



U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)

FOLDER: K100635 - 2676 pages (FOI:11008343)

COMPANY: ARROW INTL., INC. (ARROW)

PRODUCT: CATHETER,INTRAVASCULAR,THERAPEUTIC,LONG-TERM GREATER THAN 30 DAYS (LJS)

SUMMARY: Product: ARROWGARD EVOLUTION ANTIMICROBIAL
PERIPHERALLY INSERTED CENTRAL CATHET

DATE REQUESTED: Jan 6, 2012

DATE PRINTED: Jan 6, 2012

Note: Releasable Version



K100635

510(k) SUMMARY

**SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
ARROW ANTIMICROBIAL PRESSURE INJECTABLE PICC**

AUG 27 2010

1. Submitter Information

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)
Address: 2400 Bernville Road
Reading, PA 19605-9607
Telephone Number: (610) 378-0131
Contact Person: Tracy Maddock
Regulatory Affairs Specialist
Telephone Number: (610) 378-0131 Extension 3384
Fax Number: (610) 374-5360
Email: tracy.maddock@teleflexmedical.com
Date Prepared: June 4, 2010

2. Device Name

Device Trade Name: Arrow Antimicrobial Pressure Injectable Peripherally
Inserted Central Catheter (PICC)
Common Name: Peripherally Inserted Central Catheter
Classification Name: Percutaneous, implanted, long-term intravascular catheter

3. Predicate Devices

Predicate 1: Pressure Injectable PICC (K061289)
Predicate 2: 6 French Triple Lumen Pressure Injectable PICC (K080604)
Predicate 3: ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691)

4. Device Description

The Arrow Antimicrobial Pressure Injectable PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in 4.5 Fr. single lumen and 5.5 Fr. double lumen configurations with usable lengths of 40 – 55 cm. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based antimicrobial technology.

The catheters will be packaged sterile in both nursing and radiology configurations. Both configurations will include components to facilitate insertion.

5. Indications for Use

The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

6. Summary Comparing Technological Modifications

Modifications to existing Arrow products include:

- Inclusion of 4.5 Fr. single lumen and 5.5 Fr double lumen catheters to those ARROW PICCs already marketed. The increase in OD of the catheters allow for the subject devices to achieve 5 mL/sec pressure injection and to accommodate external / internal treatment.
- The catheter body material for the subject devices consist of a blending of two durometers of polyurethane resin. A blue colorant was added to the catheter body resins to differentiate from non-antimicrobial PIC catheters.
- A blue colorant was added to the juncture hub material of the subject devices to further differentiate the antimicrobial catheters.
- The catheter tip material of the subject devices includes a different radiopacifier for enhanced radiopacity.
- Antimicrobial treatment has been applied to the external catheter body surface and the entire fluid path of the device.
- The antimicrobial treatment present on the external catheter body of the subject devices consist of chlorhexidine only as opposed to chlorhexidine and silver sulfadiazine present on currently marketed Arrowgard Blue Plus central venous catheters.

7. Nonclinical Testing

Bench testing was performed on the Arrow Antimicrobial Pressure Injectable PICC in accordance with ISO 10555-1, 10555-3 and FDA Guidance on Premarket Notification [510(k)] Submission for Short- Term and Long- Term Intravascular Catheters. *In vitro* and *in vivo* testing was performed to assess the safety and efficacy of the proposed device. Testing included biocompatibility, *in vitro* antimicrobial efficacy, and *in vivo* animal infection study.

8. Summary of Verification Activities

Test	Acceptance Criteria	Results														
Air Leakage during aspiration	<p>There shall be no air leakage in the form of an air bubble in the syringe connected to the PICC after the first 5 seconds when tested per BS EN ISO 10555-1:1997 Annex D.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
Collapse Resistance	<p>The catheter shall not collapse during aspiration as evidenced by water being able to be pulled out of the catheter when vacuum is applied by a minimum of a 10 cc syringe. The extension line clamps, if present, shall be in the fully constrained position.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
Liquid Leakage under pressure	<p>There shall be no liquid leakage in the form of a falling drop of water at 300-320 kPa (43.5 -46.4) for 30 sec when tested per BS EN ISO 10555-1:1997 Annex C.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
Force at break -Tensile Testing and Catheter Elongation	<p>There must be a 95% confidence level that 95% of the population meets the specification.</p> <table border="1" data-bbox="511 1050 1161 1470"> <thead> <tr> <th>Tensile attribute</th> <th>Requirement per BS EN ISO 10555-1 and 10555-3</th> </tr> </thead> <tbody> <tr> <td>Catheter Body Force at Break</td> <td>$\geq 10N$</td> </tr> <tr> <td>Blue Flex Tip to Catheter Body Force at Break</td> <td>$\geq 4N$</td> </tr> <tr> <td>Catheter Body to Juncture Hub Force at Break</td> <td>$\geq 10N$</td> </tr> <tr> <td>Extension Line to Juncture Hub Force at Break</td> <td>$\geq 15N$</td> </tr> <tr> <td>Extension Line to Luer Hub Force at Break</td> <td>$\geq 15N$</td> </tr> <tr> <td>Catheter Body Elongation</td> <td>$> 100\%$</td> </tr> </tbody> </table>	Tensile attribute	Requirement per BS EN ISO 10555-1 and 10555-3	Catheter Body Force at Break	$\geq 10N$	Blue Flex Tip to Catheter Body Force at Break	$\geq 4N$	Catheter Body to Juncture Hub Force at Break	$\geq 10N$	Extension Line to Juncture Hub Force at Break	$\geq 15N$	Extension Line to Luer Hub Force at Break	$\geq 15N$	Catheter Body Elongation	$> 100\%$	Pass
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Catheter Body Force at Break	$\geq 10N$															
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Extension Line to Juncture Hub Force at Break	$\geq 15N$															
Extension Line to Luer Hub Force at Break	$\geq 15N$															
Catheter Body Elongation	$> 100\%$															
Radio-Detectability	The optical density contrast must be at least 0.1.	Pass														
Catheter Body Kink	Does not kink at a radius greater than 0.5 inch when tested per BS EN 13868:2002 Annex A under simulated <i>in vivo</i> conditions. This requirement shall be met with 95% assurance.	Pass														

Test	Acceptance Criteria	Results
Central Venous Pressure Monitoring	The average amplitude difference between input and output signals shall be less than or equal to 1 mmHg when tested using a 1 Hz sinusoidal input signal. This requirement shall be met with 95% assurance.	Pass
Column Strength and Tip Stiffness	<p>For catheters having a tip of different construction to the catheter body, the tip shall be constructed in accordance with the requirement 5.1.6 and shall be made of lower durometer material than that of the catheter body.</p> <p>Design of tip shall ensure that the average force required to deflect or compress the tip is no greater than the average force required to deflect or compress the catheter body.</p> <p>NOTE: Requirement 5.1.6 referenced above is taken from an internal Arrow requirements document. Requirement 5.1.6 is identical to the requirement found in ISO 10555-3 Section 4.3.</p>	Pass
Static Burst Pressure	The maximum internal static pressure during pressure injection shall not exceed the static burst pressure.	Pass
Static Burst Pressure	The maximum internal static pressure during pressure injection shall not exceed the static burst pressure.	Pass
Rate Limited Injection Testing	Each pressure injectable lumen shall withstand at least 5 repeat injections without rupture or visually evident yielding of the catheter when injected at the maximum indicated flow rate using 125 mL of contrast media or equivalent (maximum viscosity of 11.8 ± 0.2 cP) at $37 \pm 2^\circ\text{C}$.	Pass
Pressure Limited Injection Testing	The average flow rate of each catheter lumen shall be at least 90% of the maximum indicated flow rate.	Pass
Ink Adhesion Testing	The catheter shall remain legible when examined without magnification with exposure to ChloroPrep and Iodine for 1 minute each, then application and removal of semi-permeable adhesive dressing and Biopatch after 7 days. The acceptance criteria for meeting this requirement will be a legible marking.	Pass
Step Stress Testing	The catheters shall pass the first 10 injections at the maximum flow rate without visually evident yielding or rupture.	Pass
Trim Tool	<p>After trimming with the provided trimming tool and visualized under 2.5X magnification, the indwelling catheter shall terminate at the distal end with a square tip that:</p> <ul style="list-style-type: none"> • Has no points • Produces a clean, smooth surface <p>With a sample size of $n=60$, zero failures are required to show a 95% confidence level and $LTPD=5\%$ in an attribute test.</p>	Pass

