverse tapered catheter design. The *Zeus™ CT PICC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The *Zeus™ CT PICC* product line consists of the following catheters:

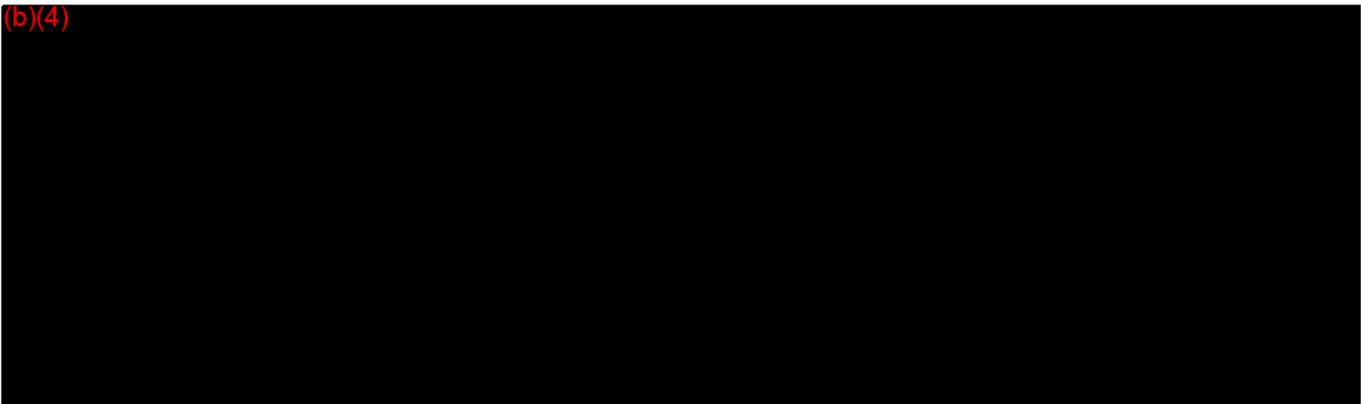
- 4 Fr single lumen
- 5 Fr single lumen
- 5 Fr dual lumen
- 6 Fr dual lumen

The catheters are trimmable by the clinician for fit to the individual patient. The PICCs are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment.

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

The *Zeus™ CT PICC* is almost identical to HDCs V-Cath (Polyurethane) Power PICC (Power-V), K071875, with the addition of a Biomimetic Coating, which is substantially equivalent to the Tyco Palindrome Emerald K060509.

(b)(4)



The advantages of (b)(4) surfactant polymer include:

- Biomimetic Coating is inert, with no biologically active component, such as heparin or an antibiotic, thereby eliminating potential complications.
- (b)(4)
- (b)(4)
- Non-toxic
- (b)(4)

The coating has been applied to the inner and outer diameter of r4 Vascular Zeus™ CT PICC by (b)(4). Testing has been performed on the coating to support the following claims:

- Reduces thrombosis occlusion by 34% when compared to a non-coated PICC catheter;
- Reduces the pressure to clean thrombus by 66% when compared to a non-coated device leading to a longer lasting catheter;
- Allows the use of a saline flush and a saline lock instead of requiring a heparinized saline lock. (Note: Following intravenous therapy, the PICC is “flushed” with saline to clear the therapy drug; the PICC is then filled with heparinized saline or in the case of the Zeus PICC, saline to prevent blood from filling the lumen. This is called locking the PICC.)
- (b)(4) Therefore, the catheter lasts longer because thrombosis occlusion is reduced and less pressure is required to clean thrombus.

Intended Use / Indication for Use:

The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

Technology and Similarity/Difference Summary

The Zeus™ CT PICC is similar in technology and materials when compared to the predicate device V-Cath (Polyurethane) Power PICC (Power-V) 510(K). The Zeus™ CT PICC has a coating and as such is using the Tyco Palindrome Emerald K060509 as coating predicate. The Palindrome Emerald is a catheter that is used in the venous system for greater than 30 days and includes Heparin Coating. The following summary table illustrates the similarities between the Zeus™ CT PICC (submission device) and the V-Cath (Polyurethane) Power PICC (Power-V) predicate device.

**Table 10.1
Technology and Similarity/Difference Table**

Characteristics	Submission Device: Zeus™ CT PICC	Power PICC (Power-V) (K071875) Predicate Device
Intended Use/ Indications for Use	The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.	The Power PICC (Power-V) is indicated for short or long term (less than or greater than 30 days) peripheral access to the central venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media. All Power PICC (Power-V) products have a maximum recommended infusion rating of 5 ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.
Target Population	Physician discretion	Identical
Sterility	100% Ethylene Oxide One time use	Identical
Biocompatibility	Biocompatibility testing was performed in accordance with ISO 10993 for a permanent blood contact device	Identical
Design /Size	4F single lumen = 50cm, 5F single lumen= 60cm, 5F dual lumen = 55cm, 6F dual lumen = 60cm Trimmable to patient specific need	4 Fr single lumen, 5 Fr single lumen, 5 Fr dual lumen, 6 Fr dual lumen Trimmable to patient specific need. Implanted useable length 60 cm
Dimensions (inches) Inner Diameter (ID) Outer Diameter (OD) Wall thickness (Wall)	(b)(4)	
Materials	(b)(4)	

	(b)(4)
Manufacturer	

The main difference between the Zeus™ CT PICC and the V-Cath Power PICC (Power-V) is the addition of the Biomimetic Coating. The Zeus™ CT PICC has a biomimetic coating and the V-Cath Power PICC (Power-V) does not.

The predicate for the coating is Tyco Palindrome Emerald, K060509, as it has a coating that reduces platelet adhesion. The Biomimetic Coating:

- Reduces thrombosis occlusion by 34% when compared to a non-coated PICC catheter;
- Reduces the pressure to clean thrombus by 66% when compared to a non-coated device leading to a longer lasting catheter;
- Allows the use of a saline flush and a saline lock instead of requiring a heparinized saline lock. (Note: Following intravenous therapy, the PICC is “flushed” with saline to clear the therapy drug; the PICC is then filled with heparinized saline or in the case of the Zeus PICC, saline to prevent blood from filling the lumen. This is called locking the PICC.)
- Does not change over time. Therefore, the catheter lasts longer because thrombosis occlusion is reduced and less pressure is required to clean thrombus.

The Palindrome Emerald has 60% less thrombus formation than an uncoated catheter in a blood loop study and 82% less thrombus than an uncoated catheter in an in vivo study.

Conclusion: Comparison of the technology show that the design and manufacture is similar to HDC’s V-Cath Power PICC (Power-V), K071875, with the addition of Biomimetic Coating. Comparison of the coating show that the performance of the r4 Vascular, Inc. Zeus™ CT PICC Biomimetic Coating is similar to the coating performance of the Tyco Palindrome Emerald.

SECTION 11.0

Device Description

11.1 Device Description

The r4 Vascular, Inc. *Zeus™ CT PICC* is a family of peripherally inserted central venous catheters (PICCs) designed to perform infusion, intravenous therapy, blood sampling and power injection for contrast media studies. The “CT” in the trade name indicates that the catheter is CT-injectable; that is, it will support the injection of contrast media in Computed Tomography (CT) procedures.

The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each *Zeus™ CT PICC* has a kink resistant, reverse tapered catheter design. The *Zeus™ CT PICC* kit includes a catheter and introduction components. The catheter is supplied sterile and nonpyrogenic in various kit configurations.

The *Zeus™ CT PICC* product line has catheters in 4 Fr and 5 Fr single lumen and 5 Fr and 6 Fr dual lumen; all of the catheters are trimmable by the physician for individual patient use. The length of the catheters as shipped varies;

- 4F single lumen = 50cm,
- 5F single lumen= 60cm,
- 5F dual lumen = 55cm,
- 6F dual lumen = 60cm.

The catheters are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment.

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector used should not exceed 300 psi.

The *Zeus™ CT PICC* is similar to HDC's V-Cath (Polyurethane) Power PICC (Power-V), K071875 in terms of design and indications for use. The only significant difference is that the Zeus has a biomimetic coating on the inside and outside of the lumen. The Zeus coating is substantially equivalent to Tyco Palindrome Emerald, K060509, which has a heparin coating and serves as a predicate for the Zeus coating.

The Biomimetic Coating provides several benefits for the clinician and patient:

- Reduces thrombosis occlusion by 34% when compared to a non-coated PICC catheter;
- Reduces the pressure to clean thrombus by 66% when compared to a non-coated device leading to a longer lasting catheter;

- Allows the use of a saline flush and a saline lock instead of requiring a heparinized saline lock. (Note: Following intravenous therapy, the PICC is “flushed” with saline to clear the therapy drug; the PICC is then filled with heparinized saline or in the case of the Zeus PICC, saline to prevent blood from filling the lumen. This is called locking the PICC.)
- Biomimetic Coating does not change over time. Therefore, the catheter lasts longer because thrombosis occlusion is reduced and less pressure is required to clean thrombus.

(b)(4)

When applied to the hydrophobic surface of a blood contacting medical device, such as a catheter, this coating prevents certain plasma proteins and platelets from adhering to the surface and so reduces the initiation of the clotting cascade. (b)(4) describes this coating in greater depth. Four NIH SBIR grants funded development of this coating at (b)(4).

(b)(4)

The advantages of (b)(4) surfactant polymer include:

- Biomimetic Coating is inert, with no biologically active ingredient, such as heparin or an antibiotic, eliminating related potential complications.
- (b)(4)
- Nontoxic,

(b)(4)

The coating has been applied to the inner and outer diameter of r4 Vascular Zeus™ CT PICC by (b)(4). Testing has been performed on coated catheters to support the reduced thrombus occlusion and saline lock following a flush in addition to standard catheter tests.

The Zeus™ CT PICC design is almost identical to the HDC V-Cath Power PICC (Power-V) PICC design. There are minor modifications to incorporate the company brand of r4 Vascular, Inc. and minor design changes as detailed below.

- change in colorants of the components
- dimensional changes that include
 - an increase in the inner diameter of the 4 Fr Single Lumen PICC for better flow,

- an increase of the radius of the “D” in the 5 Fr dual lumen PICC,
 - an increase in the septum of the 5 Fr dual lumen PICC
 - a modified hub exterior;
 - The hub originally included (b)(4) between the lumen / catheter insertion areas and the suture holes. (b)(4)
- Testing was performed as part of the verification testing, (b)(4) Section 18.

The above changes in the design did not impact the Indications For Use / Intended Use.

The product has four primary configurations as shown in the table below.

Model Number Basic Kit	Model Number Over the Wire (OTW)	Configuration
71045040	71045041	4Fr Single Lumen
71056040	71056041	5 Fr Single Lumen
72055540	72055541	5 Fr Dual Lumen
72066040	72066041	6 Fr Dual Lumen

Figure 11.1 is a picture of the 5 Fr single lumen and the 5 Fr dual lumen Zeus PICC.

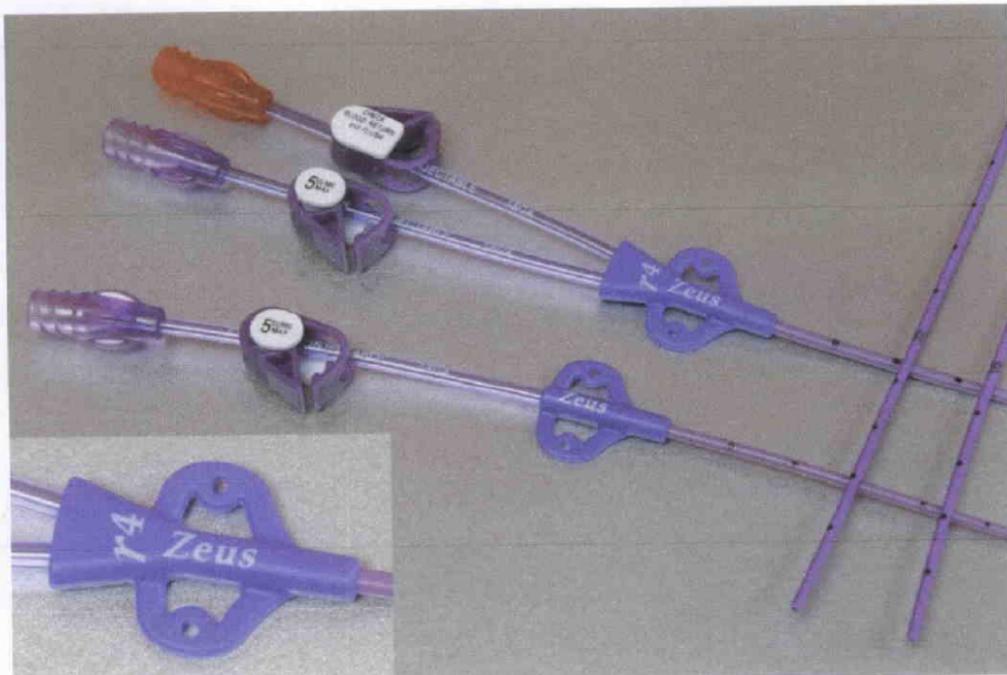


Figure 11.1 Zeus 5 Fr single and dual lumen PICC

11.2 Description of Assembled Device

The fully assembled Zeus™ CT PICC (see Figures 3 and 4) consists of an extruded polyurethane catheter insert molded into an injection-molded polyurethane hub (having integral suture tabs) that has extension leg tubing bonded to ISO standard Luer lock fittings for access attachment. The pinch clamps are placed on both extension legs and with the maximum recommended infusion rate:

- 4 and 5 FR single lumen – 5/ml sec maximum recommended infusion rate
- 5 and 6 FR dual lumen – 5/ml sec maximum recommended infusion rate

In addition, the extension leg tubing has the words “Power Injectable” and the gauge size printed on the tubing. The trimmable catheters (single and dual lumen) have depth markings to help in depth of insertion into the peripherally accessed vein. All kits are latex and Bis(2-ethylhexyl)phthalate (DEHP) free.

11.3 Description of Zeus™ CT PICC Kits

As noted in the description above the Zeus™ CT PICC will be offered in an array of commonly required introduction kits. The Zeus™ CT PICC kit includes a catheter and catheter introduction components. The Zeus™ CT PICC kit is also packaged as a Nurses Kit. The Nurses Kit includes the items in either the Basic Kit or the OTW Kit plus additional items that would typically be used by the Nurse when inserting the PICC. The list of these items is in Attachment 1.

(b)(4) will package the Zeus PICC based on the specifications from r4 Vascular, Inc. The kit assembly process including packaging, sealing and sterilization has been validated. Packaging tests are being performed by (b)(4) as part of the verification. (b)(4) will manage the sterilization process and distribution process. All of these processes have been validated and are discussed in Section 14.0 Sterilization and Section 18.0 Bench Testing.

There are two basic configurations of the Zeus Kit. One is the basic kit that consists of the PICC and the 80cm Guidewire and the other is the Over the Wire (OTW) kit that consists of the PICC and a 130 cm guidewire. The make-up of the kits is listed in the table below.

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

**r4 Vascular Zeus CT
PICC Basic Kit**

**r4 Vascular Zeus CT
PICC OTW Kit**

Description	(b)(4)
<ul style="list-style-type: none"> 4 Fr x 50 Single Zeus CT PICC 5 Fr x 60 Single Zeus CT PICC 5 Fr x 55 Dual Zeus CT PICC 6 Fr x 60 Dual Zeus CT PICC 	
Nac Plus Needle-Free Valve	
7 cmx21 ga TW Needle w/ echo	
6 x 10 cm PTFE Tearaway Intro	
<ul style="list-style-type: none"> 0.018"x80cm Nitinol Guidewire, 50cm Mark 0.018"x80cm Nitinol Guidewire, 60cm Mark 0.018"x80cm Nitinol Guidewire, 55cm Mark 0.018"x80cm Nitinol Guidewire, 60cm Mark 	
10cc Disp Luer Lock Syringe	
(b)(4) Protected Disposable Scalpel	
24" tape measure	
PICC Statlock Plus	

Description	(b)(4)
<ul style="list-style-type: none"> 4 Fr x 50 Single Zeus CT PICC 5 Fr x 60 Single Zeus CT PICC 5 Fr x 55 Dual Zeus CT PICC 6 Fr x 60 Dual Zeus CT PICC 	
Nac Plus Needle-Free Valve	
7 cmx21 ga TW Needle w/ echo	
6 Fr x 10 cm PTFE Tearaway Intro	
<ul style="list-style-type: none"> 0.018"x130cm Nitinol Guidewire, 50cm Mark 0.018"x130cm Nitinol Guidewire, 60 cm Mark .018"x 130cm Nitinol Guidewire, 55cm Mark 0.018"x 130cm Nitinol Guidewire, 60cm Mark 	
10cc Disp Luer Lock Syringe	
#11 BD Protected Disposable Scalpel	
24" tape measure	
PICC Statlock Plus	

r4 Vascular, Inc.

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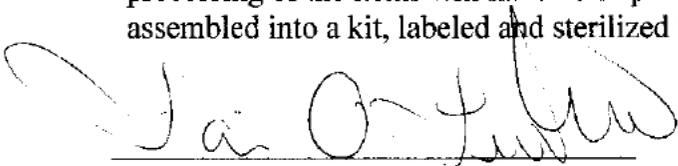
510(k) Premarket Notification Submission: *Zeus™ CT PICC***Kit Component Certification****Device Name:** Zeus™ CT PICC

I certify that in my capacity as Director, Quality and Regulatory Affairs for r4 Vascular, Inc., and to the best of my knowledge, the devices included in the kit for the Zeus™ CT PICC of this submission, have the following 510 (k) numbers or pre-amendment status:

Component 510(k) Number / Pre-amendment Status / Company

Kit Component	510(k) Number	Company
Zeus™ CT PICC 4Fr, 5 Fr single, 5Fr and 6Fr dual	Catheter subject of this submission	r4 Vascular, Inc.
Nac Plus Needle-Free Valve	K041179	(b)(4)
7 cmx21 ga TW Needle w/ echo	K890473	(b)(4)
4.5 fr x 10 cm PTFE Tearaway Intro 5 Fr x 10 cm PTFE Tearaway Intro 6 x 10 cm PTFE Tearaway Intro Viapeel Peelable Introducers	K072248	(b)(4)
0.018"x80cm Nitinol Guidewire, 50cm Mark 0.018"x 130cm Nitinol Guidewire, 50cm Mark 0.018"x80cm Nitinol Guidewire, 60cm Mark 0.018"x130cm Nitinol Guidewire, 60cm Mark 0.018"x80cm Nitinol Guidewire, 55cm Mark 0.018"x130cm Nitinol Guidewire, 55cm Mark 0.018"x80cm Nitinol Guidewire, 60cm Mark 0.018"x80cm Nitinol Guidewire, 60cm Mark	K070150	(b)(4)
10cc Disp Luer Lock Syringe	K980987	(b)(4)
(b)(4) Protected Disposable Scalpel	Pre-amendment	(b)(4)
24" tape measure	Pre-amendment	(b)(4)
PICC Statlock Plus	K942931	(b)(4)

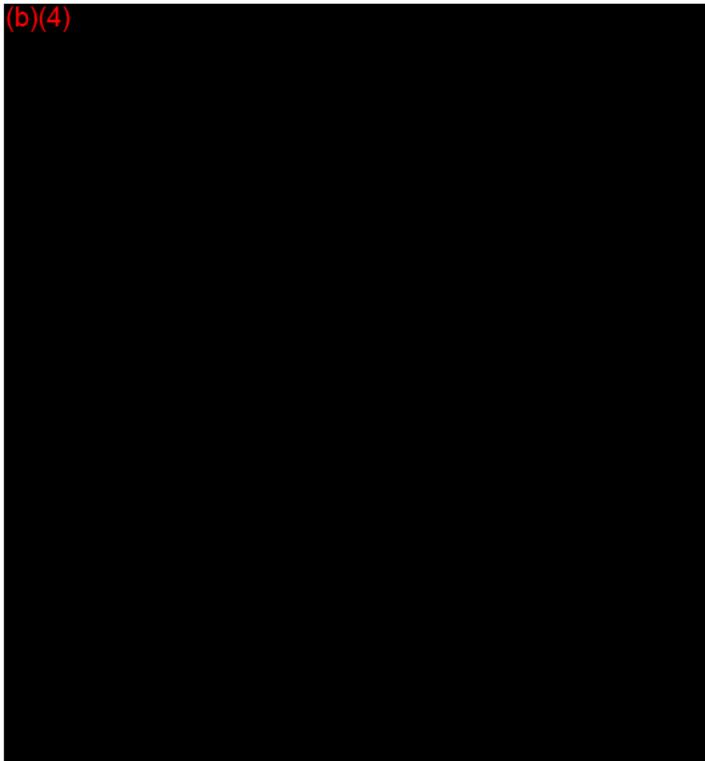
I also certify that the intended uses of the devices listed above remain the same and further processing of the items will have no impact. These components will be purchased non-sterile, assembled into a kit, labeled and sterilized by Ethylene Oxide.



Name: Laurie Lewandowski

Date: December 16, 2008

11.4 Description of Catheter Materials –



11.5 Physical and Dimensional Characteristics

The Zeus™ CT PICC is CT-injectable; that is, it will support the injection of contrast media in CT (Computed Tomography) procedures. The catheter and hub (junction region) will be purple-colored to indicate that the PICCs are CT-injectable. This aligns with industries recognition of the purple color for CT injection. The maximum recommended infusion rate is 5ml/s for power injection of contrast media not to exceed 300psi. The Zeus™ CT PICC design ensures that it can inject and extract fluids without leakage or bursting.

The Zeus™ CT PICC is coated with Biomimetic Coating that reduces platelet and allows the Zeus to be maintained with a saline lock following a saline flush.

The Zeus™ CT PICC product line includes models with single and double lumen (configurations, both of which are D-shaped). Single lumen configurations are available in 4 and 5 Fr diameters. Double lumen configurations are available in 5 and 6 Fr diameters. The Zeus™ CT PICC is made of radio-opaque polyurethane tubing with a tapered design. The catheters are trimmable for individual patient fit.

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

Dimension	4 Fr Single Lumen	5 Fr Single Lumen	5 Fr Dual Lumen	6 Fr Dual Lumen
Inner Diameter	(b)(4)			
Outer Diameter				
Wall Thickness (min)				
Septum				
Length	50 cm	60 cm	55 cm	60 cm

The Zeus™ CT PICC features a hub that enables the physician to suture anywhere along it. This added benefit provides flexibility to the physician in securing the catheter, not limiting the physician to two suture holes.

The Zeus™ CT PICC is indicated for a long term implant and meets biocompatibility and sterility requirements. It also withstands the chemicals that will be used with the PICC, including medicines and typical cleaning solvents.

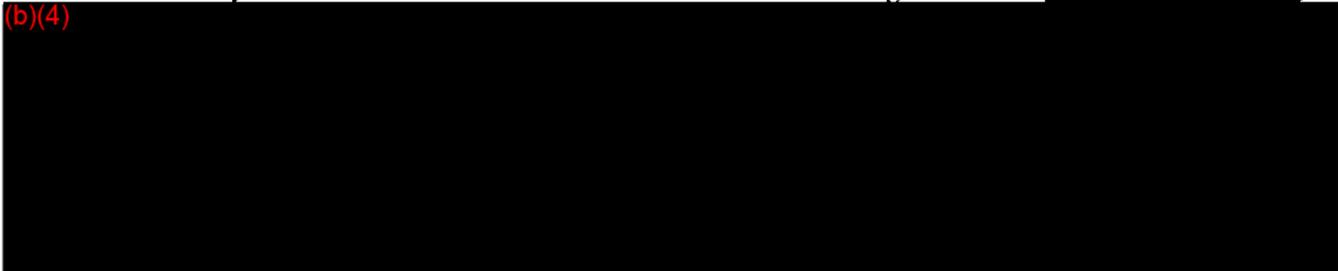
The following drawings identify the physical dimensions and requirements for the Zeus™ CT PICC.

11.6 Biomimetic Coating

11.6.1 Chemistry of Biomimetic Coating

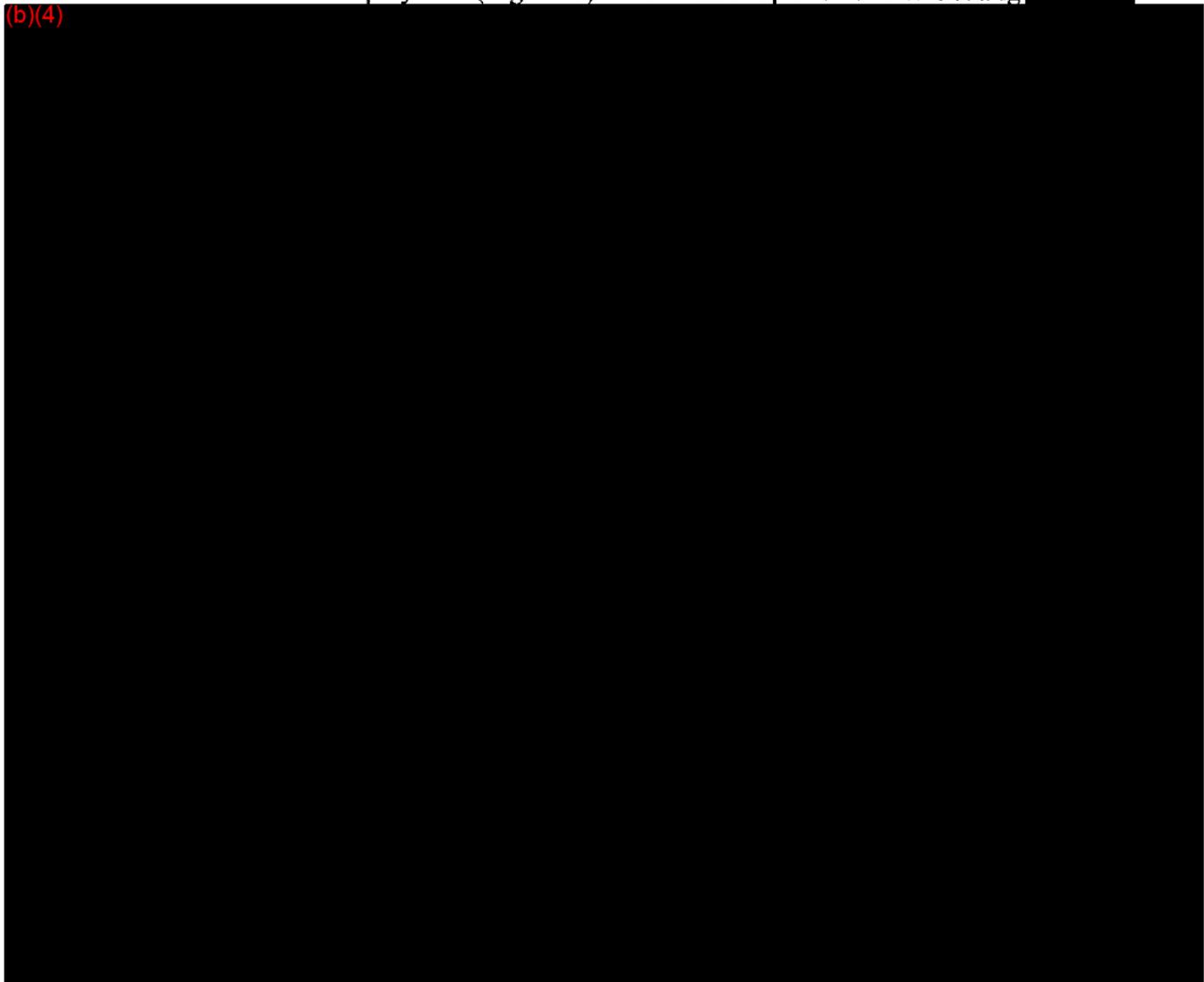
The chemistry and molecular structure of the *Biomimetic Coating* resembles (b)(4)

(b)(4)



The molecule of surfactant polymers (Fig. 11.6) which makes up Biomimetic Coating (b)(4)

(b)(4)



r4 Vascular, Inc.