Test	Acceptance Criteria	Results
<p>Luer Hub Slip</p>	<p><u>Luer Hub Slip</u></p> <p>The hub shall meet the following Luer slip requirements with 95% confidence and a LTPD of 10% when tested per BS EN 20594-1:1994, ISO 594-1:1986 Clauses 5.1 through 5.5:</p> <p>Gauging: The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.</p> <p>Liquid Leakage: No liquid leakage shall occur in the form of one or more falling drops of water.</p> <p>Air Leakage: There shall be no signs of continued formation of air bubbles.</p> <p>Separation force: The Luer hub shall remain attached to the reference fitting.</p> <p>Stress cracking: There shall be no evidence of stress cracking of the fitting.</p>	<p>Pass</p>
<p>Luer Hub Lock</p>	<p><u>Luer Hub Lock</u></p> <p>The hub shall meet the following Luer lock requirements with 95% confidence and a LTPD of 10% when tested per BS EN 1707:1997 Clauses 5.2 through 5.8:</p> <p>Gauging: When tested with the appropriate gauge, the conical part of the lock fitting shall have the plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.</p> <p>Liquid Leakage: No liquid leakage shall occur in the form of one or more falling drops of water.</p> <p>Air Leakage: There shall be no signs of continued formation of air bubbles.</p> <p>Separation force: The Luer hub shall remain attached to the reference fitting.</p> <p>Unscrewing torque: The Luer hub shall remain attached to the reference fitting.</p> <p>Ease of Assembly to Male Fitting: No resistance shall be observed until the taper of the fitting under test and the reference fitting fit together securely.</p> <p>Resistance to Overriding Male to Female Luer Connection: The reference fitting shall not override the threads or lugs of the fitting under test.</p> <p>Stress cracking: There shall be no evidence of stress cracking of the fitting</p>	<p>Pass</p>
<p>Catheter Securement</p>	<p>The catheter shall include a feature that enables the catheter to be secured to the patient's skin.</p> <p>Demonstrate a 95% confidence level and LTPD=5% by having the suture holes for all catheters fit over the Securement posts with zero failures and the retainer wings from all catheters lock into place with zero failures.</p>	<p>Pass</p>

Test	Acceptance Criteria	Results
First Article Inspection	<p>If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5cm. (BS EN ISO 10555-3: 1997 Section 4.4 and JIS T 3218:2005, Section 5.7)</p> <p>For multilumen catheters, identification of each lumen shall be apparent to the user (BS EN ISO 10555-3:1997, Item 4.5 and JIS T 3218:2005, Item 5.8)</p> <p>The French size of the catheter shall be printed on the integral juncture hub or in a location that can be seen after the catheter has been inserted.</p> <p>The tradename and/or name of the manufacturer of the catheter shall be printed on the integral juncture hub or in a location that can be seen after the catheter has been inserted.</p>	Pass
Clamp Closure Efficacy	The clamp closure capability shall be such that when the clamps are in the fully constrained position, there shall be no flow through the lumen being tested when tested in accordance with BS EN ISO 10555-3 Annex A or JIS T 3218 Annex C.	Pass
Flow restriction after clamping	The extension lines shall not be permanently deformed from the use of extension line clamps during the maximum expected clamp duration of the catheter to the point where a restriction in the extension line decreases the gravity flow through the catheter below the minimum gravity flow rate requirement (i.e. 90 mL/hr)	Pass
<i>In vitro</i> efficacy testing – external antimicrobial treatment	<p>The antimicrobial agent release rate will be sufficiently slow to provide efficacy against gram (+), gram (-) and fungi for a minimum of 7 days.</p> <p>Note: Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.</p>	Pass
<i>In vitro</i> efficacy testing – internal antimicrobial treatment	<p>The antimicrobial agent release rate will be sufficiently slow to provide efficacy against gram (+), gram (-) and fungi for a minimum of 7 days.</p> <p>Note: Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.</p>	Pass
<i>In vivo</i> animal infection study	The product shall exhibit efficacy against <i>Staphylococcus aureus</i> at minimum 7 days for <i>in-vivo</i> studies. Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.	Pass

9. Conclusions

The Arrow Antimicrobial Pressure Injectable PICCs are substantially equivalent to the Arrow Pressure Injectable PICCs (K061289) and the Arrow 6 French Triple Lumen Pressure Injectable PICCs (K080604). The subject devices have the same intended use, principles of operation and technological characteristics as the predicates. The indications for use, for the proposed catheters, are the same as the

Arrow PICC predicate device K080604 with the addition of the proposed catheter's effectiveness in reducing microbial colonization.

The antimicrobial agent for the proposed device is a similar Chlorhexidine-based solution used for the ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691). The process of application of the antimicrobial agent is also similar to that of the predicate device.

The results of the testing performed have demonstrated that the Arrow Antimicrobial Pressure Injectable PICC devices are safe and perform as intended. The differences, between subject devices and predicate devices, do not raise any new issues of safety and effectiveness. Thus, the Arrow Antimicrobial Pressure Injectable PICCs are substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ms. Tracy Maddock
Regulatory Affairs Specialist
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

AUG 27 2010

Re: K100635

Trade/Device Name: Arrow Antimicrobial Pressure Injectable Peripherally
Inserted Central Catheter (PICC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 23, 2010
Received: August 24, 2010

Dear Ms. Maddock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

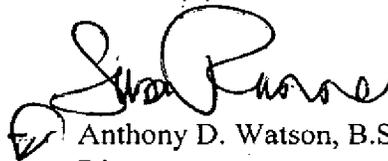
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100635

Indications for Use

510(k) Number (if known): _____

Device Name: Arrow Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter (PICC)

Indications for Use:

The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sara P...

(Division Sign-Off)
Division of Anesthesiology, General Hospital Page ___ of ___
Infection Control, Dental Devices

510(k) Number: K100635



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ms. Tracy Maddock
Regulatory Affairs Specialist
Arrow International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605

AUG 27 2010

Re: K100635

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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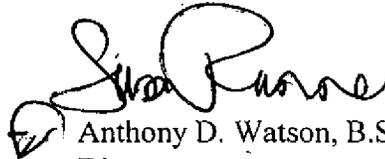
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

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<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100635

Indications for Use

510(k) Number (if known): _____

Device Name: Arrow Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter (PICC)

Indications for Use:

The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sara Papp

(Division Sign-Off)
Division of Anesthesiology, General Hospital Page ___ of ___
Infection Control, Dental Devices

510(k) Number: K100635



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 16, 2010

ARROW INTL., INC.
2400 BERNVILLE RD.
READING, PENNSYLVANIA 19605
UNITED STATES
ATTN: TRACY MADDOCK

510k Number: K100635

Product: ARROWGARD EVOLUTION
ANTIMICROB

Extended Until: 08/27/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



July 15, 2010

FDA CDRH DMC
JUL 16 2010
Received

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

**Subject: 510(k) Premarket Notification - K100635/S001
Arrow Antimicrobial Pressure Injectable PICC**

Dear Sir or Madam:

Arrow International received a request from the Center for Devices and Radiological Health on June 24, 2010 for additional information in response to our Premarket Notification of intent to market the above referenced device. Arrow has since requested a teleconference with the reviewer to discuss the deficiency noted. Since the organization of a teleconference with multiple participants may be necessary, Arrow is requesting a 30-day extension to be able to participate in the teleconference and provide a response to the Agency.

If we do not receive correspondence to the contrary, we will assume that CDRH agrees with this deadline extension request.

Sincerely,

Tracy Maddock, RAC
Regulatory Affairs Specialist

K17

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 29, 2010

ARROW INTL., INC.
2400 BERNVILLE RD.
READING, PENNSYLVANIA 19605
UNITED STATES
ATTN: TRACY MADDOCK

510k Number: K100635

Product: ARROWGARD EVOLUTION
ANTIMICROB

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



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

June 08, 2010

ARROW INTL., INC.
2400 BERNVILLE RD.
READING, PENNSYLVANIA 19605
UNITED STATES
ATTN: TRACY MADDOCK

510k Number: K100635

Product: ARROWGARD EVOLUTION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



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

May 11, 2010

ARROW INTL., INC.
2400 BERNVILLE RD.
READING, PENNSYLVANIA 19605
UNITED STATES
ATTN: TRACY MADDOCK

510k Number: K100635

Product: ARROWGARD EVOLUTION
ANTIMICROB

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

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

March 08, 2010

ARROW INTL., INC.
2400 BERNVILLE RD.
READING, PENNSYLVANIA 19605
UNITED STATES
ATTN: TRACY MADDOCK

510k Number: K100635
Received: 3/5/2010
Product: ARROWGARD EVOLUTION
CATHETER

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) 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

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/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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/AboutFDA/ReportsManualsForms/Forms/default.htm> 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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

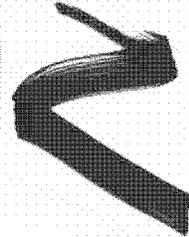
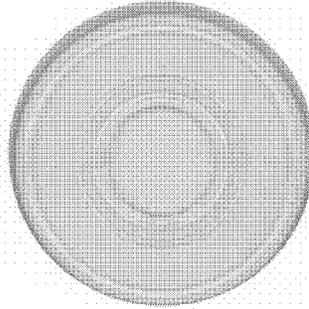
Sincerely,

510(k) Staff

ARROW
INTERNATIONAL

**ARROWg+ard Evolution Antimicrobial
Pressure Injectable PICC**

Traditional 510k Submission
04 March 2010



Arrow International, Inc.
2400 Bernville Rd.
Reading, PA 19605

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Arrow International, Inc.

**ARROWg⁺ard Evolution Antimicrobial Pressure Injectable Peripherally
Inserted Central Catheter (PICC)**

Traditional 510(k) Premarket Notification

4 March 2010

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1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

Arrow International has remitted the Medical Device User Fee of (b)(4) to the Food and Drug Administration. A copy of the Medical Device User Fee Cover Sheet is provided on the following page.

FDA CDRH DMC

MAR 05 2010

Received

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ARROW INTERNATIONAL INC 2400 BERNVILLE ROAD READING PA 19605 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)		2. CONTACT NAME Tracy Maddock 2.1 E-MAIL ADDRESS tracy.maddock@teflexmedical.com 2.2 TELEPHONE NUMBER (include Area code) 610-378-0131 3384 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 type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <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)		23-Jan-2010	

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

A copy of the CDRH Premarket Review Submission Cover Sheet is provided on the following page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission 03/03/2010	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	Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE 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):
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	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? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Arrow International, Inc. (subsidiary of Teleflex Inc.)	Establishment Registration Number (if known) 2518433		
Division Name (if applicable) Critical Care	Phone Number (including area code) (610) 378-0131		
Street Address 2400 Bernville Road	FAX Number (including area code) (610) 374-5360		
City Reading	State / Province PA	ZIP/Postal Code 19605	Country USA
Contact Name Tracy Maddock			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address tracy.maddock@teleflexmedical.com	

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

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

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<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"/> Response 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"/> 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):		

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	FOZ	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	K061289	1	Pressure Injectable PICC	1			ARROW INTL, Inc
2	K080604	2	6F Triple Lumen Pressure Injectable PICC	2			ARROW INTL, Inc
3	K993691	3	ARROWg+ard Blue Plus Multi-Lumen CVC	3			ARROW INTL, Inc
4		4		4			
5		5		5			
6		6		6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Peripherally Inserted Central Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Arrowgard Evolution Antimicrobial Peripherally Inserted Central Catheter (PICC)	1	S-44041-002, S-45041-002, S-455041-002
2	Arrowgard Evolution Antimicrobial Peripherally Inserted Central Catheter (PICC)	2	MC-44052-003, MC-45052-003, MC-45552-003
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1	1090263	2	1090263/S001	3	
4		5		6	
7		8		9	
10		11		12	

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LJS	C.F.R. Section (if applicable) 21 CFR 880.5970	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General Hospital and Personal Use Devices		

Indications (from labeling)
 The ARROWg+ard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWg+ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.

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 checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name ARROW INTL, Inc (Subsidiary of Teleflex Inc.)			Establishment Registration Number 1036844		
Division Name (if applicable)			Phone Number (including area code) (336) 498-4153		
Street Address 312 Commerce Place			FAX Number (including area code) (336) 495-1642		
City Asheboro		State / Province NC	ZIP/Postal Code 27203	Country USA	
Contact Name Matt Winton		Contact Title Quality Assurance Manager		Contact E-mail Address Matt.Winton@teleflexmedical.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name ARROW INTL, Inc (Subsidiary of Teleflex Inc.)			Establishment Registration Number 2518433		
Division Name (if applicable)			Phone Number (including area code) (610) 378-0131		
Street Address 2400 Bernville Road			FAX Number (including area code) (610) 374-5360		
City Reading		State / Province PA	ZIP/Postal Code 19605	Country USA	
Contact Name William Sullivan		Contact Title Plant Manager		Contact E-mail Address William.Sullivan@teleflexmedical.com	

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

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10555-1	BS EN ISO	Sterile, single-use Intravascular catheters - Part 1: General Requirements	1997	01/15/1997
2	10555-3	BS EN ISO	Sterile, single-use intravascular catheters - Part 2: Central venous catheters	1997	09/15/1997
3	10993-1	ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing	2003	10/09/2003
4	10993-7	BS EN ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008	12/31/2008
5	11135-1	BS EN ISO	Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization	2007	06/29/2007
6	1707	BS EN	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings	1997	06/15/1997
7	20594-1; ISO 594-1:1986	BS EN	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings	1994	01/30/1987

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

UTILIZATION OF STANDARDS

Continued from CDRH Premarket Review Submission Cover Sheet

8	Standards No.	Standards Organization	Standards Title	Version	Date
	F 1980	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2007	04/01/2007



3. 510(K) COVER LETTER

March 4, 2010

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

FDA CDRH DMC

MAR 05 2010

Received

K-49

Subject: 510(k) Notification [21 CFR 807.90(e)]

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, Arrow International is submitting the attached premarket notification for a new device; the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter (PICC).