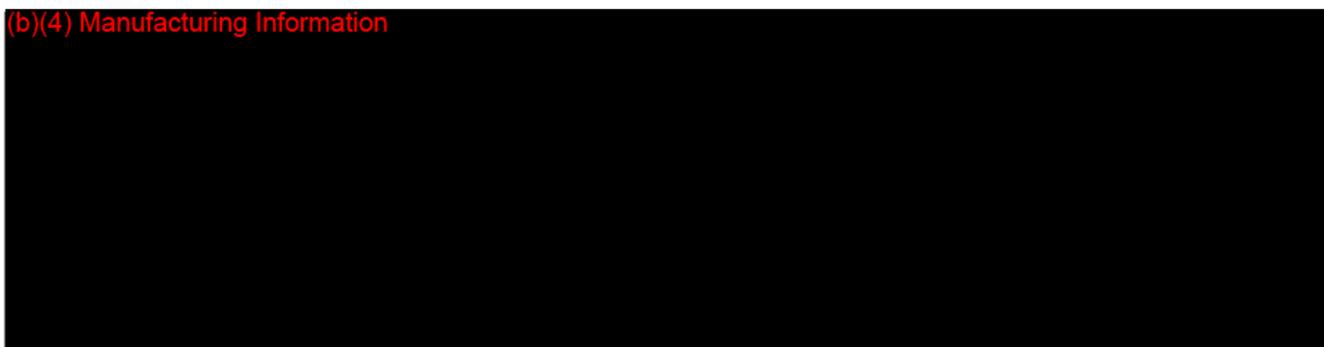
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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

(b)(4) Diagram

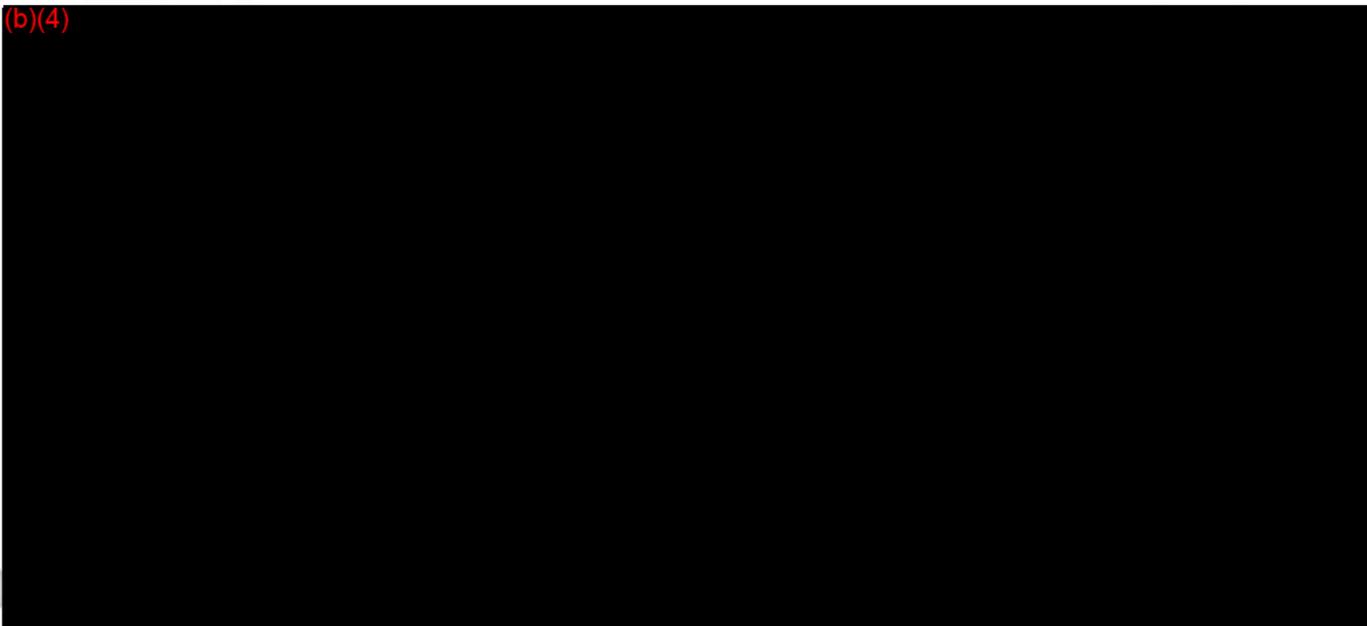


(b)(4) Manufacturing Information



11.6.2 Biomimetic Coating Adherence Mechanism

(b)(4)

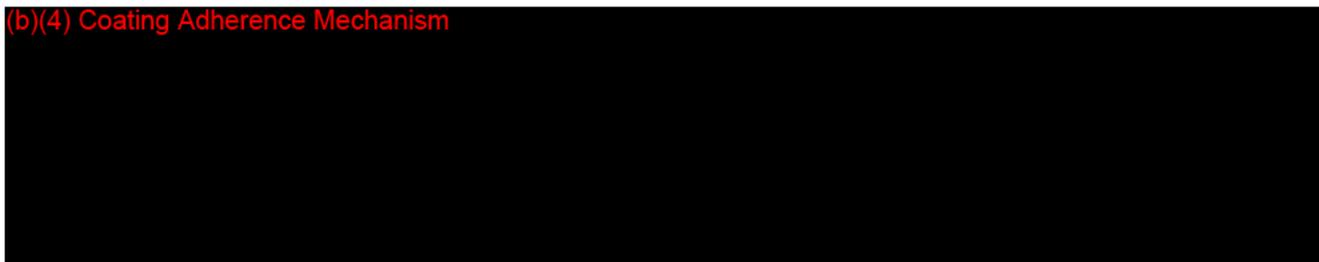


r4 Vascular, Inc.

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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

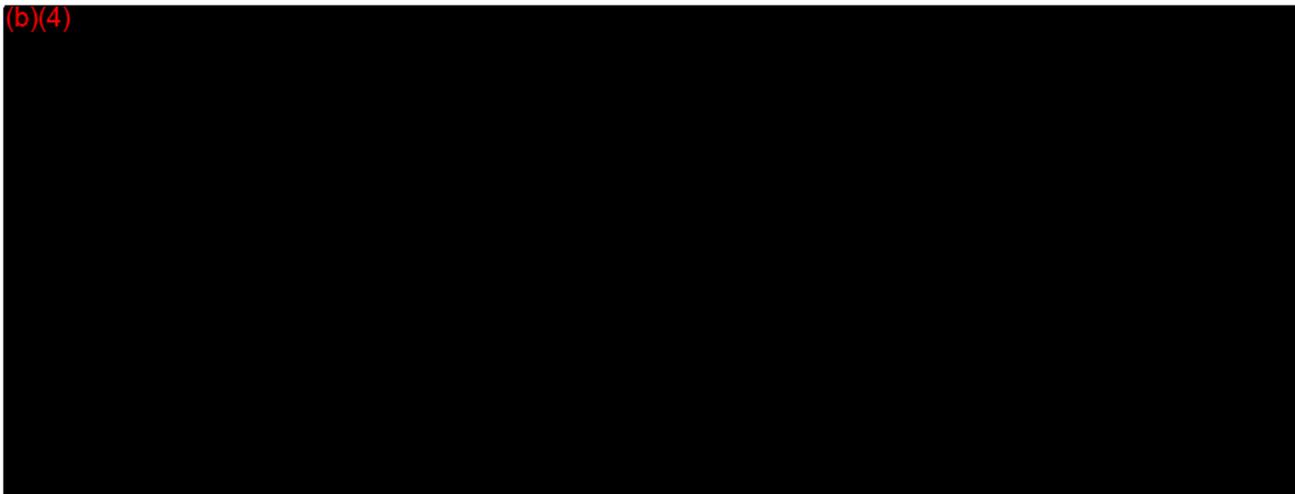
(b)(4) Coating Adherence Mechanism



11.6.3 Platelet Adhesion to Foreign Surface

Thrombosis induced by foreign materials is a major problem in circulatory support device applications and other devices having direct contact with blood. The physicochemical properties of blood-contacting foreign surfaces strongly affect their thrombogenic properties.

(b)(4)



The purpose of Biomimetic Coating developed at (b)(4) is to increase the hydrophilic properties of the blood contacting surfaces of a device thus decreasing thrombogenic properties of the hydrophobic foreign surface. In addition, (b)(4)




(b)(4)



11.6.4 Coating Claims and Test Sections

Claim / Benefit	Test
Reduces thrombosis occlusion by 34% when compared to a non-coated PICC catheter	(b)(4)
Reduces the pressure to clean thrombus by 66% when compared to a non-coated device leading to a longer lasting catheter	
Allows the use of a saline lock instead of requiring a heparinized saline lock.	
<p>Biomimetic Coating does not change over time. Therefore, the catheter lasts longer because thrombosis occlusion is reduced and less pressure is required to clean thrombus.</p> <ul style="list-style-type: none"> • Inert, no biologically active ingredient • Durable, no elution of the coating over time • Nontoxic 	

SECTION 12.0

SUBSTANTIAL EQUIVALENCE DISCUSSION

The r4 Vascular, Inc. Zeus™ CT PICC has been thoroughly evaluated. It is almost identical in design, materials, manufacture and PICC performance to the HDC V Cath Poly PICC Power V, The Zeus™ CT PICC coating exhibits a reduction in thrombus occlusion and bacterial adherence similar to the performance of the Tyco palindrome Emerald,. The following table provides a detailed comparison of the Zeus™ CT PICC and the HDC V-Cath Poly PICC Power V. The comparison between the Zeus™ CT PICC and the Tyco Palindrome Emerald coating are discussed below the table.

Attribute	r4 Vascular, Inc. Zeus™ CT PICC	HDC V Cath Poly PICC Power V K071875
Class	Class II	Class II
Product Code	LJS	LJS
Indications For Use	The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.	The Power-V PICC is indicated for patients that require repeated venous access for infusion or injection therapy. The Power-V PICC is indicated for peripheral access to the central venous system for intravenous therapy. The Power-V PICC is indicated for dwell times less than or greater than 30 days. The maximum recommended infusion rate is 5 ml/sec. The maximum pressure of power injectors used with the Power-V PICC catheter may not exceed 300 psi.
Use	5 ml/sec max for CT injection not to exceed 300psi	Identical
	Long term implantable (>30 days) or short term	Identical
Target Population	Physician discretion	Identical
Vessels	Venous System	Identical
Sterility	100% Ethylene Oxide	Identical
Biocompatibility	Biocompatibility testing was performed in accordance with ISO 10993 for a permanent blood contacting device.	Identical
Materials	(b)(4)	

r4 Vascular, Inc.

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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

	(b)(4) Materials	
Design	Double Lumen - 5Fr and 6 Fr D shaped lumens	Identical
	Reverse Tapered Design	Identical
	Kink resistant	Identical
	Catheter length <ul style="list-style-type: none"> • 4F single lumen = 50cm, • 5F single lumen= 60cm, • 5F dual lumen = 55cm, • 6F dual lumen = 60cm All catheters are trimmable	Implanted useable length 60 cm All catheters are trimmable
	(b)(4)	
	Available models include basic and OTW (over the wire)	Identical
	Hub design allows physician to suture anywhere on the hub	Hub design with suture holes
	Printing:	Identical

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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

	French size on Hub Depth markings on lumen																					
	Priming Volume Chart	Priming Volume Chart																				
	<table border="1"> <thead> <tr> <th>Catheter Size</th> <th>Priming Volume (ml)</th> </tr> </thead> <tbody> <tr> <td>4 Fr Single</td> <td>0.59</td> </tr> <tr> <td>5 Fr Single</td> <td>0.74</td> </tr> <tr> <td>5 Fr Dual</td> <td>0.55/0.55</td> </tr> <tr> <td>6 Fr Dual</td> <td>0.66/0.67</td> </tr> </tbody> </table>	Catheter Size	Priming Volume (ml)	4 Fr Single	0.59	5 Fr Single	0.74	5 Fr Dual	0.55/0.55	6 Fr Dual	0.66/0.67	<table border="1"> <thead> <tr> <th>Catheter Size</th> <th>Priming Volume (ml)</th> </tr> </thead> <tbody> <tr> <td>4 Fr Single</td> <td>0.60</td> </tr> <tr> <td>5 Fr Single</td> <td>0.75</td> </tr> <tr> <td>5 Fr Dual</td> <td>0.60/0.60</td> </tr> <tr> <td>6 Fr Dual</td> <td>0.65/0.65</td> </tr> </tbody> </table>	Catheter Size	Priming Volume (ml)	4 Fr Single	0.60	5 Fr Single	0.75	5 Fr Dual	0.60/0.60	6 Fr Dual	0.65/0.65
Catheter Size	Priming Volume (ml)																					
4 Fr Single	0.59																					
5 Fr Single	0.74																					
5 Fr Dual	0.55/0.55																					
6 Fr Dual	0.66/0.67																					
Catheter Size	Priming Volume (ml)																					
4 Fr Single	0.60																					
5 Fr Single	0.75																					
5 Fr Dual	0.60/0.60																					
6 Fr Dual	0.65/0.65																					

The comparison between the Zeus™ CT PICC and the Tyco Palindrome Emerald coating are listed below.

Attribute	r4 Vascular, Inc. <i>Zeus™ CT PICC</i>	Tyco Palindrome Emerald
Coating	Biomimetic Coating	Heparin Coated
Claims	<ul style="list-style-type: none"> Reduces thrombosis occlusion by 34% when compared to a non-coated PICC catheter; Reduces the pressure to clean thrombus by 66% when compared to a non-coated device leading to a longer lasting catheter; Allows the use of a saline lock instead of requiring a heparinized saline lock. Biomimetic coating does not change over time. Therefore, the catheter lasts longer because thrombosis occlusion is reduced and less pressure is required to clean thrombus. 	<ul style="list-style-type: none"> Reduces thrombosis 60% when compared to an uncoated catheter in vitro 82% reduction in thrombosis when compared to an uncoated catheter in vivo
Testing	(b)(4)	

As shown in the above table, the *Zeus™ CT PICC* and the HDC V Cath Poly PICC Power V are essentially the same. There is no significant difference in terms of use, design, and performance. Similarly, the performance of the Biomimetic Coating is substantially equivalent to the performance of the coating on the Tyco Palindrome Emerald.

SECTION 13.0

PROPOSED LABELING

The proposed labeling for the *Zeus™ CT PICC* was compared to the predicate labeling. The Zeus PICC labeling contains the same information, laid out in a slightly different form with the addition of the information surrounding the Biomimetic Coating. That information includes:

The *Zeus™ CT PICC* coating reduces the risk of thrombus adhering to the catheter and allows the use of a saline lock.

The information also includes the requirement of immersion and flushing the catheter prior to use to activate the coating.

In comparing the *Zeus™ CT PICC* coating portion of the labeling to the Tyco heparin coated product, Tyco included the reduction of platelet adhesion for a period of time as supported by bench and animal testing and provided detailed test results of their heparin coating in the IFU.

The proposed labeling for the *Zeus™ CT PICC* is in Attachment 2. The predicate labeling for HDC V-Cath Power PICC Power V and the Tyco IFU are in Attachment 3 (Note: Tyco Emerald IFU for the heparin coating portion is included in the Tyco Sapphire labeling. The heparin coating information is included on page 3 and 4 of the IFU. The Tyco Sapphire labeling is attached, the Tyco Emerald IFU was unavailable).

Proposed Labeling in Attachment 2

Predicate Labeling in Attachment 3

SECTION 14.0

STERILIZATION AND SHELF LIFE

14.1 STERILIZATION AND PACKAGING

The Zeus™ CT PICC will be sterile, with a sterility assurance level (SAL) of 1×10^{-6} , using a sterilization cycle that has been validated in accordance with the Quality Systems Requirements (QSR), 21 CFR 820.30 and reviewed in accordance with the FDA guidance document *Updated 510(k) Sterility Review Guidance K90-1 - Final Guidance for Industry and FDA*, dated August 30, 2002. In addition, ISO 10993-7:1995, AAMI TIR19 was used to determine residual limits

14.2 STERILIZATION METHOD

The Zeus™ CT PICC sterile unit products will be sterilized using EtO. Sterilization will be done by (b)(4). The sterilization cycle used for the Zeus™ CT PICC was based on similar products and was validated for r4 Vascular, Inc. by (b)(4) (b)(4) a division of (b)(4). The validation was performed in accordance with (b)(4) quality system requirements and ISO/AAMI/ANSI 11135-1: 2007.

14.3 STERILIZATION CYCLE VALIDATION METHODS

The sterilization cycle validation was performed and the final report is in Attachment 4. The validation method used for sterile unit product is “overkill 10^{-6} lethality, half and full cycles. Form 3654 for ISO/AAMI/ANSI 11135-1: 2007 is in Attachment 5.

14.4 STERILITY ASSURANCE LEVEL

The sterility assurance level (SAL) for the Zeus™ CT PICC will be 10^{-6} , as defined in ISO 11135:2007, *Sterilization of Health Care Products – Requirements for Validation and Routine Control— Ethylene Oxide Sterilization*.

14.5 DESCRIPTION OF PACKAGING TO MAINTAIN STERILITY

The Zeus™ CT PICC will be packaged in an appropriate package by (b)(4) that is compatible with EtO sterilization. (b)(4) performed the validation on the process and equipment that will be used in the process. Included in Attachment 6 is summary of the (b)(4) (b)(4) as an example of the testing performed performed by (b)(4).

Packaging Component	Material	Comments
Tray	(b)(4) (b)(4)	Identical to HDC V-Cath Power PICC (Power-V) predicate
Lid Stock	(b)(4) (b)(4) (b)(4)	Identical to HDC V-Cath Power PICC (Power-V) predicate

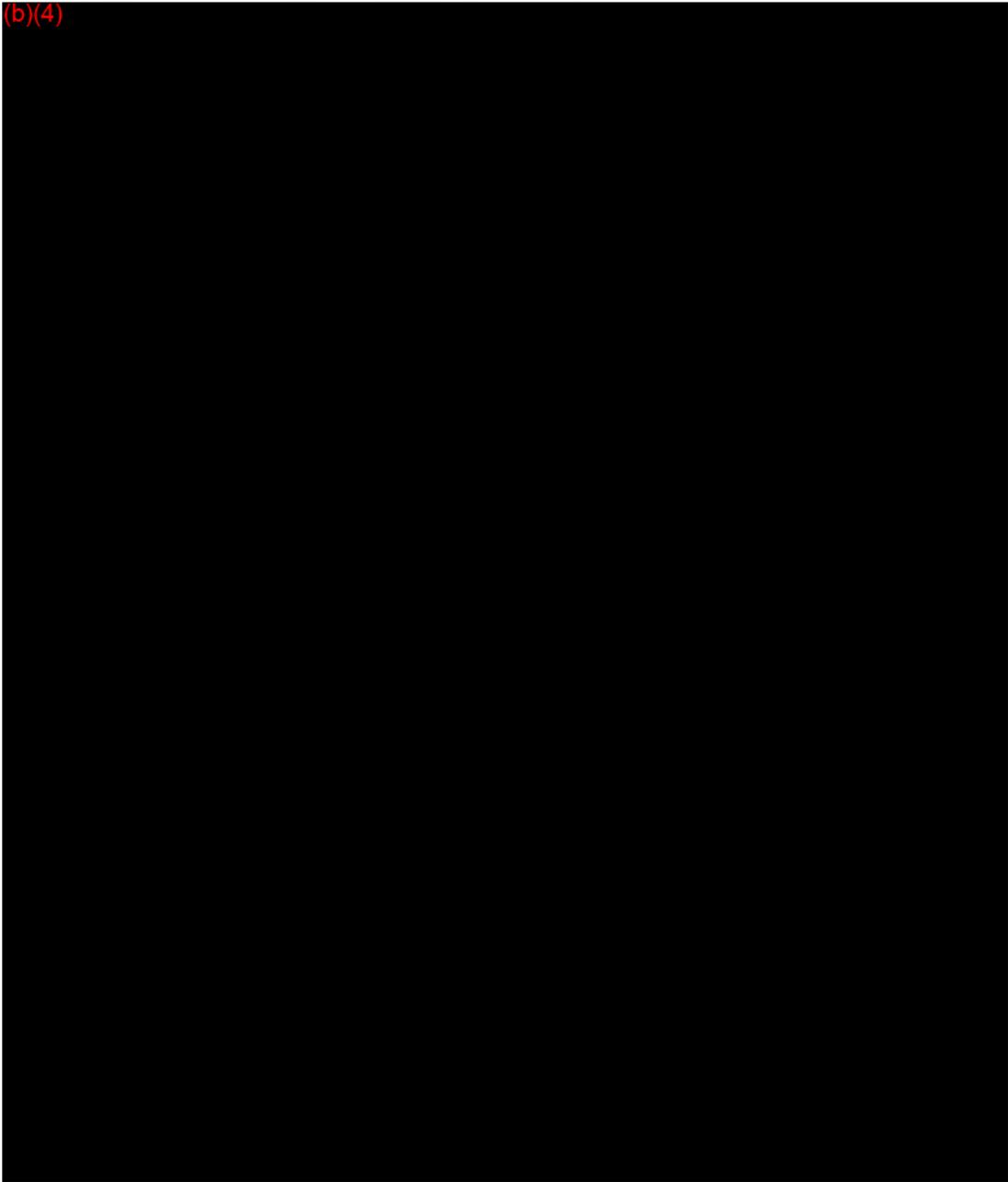
14.6 PYROGEN TESTING

The *Zeus™ CT PICC* will be “Non-pyrogenic”. Pyrogen testing will be conducted using standard (b)(4) at the time of manufacture by (bb)(4).

14.7 RESIDUALS

The *Zeus™ CT PICC* will comply with the residual guidelines noted below from ANSI/AAMI/ISO 10993-7 *Categorization of Devices and Allowable Limits of EtO (Ethylene Oxide) and ECH (Ethylene Chlorohydrin.* (b)(4).

(b)(4)



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14.8 SHELF LIFE

The *Zeus™ CT PICC* will be tested to support a shelf life claim of 1 to 3 years. (b)(4)
(b)(4) Validation has been performed in accordance with *AAMI/ISO 11507-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems* and *ASTM D4169-05 Performance testing of Shipping Containers and Systems*.

The Shelf Life Test Protocol is in Attachment 7 and includes (b)(4) ar
(b)(4)

The packages will all be EtO sterilized twice. They will then be subjected to (b)(4)
which consists of an increased temperature of (b) (b)(4) (b)(4)
(b)(4)
(b)(4)

SECTION 15.0

BIOCOMPATIBILITY

15.1 BIOCOMPATIBILITY TESTING SUMMARY

The Zeus™ CT PICC is a percutaneous, implanted, long-term intravascular catheter indicated for dwell times shorter or greater than 30 days. It is categorized as a Long Term Intravascular Catheter. According to ISO 10993, it is defined as an externally communicating device, blood contacting, long term device with contact duration of > 30 days. Form 3654 for ISO/AAMI/ANSI 10993 is in Attachment 8.

Biocompatibility testing of all materials and the Biomimetic Coating was performed. Two test vehicles, Zeus™ CT PICC and Apheresis Catheter, were used to incorporate all of the materials. The Zeus™ CT PICC was coated and sterilized prior to testing; the Apheresis catheter was sterilized prior to testing. Both test vehicles were subjected to all of the tests listed below.

The Zeus™ CT PICC biocompatibility testing incorporated the following components:

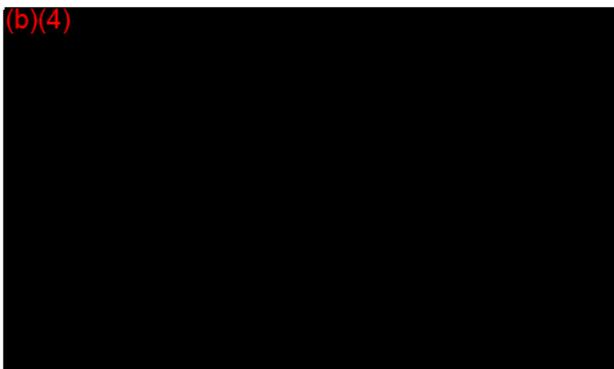
- Biomimetic Coating
- (b)(4) lumen (b)(4)
- Purple extension
- Informational Pinch Clamp Insert
- Hub
- White and Black Inks

The Apheresis biocompatibility testing incorporated the following components:

- (b)(4) clamps
- Purple extension
- Luer Connector purple
- Luer Connector red

The following tests were performed on the coated, sterilized Zeus™ CT PICC's with blue lumens and on sterilized Apheresis Catheters.

(b)(4)



(b)(4)
(b)(4)

Finished coated samples of the Zeus™ CT PICC were sterilized by ETO and subsequently tested for biocompatibility after the coating was activated by hydrating in saline. Finished samples of the Apheresis catheter were sterilized by ETO and subsequently tested for biocompatibility.

All biological tests were conducted under the direction of (b)(4) under Good Laboratory Practice (GLP) guidelines. **All of the results demonstrate that the Zeus™ CT PICC components meet ISO 10993 requirements for material safety and biocompatibility.** A summary of the conclusions is listed in Tables 8 and 9 below. Subsequent to the testing the catheter color was changed to purple. We believe the results are applicable because the purple colorant has been used previously in other implantable applications and (b)(4). (b)(4) The results were reviewed by an external Research Scientist. There is no difference in material as demonstrated by the (b)(4). Therefore, the purple dye in the catheter meets the ISO 10993 requirements for material safety and biocompatibility.

Attachment 9 includes the (b)(4) results summaries and the (b)(4).

Table 8 below summarizes the biocompatibility test results.

Table 8. Biocompatibility Testing Summary.