Pursuant to 21 CFR Part 807, Arrow International is submitting two copies of this traditional 510(k) for your review. In addition to a paper copy of the submission, an electronic copy, an exact duplicate of the paper copy, is provided to facilitate the review. Information regarding the subject device is listed below.

- **Device Common Name:** Peripherally Inserted Central Catheter
- **Device Trade Name:** ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC
- **Device Classification Name:** Percutaneous, implanted, long-term intravascular catheter
- **FDA Classification Regulation:** 21 CFR 880.5970
- **FDA Classification:** Class II
- **FDA Product Code:** LJS
- **Classification Panel:** General Hospital and Personal Use Devices
- **FDA Panel Number:** 80
- **Predicate Devices:**
 - Arrow Pressure Injectable PICC (K061289), product code: LJS
 - Arrow 6 French Triple Lumen Pressure Injectable PICC (K080604), product code: LJS
 - ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691), product code: FOZ

- **Prior FDA Formal Correspondence Document Numbers:**

Pre-IDE #I090263
Pre-IDE #I090263/S001

A summary of relevant notes taken during the May 27th meeting between Arrow International and the Agency is provided in table format on page 13. Also included in the table are the Agency's responses, received on February 16, 2010, to the supplemental pre-IDE (submitted on November 6, 2009). Arrow actions/comments in response to all of the Agency's comments are provided.

- **Manufacturing Site / Sterilization Site and Establishment Registration Number:**

Manufacturing Site
ARROW INTL, INC. (Subsidiary of Teleflex Inc.)
2400 Bernville Road
Reading, PA 19605

Establishment registration number: 2518433

Manufacturing Site and Sterilization Site
ARROW INTL, INC. (Subsidiary of Teleflex Inc.)
312 Commerce Place
Asheboro, NC 27203

Establishment registration number: 1036844

The following table is a summary of principal factors regarding the design and use of the subject device and is included as recommended in FDA Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s".

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? ^A		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X

Question	YES	NO
Does the submission include clinical information?		X*
Is the device implanted?		X

^A A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

*Clinical information is provided for predicate device for comparison purposes only.

In accordance with the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Arrow International has submitted the required application fee of (b)(4). A copy of the User Fee Cover Sheet is provided with the attached premarket notification.

Arrow International considers its intent to market the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore requests that FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act even after the existence of this application becomes public. We ask that you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

We trust that the information provided in the 510(k) is sufficient for FDA to find the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC substantially equivalent to its predicate devices for the listed indication. Should you have any questions regarding the context of this submission, please contact me at (610) 378-0131 extension 3384 or Robin Fatzinger at (610) 378-0131 extension 3731.

Sincerely,



Tracy Maddock, RAC
Regulatory Affairs Specialist

**Summary of Agency Comments and corresponding actions
taken or comments made by Arrow International**

Agency Comments	(b)(4),(b)(5)	Arrow actions/comments
(b)(4),(b)(5)		

4. INDICATIONS FOR USE STATEMENT

The Indications for Use Statement for the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is provided on the following page.

Indications for Use

510(k) Number (if known): _____

Device Name: ARROWg⁺ard Evolution Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter (PICC)

Indications for Use:

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

5. 510(K) SUMMARY

The 510(k) Summary is provided on the following page.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
ARROWg⁺ARD EVOLUTION ANTIMICROBIAL PRESSURE INJECTABLE PICC

1. Submitter Information

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)
Address: 2400 Bernville Road
Reading, PA 19605-9607
Telephone Number: (610) 378-0131
Contact Person: Tracy Maddock
Regulatory Affairs Specialist
Telephone Number: (610) 378-0131 Extension 3384
Fax Number: (610) 374-5360
Email: tracy.maddock@teleflexmedical.com
Date Prepared: March 4, 2010

2. Device Name

Device Trade Name: ARROWg⁺ard Evolution Antimicrobial Pressure Injectable
Peripherally Inserted Central Catheter (PICC)
Common Name: Peripherally Inserted Central Catheter
Classification Name: Percutaneous, implanted, long-term intravascular catheter

3. Predicate Devices

Predicate 1: Pressure Injectable PICC (K061289)
Predicate 2: 6 French Triple Lumen Pressure Injectable PICC (K080604)
Predicate 3: ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691)

4. Device Description

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in 4.5 Fr. single lumen and 5.5 Fr. double lumen configurations with usable lengths of 40 – 55 cm. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based antimicrobial technology.

The catheters will be packaged sterile in both nursing and radiology configurations. Both configurations will include components to facilitate insertion.

5. Indications for Use

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.

6. Technological Characteristics and Substantial Equivalence

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is substantially equivalent to the Arrow Pressure Injectable PICC (K061289) and the Arrow 6 French Triple Lumen Pressure Injectable PICC (K080604) in terms of overall design, manufacturing process, functional performance, and materials of construction. The indications for use, for the proposed catheter, are the same as the Arrow PICC predicate device K080604 with the addition of the proposed catheter's effectiveness in reducing microbial colonization. The antimicrobial treatment does not affect the intended use of the product as the principle of operation of the device is unchanged.

The antimicrobial agent for the proposed device is a similar Chlorhexidine-based solution used for the ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691). The process of application of the antimicrobial agent is also similar to that of the predicate device.

7. Nonclinical Testing

Bench testing was performed on the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC in accordance with ISO 10555-1, 10555-3 and FDA Guidance on Premarket Notification [510(k)] Submission for Short- Term and Long- Term Intravascular Catheters. *In vitro* and *in vivo* testing was performed to assess the safety and efficacy of the proposed device. Testing included biocompatibility, *in vitro* antimicrobial efficacy, and *in vivo* animal infection study.

8. Conclusions

The results of the testing performed have demonstrated that the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC device is safe and performs as intended and therefore is considered substantially equivalent to the cited predicate devices.

6. TRUTHFUL AND ACCURATE STATEMENT

The signed Truthful and Accurate Statement is provided on the following page.

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

[As Required by 21 CFR 807.87(k)]

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

Tracy Maddock

(Signature)

Tracy Maddock

(Typed Name)

04-March-2010

(Date)

(Premarket Notification [510(k)] Number)

7. CLASS III SUMMARY AND CERTIFICATION

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is a Class II device. A Class III Summary and Certification is not applicable.

8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

No clinical studies were performed for the proposed device. This section is not applicable.

9. DECLARATION OF CONFORMITY AND SUMMARY REPORTS

Consistent with FDA's guidance documents entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), Arrow is including this statement that the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC complies with the following recognized consensus standards:

Standard	Title
BS EN ISO 10555-1:1997	Sterile, single-use intravascular catheters - Part 1: General Requirements
BS EN ISO 10555-3:1997	Sterile, single-use intravascular catheters - Part 2: Central venous catheters
BS EN ISO 10993-1:2003	Biological evaluation of medical devices - Part 1: Evaluation and testing
BS EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
BS EN ISO 11135-1:2007	Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization
BS EN 1707:1997	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
BS EN 20594-1:1994; ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
ASTM F 1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

A Standards Data Report for 510(k)s Form (FDA Form 3654) is provided on the pages that follow for each standard listed above.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION .

Traditional Special Abbreviated

STANDARD TITLE¹
BS EN ISO 10555-1 Sterile, single-use intravascular catheters - Part 1: General requirements 1997

Please answer the following questions Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 6-161

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: Guidance on Premarket Notification submission for short-term and long-term intravascular catheters

<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>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
BS EN ISO 10555-1 Sterile, single-use intravascular catheters - Part 1: General requirements 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General	<input checked="" 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?
4.2	Biocompatibility	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Refer to Section 15 Biocompatibility for discussion. Some in vitro studies indicated cell cytotoxicity and red blood cell hemolysis.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Surface	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

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.

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

BS EN ISO 10555-1 Sterile, single-use intravascular catheters - Part 1: General requirements 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Corrosion resistance	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

The Arrowgard Evolution Antimicrobial PICC does not include metallic components, therefore this section does not apply.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.5	Force at break	<input checked="" 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?
4.6.1	Freedom from leakage - Liquid leakage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Catheter connected to leak tester instead of syringe as stated in Annex C of ISO std.

DESCRIPTION

JUSTIFICATION

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

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Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
BS EN ISO 10555-1 Sterile, single-use intravascular catheters - Part 1: General requirements 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.6.2	Freedom from leakage - Air leakage	<input checked="" 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?
4.7	Hubs	<input checked="" 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?
4.8	Flowrate	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION
Section 4.6 of BS EN ISO 10555-3:1997 specifies flow rate requirements

JUSTIFICATION
This part of BS EN ISO 10555-1 does not specify requirements for flow rate, therefore this section does not apply.

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

Paperwork Reduction Act Statement

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

BS EN ISO 10555-1 Sterile, single-use intravascular catheters - Part 1: General requirements 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.0	Designation of nominal size	<input checked="" 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?
5.1	Outside Diameter	<input checked="" 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?
5.2	Effective length	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.0	Information to be supplied by manufacturer	<input checked="" 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		
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		
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Department of Health and Human Services
Food and Drug Administration
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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

BS EN ISO 10555-3 Sterile, single-use intravascular catheters - Part 3: Central venous catheters 1997

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 16-171

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

Title of guidance: Guidance on Premarket Notification submission for short-term and long-term intravascular catheters

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

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

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

BS EN ISO 10555-3 Sterile, single-use intravascular catheters - Part 1: Central venous catheters 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General	<input checked="" 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?
4.2	Radio-detectability	<input checked="" 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?
4.3	Tip configuration	<input checked="" 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
BS EN ISO 10555-3 Sterile, single-use intravascular catheters - Part 1: Central venous catheters 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Distance markings	<input checked="" 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?
4.5	Lumen markings	<input checked="" 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?
4.6	Flowrate	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Refer to Arrow International (b)(4) for a detailed explanation.

- * For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.
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STANDARD TITLE
BS EN ISO 10555-3 Sterile, single-use intravascular catheters - Part 1: Central venous catheters 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.7	Force at break	<input checked="" 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?
4.8	Information to be supplied by the manufacturer	<input checked="" 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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ISO 10993-1 Biological evaluation of medical devices: Part 1: Evaluation and testing 2003

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 2-98

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
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Does this standard include acceptance criteria?
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Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1 Biological evaluation of medical devices: Part 1: Evaluation and testing 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.1	General	<input checked="" 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?
5.2.2	Cytotoxicity	<input checked="" 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?
5.2.3	Sensitization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1 Biological evaluation of medical devices: Part 1: Evaluation and testing 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.4	Irritation	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
The Intracutaneous Injection test was performed as it is a more appropriate test for the Arrow Evolution Antimicrobial PICC.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.5	Intracutaneous Reactivity	<input checked="" 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?
5.2.6	Systemic Toxicity (acute toxicity)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1 Biological evaluation of medical devices: Part 1: Evaluation and testing 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2.7	Subacute and subchronic toxicity	<input checked="" 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?
5.2.8	Genotoxicity	<input checked="" 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?
5.2.9	Implantation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 10993-1 Biological evaluation of medical devices: Part 1: Evaluation and testing 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

5.3.4

SECTION TITLE

Reproductive and developmental toxicity

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

There are no potential effects of this device on reproductive function, embryonic development, or prenatal development.

SECTION NUMBER

5.3.5

SECTION TITLE

Biodegradation

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

There is no potential for resorption and/or degradation to exist when the device is used as intended.

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ANSI/AAMI/ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals 2008

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 14-279

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
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Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI/ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals 2008

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER All sections	SECTION TITLE	CONFORMANCE? <input checked="" 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
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ANSI/AAMI/ISO 11135-1 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development.. 2007

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 14-228

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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Title of guidance: _____

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² Authority [21 U.S.C. 380d], www.fda.gov/ocdrh/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/ocdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI/ISO 11135-1 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development.. 2007

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE See attached matrix of ISO section Titles/Requirements	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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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
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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
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

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EN ISO 11135 Part 1-1:2007 STANDARD COMPLIANCE CHECKLIST	ANITMICROBIAL PICC CATHETER
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Standard & Title: Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135 Part 1:2007)

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification #
1 - 3	Scope, Normative References, Definitions	n/a	
4	Quality management systems		
4.1	Documentation	Full	(b)(4)
4.1.1	Procedures for development, validation, routine control, and product release from sterilization shall be specified.		
4.1.2	Documents and records will be approved by personnel that have been specified. Shall be in accordance with ISO 13485.	Full	
4.2	Management responsibility	Full	
4.2.1	Responsibility and authority for implementing and meeting the requirements of this standard shall be specified. Shall be assigned to competent personnel.	Full	
4.2.2	If requirements of ISO 11135 Part 1 are undertaken by other organizations with separate quality management systems, the responsibility and authority of each party shall be specified	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
4.3	Product realization		(b)(4)
4.3.1	Procedures for purchasing shall be specified. These procedures shall comply with the applicable clauses of ISO 13485	Full	
4.3.2	Procedures for identification and traceability of product shall be specified. These procedures shall comply with the applicable clauses of ISO 13485	Full	
4.3.3	A system complying with the applicable clauses of ISO 13485 or ISO 10012 shall be specified for the calibration of all equipment, including instrumentation for test purposes, used in meeting the requirements of this part of ISO 11135 Part 1.	Full	
4.4	Measurement, analysis and improvement — Control of nonconforming product Procedures for control of product designated as nonconforming and for correction, corrective action and preventive action shall be specified. These procedures shall comply with the applicable clauses of ISO 13485.	Full	
5	Sterilizing agent characterization		
5.1	Sterilizing agent The composition, storage conditions and shelf life for the sterilizing agent shall be specified.	Full	
5.2	Microbicidal effectiveness Microbicidal effectiveness data shall be developed if it is proposed to use the ethylene oxide outside of the range of compositions that are widely recognized or if a novel diluent is to be used.	N/A	

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Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
9.3.1.2	<p>packaging, loading patterns, equipment or process parameters, unless equivalence to a previously validated product, packaging or loading pattern combination has been demonstrated. The demonstration of equivalence shall be documented. PQ is performed in the equipment used to sterilize the product.</p> <p>PQ shall use product to demonstrate that equipment consistently operates in accordance with predetermined criteria and that the process produces product that is sterile.</p>	Full	(b)(4)
9.3.1.3	<p>The load used for PQ shall be representative of that to be sterilized routinely and shall be defined based upon the most challenging routine load. The load may consist of product or materials that have characteristics similar to those of a load to be sterilized routinely.</p> <p>NOTE If saleable product has been used during validation, see 7.2 and 11.3.</p> <p>If material other than product is used, it shall present at least as great a challenge to the sterilization process as the product.</p> <p>If loads are reused for the validation cycles, they should be aerated between exposures to ensure that ethylene oxide residues in the load do not affect the biological indicator.</p> <p>The loads shall be re-evaluated at a predetermined frequency for appropriateness.</p>	Full	(b)(4)
9.3.1.4	<p>The manner of presenting product for sterilization, including the loading pattern of the product, shall be specified.</p>	Full	(b)(4)