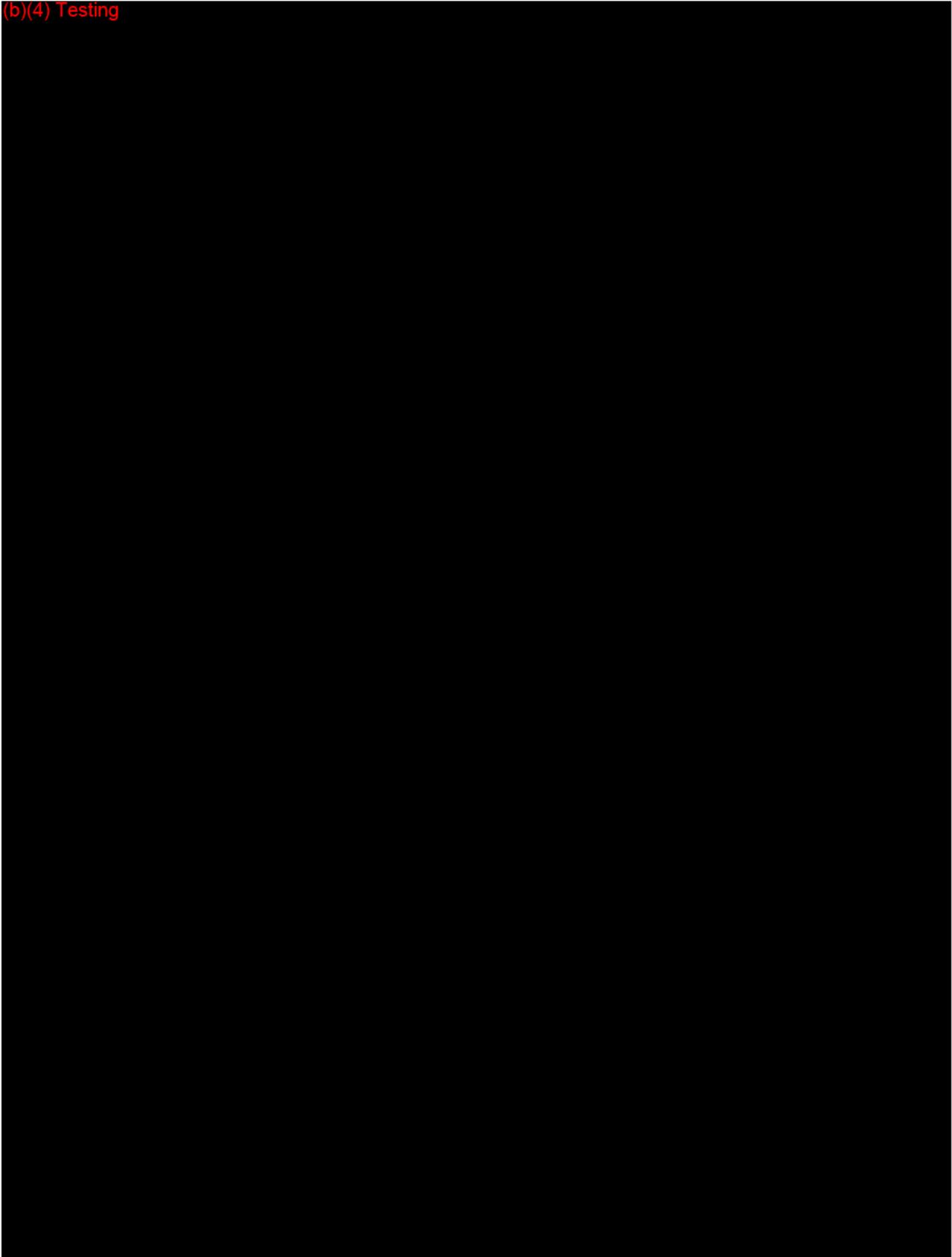
Biocompatibility Test	Conclusion
(b)(4)	

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(b)(4) Testing



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SECTION 16.0

SOFTWARE

(This Section Is Not Applicable)

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SECTION 17.0

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

(This Section Is Not Applicable)

SECTION 18.0

PERFORMANCE BENCH TESTING

18.0 Bench Testing

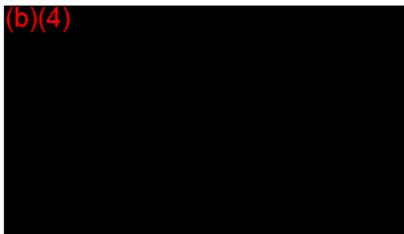
Bench testing was performed in two main categories, verification and validation. The validation testing was performed to ensure the product was exposed to simulated clinical procedures and functioned appropriately. Verification testing was performed to determine specifications were met.

Coated samples were used for the 4 Fr single lumen and 5 Fr dual lumen PICC testing; uncoated samples were used for the 5 Fr single lumen and 6 Fr dual lumen PICC testing. Testing of the coated and uncoated samples was performed to demonstrate that the coating did not impact the device performance which is consistent with the coating design. Test results indicated that the devices all met specifications regardless of the addition of the Biomimetic Coating.

18.1 Validation Testing

Validation testing was performed on a representative sample of devices. In some cases, (b)(4) (b)(4) a single catheter configuration was chosen as a worst case sample. Validation testing consisted of the following tests.

(b)(4)



18.2 Verification Testing

Verification testing was performed on all models of devices, in all cases except the (b)(4) (b)(4) test where one model of single lumen and one model of dual lumen devices represent all of the (b)(4).

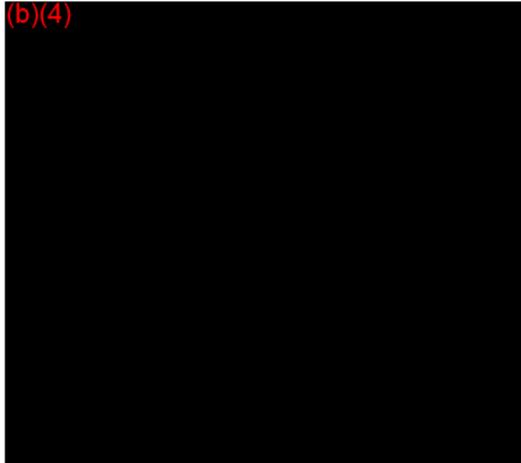
The Biomimetic Coating does not affect the Verification and Validation testing (b)(4) (b)(4). Therefore, the half of the devices were coated, the 5 Fr Single Lumen and 6 Fr Dual Lumen and half of the devices were not coated, the 4 Fr Single Lumen and the 5 Fr Dual Lumen. As demonstrated in the V&V testing all of the devices met the requirements whether coated or uncoated thereby confirming the coating does not impact the V&V testing.

Verification testing consisted of the following tests.

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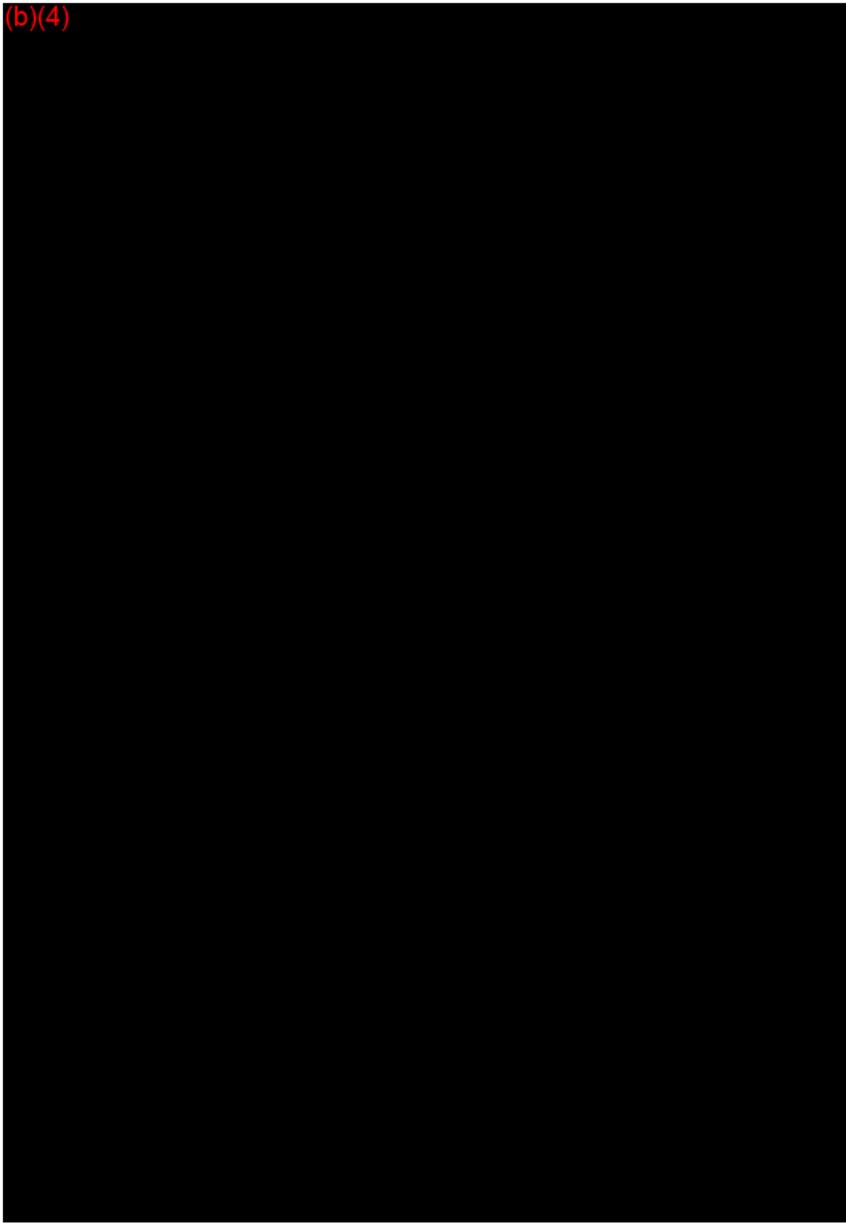
The following flow chart indicates the quantity and test order of the verification testing.

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(b)(4)



These tests provide a comprehensive analysis of the Zeus™ CT PICC. The V&V Zeus PICC test report is in Attachment 10. Attachment 11 includes Form 3654 for:

- ISO 10555-1:1997 Sterile, Single-use Intravascular Catheters, General requirements;
- ISO 594 Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part 1: General requirements

Summary of the Bench Test Results :

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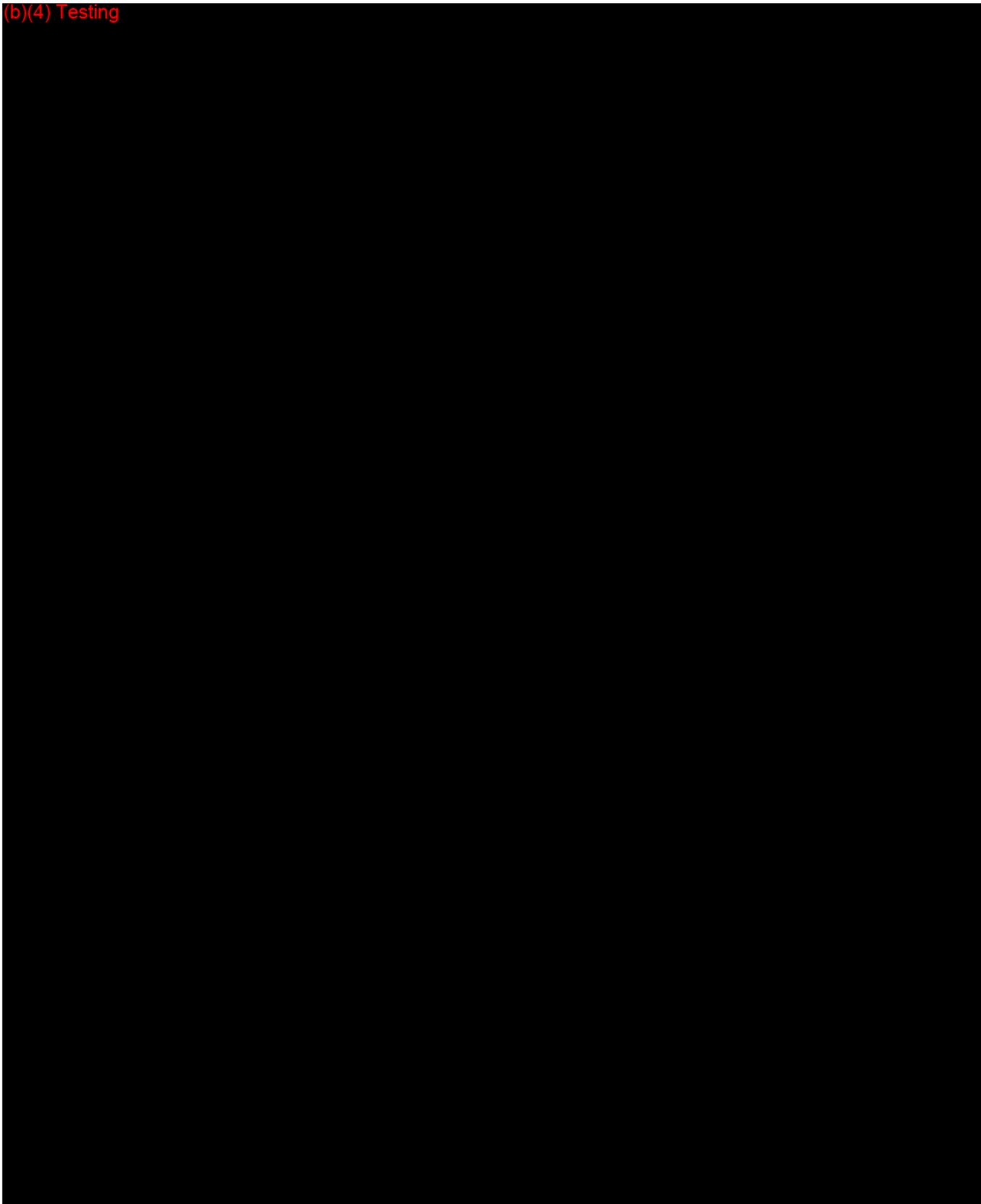
Validation Test	Results Summary
(b)(4)	

Verification Test	Results Summary
(b)(4)	

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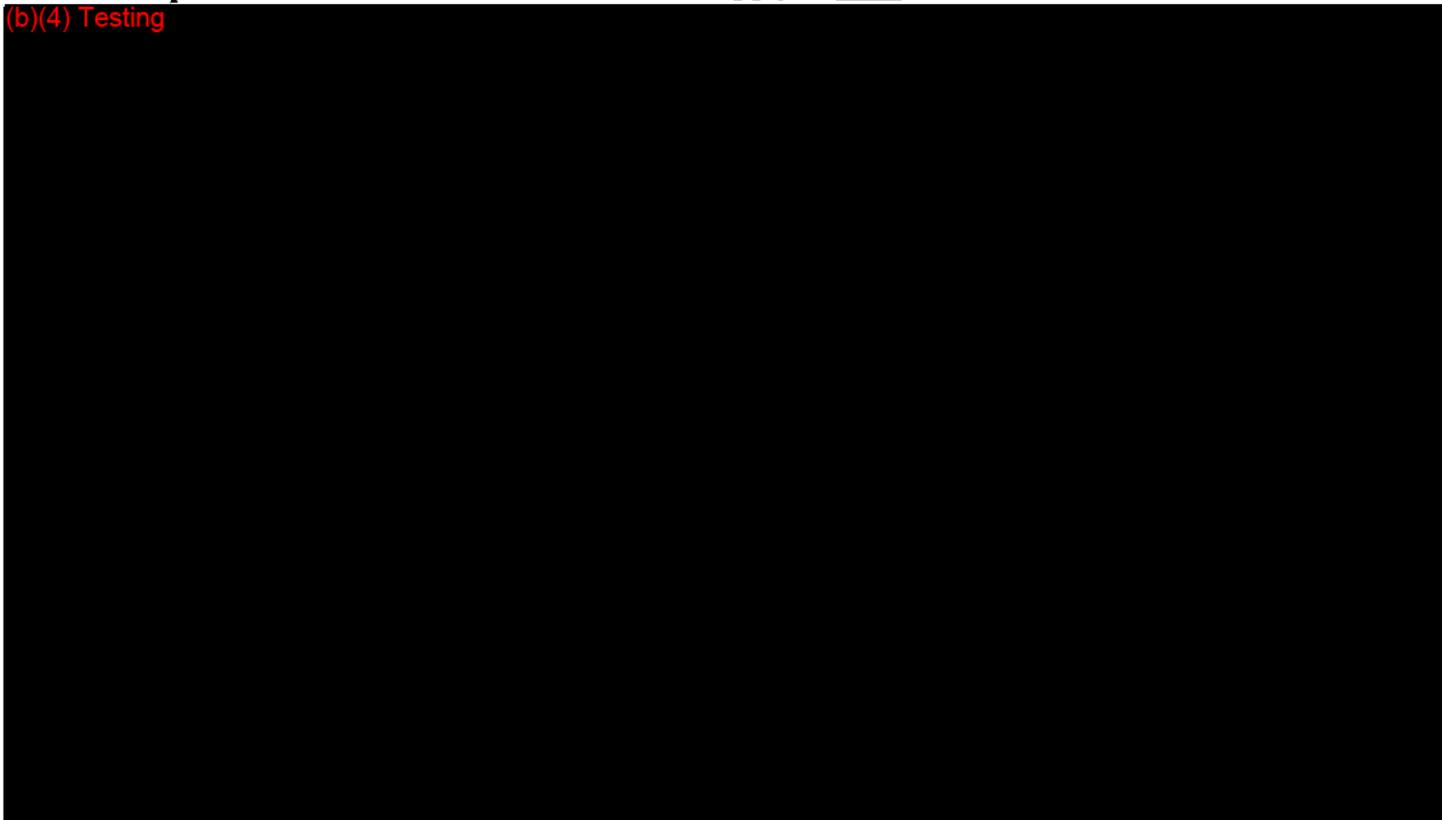
510(k) Premarket Notification Submission: *Zeus™ CT PICC*

(b)(4) Testing



Description of Methods and Conditions which apply to ALL tests performed:

(b)(4) Testing



Validation Testing

Validation testing demonstrates that the Zeus™ CT PICC will function in applications for which they are designed.

Priming Volume

Critical Features to be Verified

The internal volume of the catheter to be determine the fluid volume for flushing the catheter.

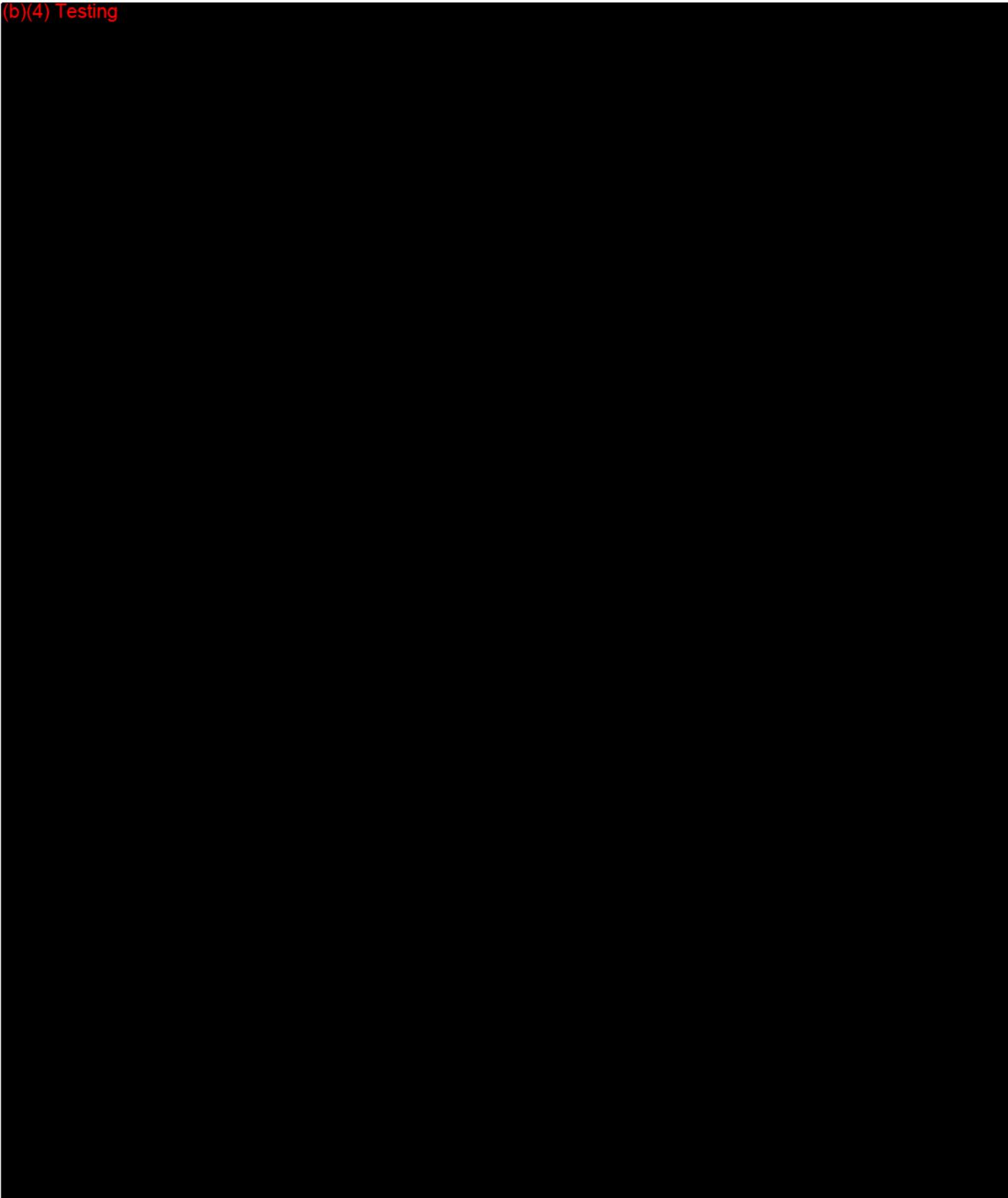
Test Method

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(b)(4) Testing



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(b)(4) Testing



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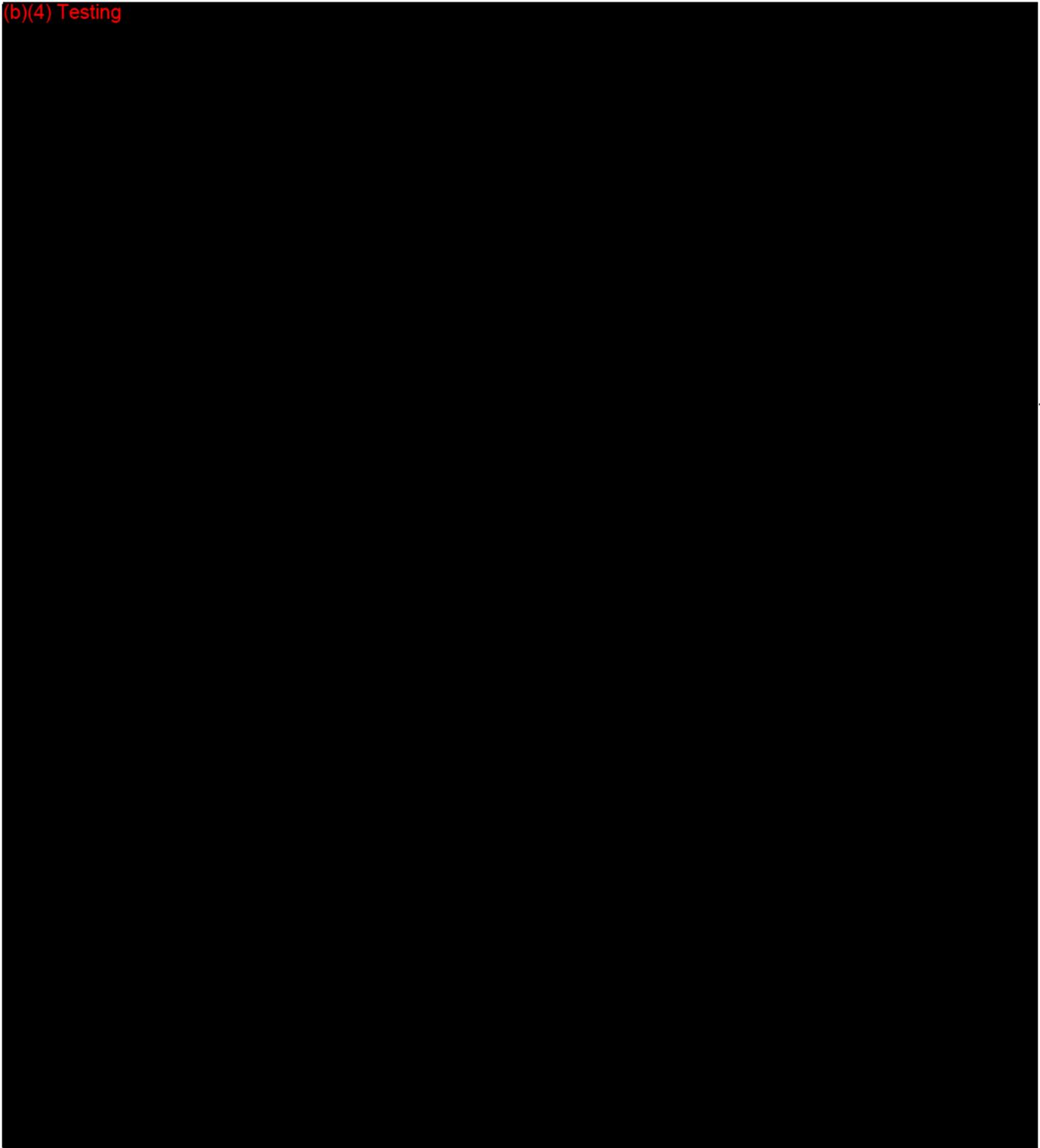
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Section 19.0

Performance Testing – (b)(4)

(b)(4) Testing



SECTION 20.0

Performance Testing – Clinical

This section is not applicable

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ATTACHMENT 1

Nurses Kit

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

The Zeus™ CT PICC Nurses Kit

500046-001	500046-002	500046-003	500046-004	510K Number	r4 Vendor
4 Fr Single PICC	5 Fr Single PICC	5 Fr Dual PICC	6 Fr Dual PICC	Subject of this submission	(b)
6 Fr x 11 cm PTFE Tearaway Intro	5 Fr x 11 cm PTFE Tearaway Intro	5 Fr x 11 cm PTFE Tearaway Intro	4.5 Fr x 11 cm PTFE Tearaway Intro	K072248	(b)

Remaining contents of the Nurses Kit with Vendor and 510K number where applicable and available

Description	510K Number	r4 Vendor
.030 ID Adaptor w/Sideport		(b)(4)
.015 x 75cm Twisted Wire Stylet		(b)(4)
Needle-Free Valve	K041179	(b)(4)
7 cm x 21 ga Safety Needle	K890473	(b)(4)
.018" x 45 cm Nitinol/SS Tip Guidewire	K070150	(b)(4)
5 ml luer lock syringe	K081436	(b)(4)
10cc Disp Luer Lock Syringe	K980987	(b)(4)
Safety scalpel	Pre-amendment	(b)(4)
24" tape measure	Pre-amendment	(b)(4)
PICC Statlock Plus	K942931	(b)(4)
Vials of sterile saline 10 cc's ea.		(b)(4)
Vial of lidocaine 5 cc's		(b)(4)
25ga lidocaine safety needle	K951254	(b)(4)
Tegaderm - Chlorohexadine	K080620	(b)(4)
Probe cover	Pre-amendment	(b)(4)
Sterile gel	Pre-amendment	(b)(4)
Rubber band	Pre-amendment	(b)(4)
Absorbant 3 ply drapes	K964142	(b)(4)
Drape: Under Arm	Pre-amendment	(b)(4)
Drape: Full Body (huge)	Pre-amendment	(b)(4)
Drape: Fenestrated	Pre-amendment	(b)(4)
Gloves non-latex (Size 7)	K052568	(b)(4)
Surgical Mask	K955556	(b)(4)
Bouffant Hair Net	Exempt	(b)(4)
Tourniquet	Exempt	(b)(4)
Chlor prep stick		(b)(4)
4 x 4 gauze- one packet (10ea)	Exempt	(b)(4)
2x2 gauze squares (6ea)	Exempt	(b)(4)
Filter straw for lidocaine		(b)(4)
Steri-Strips Anchor (2 cards of 3ea)	K874813	(b)(4)
Surgical Tape (20in)	Exempt	(b)(4)
Disposable Scissors	Exempt	(b)(4)
Alcohol Wipes	Exempt	(b)(4)

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Drape to wrap kit tray	K061762	(b)(4)
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ATTACHMENT 2

Proposed labeling for the *Zeus™ CT PICC*

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

Zeus™

Power Injectable Coated Polyurethane PICC

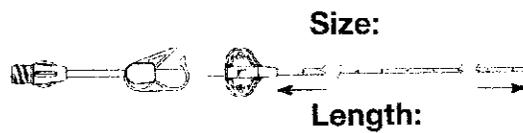
Contains:

REF

LOT



QTY:



Zeus™



Zeus™



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

Manufactured for:
r4 Vascular, Inc.
7550 Meridian Circle North
Suite 150
Maple Grove, MN 55369

www.r4vascular.com
Assembled in U.S.A.

200022 001 Rev A

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

Zeus™

Power Injectable Coated Polyurethane PICC

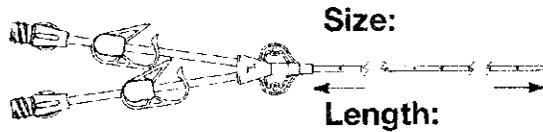
Contains:

REF

LOT



QTY:



Zeus™



Zeus™



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

Manufactured for:
r4 Vascular, Inc.
7550 Meridian Circle North
Suite 150
Maple Grove, MN 55369

www.r4vascular.com
Assembled in U.S.A.

200022-002 Rev A

ZEUS* CATHETER INSTRUCTIONS FOR USE

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PRODUCT DESCRIPTION

A family of peripherally inserted central catheters made from specially developed and processed medical grade materials. Each Zeus* catheter has a kink resistant, reverse tapered design and allows for contrast enhanced computed tomography studies. r4 Vascular packages its catheters in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.

STERILE  Sterilized by ethylene oxide.  Do not re-sterilize.

ZEUS* CATHETER COATING

The Zeus* catheter coating reduces the risk of thrombus adhering to the catheter and allows the use of a saline lock.

INDICATIONS

The Zeus™ *CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

CONTRAINDICATIONS

Use of the Zeus catheter is contraindicated in the following situations:

- If the patient is suspected or known to have bacteremia or septicemia or other infection.
- The patient has a known allergy to polyurethane.
- Insertion of the catheter through damaged or irradiated tissue.
- Inability to properly secure the catheter to the patient.

WARNINGS

GENERAL WARNINGS

- Avoid prolonged or excessive contact when using alcohol or alcohol containing antiseptics to clean the Zeus catheter or surrounding skin site.
- Do not wipe the catheter with acetone based solutions or polyethylene glycol (PEG) containing ointments. These can damage the polyurethane material if used over time.
- Do not fill the catheter with alcohol or any alcohol containing solution. Prolonged exposure to alcohol may cause degradation of the catheter material.
- Do not use the catheter if it is damaged or leaking.
- If extravasation occurs then immediately stop the injection or infusion and seek immediate medical attention.

- Allow antiseptic solutions to completely dry before applying an occlusive dressing. Chlorhexidine gluconate or povidone iodine are the suggested antiseptics to use.
- Intended for Single Patient Use. Do not reuse or reimplant. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned catheters may not be effective. Do not reuse or resterilize any contaminated catheter. ②
- After use, this product may be a potential biohazard. Handle and discard under accepted medical practice and applicable local, state and federal laws and regulations.

PLACEMENT WARNINGS

- Do not insert the catheter into an artery. It is not intended for intraarterial use.
- Place the catheter above the antecubital fossa. Placement at or below the antecubital fossa increases the risk of phlebitis.
- Avoid positioning the catheter tip in the right atrium. Placement of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.
- NEVER trim the stylet.
- NEVER pull the guidewire or catheter back through a needle.
- NEVER use clamping instruments with teeth or sharp edges on the catheter.
- AVOID excessive pulling on the catheter during removal.

• POWER INJECTION WARNINGS

- Only power inject through lumens labeled for such use. Otherwise the catheter may fail.
- Do not exceed a fluid flow rate of 5 ml/sec or a pressure of 300 psi when power injecting the catheter. Exceeding these maximum limits may result in catheter failure or catheter tip displacement.
- Always ensure patency of the catheter before connecting the catheter to a power injector.
- Failure to warm contrast media to body temperature before power injection may result in catheter failure.
- The pressure limiting regulator of the power injector may not prevent over-pressurization of the catheter and thereby lead to catheter rupture.
- Note: The indication for power injection of contrast media implies the catheter's ability to withstand the procedure but does not infer appropriateness of the procedure for a particular patient. A suitably

trained clinician is responsible for evaluating the health status of a patient as it applies to a power injection procedure.

PRECAUTIONS

GENERAL PRECAUTIONS

Follow these precautions to help avoid catheter damage or patient injury:

- **STERILE EO** Sterilized by ethylene oxide. Do not resterilize. ②
- Federal (U.S.A.) law restricts this catheter to sale by or on the order of a physician.
- Only qualified health care practitioners should insert, manipulate and remove these catheters.
- Carefully read and follow all instructions before use.
- Examine the package carefully before opening to confirm its integrity and the expiration date has not passed. Do not use if package is damaged, opened or the expiration date has passed.
- Inspect kit for inclusion of all items.
- Follow maximal barrier precautions and aseptic techniques when inserting and caring for the catheter.
- Flush the catheter with sterile normal saline before use. Wet catheter stylet before placing, repositioning or withdrawing it.
- DO NOT USE A SYRINGE SMALLER THAN 10 ml.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates including contrast media, as specified by their manufacturer.
- Secure the catheter in place to reduce the risk of catheter breakage and malposition.
- Do not use acetone or tincture of iodine with this catheter.
- Accessories and items used with this catheter should incorporate luer lock connections.

PRECAUTIONS RELATED TO PLACEMENT PROCEDURE

- The Zeus* catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. It is recommended that the Zeus* catheter be inserted above the antecubital fossa.
- Do not kink the catheter during placement or securement. Acute angulation of the catheter may compromise patency of the catheter lumen.
- Do not cut stylet.

- Simultaneously remove both the needle and guidewire to prevent the needle from damaging or shearing the guidewire.
- Do not forcibly remove the stylet. Removing the stylet with resistance can damage the catheter.
- Do not use of sharp instruments with the catheter. Use only smooth-edged atraumatic clamps or forceps.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- When not in use secure a sterile Luer end cap on the catheter hub to prevent contamination.

POSSIBLE COMPLICATIONS

The potential exists for serious complications including:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Catheter
- Laceration of Vessels or Viscus
- Myocardial Erosion
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion

INSERTION INSTRUCTIONS

1. Identify an appropriate catheter size.
 - a. For blood sampling or infusion therapy use a 4 French or larger catheter.
 - b. For central venous pressure monitoring, r4 Vascular recommends use of a catheter lumen of 20 gauge or larger.
2. Identify an appropriate vein and catheter insertion site.
 - A. Apply a tourniquet above the anticipated insertion site.
 - B. Select a vein by assessing patient anatomy and condition. Recommended veins are cephalic, basilic or median cubital basilic.

<<< Show cephalic, basilic and median cubital basilic in a graphic >>>

Caution: The Zeus* catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. It is recommended that the Zeus* catheter be inserted above the antecubital fossa.
 - C. Release tourniquet.
 - D. Set up the sterile field as per maximal barrier precaution guidelines.
2. Preflush the Catheter and Stylet
 - A. Flush each catheter lumen with heparinized saline solution or sterile normal saline.
 - B. Soak or wipe the catheter with heparinized saline solution or sterile normal saline to activate its coating.

<<< Show graphic of catheter being flushed >>>
 - C. Soak or wipe the stylet surface.
 - D. Remove the stylet from its holder and insert it into the catheter. Only advance the stylet to the distal end of trimmed catheters.

Note: If the surface of the stylet becomes dry after removal from the holder, wetting with more sterile normal saline will renew the hydrophilic effect.
3. Apply Tourniquet and Drape
 - A. Position arm at 90° angle.
 - B. Reapply the tourniquet above the intended insertion site to distend the vein.
 - C. Prepare the site according to institution policy using sterile technique.
 - D. Drape the patient by placing the fenestrated drape over the anticipated puncture site.
4. Perform Venipuncture
 - A. Remove the needle guard.
 - B. Insert the needle into the vein using manual techniques or imaging guidance.

WARNING: Plug the sheath opening with a finger and ask the patient to perform the Valsalva maneuver until the catheter is inserted into the sheath, to reduce the risk of blood loss and risk of air aspiration.

5. Advance Guidewire

- A. Insert the guidewire through the needle and advance the guidewire 15 to 20 cm into the vein. Do not advance the guidewire if there is resistance.

Caution: Do not advance the wire past the axilla without fluoroscopic guidance or other tip locating methods.

<<< show proper wire placement location and axilla in a graphic >>>

6. Remove Needle

- A. Release tourniquet. Apply slight pressure on the vessel above the insertion site to reduce blood flow.
- B. If necessary, enlarge the puncture site with a scalpel blade.
- C. Withdraw the needle while maintaining position of the guidewire.

7. Insert the Peelable Sheath

- A. Insert the sheath assembly over the guidewire. Using a twisting motion, advance the sheath into the vein.

8. Measure Distance to Tip Location

- A. Using fluoroscopic control, determine the correct catheter length by advancing the guidewire to the wanted catheter tip location in the SVC.
- B. Once the guidewire tip is in proper position, mark the length by clamping forceps onto the guidewire at the skin site.

9. Removing Dilator and Guidewire

- A. Rotate locking collar of dilator and remove dilator from sheath.
- B. Withdraw the dilator and guidewire, leaving the small sheath in place.

WARNING: Place a finger over the sheath opening, and ask the patient to Valsalva until the catheter is inserted into the sheath, to minimize blood loss and risk of air aspiration.

10. Adjustment of Catheter Length

Note: Cut catheters to length according to hospital protocol if preferred because of patient size and needed point of insertion. Catheter depth markings are in centimeters.

- A. Measure the distance from the insertion site to the wanted tip location.
- B. Use the guidewire to determine needed catheter length, and retract the stylet behind the point the catheter is to be cut (if applicable).
- C. Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy (if applicable).
- D. Record the catheter length on the patient chart and patient card for future use determining priming volumes.

Caution: Do not cut stylet.

- E. Inspect cut surface to assure there is no loose material.
- F. Readvance the stylet to the distal end of the trimmed catheter (if applicable).

11. Insert and Advance the Catheter

- A. Insert the catheter (and stylet, if applicable) into the sheath.
- B. Advance the catheter slowly.
- C. Stabilize the catheter position by applying pressure to the vein distal to the sheath.
- D. Withdraw the sheath from the vein and away from the site.

E. Split the sheath and peel it away from the catheter.

12. Complete Catheter Insertion

A. Continue to advance the catheter. For central placement, when the tip reaches the shoulder, have the patient turn head (chin on shoulder) toward the insertion side to prevent possible cannulation into the jugular vein.

Caution: The Zeus* catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. R4 Vascular recommends placing the Zeus* catheter above the antecubital fossa.

<<< show catheter insertion path including the antecubital fossa, shoulder, and right atrium in a graphic >>>

B. Position the arm at a 90° angle, preserving sterility. Advance catheter into the wanted position.

WARNING: This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade.

C. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.

Slowly remove the stylet, if applicable

D. Place a finger over the catheter opening to reduce blood loss.

13. Aspirate and Flush

A. Attach primed extension set or saline-filled syringe.

B. Aspirate for satisfactory blood return and flush catheter with 10 ml normal saline to ensure patency.

Caution: Apply a sterile needleless injection cap or end cap on the catheter hub to prevent contamination when not in use.

C. Cap catheter.

WARNING: Hold the connector below the patient's heart when removing the injection cap to stop the fluid level in the catheter from dropping and aspirating air.

14. Dress Catheter <<<Need Graphics Here! >>>

STATLOCK* CATHETER STABILIZATION PROCEDURE

1. Secure catheter with StatLock* catheter stabilization device.
2. Cover site and StatLock* catheter stabilization device with transparent dressing.
3. Place 1st anchor tape sticky side up, under one extension leg. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.
4. For multilumen catheters, place more anchor tape(s) sticky side up under remaining hub(s). Wedge tape between hub(s) and wings.
5. Chevron anchor tape on top of transparent dressing.

TAPE STRIP SECUREMENT PROCEDURE

1. Place 1st anchor tape over wings or bifurcation.
2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.

3. Place 2nd anchor tape sticky side up under one hub and close to transparent dressing. Wedge tape between hub and wings.
4. Chevron anchor tape on top of transparent dressing.
5. Optional: For multilumen catheters, place more anchor tapes sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing.

Caution: Secure the catheter in place to reduce the risk of catheter breakage and embolization.

WARNING: When using alcohol or alcohol containing antiseptics with polyurethane PICCs, take care to avoid prolonged or excessive contact. Allow solutions to dry completely before applying an occlusive dressing. Chlorhexidine gluconate or povidone iodine are the suggested antiseptics to use.

WARNING: Do not use alcohol to lock, soak or de clot polyurethane PICCs because alcohol degrades polyurethane catheters over time with repeated and prolonged exposure.

WARNING: Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.

15. Verify Placement

- Position PICCs with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or suitable technology.

POWER INJECTION PROCEDURE

WARNING: Zeus* catheter indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not infer appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it applies to a power injection procedure.

- A. Use appropriate imaging techniques such as a chest x-ray to ensure the catheter tip is properly positioned in the patient's superior vena cava.
- B. Remove the injection cap from the Zeus* catheter.
- C. Attach a 10 ml or larger syringe filled with sterile normal saline.
- D. Aspirate for satisfactory blood return and vigorously flush the catheter with the full 10 ml of sterile normal saline. Do not power inject if blood return is unsatisfactory.

WARNING: Failure to ensure patency of the catheter before power injection studies may result in catheter failure.

- E. Detach syringe.
- F. Attach the power injection catheter to the Zeus* catheter according to manufacturer's recommendations.
- G. Warm contrast media to body temperature before power injecting.

WARNING: Failure to warm contrast media to body temperature before power injection may result in catheter failure.

H. Use only lumens identified as power injectable for power injection of contrast media.

<<< add graphic showing Zeus' power injection identification means >>>

WARNING: Use of lumens not identified as power injectable, for power injection of contrast media may cause failure of the catheter.

I. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate of 5ml/sec.

WARNING: Exceeding the maximum flow rate of 5 ml/sec, or the maximum pressure of power injectors of 300 psi, may result in catheter failure or catheter tip displacement.

WARNING: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.

J. Disconnect the power injector.

K. Replace the injection cap on the Zeus* catheter.

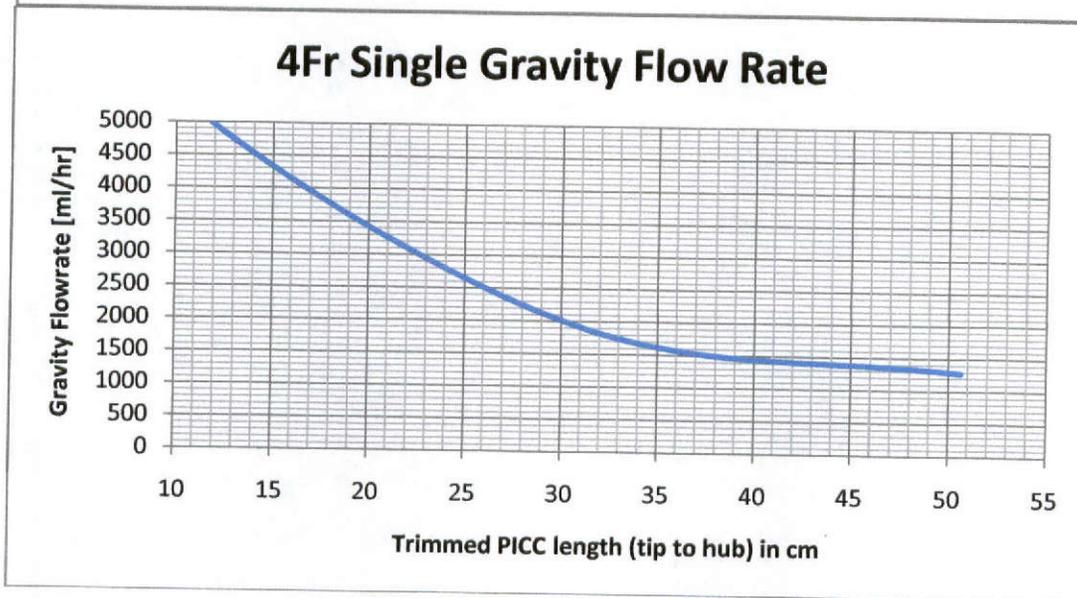
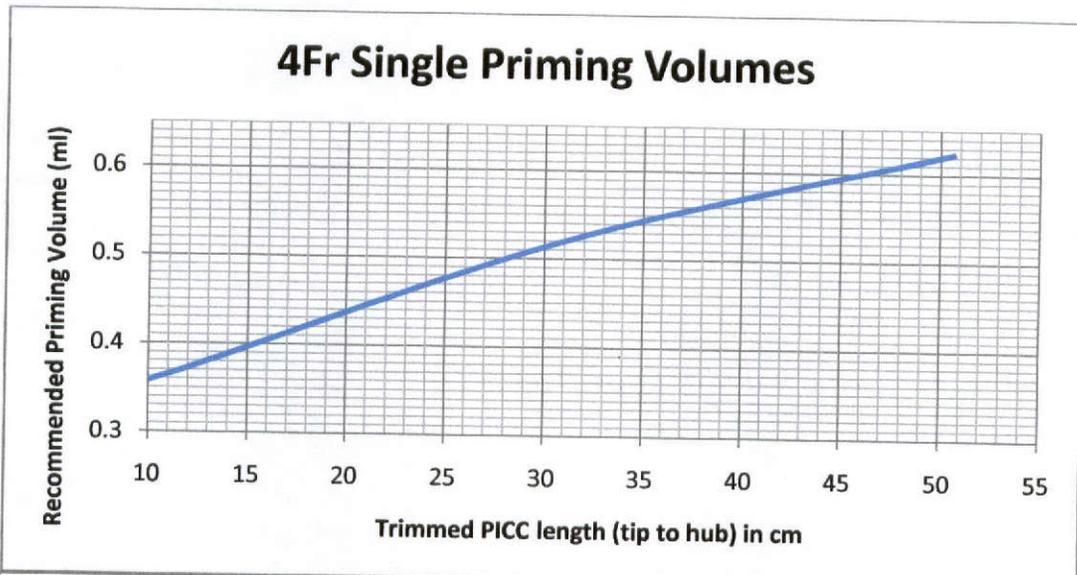
L. Flush the Zeus* catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe. Use of heparinized saline to lock each lumen of the catheter is optional.

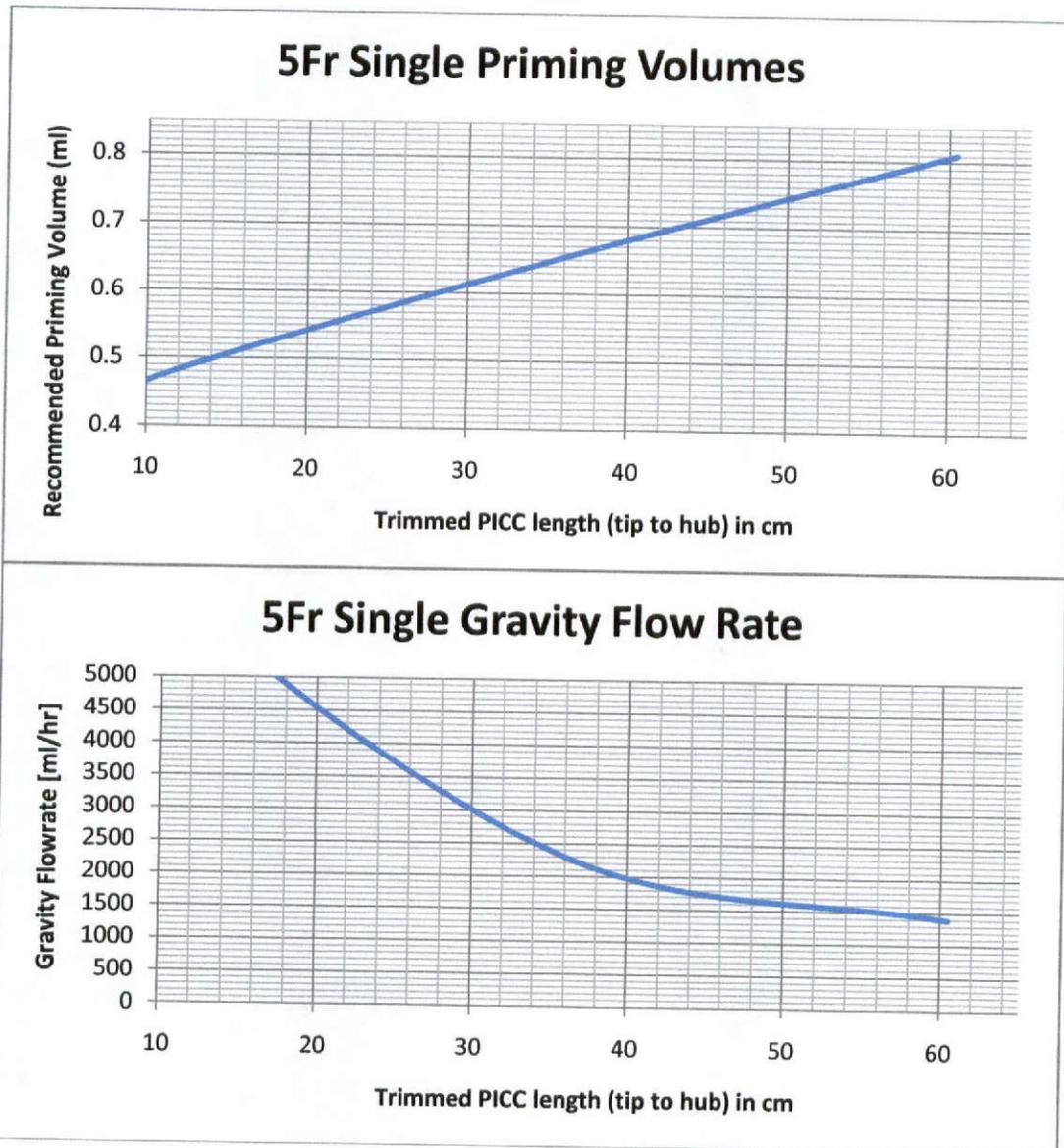
• **The Zeus* catheter testing included 15 power injection cycles.**

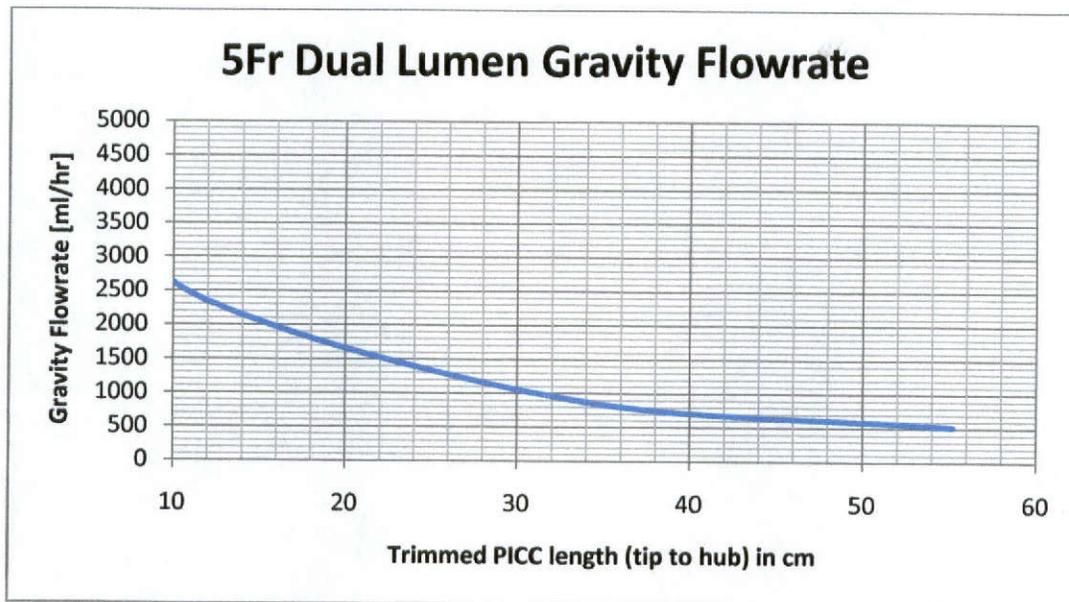
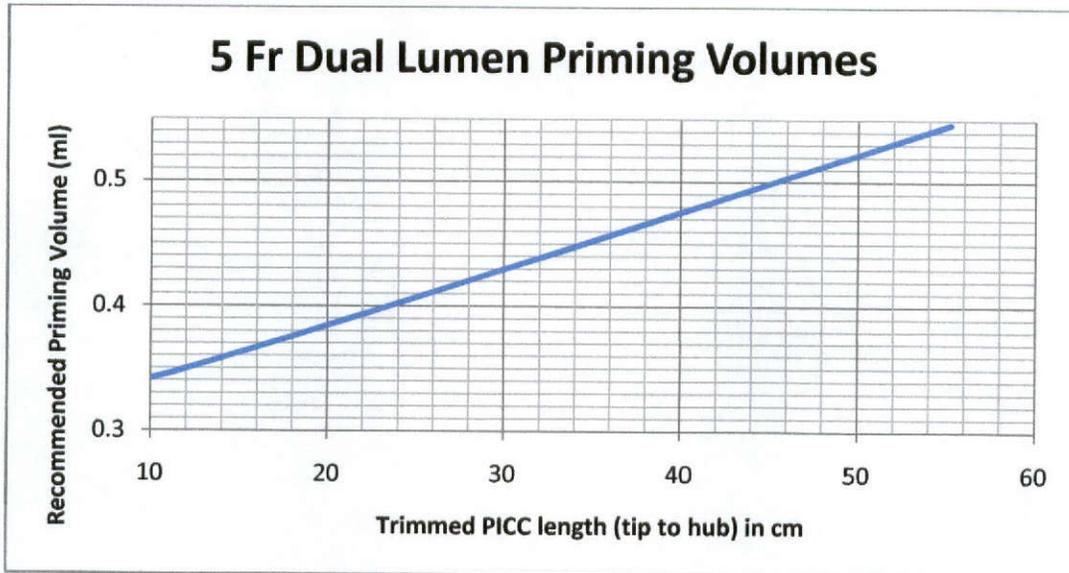
SUGGESTED CATHETER MAINTENANCE