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
9.3.1.5	<p>If chemical indicators are used as part of PQ, these shall comply with ISO 11140-1.</p> <p>Chemical indicators shall not be used as the sole means of PQ.</p>	N/A	(b)(4)
9.3.2	<p>Performance qualification — Microbiological</p>		
9.3.2.1	<p>The microbiological PQ shall demonstrate that, on application of the sterilization process, the specified requirements for sterility are met. Studies shall be performed in the production chamber using defined process parameters selected to deliver less lethality than the specified sterilization process. During microbiological PQ, it is common practice to reduce the set point of one or more process variables (e.g. EO concentration, temperature, humidity) compared to the set points used in routine sterilization. The defined parameters may be at or below the minimum levels specified for routine control.</p>	Full	
9.3.2.2	<p>Microbiological PQ shall confirm the effectiveness of the defined process for the product/load combination in a production sterilizer.</p>	Full	
9.3.2.3	<p>The lethality of the cycle shall be determined using one of the methods described in Annex A or Annex B or by an alternative validated method that demonstrates achievement of the required SAL.</p>	Full	
9.3.2.4	<p>If process definition was determined in a developmental chamber, the microbiological PQ shall include at least three fractional or half-sterilization cycles in the production sterilizer that confirm the data from the developmental chamber. All biological indicators shall be deactivated with one or more of these validation cycles.</p>	N/A	
9.3.2.5	<p>Sterilization equipment that delivers the same process parameters, having undergone installation IQ and OQ, shall be qualified either</p> <p>a) in the same manner as the original chamber or</p> <p>b) using a reduced PQ that demonstrates the delivery of the required</p>	N/A	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
9.3.3	<p>level of microbiological lethality; the rationale for this reduced qualification shall be recorded and documented. The influence of different geographical locations on the load properties should be determined.</p>		
9.3.3.1	<p>Performance qualification – physical Physical PQ shall demonstrate: a) reproducibility of the process, and shall include a minimum of three consecutive, planned qualification runs in which all the specified acceptance criteria are met; b) that the specified acceptance criteria are met throughout the load for the duration of the proposed routine process specification. Elements of the physical PQ may be conducted during the microbiological PQ. If a) is performed in parallel with the microbiological PQ, then at least one additional qualification run shall be performed to demonstrate compliance with this requirement. If a failure can be attributed to factors not relevant to the effectiveness of the process being validated, this may be documented as unrelated to the performance of the process without requiring three further consecutive successful runs. Examples of this type of failure may include, but are not limited to, power failures, other loss of services, or failure of external monitoring equipment.</p>	Full	(b)(4)
9.3.3.2	<p>Physical PQ shall confirm the process such that: a) at the end of the defined preconditioning time (if used), the sterilization load is within the defined temperature and humidity ranges; b) the specified maximum elapsed time between the completion of preconditioning (if used) and the commencement of the sterilization cycle is appropriate; c) gaseous ethylene oxide has been admitted to the sterilizer chamber; d) pressure rise and the quantity of ethylene oxide used [see 9.5.4 c)] or the concentration of ethylene oxide in the sterilizer chamber [see</p>	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
	<p>9.5.5 b)] are within the ranges specified; e) during the sterilization cycle, the temperature and humidity of the chamber and, where applicable, other process parameters are within the ranges documented in the sterilization process specification; f) the temperature of the product load during exposure is within the defined range; g) during aeration, the sterilization load is within the specified temperature range.</p>		
9.4	<p>Varying load configurations For establishments that have widely varying load configurations, the extent to which the variation affects the sterilization process shall be evaluated. It shall be demonstrated that all product sterilized with a cycle achieves the required level of sterility assurance.</p>	Full	(b)(4)
9.5	<p>Review and approval of validation</p>		
9.5.1	<p>The purpose of this activity is to undertake and document a review of the validation data to confirm the acceptability against the approved protocol for the sterilization process and to approve the process specification.</p>	Full	
9.5.2	<p>Information gathered or produced during product definition, process definition, IQ, OQ and PQ, including results from incubation of biological indicators shall be recorded and reviewed for acceptability (see also 4.1.2). The results of this review shall be recorded.</p>	Full	
9.5.3	<p>A validation report shall be prepared. The report shall be reviewed and approved by the designated responsible person(s).</p>	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
9.5.4	<p>Report shall contain or reference specific validated product, the defined loading patterns and the documented specification for the EO sterilization process. Shall include value and tolerances for :</p> <p>A) preconditioning</p> <ol style="list-style-type: none"> 1) time in chamber/area, temperature and humidity of chamber/area 2) minimum temperature of product permitted to enter preconditioning 3) temperature and RH of the sterilization load 4) maximum elapsed time between removal of load from preconditioning and commencement of the sterilization cycle <p>B) conditioning (if used)</p> <ol style="list-style-type: none"> 1) initial vacuum level and time taken to achieve it 2) holding time under vacuum 3) time in chamber, temperature, pressure and RH within chamber 4) temperature and RH of sterilization load <p>C) Ethylene Oxide (EO) injection and exposure</p> <ol style="list-style-type: none"> 1) EO injection pressure rise, time and final pressure 2) EO concentration determined independently from the increase in pressure, utilizing at least one of the following: <ol style="list-style-type: none"> i) mass of EO used ii) volume of EO used iii) direct measurement of EO conc. Within chamber 3) sterilizer chamber temp 4) exposure time 5) temperature of the sterilization load 6) indication of the satisfactory operation of the chamber gas circulation system (if used) during exposure. <p>d) aeration (if used)</p>	Full	(b)(4)