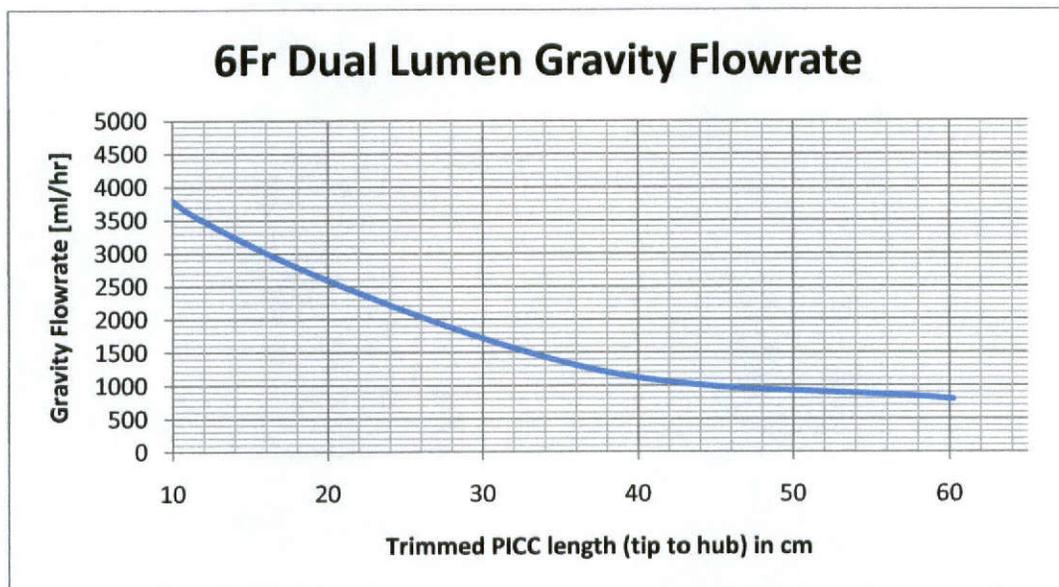
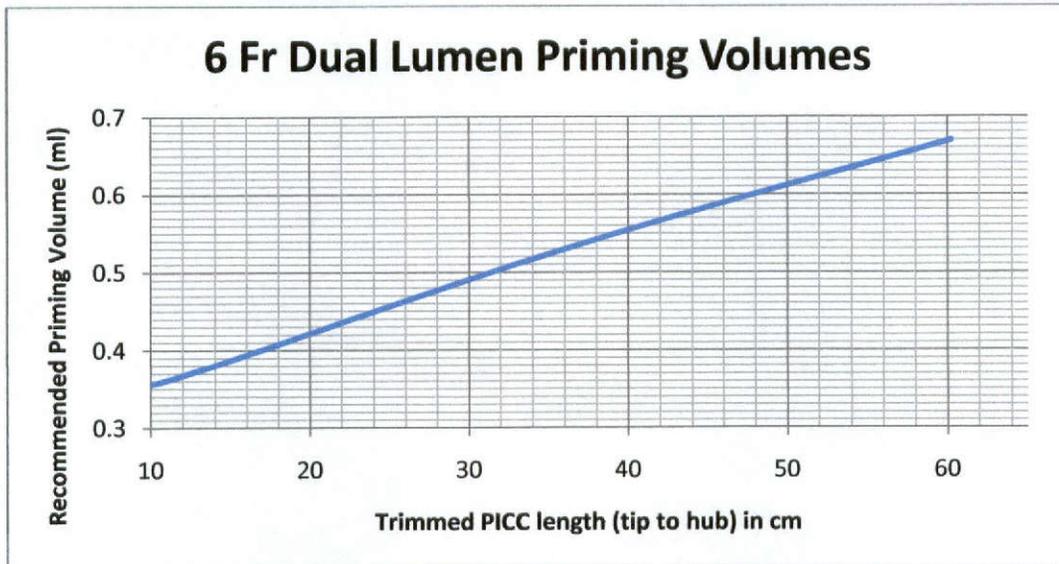
A. DETERMINING PRIMING VOLUME AND APPROXIMATING GRAVITATIONAL FLOW RATES

- A. Check the patient record or patient card to determine the catheter length, then use the following chart to calculate the PICC's internal lumen volume and to approximate gravitational flow rates (for fluids with viscosity similar to water):









B. DRESSING CHANGES

1. Assess the dressing in the first 24 hours for build-up of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the likelihood of catheter tip migration. Periodically confirm catheter placement, tip location, patency and security of dressing.
2. Maintain according to hospital protocol. Avoid using acetone based solutions, or ointment. These substances degrade polyurethane.
3. Chlorhexidine gluconate and Povidone-iodine are the suggested antiseptics to use during dressing changes.
4. Allow all cleaning agents/ antiseptics to dry completely before applying dressing.

Caution: Do not use acetone or tincture of iodine.

WARNING: When using alcohol or alcohol containing antiseptics with polyurethane PICCs, take care to avoid prolonged or excessive contact. Allow solutions to dry completely before applying

an occlusive dressing. Chlorhexidine gluconate and povidone iodine are the suggested antiseptics to use.

B. RECOMMENDED MAINTENANCE PROCEDURE

Maintain the catheter following standard hospital protocols. Recommended catheter maintenance is as follows:

1. Flush the catheter after every use, or daily when not in use. Use a 10 ml or larger syringe.
2. Flush the catheter with a minimum of 10 ml of 0.9% sodium chloride, using a "pulse" technique. Use of heparinized saline to lock each lumen of the catheter is optional.
3. Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely.
4. Before blood sampling when infusing TPN, follow routine maintenance procedure except use 20 ml saline and flush to clear TPN from the catheter.
5. Do not flush if the syringe meets unusual resistance. Further flushing could result in catheter rupture with possible embolization. Refer to institution protocol for clearing occluded catheters.

NOTE: When injecting or infusing medications that are incompatible, always flush the catheter with a minimum of 10 ml saline before and after each medication.

NOTE: When maintained under these instructions, the Zeus* catheter does not need the use of heparinized saline to lock the catheter lumens sterile normal saline may be used. However, use of heparinized saline will not adversely affect the catheter. Heparinized saline may be preferable for some patients or use of alternate flushing and locking techniques.

Caution: When handling the catheter, use aseptic techniques.

Caution: Apply a sterile needleless injection cap or end cap on the catheter hub to prevent contamination when not in use.

Warning: Do not use alcohol to lock, soak or de clot polyurethane PICCs because alcohol degrades polyurethane catheters over time with repeated and prolonged exposure.

C. OCCLUDED CATHETER

Occluded catheters may resist flushing and aspiration. Do not flush against resistance. Declot lumens occluded with blood by following your institution's de clotting protocol.

D. WHEN CLEANING THE EXIT SITE

WARNING: Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.

- Maintain according to hospital protocol. Avoid acetone based solutions, or polyethylene glycol based ointments. These substances degrade polyurethane.
- Use chlorhexidine gluconate or povidone iodine to clean the exit site around the catheter.
- Allow all cleaning agents to dry completely before applying dressing.

CENTRAL VENOUS PRESSURE MONITORING

Before conducting central venous pressure (CVP) monitoring:

- Ensure proper positioning of the catheter tip.
- Flush catheter vigorously with sterile normal saline.
- Ensure the pressure transducer is at the right atrium.
- Keep a continuous infusion of saline (3 ml/hr) through the catheter while measuring CVP to improve accuracy of CVP results.
- Use your institution's protocols for central venous pressure monitoring procedures.

WARNING: Use other patients' assessment metrics with CVP monitoring when evaluating cardiac function.

r4 Vascular, Inc.

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CATHETER REMOVAL

- Remove any dressings, StatLock⁺ catheter stabilization devices, or tape securement strips.
- Grasp catheter near insertion site.
- Pull slowly. Do not use excessive force.
- Stop pulling if catheter resists removal. Apply warm compress and wait 20-30 minutes.
- Resume removal procedure.
- Examine catheter tip to verify removal of the entire catheter.

R4 Vascular wrote this Instructions for Use in December 2008. If referencing this document after December 2010, contact r4 Vascular, Inc. to see if additional product information is available.

*r4, Zeus, and "technologies that save" are trademarks or registered trademarks of r4 Vascular, Inc.

StatLock is a registered trademark of C. R. Bard, Inc. or an affiliate.

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U.S. Patents Pending.

R4 Vascular, Inc.

7550 Meridian Circle North

Suite 150

Maple Grove, MN, 55369

Clinical Information: <<<insert phone number here>>>

Ordering Information: <<<insert phone number here>>>

www.r4vascular.com

200019-001 Rev 0

r4 Vascular, Inc.

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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

ATTACHMENT 3

Predicate labeling for HDC V-Cath Power PICC Power V and the Tyco Emerald

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

**Primary Packaging of the V-Cath (Polyurethane) Power PICC (Power-V)
(K071875)**

NeoMedical™ Power-V™ PICC



REF: 4019-1660 Single Lumen

**4.0Fr Single Lumen Power Rated PICC with E-Z Flush®
Stylet and Nurse's Modified Seldinger Insertion Kit**

	TYPE	SIZE	LENGTH	PRIMING VOL.	STYLET
CATHETER	Single	4.0 Fr	60 cm (24")	0.60 cc	E-Z Flush®
INTRODUCER	SELDINGER	4.0Fr	5.0 cm		

Single-Use Only
 Read Instructions

QTY: 1 TRAY

LATEX FREE

**4.0F
MST(N)
ADV**

TRAY CONTENTS
(1) 4.0 Fr Single Lumen PICC with Clamp
(1) MST with
(a) 7.0cm Nurses Safety Seldinger Needle
(b) 0.48mm (018") Nitinol Guidewire (40cm)
(c) 4.0Fr Sheath/Dilator Assembly
(1) Safety Scalpel
(1) Device Placement Sticker

(1) 12cc Syringe
User's Manual(s)
(1) Patient's Manual
(1) Securing Device
(1) Implant Record Card
(1) Sterile Field
(1) Paper Ruler
(1) Small Forceps, Disposable
(3) Barcode Stickers

STERILE EO

NONPYROGENIC

Store at Room
Temperature 21°C
(+/- 5°C)

Contents sterile nonpyrogenic in unopened, undamaged package.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

LOT ▶ 0000 ▶ 0000-00 ▶ 000000



(01)00616542401910(240)40191660(17)000000(10)0000(30)1

CE 0086

Manufactured for NeoMedical by
HDC Corporation and Health Line International Corporation
Milpitas, California 95035
(408) 942-7340 Fax (408) 586-8680
(800) 227-8162 www.hdccorp.com
Made in U.S.A.

European Representative
Aprime S.A./n.v.
Terhulpesteenweg 6 D
1860 Hoeftsaar
Belgium

U.S. Patents
5,357,861
5,823,961
5,776,096

REV. B
T50-281-00

**Other Patents Pending

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

**Secondary Packaging of the V-Cath (Polyurethane) Power PICC (Power-V)
(K071875)**

NeoMedical™ Power-V™ PICC

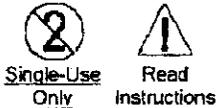


REF: 4062-1660 Single Lumen

**4.0Fr Single Lumen Power Rated PICC with E-Z Flush®
Stylet and Seldinger Insertion Kit**

	TYPE	SIZE	LENGTH	PRIMING VOL.	STYLET
CATHETER	Single	4.0 Fr	60 cm (24")	0.60 cc	E-Z Flush®
INTRODUCER	SELDINGER	4.0Fr	10.0 cm		

LATEX FREE



TRAY CONTENTS:

- (1) 4.0 Fr Single Lumen PICC with Clamp
- (1) SEL with
 - (a) 7.0cm Non-Safety Seldinger Needle
 - (b) 0.46mm (018") SS-SS Guidewire (80cm)
 - (c) 4.0Fr Sheath/Dilator Assembly
- (1) Safety Scalpel
- (1) Device Placement Sticker
- (1) 12cc Syringe
- User's Manual(s)
- (1) Patient's Manual
- (1) Securing Device
- (1) Implant Record Card
- (1) Sterile Field
- (1) Paper Ruler
- (3) Barcode Stickers

**4.0F
IR**

STERILE EO

NONPYROGENIC

Contents sterile nonpyrogenic in unopened, undamaged package.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Store at Room Temperature 21°C (+/- 5°C)

LOT ▶ 0000 ▶ 0000-00 ▶ 0000-00



**QTY: 1 CASE
10 TRAYS**

(01)00615542406212(240)40621660(17)000000(10)0000(30)10

CE 0056

Manufactured for NeoMedical by:
HDC Corporation and Health Line International Corporation
Milpitas, California 95035
(408) 942-7340 Fax (408) 506-8680
(800) 227-8162 www.hdccorp.com
Made in U.S.A

European Representative
Aphme s.a./n.v.
Terulpesteenweg 6 D
1560 Hoeftaart
Belgium

U.S. Patents
5,357,961
5,823,961
5,776,096

REV. A
T50-281-00

**Other Patents Pending

(K071875)

POWER-V™**INSTRUCTIONS FOR USE****1. Product Description**

The Power-V PICC is a family of peripherally inserted central catheters designed to allow for contrast media studies. The catheter is supplied sterile and non-pyrogenic in a variety of tray configurations.

2. Indications

The Power-V PICC is indicated for patients that require repeated venous access for infusion or injection therapy. The Power-V PICC is indicated for peripheral access to the central venous system for intravenous therapy. The Power-V PICC is indicated for dwell times less than or greater than 30 days. The maximum recommended infusion rate is 5 ml/hr. The maximum pressure of power injectors used with the Power-V PICC catheter may not exceed 334 psi.

3. Contraindications

Power-V is contraindicated for patients who have infections, septicemia, or bacteremia.

4. Warnings And Precautions

- This is not a right atrium catheter. Do not place the tip of the catheter into the right atrium.
- NEVER trim the stylet.
- NEVER attempt to pull the catheter back through a needle.
- NEVER attempt to pull a guidewire back through a needle.
- AVOID excessive pulling on catheter during removal. If removal is difficult, notify MD and refer to institutional policy and procedure.
- NEVER use clamping instruments with teeth or sharp edges on the Power-V.
- When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.
- Alcohol should not be used to soak or decontaminate PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposures.
- Acetone and polyethylene glycol containing ointments should not be used with polyurethane catheters as the same may cause failure of the device.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Use of lumens not marked "Power Injector" for power injection of contrast media may cause failure of the catheter.
- Power injector machine pressure rating feature may not prevent over-pressurization of an occluded catheter which may cause catheter failure.
- Exceeding the maximum flow rate of 5 ml/sec, and the maximum pressure of power injectors of 300 psi may result in catheter failure and/or catheter displacement.
- Power PICC catheter indication for power injection implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a particular patient as it pertains to a power injection procedure.
- The Power-PICC catheter features a reverse-taper catheter design. Placement of a larger catheter at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the Power-PICC catheter above antecubital fossa is recommended.

5. Potential Complications:Insertion-related:

- Arterial puncture
- Air embolus
- Nerve injury
- Catheter malposition
- Catheter embolus
- Cardiac arrhythmia

Post-insertion related:

- Cardiac arrhythmia
- Bleeding at insertion site
- Thrombosis
- Infection
- Catheter occlusion
- Cardiac tamponade

6. Pre-insertion Instructions

Power-V is for use only by clinicians thoroughly trained in the use of vascular access products.

- Use strict aseptic technique.
- Pre-flush the Power-V with at least 2cc of sterile Normal Saline.
- If using the Power-V dual lumen, flush both lumens prior to insertion.
- If catheter trimming is required, pull the Power-V EZ flush stylet back until it is approximately 1cm from the desired new tip. Using sterile scissors or scalpel trim the catheter with a blunt tip. The stylet must be completely covered by the catheter.

7. Insertion Techniques**INSTRUCTIONS FOR USING THE SAFE-T-PEEL™**

1. Remove the cover from the Safe-T-Peel introducer.
2. Apply a tourniquet to occlude the vessel. With needle bevel up, enter the skin approximately 1cm back from the desired point of entry into the vein at a 15 to 30 degree angle. Carefully advance the needle into the vessel and look for blood return in the flashback chamber.
3. Advance the unit as a whole another 1/4" to 1/2" to assure that the catheter sheath tip is correctly placed in the vein.
4. Holding onto one wing with one hand and stabilizing the flashback chamber with the other hand, advance the sheath into the vessel. If any resistance is felt, advance the whole and further.
5. When you are sure that the catheter sheath is correctly placed in the vein, release the tourniquet.
6. Remove the introducer needle and activate the safety mechanism.
7. Using the silicone tipped forceps, gently grip the catheter and thread through the introducer sheath. Advance the catheter slowly into the vein until desired length is achieved. You may flush the catheter while threading to float the catheter past any venous valves or other obstructions.
8. Before withdrawing introducer sheath, place pressure on skin just beyond the introducer sheath tip to hold the catheter stationary in the vein. Withdraw the introducer sheath until it is free from the insertion site. Grip the wings of the introducer, one wing between each thumb and index finger, and carefully peel outward. This action will cause the sheath to begin splitting. Then peel the sheath away from the catheter.
9. Complete catheter insertion in accordance with the catheter IFU.

INSTRUCTIONS FOR USING THE MODIFIED SELINGER METHOD

1. After prepping the access site according to institution protocol, introduce the guide-wire/introducer needle into the vessel.
2. Introduce the guide-wire through the needle, advance the wire 15 to 20 cm into the vessel. DO NOT pull guide-wire back through needle.
3. Leaving the guide-wire in place, withdraw the needle.
4. Introduce the Tear-away set over the guide-wire. A slight rotational motion can preclude the requirement of skin nicking. If necessary, make a small skin nick with sterile scalpel to ease entry of tear-away. Advance the set into the vessel.
5. Leaving the sheath in place, remove the dilator and guide-wire.
6. Introduce the catheter using sterile technique and advance the catheter into position.
7. Once the catheter is advanced within 10 cm of the desired tip position, pull the sheath back, break sheath wing and peel sheath away from the catheter.
8. Complete catheter insertion in accordance with the catheter IFU.

INSTRUCTIONS FOR USING THE RESEALING METHOD

1. Before use, inspect the catheter for any damage. Do not use if the catheter is damaged.
2. To seal the catheter, gently pull the catheter back until the catheter is fully inserted into the vein. Do not pull the catheter back further.
3. To remove the catheter, gently pull the catheter back until the catheter is fully inserted into the vein. Do not pull the catheter back further.
4. To flush the catheter, gently pull the catheter back until the catheter is fully inserted into the vein. Do not pull the catheter back further.
5. To change the catheter, gently pull the catheter back until the catheter is fully inserted into the vein. Do not pull the catheter back further.
6. To remove the catheter, gently pull the catheter back until the catheter is fully inserted into the vein. Do not pull the catheter back further.

9. **Post Insertion Instructions**
 1. Flush the catheter with 10 mL of 0.9% Sodium Chloride Injection, USP (0.9% NaCl) before use.
 2. Flush the catheter with 10 mL of 0.9% Sodium Chloride Injection, USP (0.9% NaCl) after use.

Caution: Do not use the catheter for intravenous (IV) therapy. Do not use the catheter for intravenous (IV) therapy.

10. **Power Injection Instructions**
 1. Before each power injection it is strongly recommended that a chest X-ray or radiographic image be taken to ensure proper central placement of the catheter tip in addition to checking for blood flush and ease of flushing.
 2. The maximum pressure of power injection used with the Power V PICC catheter may not exceed 300 psi.
 3. Warm contrast media to body temperature prior to power injection.
 4. Flush the catheter with 10 mL of 0.9% Sodium Chloride Injection, USP (0.9% NaCl) before use.
 5. Flush the catheter with 10 mL of 0.9% Sodium Chloride Injection, USP (0.9% NaCl) after use.

Warning: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure. Power injector machine locking (safety cut-off) settings may not prevent over pressurization of an occluded catheter.

11. **Caution:** Do not use the catheter for power injection. Do not use the catheter for power injection.
12. **Warning:** Exceeding the maximum flow rate of 5 mL/sec may result in catheter failure and/or catheter tip displacement.
13. Do not use the catheter for power injection.
14. Do not use the catheter for power injection.
15. Do not use the catheter for power injection.

Parameter	Flow Rate (mL/hr)	Flow Rate (mL/min)	Maximum Flow Rate (mL/min)	Maximum Pressure (psi)
Flow Rate	5	0.083	5	300
Flow Rate	10	0.167	10	300
Flow Rate	15	0.25	15	300
Flow Rate	20	0.333	20	300

11. Suggested Catheter Maintenance

The catheter should be flushed with 10 mL of 0.9% Sodium Chloride Injection, USP (0.9% NaCl) before use.

Disinfecting Changes
Do not use the catheter for power injection. Do not use the catheter for power injection.

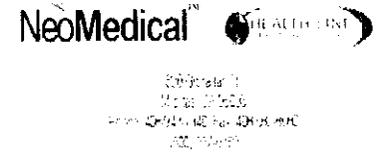
Flushing
Flush the catheter with 10 mL of 0.9% Sodium Chloride Injection, USP (0.9% NaCl) before use.

Syringe and Extension Set Removal
Remove the syringe and extension set from the catheter before use.

Occluded or Partially Occluded Catheter
Do not use the catheter for power injection. Do not use the catheter for power injection.

Cleaning and Site
Clean the catheter site with 70% alcohol before use.

Catheter Removal
Remove the catheter from the vein before use.



NeoMedical
10000
10000
10000

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

REF: 4019-1660

4.0 Fr Power-Injectable Single Lumen PICC



(01)00615542401910(240)40191660(17)000000(10)000(30)1

Lot: 0000

Patient
Charge

REF: 4019-1660

4.0 Fr Power-Injectable Single Lumen PICC



(01)00615542401910(240)40191660(17)000000(10)000(30)1

Lot: 0000

Patient
Chart

REF: 4019-1660

4.0 Fr Power-Injectable Single Lumen PICC



(01)00615542401910(240)40191660(17)000000(10)000(30)1

Lot: 0000

Inventory
Control

T50-282-03

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

MEDICAL ALERT

THIS PATIENT HAS AN IMPLANTED

4 OFr Prim Vol 0 60cc
Ref 4019-1660 Lot 0000

VASCULAR ACCESS DEVICE



HDC Corporation

628 Gibraltar Court
Milpitas, California 95035
(408) 942-7340 Fax (408) 586-8680
(800) 227-8162 www.hdccorp.com

European Representative
Aprime s a /n v
Terhulpssteenweg 6 D
1560 Hoeilaar
Belgium



(fold here)

HDC VASCULAR ACCESS SYSTEM IMPLANT RECORD

PATIENT: _____

SURGEON/NURSE: _____

TELEPHONE: _____

HOSPITAL/HOME CARE: _____

CITY/STATE: _____

DATE OF INSERTION: _____

CATHETER LENGTH: _____

EXPOSED CATHETER LENGTH: _____

UPPER ARM CIRCUMFERENCE: _____

LOCATION: RIGHT BASILIC
 LEFT CEPHALIC

OTHER: _____

P/N T50-212-01 REV. A

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

Other included labeling for V-Cath (Polyurethane) Power PICC (Power-V) (K071875)

NeoMedical™ Power-V™

DEVICE PLACEMENT INFORMATION
REMOVE FOR PATIENT RECORDS

CATHETER: 4.0Fr Single Lumen Power-V PICC

REORDER #: 4019-1660

LOT #: 0000 EXPIRATION DATE: 0000-00

OPERATOR: _____

DATE OF PLACEMENT: _____ TIME: _____

VEIN USED: R of L Basilic Cephalic Median Cubital
 Other: _____

CATHETER UTILIZATION: Antibiotics Blood Products
 Chemotherapy Medications Blood Sampling
 CVP Monitor TPN
 Other: _____

REMARKS/SPECIAL INSTRUCTIONS: _____

SIGNATURE: _____

PHONE #: (____) _____



Manufactured for NeoMedical by
MDC Corporation and Health Law International Corporation
Milpitas, California 95035
(408) 942-7348 Fax (408) 588-8680
(800) 727-8162 www.mdcorp.com
Made in U.S.A

European Representative
Aprime s.a./n.v.
Terhulpesteenweg 8 D
1580 Hoeilaart
Belgium

REV.B
PIN: T50-257-00

English

Sterilized with ethylene oxide. Sterile and non-pyrogenic in unopened and undamaged package.

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

READ ALL INSTRUCTIONS, WARNINGS, AND CAUTIONS CAREFULLY PRIOR TO USE.

DESCRIPTION:

The PALINDROME SAPPHIRE 14.5 Fr Cuffed Catheter is a radiopaque, urethane catheter with felt cuff, dual extensions, heparin coating, and silver impregnated sleeve.

Each extension has an in-line clamp and luer-lock adapter that is color coded: red for "arterial" outflow of blood, blue for "venous" return. Injection sealing caps are included with the catheter.

The PALINDROME SAPPHIRE contains a heparin coating technology applied to the external catheter surfaces (extending from the cuff of the device to the tip) and to the internal catheter surfaces (extending from the luer adapters to the tip).

The coating technology provides a unique biocompatible surface coating involving heparin to reduce platelet adhesion on the catheter and inhibit fibrin sheath propagation.

The PALINDROME SAPPHIRE also contains a silver impregnated sleeve on the external surface of the catheter between the cuff and hub of the device.

The silver impregnated sleeve provides protection against catheter colonization in the subcutaneous tunnel tract.

DIMENSIONS:

CATHETER O. D.	14.5 Fr/Ch (4.85 mm)			
OVERALL LENGTH	36 cm	40 cm	45 cm	58 cm
IMPLANT LENGTH	19 cm	23 cm	28 cm	33 cm

PALINDROME™ SAPPHIRE™ FLOW TABLE WITH SIDE SLOTS

PLATELET RATE (platelets)	Implant Lengths							
	19 cm		23 cm		28 cm		33 cm	
	+VP	-AP	+VP	-AP	+VP	-AP	+VP	-AP
200	18	-18	21	-23	23	-24	26	-28
250	24	-28	29	-32	33	-36	37	-40
300	33	-38	39	-44	45	-48	51	-54
350	44	-50	50	-58	58	-64	67	-72
400	56	-64	65	-74	75	-82	83	-93
450	71	-80	78	-88	81	-108	102	-117
500	87	-98	98	-112	108	-126	120	-143

*positive (+VP) Venous Pressure (mm Hg)
 **negative (-AP) Arterial Pressure (mm Hg)

INDICATIONS:

The KENDALL 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (PALINDROME SAPPHIRE) is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown.

The performance of the heparin coating on this catheter in reducing platelet adhesion on the catheter surface for up to 720 hours of dialysis treatment is supported by bench and animal testing.

The performance of the silver impregnated sleeve in reducing colonization on the catheter surface for up to 30 days is supported by bench and animal testing.

HEPARIN COATING TEST SUMMARY:

The performance of the heparin coating on this catheter in reducing platelet adhesion on the catheter surface for up to 720 hours of dialysis treatment is supported by:

- A two hour circulating blood loop test demonstrating a 60% reduction in platelet adhesion on the catheter surface at p<0.05.
- A coating durability test, where the catheter was subjected to 720 hours of simulated dialysis conditions, and maintained

tyco / Healthcare
KENDALL

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™ HIBICLENS is a trademark of Regent Medical Ltd.

™ NEOSPORIN is a trademark of Warner-Lambert Co. LLC.

™ BACTROBAN is a trademark of Smith Kline Beecham Corp.

™ CHLORAPHEP is a trademark of Entulab Inc.

Covered by one or more of the following U.S. patents: 5369182; 5665867; 5967486; 5470385; 7090654; 7141035 and foreign counterparts. Other patents pending.

U.S. Pat. Nos. 6406687 and 6096798 used under license from Bioteractions, Limited, United Kingdom.

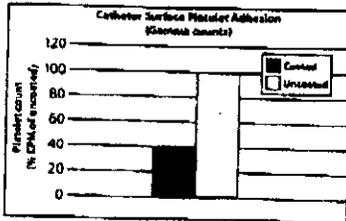
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heparin activity levels at twice the minimum activity level required to achieve a 60% reduction in platelet adhesion.

- An *in vivo* ovine model using six sheep (periodically perfused to simulate dialysis for 24 days) where the reduction in thrombus formation was 82% at $p < 0.05$. Visual inspection demonstrated inhibition of fibrin sheath propagation along the coated catheter surface.

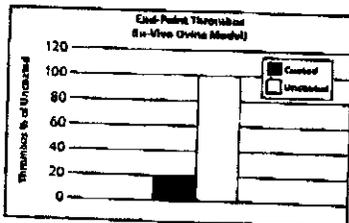
TEST METHOD DETAILS:

In vitro evaluations of the coated catheters were performed using a test model which incorporates fresh heparinized bovine blood to assess the relative thromboresistance of the coated catheter as compared to a non-coated catheter. The blood, with radiolabeled autologous platelets, was circulated for 2 hours. Heparinized catheters were visually inspected and then placed in a gamma counter for quantification of platelet adhesion on the catheter surface. The radioactivity data demonstrates that the coated catheter had 60% less platelets adhered to the surface compared with the uncoated catheter ($p < 0.05$).

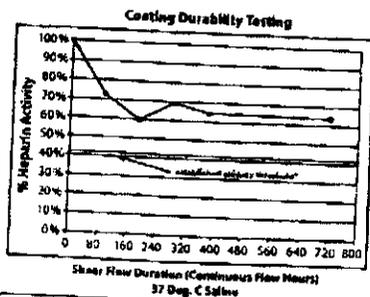


Total end-point platelet accumulation normalized to the uncoated control.

In vivo evaluations of the coated catheters were performed using an ovine model. The testing was conducted on 6 sheep with a coated and non-coated catheter implanted into the right and left jugular veins of the same sheep. Routine blood perfusion sessions were performed on both catheters to simulate dialysis. Gravimetric analysis performed on the thrombus extracted from the external surfaces of both the coated and non-coated catheters demonstrated an 82% reduction in total thrombus formation after an average of 24 days of implantation as compared to a non-coated catheter. Visual inspection demonstrated inhibition of fibrin sheath propagation along the coated catheter surface.



The durability of the coating was assessed in an *in vitro* test model that simulates the dynamic flow environment of a dialysis session. The model involves 37°C Saline flowing through the internal surfaces and around the external surfaces of the catheter for a time period that simulates over 12 months of dialysis sessions on the ID of the catheter and over 30 days on the OD of the catheter. The chart below shows that between 60% and 70% of the PALINDROME SAPPHIRE catheter heparin activity remains after 720 hours of continuous flow. This heparin activity is significantly above the minimum heparin activity established during *in vitro* blood flow evaluations to achieve a 60% reduction in platelet adhesion.



4 PALINDROME SAPPHIRE 14.5Fr Cuffed Dual Lumen Catheter

* The established efficacy threshold was determined in an *in vitro* circulating bovine blood model using coated catheters with varying levels of heparin activity. The blood, with radiolabeled autologous platelets, was circulated for 2 hours. Platelet counts were quantified for each of the coated catheters with varying heparin activity levels and compared to the uncoated catheter. The results demonstrated that a catheter with 45% of the PALINDROME SAPPHIRE catheter heparin activity still provides a 60% reduction in platelet adhesion on the catheter surface.

SILVER IMPREGNATED SLEEVE TEST SUMMARY:

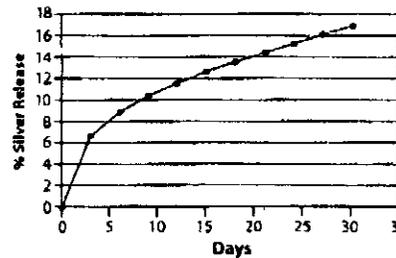
The PALINDROME SAPPHIRE catheter has shown *in vitro* a significant reduction (between 2.1 and 5.5 log₁₀ reduction) in microbial colonization on the silver impregnated sleeve. The following organisms (all clinical isolates) commonly associated with catheter colonization were tested:

- Staphylococcus aureus* (3 strains)
- Coagulase-negative staphylococcus (3 strains)
- Candida albicans* (3 strains)
- Escherichia coli* (3 strains)

In vitro studies of the silver impregnated sleeve were performed using a modified version of ASTM E2149. Samples were soaked in 50% bovine serum at 37°C for up to 30 days. At 5-day intervals the samples were challenged with a 10⁵ cfu/mL suspension of each clinical isolate to determine colonization over time.

The PALINDROME SAPPHIRE catheter has shown *in vivo* a significant reduction (between 2.5 and 4.9 log₁₀ reduction) in microbial colonization on the silver impregnated sleeve. Studies of the silver impregnated sleeve were performed using a rabbit infection model. Samples were implanted into the subcutaneous tissue of rabbits and repeatedly inoculated with 10⁵ cfu of *Staphylococcus aureus* over a 30 day period. Samples were evaluated at 5-day intervals, starting 10 days after implantation.

The silver release was characterized in an *in vitro* model that simulated the interstitial fluid found in the subcutaneous tunnel tract. Silver impregnated sleeve samples were soaked in 50% serum at 37°C. The solution was exchanged every three days. After 30 days, 17% of the total silver in the sleeve was released.



CONTRAINDICATIONS:

Do not use this catheter in thrombosed vessels or for subclavian puncture when ventilator is in use.

Heparin coated catheters should not be used in individuals with documented hypersensitivity to heparin or porcine based products. Heparin coated catheters should not be used in patients with severe thrombocytopenia or in patients with uncontrollable active bleeding disorders.

Catheters containing silver should not be used in patients with known hypersensitivity to silver.

POTENTIAL COMPLICATIONS:

Potential complications include:

- sepsis; thrombosis/stenosis of vein, exit site infection, cardiac arrhythmia; air embolism; subcutaneous tunnel infection; hemorrhage; hemothorax, pneumothorax, hematoma; cardiac tamponade; trauma to major vessel or right atrium; brachial plexus injury; catheter thrombosis; retroperitoneal bleed; femoral nerve damage; femoral artery damage; femora; artery dissection; femoral vein occlusion; lower extremity ischemia; pulmonary embolism; arterial puncture; mediastinal widening; deep vein thrombosis of the lower extremity; heparin-induced thrombocytopenia; hemothorax; recurrent laryngeal nerve palsy; dissection or occlusion of the carotid artery.

5 PALINDROME SAPPHIRE 14.5Fr Cuffed Dual Lumen Catheter

WARNINGS AND PRECAUTIONS:

- Although the PALINDROME SAPPHIRE catheter incorporates a firmly bonded coating, care should be exercised to avoid excessive abrasion of the surface.
- The heparin coating used on the PALINDROME SAPPHIRE catheter is not intended as a replacement for priming the catheter lumens with heparinized saline. Standard priming procedures still apply.
- As with any heparin-based product, the following conditions should be considered:
 - Hypersensitivity: Patients with documented hypersensitivity to heparin or porcine based products should not receive heparin coated catheters
 - Thrombocytopenia: Heparin-induced thrombocytopenia has been reported with the use of heparin-coated catheters.
- As with any silver-based product, patients with known hypersensitivity to silver should not receive silver impregnated catheters.
- The silver impregnated sleeve is not intended to be used as a treatment for existing catheter-related infections.
- The catheter should be inserted and removed only by a qualified, licensed physician or other healthcare practitioner authorized by and under the direction of such physician.
- The medical techniques and procedures described in these instructions 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.
- Observe sterile technique at all times when handling or using the catheter.
- Do not use the catheter if package has been previously opened or is damaged.
- Do not use the catheter if it appears damaged or defective.
- Avoid air embolism by keeping catheter extension tubing clamped at all times when not in use and by filling the catheter with sterile saline prior to implantation. With each tubing change, purge air from the tubing and aspirate any air in catheter.
- Do not clamp extension tubing with insertion stylets loaded as it may result in stylet damage.
- Percutaneous insertion of the catheter in the subclavian vein can be technically difficult. The right internal jugular is preferable.
- To avoid vessel perforation and damage, do not insert the guidewire, dilators, or valved pull-apart sheath/introducer forcibly.
- Do not insert the valved pull-apart sheath/introducer further than necessary; depending upon patient size and access site, it may not be necessary to insert the entire length of the introducer into the vessel.
- The valved pull-apart sheath/introducer is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve.
- The valved pull-apart sheath/introducer is not intended to create a complete two-way seal nor is it intended for arterial use.
 - The valve will substantially reduce air intake. At -12 mm Hg vacuum pressure the valved pull-apart sheath/introducer may allow up to 4 cc/sec of air to pass through the valve.
 - The valve will substantially reduce the rate of blood flow but some blood loss through the valve may occur.
- Use the guidewire straightener to insert the 21" end of the guidewire into the introducer needle. Do not insert or withdraw the guidewire forcibly from any component; the wire could break or unravel.
- Do not nick the catheter when suturing.
- Do not tie the suture too tightly at the venotomy site
- Prolonged exposure to ultraviolet light can damage the catheter.
- Do not use acetone on any part of the catheter. Aqueous-based povidone iodine, EXSEPT™, HIBICLENS™ (Chlorhexidine), amukin 50% hydrogen peroxide, NEOSPORIN™ antibiotic ointment, bacitracin ointment, BACTROBAN™ cream, Isopropyl alcohol 70%, CHLORAPREP™ can be used. Inter-mixing of these solutions has not been tested and is not recommended.

- Overtightening catheter connections can crack some adapters.
- Do not clamp the dual lumen portion of the catheter; clamp only the extensions. Use only smooth-jawed forceps for clamping when not using the clamp supplied with the catheter.
- Clamping the catheter repeatedly in the same spot could weaken the tubing; change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter and hub.
- Exercise caution when using sharp instruments near the catheter. Catheter tubing can tear when subjected to nicks, excessive force, or rough edges.
- Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.
- When infusing heparin, flush quickly and clamp immediately to ensure heparin reaches the distal end of the lumen. Do not infuse against a closed clamp or forcibly infuse a blocked catheter; back pressure could force the adapter out of the tubing.
- Remove the catheter as soon as it is no longer necessary.
- When removing the catheter, DO NOT use a sharp, jerking motion or undue force; this may tear the catheter. Free the cuff and surfaces from the tissue prior to removal.
- Discard the catheter after single use. Do not sterilize.

PRECAUTIONS:

- Consult pharmacy or appropriate literature for compatibility data before using heparin coated catheters with any drug product. Drugs that bind or interact with heparin should not be infused through the lumens of the heparin coated catheter.

RECOMMENDED

- Use only luer-lock (threaded) connections (including syringes, bloodlines, and injection caps) with the catheter's adapters.
- Use a straight tip guidewire when removing a PALINDROME SAPPHIRE catheter with side slots for an over-the-guidewire catheter exchange.

INSERTING THE PALINDROME SAPPHIRE 14.5 Fr CUFFED CATHETER

Sterile Supplies Required

Catheter	Normal Saline
Prepping Agents	#11 Scalpel
Drapes	Tumeler
Mask, Gloves, Gown	Needle Holder
Syringes/Needles	Suture with Curved Needle
Local Anesthetic	Injection Sealing Caps
Sponges	Wound Dressing
Heparin (in concentrations approved by your institution)	Razor (optional)

Percutaneous placement also requires the following items:

- 18 gauge introducer needle
- 0.038" / Straight Guidewire
- 16 Fr pull-apart sheath/introducer
- 2 cc syringe
- Tissue Dilators (optional)
- insertion stylets (optional)

INSERTION SITE

The PALINDROME SAPPHIRE 14.5 Fr Cuffed Catheter is ideally placed in the right atrium via the right internal jugular. While the catheter also can be placed in the external jugular, subclavian, or saphenous vein, the right internal jugular is strongly recommended for the following reasons:

- The internal jugular permits easier positioning of the catheter tip in the right atrium.
- The size and location of the external jugular makes insertion difficult.
- Use of the subclavian vein for catheter placement may result in subclavian vein stenosis. Subclavian vein stenosis may prevent the future use of the ipsilateral extremity for permanent access.
- Subclavian vein placements are at risk for higher insertion complications

- The saphenous vein should be used only as a last alternative due to the possibility of insertion complications.

For optimal catheter function: Per Dialysis Outcome Quality Initiatives (DOQI), the catheter tip must be adjusted to the level of the cavo: atrial junction or beyond to ensure optimal blood flow. For this reason, it is preferable to insert the catheter on the patient's right side. For large patients, and for patients whose right-side veins are unusable, 40 cm, 45 cm, 50 cm catheters are available for placement via the left jugular or subclavian vein.

PREPARATION

The operating room or IR suite are the preferred locations for catheter placement. Both cutdown and percutaneous procedures require confirmation of correct placement by fluoroscopy or chest X-ray.

1. Provide a sterile operative field; use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear a gown, cap, gloves, and mask. Have the patient wear a mask.
2. Place the patient in a supine position and expose the upper chest or the groin side to be accessed.

For subclavian and jugular insertion: Turn the patient's head slightly to the side to expose the insertion site. The Trendelenberg position may facilitate insertion.

3. Shave the access site (optional) and prep the area in the established manner. Isolate the access site with sterile drapes.

NOTE: When performing a subclavian insertion on a patient with large breasts, it is best to draw landmarks while the patient is sitting up to prevent catheter tip migration.

4. Fill the catheter with sterile heparinized saline and clamp the extensions immediately.
5. Administer local anesthetic to the skin and underlying tissue at the insertion site.

WARNING: To prevent air embolism, keep the catheter clamped at all times when not attached to a syringe, IV tubing, or bloodlines.

NOTE: If using insertion stylets, catheter will not be filled until after placement. Load stylets into catheter lumens such that a minimum length of 8 cm extends distal from the catheter adapters, in order to allow for proper catheter tunneling.

PERCUTANEOUS PROCEDURE MODIFIED SELDINGER (LITTLEFORD-SPECYOR) TECHNIQUE

Cannulating the Vessel

1. Flush an 18 gauge introducer needle with heparinized normal saline. Insert the needle through the primary incision and advance it into the vein, in the direction of blood flow. Aspirate a small amount of blood to ensure the needle is correctly positioned in the vein.

CAUTION: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that the bleeding has stopped and that no hematomas have developed before attempting to cannulate the vein again.

2. Disconnect the syringe from the needle and promptly insert the flexible "J" end of the guidewire through the introducer needle. Failure to insert the wire promptly may lead to blood loss through the needle. Advance the wire into the vein.

CAUTION FOR JUGULAR AND SUBCLAVIAN INSERTION: The length of wire inserted is determined by the size of the patient. Cardiac arrhythmia may result if the guidewire passes into the right atrium. If symptoms occur, pull back the guidewire until they disappear.

If the guidewire meets resistance, do not pull it back through the needle. Remove the wire and the needle together as a unit and begin again with new needle and guidewire (Figure 1).

NOTE: If utilizing the stylets for insertion, the guidewire provided is recommended. Otherwise, greater than a 0.035 inch hydrophilic or greater than a 0.038 inch stainless steel wire is contraindicated.

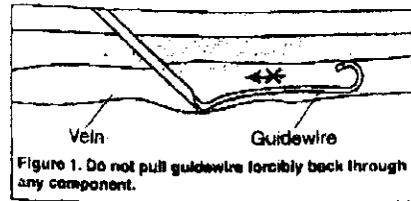


Figure 1. Do not pull guidewire forcibly back through any component.

- 2b. Withdraw the introducer needle, leaving the guidewire in the vein.

CREATING THE SUBCUTANEOUS TUNNEL

NOTE: For ease in dressing the exit site and for patient comfort, locate the subcutaneous tunnel below the entry site. A tunnel with a wide, gentle arc lessens the risk of kinking at the cuff. The tunnel should be short enough to keep the Y-hub of the catheter from entering the exit site, yet long enough to keep the cuff a minimum of 2 cm from the exit site, and a minimum of 3 cm from the insertion site.

1. Make a small incision at the insertion site. (The right internal jugular is the preferable site for percutaneous placement as subclavian placement is technically difficult.) Make a second incision parallel to the first at the exit site. Make the exit incision just long enough to accommodate the cuff, approximately 1 cm.
2. Use blunt dissection to create the subcutaneous tunnel.
 - a. Attach the catheter to the tunneler by sliding the catheter tip onto the bifurcated tunneler tines until the catheter tip meets the base of the tines. Slide the sheath completely over the connection until it stops, being careful that the sheath smoothly transitions over the catheter tip (see Figure 2). If desired, bend the tunneler into a wide arc to make a curved tunnel.

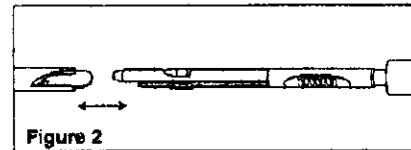


Figure 2

- b. Insert the tunneler into the exit site and create a short subcutaneous tunnel (5 cm minimum), emerging at the insert-on site. The catheter will thread through the tissue as the tunnel is created. Ensure the catheter passes through the tunnel to the primary insertion site.
- c. Remove the catheter carefully from the tines. To do so, slide the sheath back, grasp the tip of the catheter, and gently pull the catheter from the tunneler tines. Discard the tunneler.

INSERTING THE CATHETER USING THE VALVED PULL-APART SHEATH/INTRODUCER

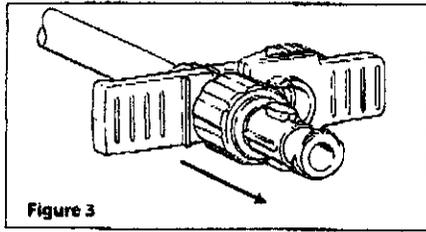
OPTIONAL: To ease insertion of the valved pull-apart sheath/introducer, the vein can be pre-dilated with the dilator(s) provided.

1. Thread the dilator(s) over the end of the guidewire and advance it into the vein using a rotating motion to assist passage through the tissue.

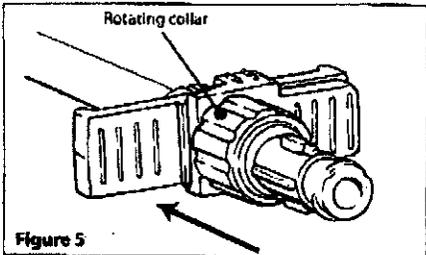
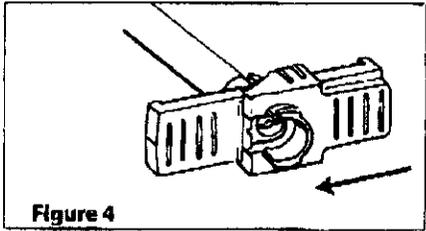
CAUTION: Do not force the dilator(s). Ensure that the guidewire does not advance further into the vein.

Remove and discard the dilator(s).

2. Remove the valved pull-apart sheath/introducer assembly from the package; remove dilator from the sheath (Figure 3).

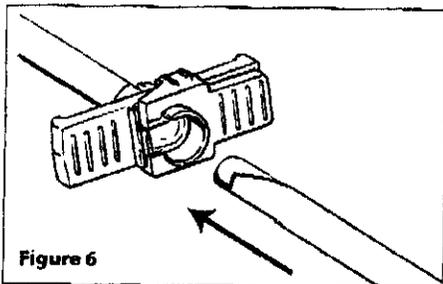


3. Slide the valve over the sheath opening, and insert the dilator through the valve and lock in place using the rotating collar. (Refer to Figures 4 and 5.)



4. a. Thread the locked valved pull-apart sheath/introducer assembly over the end of the guidewire.
CAUTION: To avoid damaging the tissue and the sheath tip, do not let the sheath advance over the dilator. The two must be grasped as one unit.
b. With a rotational motion, advance the assembly into the vein only as far as necessary.
Do not force the introducer into the vessel. Do not insert it further than necessary for the patient's size and access site. Ensure that the guidewire does not move further into the vein.

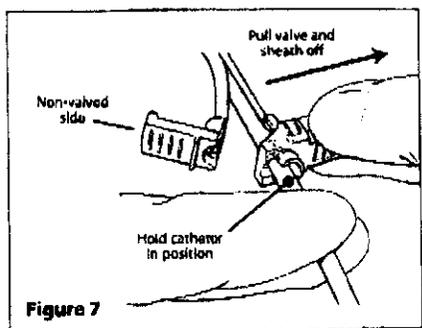
c. Hold the sheath in place, unlock the rotating collar, and gently remove the dilator and guidewire together (discard the dilator and the guidewire).
5. Advance catheter through the valve. To prevent kinking the catheter, it may be necessary to advance in small steps by grasping the catheter close to the sheath (Figure 6).
WARNING: Ensure the catheter is filled with heparinized saline and is free of air bubbles before inserting it into the vein.



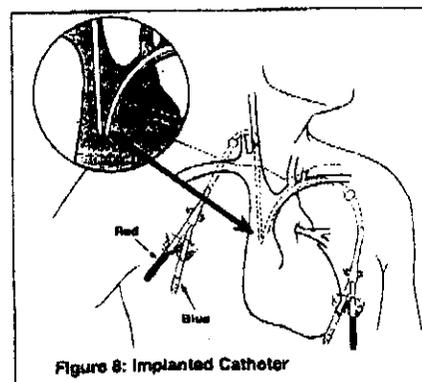
6. Continue inserting the catheter through the valved sheath and into the vein. For optimal catheter function: Per Dialysis Outcome Quality Initiatives (DOQI), the catheter tip must be adjusted to the level of the caval atrial junction or beyond to ensure optimal blood flow (Figure 8).
7. Aspirate to verify patency and clamp the extension.
8. After the catheter has been positioned, grasp both tabs firmly and crack the sheath handle in half.

NOTE: Steps 9 and 10 refer to Figure 7.
9. Peel the non-valved side of the handle partially away from the catheter.
10. Near the valve, hold the catheter firmly in position and pull the valve off of the catheter.

NOTE: Some resistance will be experienced while pulling the valve off of the catheter.



11. Remove the sheath from the patient by holding the catheter in place and pulling the separated tabs away from the entry site simultaneously at a 180° angle. The sheath will separate from the catheter, leaving the catheter in the vein.
CAUTION: Do not allow the catheter to move out of the vein with the sheath. Ensure that the vein is not bleeding around the catheter.
12. Use fluoroscopy or portable x-ray to view the catheter. Position the catheter correctly in the right atrium.



13. Confirm correct placement and catheter function by aspirating venous blood from both the arterial and venous lumens, then flush 5 cc of sterile normal saline into each lumen. Follow with heparinized saline. Clamp the extensions immediately utilizing the positive pressure technique. (See priming volumes under HEPARINIZATION.) Attach a sterile injection cap to each adapter.
WARNING: To prevent air embolism, expel all air from syringes before injecting solutions.

This may be dilated further using a mosquito hemostat.

WARNING: Ensure the catheter is filled with heparinized saline and is free of air bubbles before inserting it into the vein.

- Grasp the end of the catheter with forceps and insert it into the vein. Slacken the proximal ligature to allow the catheter to pass with minimal back bleeding. Advance the catheter into the vein; for subclavian and jugular insertion, advance the catheter tip into the right atrium. For optimal catheter function: Per Dialysis Outcome Quality Initiatives (DOQI), the catheter tip must be adjusted to the level of the caval atrial junction or beyond to ensure optimal blood flow. (See Figure 8 in Percutaneous Procedure section.)

- Pull the purse string suture (or proximal ligature) closed, but do not tie it before determining the exact position of the catheter.

- Use fluoroscopy or portable x-ray to view the catheter. Move or reposition the catheter until it is positioned correctly in the right atrium as indicated in Figure 8 in Percutaneous Procedure section.

- Tie the purse string suture (or proximal ligature) snugly around the catheter. Tie it just tightly enough to control bleeding at the venotomy; do not occlude the catheter.

CAUTION: Do not allow the cuff to enter the vein or the venotomy. Ideally, it should not touch the vein.

- Confirm correct placement and catheter function by aspirating venous blood from both the arterial and the venous lumina, then flush 5 cc sterile normal saline into each lumen. Follow with heparinized saline. Clamp the extensions immediately utilizing the positive pressure technique. (See priming volumes under HEPARINIZATION.) Attach a sterile injection cap to each adapter.

WARNING: To prevent air embolism, expel all air from syringes before injecting solutions.

- Suture the entry site. The exit site should not require suture.
- If a skin suture is desired, suture the catheter hub to the skin utilizing a prolene or nylon 3-0 or 4-0 suture on the extension wings.

CAUTION: Do not suture through any part of the catheter. Remove skin suture by the 4th or 5th day to diminish erythema in the area. The catheter also can be immobilized with ether gauze or transparent dressings.

- Apply dressing to the catheter exit site and cutdown incision.