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
	1) time and temperature 2) pressure changes(if any) within the chamber and/or room 3) rate of change of air or other gas 4) temperature of the sterilization load		
9.5.5.	If parametric release is to be used, the report shall specify: a) the value and tolerances for chamber RH by direct measurement during conditioning b) the value and tolerances for EO concentration, determined from direct analysis of chamber atmosphere at defined intervals sufficient to verify the required conditions throughout the exposure time.	N/A	(b)(4)
9.5.6	A process specification, including the process parameters and their tolerances, shall be confirmed. This process specification shall also include the criteria for designating an individual sterilization process used for a particular sterilization load as conforming.	Full	
10	Routine monitoring and control Data shall be recorded and retained for each sterilization cycle to demonstrate that the sterilization process specification has been met. These data shall include at least the following:		
10.1 a	evidence that the minimum required temperature of product entering preconditioning (if used) has been achieved; this may be achieved by allowing loads to acclimate for a specified minimum time;	Full	
10.1 b	temperature and humidity within the preconditioning area (if used), monitored and recorded from a specified position;	Full	
10.1 c	time of commencement and of removal of load from preconditioning (if used) of each sterilization load;	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
10.1 d	indication of the satisfactory operation of the chamber gas circulation system (if used) during gas exposure;	Full	(b)(4)
10.1 e	elapsed time between removal of the sterilization load from preconditioning (if used) and the commencement of the sterilization cycle;	Full	
10.1 f	temperature and pressure in the chamber throughout the sterilization cycle;	Full	
10.1 g	chamber humidity during conditioning by pressure and/or direct monitoring;	Full	
10.1 h	evidence that the gaseous ethylene oxide has been admitted to the sterilizer chamber;	Full	
10.1 i	pressure rise and the quantity of ethylene oxide used or the concentration of ethylene oxide in the sterilizer chamber;	Full	
10.1 j	Conditioning time	Full	
10.1 k	Exposure time	Full	
10.1 (l)	time, temperature, pressure changes (if any) and/or the operation of the air supply (if used) during aeration. If biological indicators are used in routine monitoring, they shall comply with 8.6. If chemical indicators are used in routine monitoring, they shall comply with 8.8.	Full	
10.2 a	If parametric release is performed, the following additional data shall be recorded and retained: a) temperature in the chamber from a minimum of two locations throughout the sterilization cycle; b) chamber humidity during conditioning as determined by direct measurement; c) the ethylene oxide concentration, determined from direct analysis of chamber atmosphere at defined	N/A	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
11.1 a	<p>intervals sufficient to verify the required conditions throughout the exposure time.</p> <p>Product release from sterilization The criteria for designating conformance of the sterilization process used for a particular sterilization load shall be documented. These criteria shall include: a) confirmation that the data recorded during routine processing meet sterilization process specification; b) confirmation of no growth of the test organism from any biological indicator (if used).</p>	Full	(b)(4)
11.2	<p>Product shall be considered as non-conforming and handled in accordance with the applicable clauses of ISO 13485 if one or more of the conformance criteria of 11.1 are not fulfilled.</p>	Full	
11.3	<p>If saleable product has been used during validation, the requirements for release of this product for distribution shall be generated before the start of the validation activities.</p>	N/A	
12	<p>Maintaining process effectiveness</p>		
12.1.1	<p>The continued effectiveness of the system for ensuring the condition of the product presented for sterilization (see 7.3.1) shall be demonstrated. This may include, for example, routine monitoring of product bioburden and/or monitoring the effectiveness of the cleaning process.</p>	Full	
12.1.2	<p>The accuracy and reliability of the instrumentation used to control and monitor the sterilization process shall be verified periodically in accordance with 4.3.3.</p>	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
12.2.1	<p>Maintenance of Equipment</p> <p>Preventative maintenance shall be planned and performed in accordance with documented procedures. All procedures shall follow manufacturers' recommendations as well as any pertinent national, regional or local requirements.</p>	Full	(b)(4)
12.2.2	Equipment shall not be used to process product until all specified maintenance tasks have been satisfactorily completed and recorded.	Full	
12.2.3	Records of maintenance shall be retained (see 4.1.2).	Full	
12.2.4	The maintenance scheme, maintenance procedures and maintenance records shall be reviewed at specified intervals by a designated person and the results of the review shall be documented.	Full	
12.3	Requalification	Full	
12.3.1	Requalification of a sterilization process carried out with specified equipment shall be performed at defined intervals against specified acceptance criteria and in accordance with documented procedures. These intervals shall be justified. Requalification may include verification that allowable product EO residuals as delineated in ISO10993-7 are being met.	Full	
12.3.2	IQ, OQ, PQ and subsequent Requalification(s) shall be reviewed and a decision shall be taken and documented to what extent requalification is required, including the confirmation of the specified SAL through microbiological studies.	Full	
12.3.3	The appropriateness of the biological indicator in relation to the bioburden of the product shall be confirmed at specified intervals (see 8.6).	Full	
12.3.4	The load and loading pattern shall be re-evaluated at a predetermined frequency for its appropriateness, and the results of this re-evaluation	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
	shall be documented in accordance with 4.1.2.		(b)(4)
12.3.5	The validated sterilization process shall be reviewed whenever there has been a change to the sterilization equipment and/or product that could alter the efficacy of the process (see 8.1).	Full	
12.3.6	If failures during requalification and/or routine monitoring and control indicate that the sterilization process might no longer be capable of achieving the required SAL, the cause of the failure shall be determined. If this determination shows the process to be no longer adequate, the sterilization process shall be modified to achieve the required SAL, and validated.	Full	
12.3.7	Records of reviews of requalification data, reports and resulting corrective actions (if required) shall be retained (see 4.1.2).	Full	
12.3.8	If parametric release is used, the following additional requirements shall apply: a) Requalification shall be performed at least annually; b) Requalification shall include confirmation of the specified SAL through microbiological studies.	N/A	
12.4	Assessment of change		
12.4.1	A change to equipment, product, packaging, presentation of product for sterilization or loading pattern, or a modification to the sterilizing agent and/or its presentation shall be assessed for its effect on the effectiveness of the sterilization process.	Full	

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Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
12.4.2	The magnitude of the change shall be considered in determining the extent to which process definition, IQ, OQ or PQ is undertaken.	Full	(b)(4)
12.4.3	The extent of qualification that is necessary shall be determined. The outcome of the assessment, including the rationale for decisions reached, shall be documented.	Full	(b)(4)

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
5.3	<p>Material effects</p> <p>The effects of ethylene oxide on a wide variety of materials used to manufacture medical devices have been comprehensively documented and such documentation is of value to those designing and developing medical devices that are to be sterilized by ethylene oxide. This part of ISO 11135 Part 1 does not require the performance of specific studies on material effects, but does require performance of studies of the effects of ethylene oxide on product (see Clause 7). The materials and outcomes of all tests shall be recorded, together with the criteria against which the properties of materials were assessed.</p>	Full	(b)(4)
5.4 5.4.1	<p>Environmental Conditions</p> <p>The potential effect on the environment of the operation of the sterilization process shall be assessed and measures to protect the environment shall be identified. This assessment, including potential impact and measures for control, shall be documented.</p>	Full	(b)(4)
5.4.2	Users of ethylene oxide shall comply with applicable local, national and international requirements regarding the emission and disposal of ethylene oxide and its diluents.	Full	(b)(4)
6	Process and equipment characterization		(b)(4)
6.1.1	The range of process variables and the equipment necessary to deliver the sterilization process safely and reproducibly shall be defined and documented.	Full	(b)(4)
6.1.2	<p>Process characterization shall include:</p> <ul style="list-style-type: none"> a) preconditioning (if used); b) the sterilization cycle; c) aeration (if used). 	Full	(b)(4)
6.1.3	<p>The characterization of the sterilization cycle shall include:</p> <ul style="list-style-type: none"> a) air removal; 		(b)(4)

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Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
	<ul style="list-style-type: none"> b) conditioning (if used); c) ethylene oxide injection; d) maintenance of specified conditions for the exposure time; e) ethylene oxide removal; f) flushing (if used); g) air/inert gas admission. 	Full	
6.1.4	<p>(Pre)treatment of product to achieve specified temperature and humidity within the load shall be accomplished by preconditioning and/or conditioning and shall be performed under controlled conditions. Humidity used for the preconditioning and/or conditioning of product shall be generated by steam.</p>	Full	
6.1.5	<p>The tolerances for the process variables, including but not limited to temperature, humidity, ethylene oxide concentration, pressure/vacuum and time, shall be established and specified.</p>	Full	
6.1.6	<p>The means of monitoring and controlling the process variables shall be determined and specified.</p>	Full	
6.2	<p>Equipment characterization</p>		
6.2.1	<p>The specification for the equipment to be used shall be developed and documented. This spec shall include the preconditioning area (if used), the sterilizer, and the aeration environment.</p>	Full	
6.2.2	<p>The specification shall include:</p> <ul style="list-style-type: none"> a) description of the equipment, together with any necessary ancillary items, including materials of construction; b) composition of the sterilizing agent and the means by which it is delivered to the chamber; c) description of any other gas(es) used in the process and the means by which they are delivered to the chamber; d) purity and quality of steam to ensure that it is suitable for its intended use with equipment and product; e) description of instrumentation for monitoring, controlling and recording the sterilization process, including 	Full	(b)(4)