REMOVING THE PALINDROME SAPPHIRE

14.5 Fr CUFFED CATHETER

To remove the catheter, free the cuff from the tissue and pull the catheter gently and smoothly. Do not use sharp, jerking motions or undue force. This could tear the catheter.

WARNING: If the catheter offers resistance, do not pull further. Perform a cutdown and remove all sutures at the venotomy site.

DISPOSAL

After use, the catheter and accessories are considered a biohazard. Handle and dispose of these in accordance with accepted medical practice and all applicable laws and regulations.

HEPARINIZATION

To maintain patency between dialysis or apheresis treatments, keep the lumina of the catheter filled with the appropriate concentration and volume of heparin. In most cases, 5,000 units/cc is most successful (refer to the priming volume of the catheter). Approved heparin concentrations vary with each institution. Be sure to use those concentrations approved by your facility.

PRIMING VOLUMES

Catheter	Overall Length	Arterial	Venous
ADULT	36 cm	1.6 cc	1.6 cc
	40 cm	1.9 cc	1.9 cc
	45 cm	2.1 cc	2.1 cc
	50 cm	2.3 cc	2.3 cc

14 PALINDROME SAPPHIRE 14.5Fr Cuffed Dual Lumen Catheters

Heparinize only after use. Before initiating treatment, aspirate indwelling heparin and discard. After treatment, flush well and instill fresh heparin. If the interdialytic period is less than two days, or if apheresis is performed daily, a lower concentration of heparin may be desirable.

In all cases, the patient's condition must be considered when choosing a heparin regime. Use less heparin in children and in adults with bleeding disorders.

SUPPLIES

- 10-20 cc syringes
- 3 cc syringe
- 20 gauge 2.5 cm needles
- vial heparin (in concentration approved by your institution)
- vial sterile normal saline
- povidone-iodine swabs

PREPARATION

- Prepare supplies on a clean surface.
- Wash hands thoroughly with soap and water.
- Scrub the area surrounding the cap and catheter for 5 minutes with a povidone-iodine swab. Allow to air dry.
- Open syringe and needle packages. Place the needle on the sterile syringe, using aseptic technique.
- Remove the tops of the saline and heparin vials and swab the injection area with povidone-iodine. Allow to air dry.
- Prepare the appropriate dilute heparin solution.

PROCEDURE

- Remove injection sealing cap and aspirate indwelling heparin from the catheter before infusing fresh heparin or initiating treatment.

- Flush the lumen with 10 to 20 cc sterile normal saline.

CAUTION: Before flushing, pull the plunger back to verify blood flow and to ensure there are no blood clots. Do not flush clots through the catheter (see "Thrombus Formation").

- Infuse fresh heparin, flushing quickly to ensure that heparin reaches the distal end of the lumen, and clamp immediately. Infusing or clamping too slowly may cause heparin to exit the catheter from the catheter slot, leaving the distal catheter tip unprotected from thrombus formation. Do not infuse against a closed clamp or forcibly infuse a blocked catheter; back pressure could force the adaptor to loosen and potentially come out of the tubing. Perform procedure for both lumina.

Once the lumen has been primed, keep the extension clamped when not attached to a bloodline or syringe. If the extension is unclamped, the priming volume will increase slightly as a result of the tube returning to its "normal" unclamped state. This creates a vacuum at the tip, causing blood to be drawn into the distal portion of the catheter, ultimately resulting in a thrombus.

MANAGEMENT OF ONE-WAY OBSTRUCTION

One-way obstruction, which exists when a lumen can be flushed easily, but blood cannot be aspirated, usually is caused by tip malposition. One of the following adjustments may resolve the obstruction:

- Reposition the patient.
- Have the patient cough.
- Provided there is no resistance, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

The following procedures may require a physician's order:

- Consider using a thrombolytic agent.
- If the one-way obstruction exists in the arterial lumen, consider reversing the bloodlines. The patient may be dialyzed by connecting the arterial bloodline to the venous adapter and the venous bloodline to the arterial adapter.

THROMBUS FORMATION

NEVER FORCIBLY FLUSH AN OBSTRUCTED LUMEN.

If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may attempt to lyse the clot with a thrombolytic agent.

WARNING: Thrombolytic agents may cause systemic fibrinolysis if infused into the circulation. Refer to

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manufacturer's instructions, indications for use, and contraindications before using thrombolytic agents. Streptokinase is not recommended; it is reported to be anaphylactogenic.

DIALYSIS

For priming volumes, see Heparinization section of these instructions.

1. Prepare dialysis machine and prime bloodlines in the usual manner. Maintain sterile technique when handling or using the catheter. Scrub the adapters, injection caps, clamps, extension tubes, and Y-connector of the catheter with an aqueous-based povidone-iodine solution.
2.
 - a. Verify that the arterial extension is clamped before removing the injection cap.
 - b. Remove the injection cap from the adapter and attach a luer-lock syringe.
 - c. Confirm patency of the lumen by aspirating indwelling heparin until venous blood appears. Leave the syringe in place.
 - d. Close the clamp on the extension.
3. Repeat Steps 2a. through 2d. for the venous lumen.

WARNING: When connecting bloodlines to the catheter, do not permit air to enter the blood path.

4. Remove the syringe and connect the arterial bloodline to the arterial (red) adapter. Open the clamps on the arterial extension and arterial and venous bloodlines and turn on the blood pump.
5. Prime the extracorporeal circuit with the patient's blood and turn off the blood pump. Ensure the venous extension is clamped, then remove the syringe and connect the venous bloodline to the catheter's venous (blue) adapter. Open the clamps on the venous extension and bloodline and turn on the pump.
6. Begin treatment.

POST DIALYSIS

Prepare syringes with sterile normal saline and heparin.

1. Stop the blood pump. Close the clamp on the arterial extension and clamp the arterial bloodline at the connection site. Disconnect the arterial bloodline from the adapter of the catheter.
2. Connect a 10-20 cc syringe filled with sterile normal saline to the arterial adapter; open the clamp on the arterial extension and flush the blood from the arterial lumen of the catheter. Reclamp the extension. Heparinize the lumen with the appropriate volume/concentration of heparin.
3. Rinse back the blood in the extracorporeal circuit via the catheter's venous lumen.
4. After the patient's blood has been rinsed back, turn off the blood pump. Clamp the venous extension and disconnect the venous bloodline from the venous adapter of the catheter.
5. Connect a 10-20 cc syringe filled with sterile normal saline to the venous adapter. Open the clamp on the venous extension and flush all remaining blood from the venous lumen of the catheter. Reclamp. Heparinize the lumen with the appropriate volume/concentration of heparin.
6. Ensure the clamps are closed on both extensions. Remove syringes and attach an injection sealing cap to each adapter.

WARNING: Keep the catheter clamped at all times except when connected to bloodlines or syringes during treatment.

CATHETER CARE GUIDES

For further information and a copy of Catheter Care guidelines for the clinician, contact your representative at Kendall, a division of The Tyco Healthcare Group LP. In the United States call 1-800-962-9888 and for International inquiries, call 508-261-8000.

ADDITIONAL READING

Moss, Alvin H. et al. "Use of a Silicone Catheter with a Dacron Cuff for Dialysis Short-Term Vascular Access." *American Journal of Kidney Diseases*, Vol. XII, No. 6 (December), 1988: pp. 492-498.

Schwab, Steve J. et al. "Prospective Evaluation of a Dacron Cuffed Hemodialysis Catheter for Prolonged Use." *American Journal of Kidney Diseases*, Vol. XI, No. 2 (February), 1988: pp. 166-169.

Kirkpatrick, W. G., Culpepper, R. M. & Sirman, M.D., Frequency of Complications with Prolonged Femoral Vein Catheterization for Hemodialysis Access. *Nephron*; 1996; 73: pp. 58-62.

Zaleski, G. X., Lorenz, J. M., Garofalo, R. S., Moscato, M. A., Rosenblum, J. D. and Leef, J. A. (1998). Experience with Tunneled Femoral Hemodialysis Catheters. *American Journal of Radiology*, 172: pp. 493-496.

DOQI Guidelines, 2006.

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ATTACHMENT 4

STERILIZATION VALIDATION

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ATTACHMENT 5

Form 3654 for ISO/AAMI/ANSI 11135-1: 2007

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE AAMI / ANSI / ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the developme		
Please answer the following questions		Yes No
Is this standard recognized by FDA ²		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		# 14-228
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?		<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input type="checkbox"/>
Title of guidance:		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or		certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
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DESCRIPTION		
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JUSTIFICATION		
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DESCRIPTION		
JUSTIFICATION		
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DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

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ATTACHMENT 6

Tray Sealer OQ

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ATTACHMENT 7

(b)(4) Validation Protocol

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ATTACHMENT 8

Form 3654 for ISO / AAMI / ANSI 10993

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Form Approved OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration		
STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION		
<input checked="" type="checkbox"/> Traditional	<input type="checkbox"/> Special	<input type="checkbox"/> Abbreviated
STANDARD TITLE ¹		
AAMI / ANSI / ISO 10993-3:2003, Biological evaluation of medical devices - (b)(4)		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	# 2-117	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance:		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.	
² Authority (21 U.S.C. 360d), www.fda.gov/cdrh/stdsprog.html	⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm	
³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm	⁶ The online search for CDH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html	
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or		

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
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DESCRIPTION (b)(4)		
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TYPE OF DEVIATION OR OPTION SELECTED * (b)(4)		
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<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

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Form Approved: OMB No. 0910-0120. Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ AAMI / ANSI / ISO 10993-5:1999, Biological evaluation of medical devices – Part 5: Tests for (b)(4) (Biocompat		
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FDA Recognition number ³		# 2-64
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Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510(k)?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance:		
<small> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cf/Standards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard, requirements not applicable to the device, and the name and address of the test laboratory or </small>		<small> certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cf/Standards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>

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510(k) Premarket Notification Submission: Zeus™ CT PICC

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b)(4) (b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER (b)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)s	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
(b)(4)		
JUSTIFICATION		
(b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
(b)(4)		
JUSTIFICATION		
(b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
(b)(4)	(b)(4)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
(b)(4) (b)		
JUSTIFICATION		
(b)(4)		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

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510(k) Premarket Notification Submission: Zeus™ CT PICC

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b)(4) (b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER (b)(4)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER (b)(4)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* (b)(4) (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>		

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Form Approved: OMB No. 0910-0120; Expiration Date 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).		
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ AAMI / ANSI / ISO 10993-6:2007, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation. (B)		
Please answer the following questions		
Is this standard recognized by FDA ² ?	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³		# 2-120
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____		
<small> ¹ The formatting convention for the title is: {SDO} [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>		

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER (b)(4)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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510(k) Premarket Notification Submission: Zeus™ CT PICC

Form Approved OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE: AAMI / ANSI / ISO 10993-10:2002, Biological evaluation of medical devices - (b)(4)	
Please answer the following questions	
Is this standard recognized by FDA ² ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
FDA Recognition number ³	# 2-87
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance:	
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html	⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/ocrh/cfdocs/cfStandards/search.cfm
³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm	⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods), choices made when options or a selection of methods are described, deviations from the standard, requirements not applicable to the device, and the name and address of the test laboratory or	

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b)(4) (b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER (b)(4)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* (b)(4)		
DESCRIPTION (b)(4) (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER (b)(4)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* (b)(4)		
DESCRIPTION (b)(4) (b)		
JUSTIFICATION (b)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER (b)(4)	SECTION TITLE (b)(4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4) (b)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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ATTACHMENT 9

(b) Results Summaries and the (b)(4) (b)(4)

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MEMORANDUM

Date: December 5, 2008

To: Laurie Lewandowski

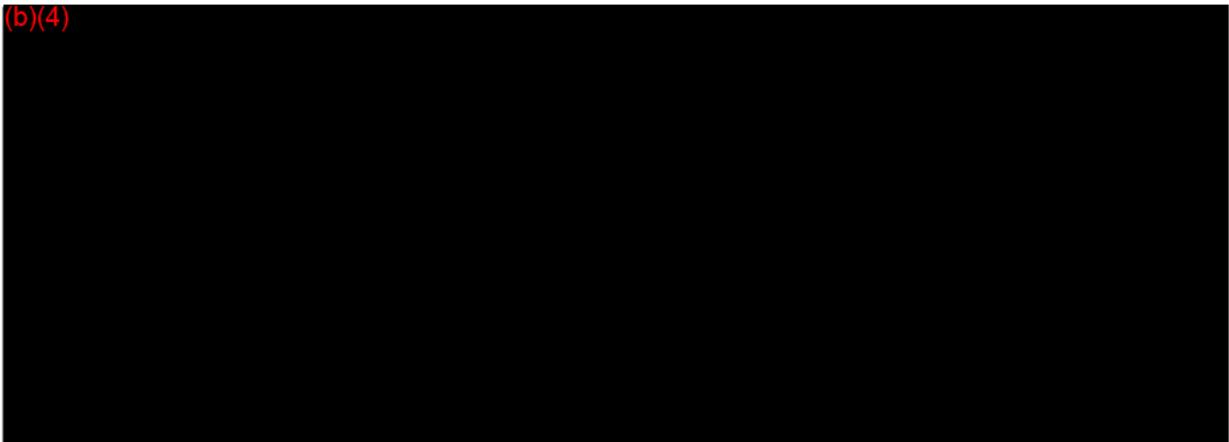
From: (b)(6)

Re: Review of (b)(4) report (b)(4)

As requested I have reviewed the report by (b)(4) concerning the (b)(4) (b)(4)

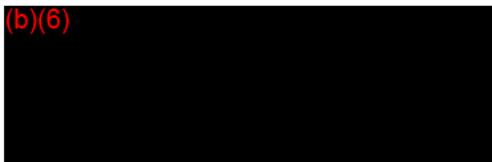
A summary of my review is detailed below:

(b)(4)



The biocompatibility testing from (b)(4) is adequate based on the (b)(4) to prove the biocompatibility of (b)(4). This assumes that the testing meets the requirements of 10993-1 and all of the testing met the test limits set forth in the testing protocols.

(b)(6)



Research Scientist

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ATTACHMENT 10

V & V Protocol

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REVISION HISTORY

Rev	DCR	Change Description	Release Date
(b)(4)			12/16/2008

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2. SCOPE227

3. BACKGROUND227

4. RESPONSIBLE FUNCTIONAL GROUPS228

5. REFERENCES229

6. EQUIPMENT AND MATERIALS229

7. TEST ARTICLES229

8. (b)(4)237

9. VERIFICATION TESTING239

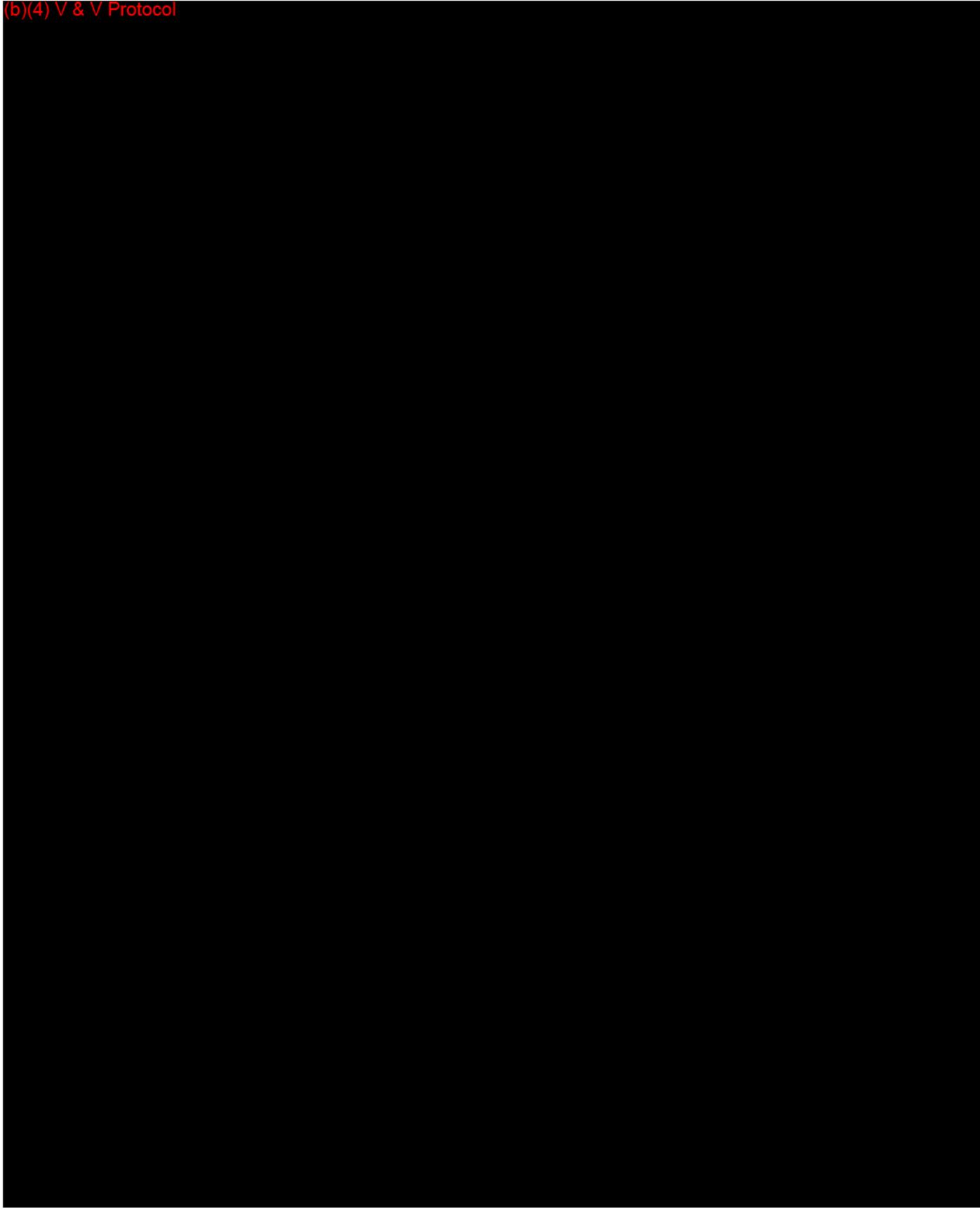
10. VALIDATION TESTING24

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(b)(4) V & V Protocol



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ATTACHMENT 11

Form 3654 for ISO 10555-1 and ISO 594

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510(k) Premarket Notification Submission: Zeus™ CT PICC

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>				
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).				
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated				
STANDARD TITLE ¹ ISO 10555-1 - Sterile, single-use intravascular catheters - Part 1: General Requirements				
Please answer the following questions				
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
FDA Recognition number ³	# 6-161			
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Title of guidance: _____				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or </td> <td style="width: 50%; border: none; vertical-align: top;"> certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </td> </tr> </table>			¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or	certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html			

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ ISO 594 - Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment-Part1: General reqmts	
Please answer the following questions	
Is this standard recognized by FDA ² ?	Yes No <input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	# 6-11
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Title of guidance:	
<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or</p>	<p>certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.</p> <p>⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p>

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

r4 Vascular, Inc.

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510(k) Premarket Notification Submission: *Zeus™ CT PICC*

ATTACHMENT 12

(b)(4)

r4 Vascular, Inc.

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

	Document Number (b)(4)	Rev (b)	Sheet 1 of 4
STANDARD OPERATING PROCEDURE	Title RISK ASSESSMENT AND SAMPLE SIZE DETERMINATION		
<i>Confidential & Proprietary</i>			

RISK ASSESSMENT AND SAMPLE SIZE DETERMINATION

(b)(4)

Reference document printed on 12/14/08

r4 Vascular, Inc.

Page 278

510(k) Premarket Notification Submission: *Zeus™ CT PICC*

ATTACHMENT 13

(b)(4) [REDACTED] Study



COVER SHEET MEMORANDUM

From: Reviewer Name Scott Colburn
Subject: 510(k) Number K083763
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
All Pediatric Patients age <=21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days -< 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years -< 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years -< 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Nanotechnology		<input type="checkbox"/>	<input checked="" type="checkbox"/>

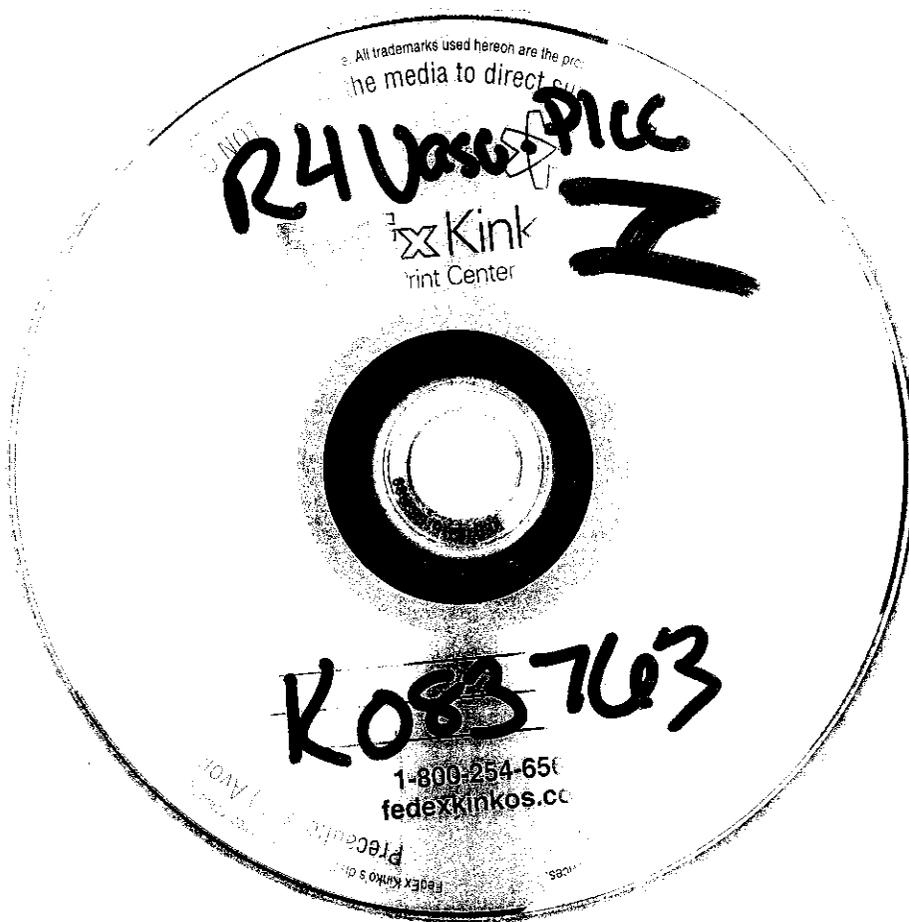
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

Regulation Number Class* Product Code
880.5970 II LTS
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: *[Signature]* 610 3/13/09
(Branch Chief) (Branch Code) (Date)

Final Review: *[Signature]* 03-16-09
(Division Director) (Date)





DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K083763

Date: March 13, 2009

To: The Record

From: Scott A. Colburn, MS, BSN, LCDR, USPHS

Office: CDRH/ODE

Division: DAGID/GHDB

510(k) Holder: R4 Vascular Inc.

Device Name: R4 Vascular Inc. Zeus™ CT PICC

Contact: Laurie Lewandowski

Phone: 763-494-8400

Fax: 763-494-8484

Email: lalew@r4vascular.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce R4 Vascular Inc. Zeus™ CT PICC catheter in 4Fr. and 5Fr single lumen and 5Fr and 6Fr dual lumen into interstate commerce.

Discussion: **Acceptable**

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
<u>510(k) Summary</u> or 510(k) Statement	x		
Standards Form	x		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)?		x	
Are "cleaning" instructions included for the end user?			

The r4 Vascular, Inc. *Zeus™ CT PICC* is a family of peripherally inserted central venous catheters designed to perform infusion, intravenous therapy, blood sampling and also power injection for contrast media studies. The catheters, made of radiopaque polyurethane tubing, are inserted peripherally. Each *Zeus™ CT PICC* has a kink resistant, reverse tapered catheter design. The *Zeus™ CT PICC* kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations. The *Zeus™ CT PICC* product line consists of the following catheters:

- 4 Fr single lumen
- 5 Fr single lumen
- 5 Fr dual lumen
- 6 Fr dual lumen

The catheters are trimmable by the clinician for fit to the individual patient. The PICCs are attached to an injection-molded polyurethane hub that has extension legs with Luer lock fittings for access attachment.

The *Zeus™ CT PICC* is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

The *Zeus™ CT PICC* is very similar to HDCs V-Cath (polyurethane) Power PICC (Power V), K071875, with the addition of a Biomimetic Coating, which is substantially equivalent to the Tyco Palindrome Emerald K060509 which uses a heparin coating.

(b)(4)

(b)(4)

The advantages of (b)(4) surfactant polymer include:

Biomimetic Coating is inert, with no biologically active component, such as heparin or an antibiotic, thereby eliminating potential complications.

- (b)(4)
- (b)(4)
- Non-toxic

(b)(4)

The coating has been applied to the inner and outer diameter of r4 Vascular *Zeus™ CT PICC* by (b)(4). Testing has been performed on the coating to support the following claims:

- Reduces thrombosis occlusion by 34% when compared to a non-coated PICC catheter;
- Reduces the pressure to clean thrombus by 66% when compared to a non-coated device
- Leading to a longer lasting catheter;
- Allows the use of a saline flush and a saline lock instead of requiring a heparinized saline lock.

(Note: Following intravenous therapy, the PICC is "flushed" with saline to clear the therapy drug; the PICC is then filled with heparinized saline or in the case of the *Zeus PICC*,

recommended to use saline to prevent blood from filling the lumen. This is called locking the PICC.)

- (b)(4). Therefore, the catheter lasts longer because thrombosis occlusion is reduced and less pressure is required to clean thrombus.

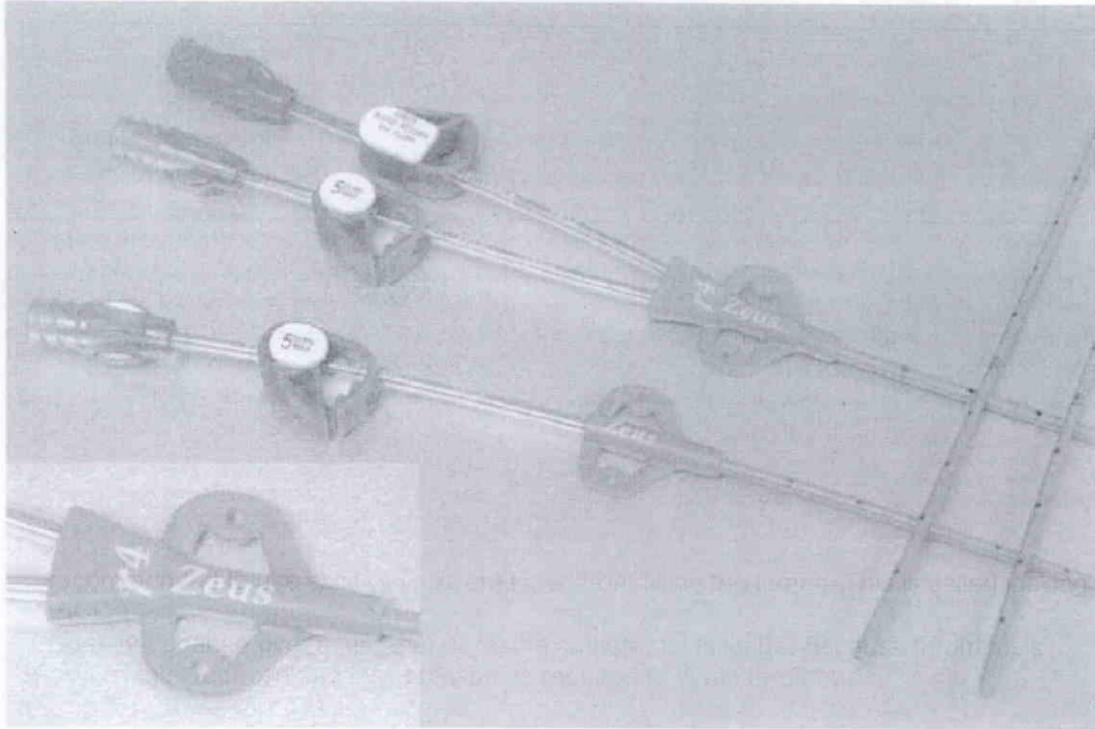


Figure 11.1 Zeus 5 Fr single and dual lumen PICC

The fully assembled Zeus™ CT PICC (see Figures 3 and 4) consists of an extruded polyurethane catheter insert molded into an injection-molded polyurethane hub (having integral suture tabs) that has extension leg tubing bonded to ISO standard Luer lock fittings for access attachment. The pinch clamps are placed on both extension legs and with the maximum recommended infusion rate:

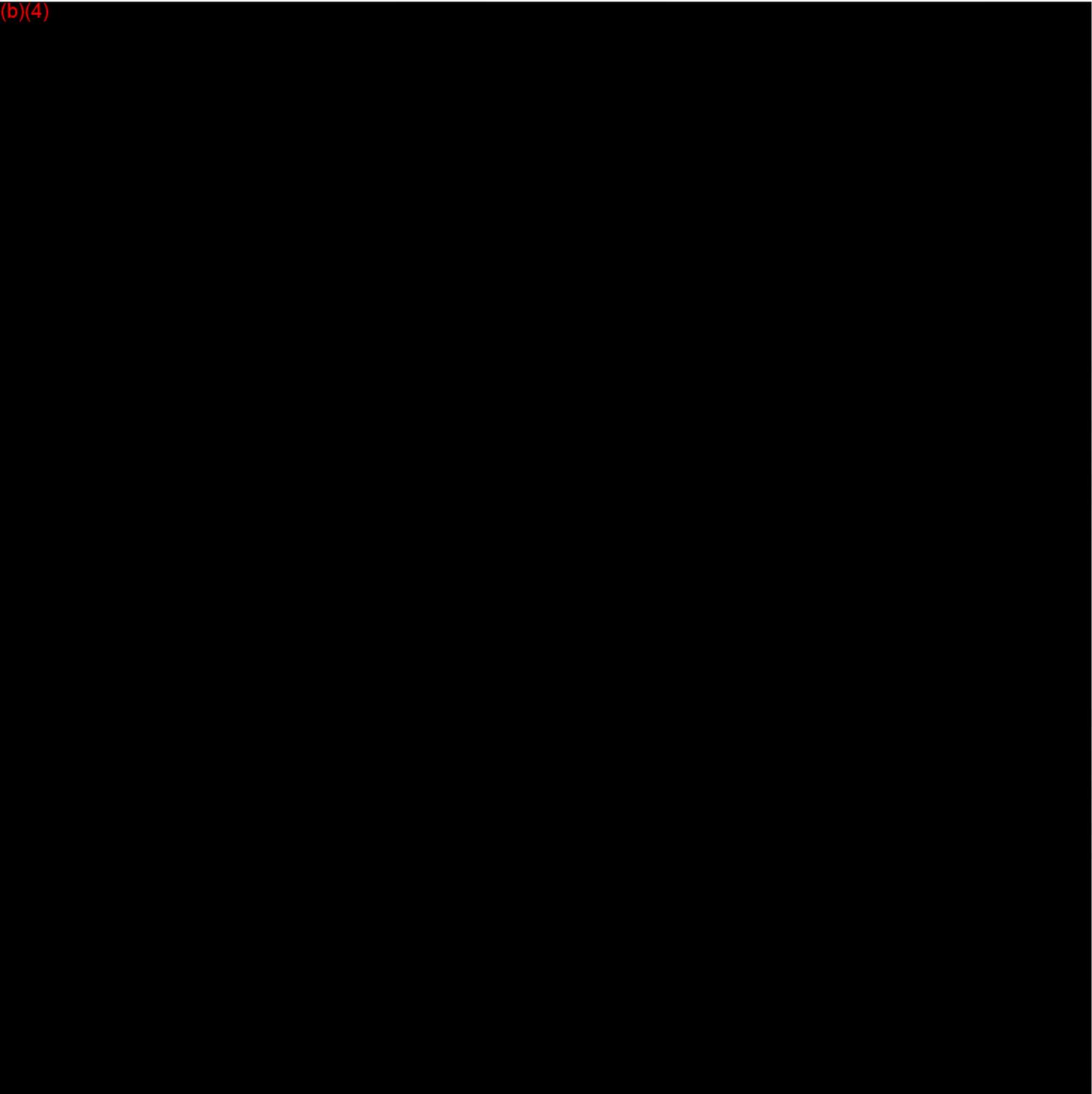
- 4 and 5 FR single lumen - 5/rnl sec maximum recommended infusion rate
- 5 and 6 FR dual lumen - 5/rnl sec maximum recommended infusion rate

In addition, the extension leg tubing has the words "Power Injectable" and the gauge size printed on the tubing. The trimmable catheters (single and dual lumen) have depth markings to help in depth of insertion into the peripherally accessed vein.

Biomimetic Coating

(b)(4)

(b)(4)



Discussion: The sponsor has provided a robust description of the device, its similarities and notable but acceptable differences (biomimetic coating vs. heparin coating of predicate device).
- **Acceptable**

IV. Indications for Use

The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power

injector utilized should not exceed 300 psi.

Discussion: The indications for use of the Zeus PICC and the predicate device; the HDC V-Cath Power PICC CVC are similar. Both are indicated for access to the central venous system for short and long-term intravenous therapy and power injection of contrast media. The firm is not making an intended use that the device reduces thrombus formation or catheter occlusion, however this is stated in the device description and labeling. - **Acceptable**

V. Predicate Device Comparison

Characteristics	<i>Submission Device: Zeus™ CT PICC</i>	<i>Power PICC (Power-V) (K071875) Predicate Device</i>
Intended Use/ Indications for Use	The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.	The Power PICC (Power-V) is indicated for short or long term (less than or greater than 30 days) peripheral access to the central venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media. All Power PICC (Power-V) products have a maximum recommended infusion rating of 5 ml/sec. The maximum pressure or pounds per square inch (psi) of the power injector utilized should not exceed 300 psi.
Target Population	Physician discretion	Identical
Sterility	100% Ethylene Oxide One time use	Identical
Biocompatibility	Biocompatibility testing was performed in accordance with ISO 10993 for a permanent blood contact device	Identical
Design /Size	4F single lumen = 50cm, 5F single lumen= 60cm, 5F dual lumen = 55cm, 6F dual lumen = 60cm Trimnable to patient specific need	4 Fr single lumen, 5 Fr single lumen, 5 Fr dual lumen, 6 Fr dual lumen Trimnable to patient specific need. Implanted useable length 60 cm
Dimensions (inches) Inner Diameter (ID) Outer Diameter (OD) Wall thickness (Wall)	(b)(4)	
Materials		

(b)(4) Materials



(b)(4) Materials

Manufacturer

Discussion:

(b)(4)



VI. Labeling

The Sponsor provided adequate labeling for its Unit, Case, Shipper Labeling and Instructions for Use. Labeling is consistent for the intended use of this device and adequate instructions for the device

(b) (4)



See performance in section XI below for specific limits reported. - **Acceptable**

VII. Sterilization/Shelf Life/Reuse

1. Sterilant:

YES

NO

(b) (4)



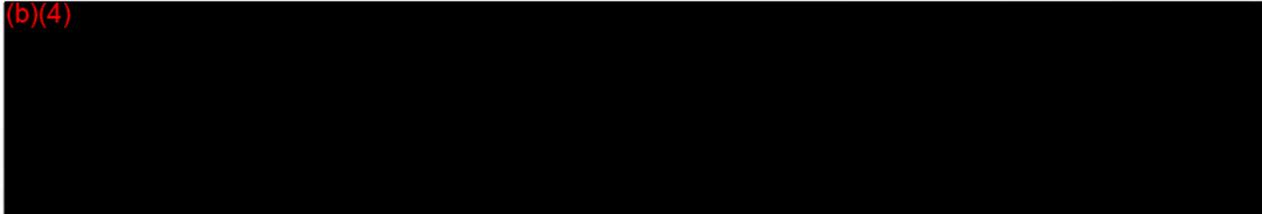
VIII. Biocompatibility

IX.

The Zeus™ CT PICC is a percutaneous, implanted, long-term intravascular catheter indicated for dwell times shorter or greater than 30 days. It is categorized as a Long Term Intravascular Catheter. According to ISO 10993, it is defined as an externally communicating device, blood contacting, long term device with contact duration of > 30 days. Form 3654 for *ISO/AAMI/ANSI 10993* was provided for compliance to testing

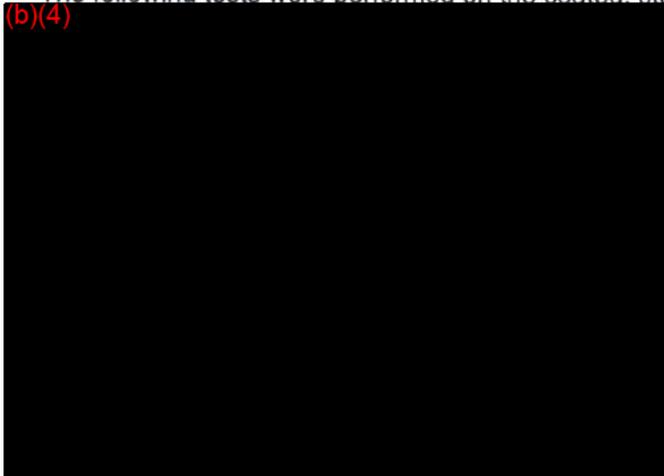
Biocompatibility testing of all materials and the Biomimetic Coating was performed.

(b)(4)



The following tests were performed on the coated, sterilized Zeus™ CT PICCs.

(b)(4)



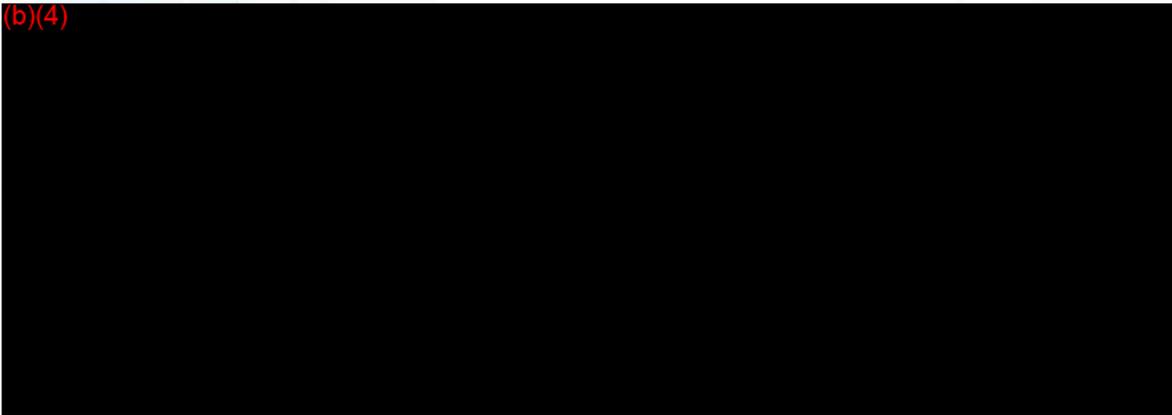
Discussion: All testing demonstrated material safety - **Acceptable**

X. Software - N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety - N/A

XI. Performance Testing – Bench

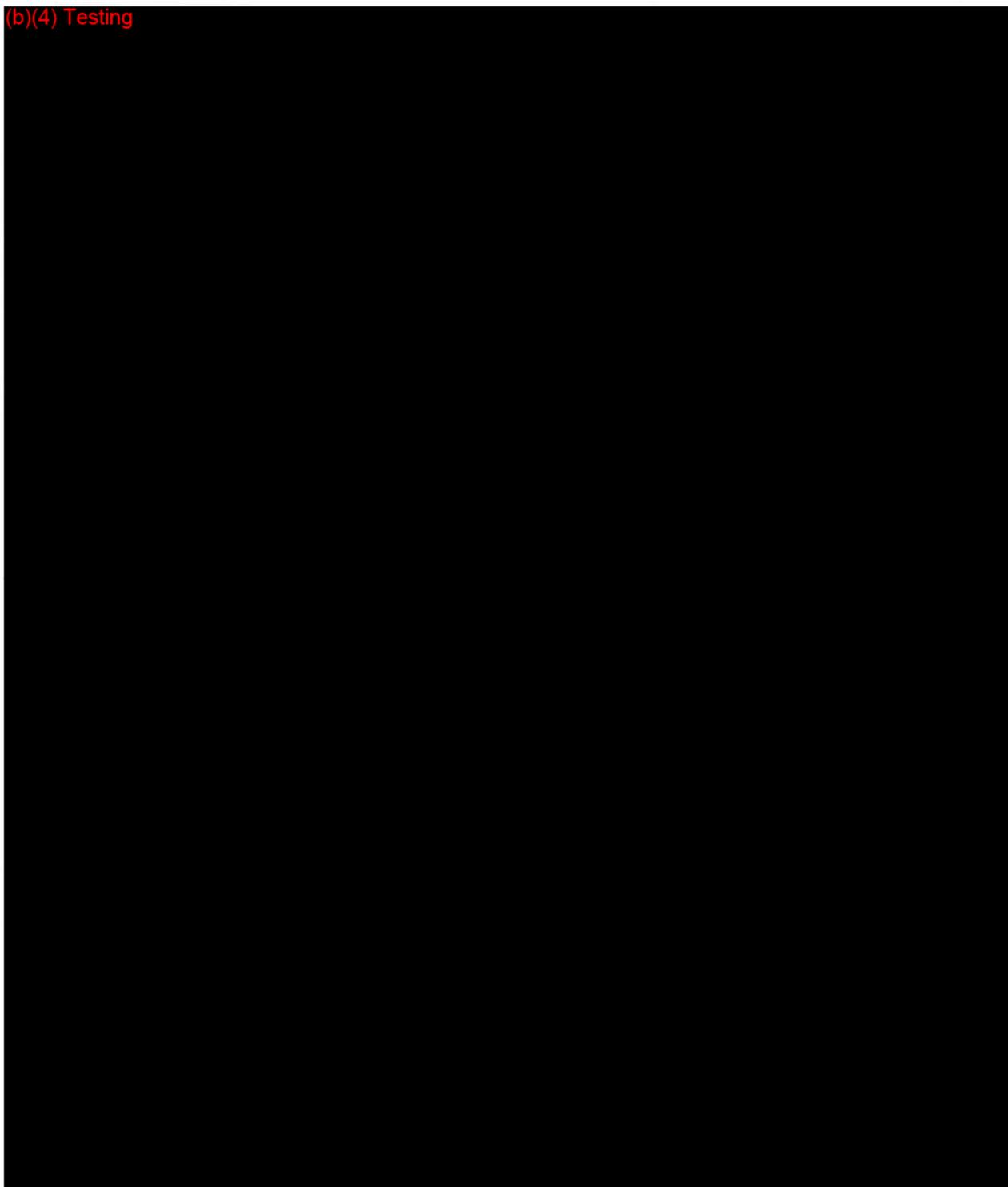
(b)(4)



Verification Testing consisted of the following tests:

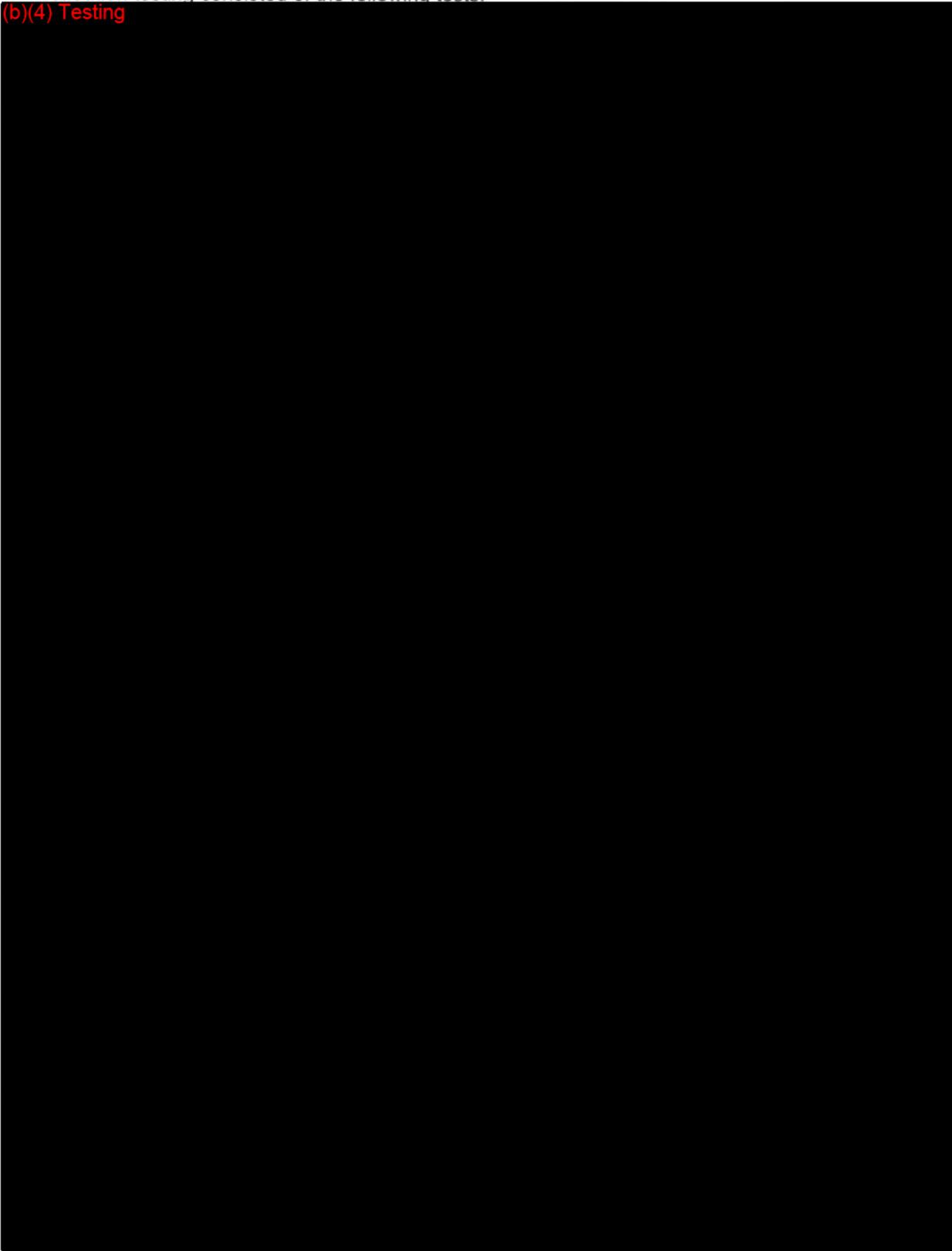
Verification Test	Results Summary
(b)(4)	

(b)(4) Testing



Validation testing consisted of the following tests:

(b)(4) Testing



XIV. Substantial Equivalence Discussion

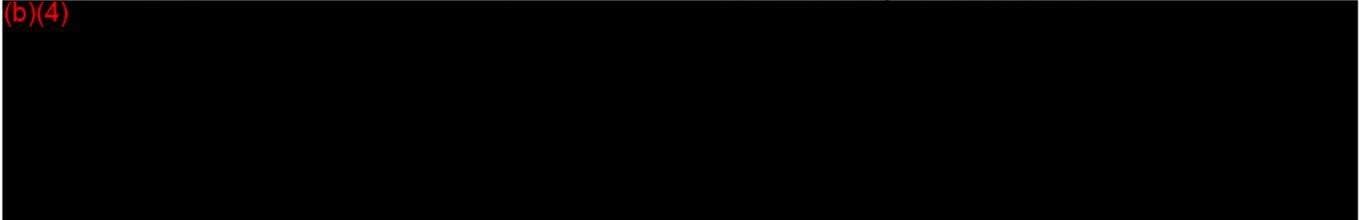
	Yes	No	
1. Same Indication Statement?	x		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	x		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	x		If NO = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: SE

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

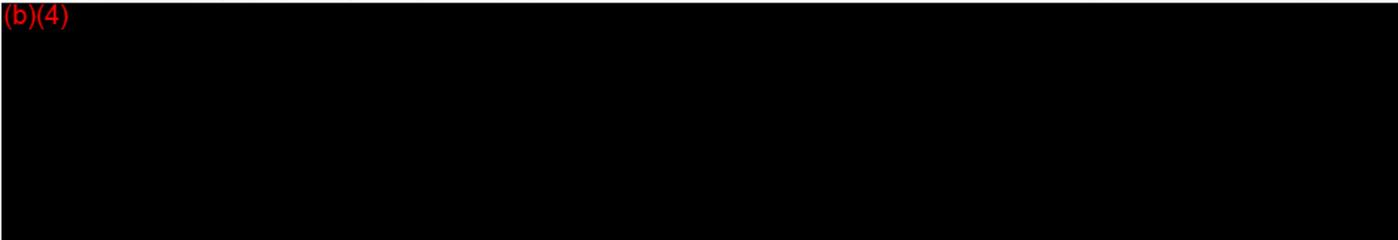
1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:

(b)(4)



6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

(b)(4)



XV. Deficiencies – (b)(4)



XVI. Contact History

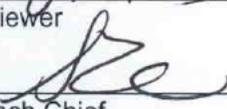
(b)(4)

XVII. Recommendation SE

Regulation Number: 21 CFR 880.5970
Regulation Name: Long Term Intravascular catheter
Regulatory Class: Class II
Product Code: LJS



Reviewer



Branch Chief

3/13/09
Date

3/13/09
Date

Colburn, Scott A

From: Laurie Lewandowski [lalew@r4vascular.com]
Sent: Tuesday, March 10, 2009 11:28 AM
To: Colburn, Scott A
Subject: RE: r4 Vascular K083763

Thank you,
I concur.

Laurie Lewandowski
r4 Vascular, Inc.
763-494-8400
612-770-4038 Cell



From: Colburn, Scott A [mailto:Scott.Colburn@fda.hhs.gov]
Sent: Tuesday, March 10, 2009 10:01 AM
To: Laurie Lewandowski
Subject: FW: r4 Vascular K083763

Sorry to be picky but I will need to raise the lower part so the "line" is not so far down on the page. The Agency needs to place its date stamp and Division Signature below the "line" and needs ~3 inches. I just don't want this sent back for any reasons that we can prevent now.

I made this modification for you in the attached but just need your concurrence. I will print off this version.

Thanks,

Scott Colburn, MS, BSN, RN, LCDR, USPHS
Acting Branch Chief
General Hospital Devices
FDA/CDRH/ODE/DAGID
240-276-3707

From: Laurie Lewandowski [mailto:lalew@r4vascular.com]
Sent: Tuesday, March 10, 2009 9:54 AM
To: Colburn, Scott A
Subject: RE: r4 Vascular K083763

Thank you Lieutenant Colburn for your response,

I (b)(4) did you want this officially resubmitted through the document mail center as well?

3/10/2009

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1103; Released by CDRH on 09-12-2016

I appreciate you letting me know the form was updated. I did use the same form on a recent submission, but will ensure future submissions include the updated form.

I look forward to working with you,

Laurie

Laurie Lewandowski
r4 Vascular, Inc.
763-494-8400
612-770-4038 Cell



From: Colburn, Scott A [mailto:Scott.Colburn@fda.hhs.gov]
Sent: Monday, March 09, 2009 10:58 PM
To: Laurie Lewandowski
Colburn, Scott A
Subject: RE: r4 Vascular K083763

Mrs. Lewandowski,

I am completing my initial review of your document and will try to contact you within the next few days if there are additional information requests by the Agency.

If you can respond to the following request: (b)(4)

[REDACTED] I have attached the updated version to this letter or you may also find the form at <http://www.fda.gov/cdrh/ode/indicate.pdf>. Please send the revised form to me via email if possible for this request.

As mentioned above, if there are additional information requests I will contact you in the next few days.

Regards,

Scott Colburn, MS, BSN, RN, LCDR, USPHS
Acting Branch Chief
General Hospital Devices
FDA/CDRH/ODE/DAGID
240-276-3707

From: Laurie Lewandowski [mailto:lalew@r4vascular.com]
Sent: Monday, March 09, 2009 4:21 PM
To: Colburn, Scott A
Subject: r4 Vascular K083763

Lieutenant Colburn,

3/10/2009

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

I'm wondering if you can share with me when you believe you will be done with the review of the Zeus 510K application, K083763. I do know the 90 day date is 3/18/09 however, if it's possible that your review will be completed earlier that would be great. Let me provide the reasons I ask:

- 1) I often work from home so I'd like to be able to review the questions (or approval ☺) first if possible.
- 2) The SIR meeting (Society of Interventional Radiology) is in process and it would be nice to be able to communicate the review status and when we can expect feedback.
- 3) Spring break is approaching for all of us in MN (much needed after this long winter) and I would like to be able to prepare folks to address any potential questions you may have.
- 4) We are a start-up company so timing is critical.

I am almost always available on cell phone and/or e-mail. Thank you in advance and I look forward to hearing from you,

Laurie

Laurie Lewandowski
r4 Vascular, Inc.
763-494-8400
612-770-4038 Cell



3/10/2009

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

r4 Vascular, Inc.

510(k) Premarket Notification Submission: Zeus™ CT PICC

Section 4.0

Indications for Use

510(k) Number (if known): K083763

Device Name: Zeus CT PICC

Indications For Use:

The Zeus™ CT PICC is indicated for short or long-term (less than or greater than 30 days) peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The maximum recommended infusion rate is 4 ml/sec for power injection of contrast media. The maximum pressure of the power injector utilized should not exceed 300 psi.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)