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Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
	<p>sensor characteristics and their locations;</p> <p>f) fault(s) recognized by the sterilizing equipment;</p> <p>g) safety features, including those for personnel and environmental protection;</p> <p>h) installation requirements, including requirements for the control of emissions, if applicable.</p>		(b)(4)
6.2.3	<p>Software used to control and/or monitor the process must be prepared and validated in accordance with the elements of a quality system that provides documented evidence that the software meets its design specification.</p>	Full	
6.2.4	<p>Means shall be provided to ensure that a failure in a control function does not lead to a failure in recording of process parameters such that an ineffective process appears effective.</p>	Full	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation / description / justification
7	Product definition		
7.1 General 7.1.1	Product definition must be performed prior to the introduction of a new or altered product package or loading pattern.	Full	
7.1.2	A demonstration of equivalence (with reference to the challenge to the sterilization process) to a previously validated product, package or loading pattern shall be considered to meet the requirement of 7.1.1. Any demonstration of equivalence shall be documented.	Full	
7.1.3	Product shall be designed to allow the penetration of humidity and ethylene oxide to the most difficult to-sterilize locations.	Full	
7.1.4	Packaging shall be designed to allow removal of air and penetration of humidity and ethylene oxide.	Full	
7.1.5	It shall be demonstrated that the specified sterilization process is effective at the most difficult-to sterilize location within the product. This may be achieved by a demonstration of equivalence to a previously validated product or process challenge device (PCD) used to qualify the sterilization process. Equivalence may also be demonstrated by performing process definition and validation of the new product	Full	(b)(4)

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
7.2	Product safety and performance		
7.2.1	It shall be confirmed that the product and its packaging meet specified requirements for safety, quality and performance following the application of the defined sterilization process at the most challenging process parameters for the product/package. The influence of the tolerances for the process parameters shall be taken into consideration.	Full	(b)(4)
7.2.2	If multiple sterilization cycles are permitted, the effects of such processing on the product and its packaging shall be evaluated.	N/A	(b)(4)
7.2.3	The biological safety of product following exposure to the sterilization process shall be established in accordance with ISO 10993-1 and any subsequent parts of ISO 10993 that apply.	Full	(b)(4)
7.2.4	Maximum allowable limits for ethylene oxide residuals in ethylene-oxide-sterilized medical devices are given in ISO 10993-7. Means shall be established to reduce ethylene oxide residual levels such that the processed products comply with the requirements of ISO 10993-7.	Full	(b)(4)
7.3	Microbiological quality		
7.3.1	A system shall be specified and maintained to ensure that the		

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
7.3.2	<p>microbiological quality and cleanliness of the product presented for sterilization is controlled and does not compromise the effectiveness of the sterilization process.</p> <p>The effectiveness of the system defined in 7.3.1 shall be demonstrated. For medical devices to be supplied for single use, this demonstration shall include an estimation of bioburden at a defined interval in accordance with ISO 11737-1. For re-usable medical devices, this demonstration shall include an assessment of the effectiveness of the specified cleaning and, if applicable, disinfecting process. This shall also include an assessment of organic and inorganic contamination.</p>	Full	(b)(4)
7.4	<p>Documentation</p> <p>The results of product definition shall be documented.</p>	Full	(b)(4)
8.0	<p>Process definition</p>		(b)(4)
8.1	<p>The sterilization process to be validated shall be specified prior to the introduction of a new or altered product, package or loading pattern.</p>	Full	(b)(4)
8.2	<p>Process definition activities shall be performed in a sterilization chamber that has undergone Installation Qualification (IQ) and</p>		(b)(4)

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
	Operational Qualification (OQ) procedures (see 9.1 and 9.2). Process definition may be performed in a research sterilizer or in the equipment to be used to sterilize the product.	Full	(b)(4)
8.3	The sterilization process applicable for the defined product shall be established.	Full	
8.4	Documentation and records shall support the validity of process parameters and their tolerances as defined in the process specification.	Full	
8.5	The rate of inactivation of the cycle shall be determined using one of the methods described in Annexes A or B or by an alternative validated method that demonstrates the achievement of the required sterility assurance level (SAL).	Full	
8.6	Biological indicators used as part of the establishment of the sterilization process shall: a) comply with Clauses 5 and 9.5 of ISO 11138-2:2006; b) be shown to be at least as resistant to ethylene oxide as is the bioburden of product to be sterilized; c) be placed within the product at location(s) where sterilizing conditions are most difficult to achieve or be placed within a PCD. If a PCD is used for process definition, validation or routine monitoring and control, the appropriateness of the PCD shall be determined. The PCD shall be equivalent or more challenging to the process than the most difficult-to-sterilize part of the product.	Full	
8.7	Commercially supplied biological indicators used in the definition of the sterilization process should comply with the applicable clauses of ISO 11138-1 and -2:2006	Full	
8.8	If chemical indicators are used as part of the definition of the	N/A	

Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
8.9	<p>sterilization process, these shall comply with ISO 11140-1. Chemical indicators shall not be used as the sole means of establishing the sterilization process.</p> <p>If tests of sterility are performed during the definition of the sterilization process, they shall comply with ISO 11737-2.</p>	N/A	
9	Validation		
9.1.1	<p>Installation qualification Installation Qualification shall demonstrate that the sterilization equipment and any ancillary items have been installed in accordance with their specification.</p>	Full	
9.1.2	<p>All equipment used to deliver the ethylene oxide, including any ancillary items, shall be established and specified.</p>	Full	
9.1.3	<p>The operating procedures for the equipment (see 6.2) shall be specified. These operating procedures shall include but are not limited to:</p> <ul style="list-style-type: none"> a) step-by-step operating instructions; b) fault conditions, the manner in which they are indicated and actions to be taken; c) instructions for maintenance and calibration; d) details of contacts for technical support. 	Full	

(b)(4)

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Section Number	Description	Compliance to Standard (Full / Partial / NA)	Type of deviation/ description/ justification
9.1.4	The location in which the equipment is to be installed shall be specified. Any special precautions and provisions shall be identified.	Full	(b)(4)
9.1.5	Instructions for the installation shall be documented and shall include instructions pertinent to the health and safety of personnel. <i>National and local requirements for occupational health and safety should be consulted as they apply to potential EO exposure.</i>	N/A	
9.1.6	Drawings of the equipment installed, plumbing, and other ancillary equipment shall be finalized during Installation Qualification	N/A	
9.2	Operational qualification		
9.2.1	Prior to operational qualification (OQ), the calibration of all instrumentation (including any test instruments) used for monitoring, controlling, indicating or recording shall be confirmed (see 4.3.3).	Full	
9.2.2	Operational qualification (OQ) shall demonstrate that the installed equipment is capable of delivering the specified process (see Clause 8) within defined tolerances.	Full	
9.3	Performance qualification		
9.3.1.1	Performance qualification (PQ) shall be performed on the introduction of new or altered products,	Full	

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

BS EN 1707 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Lock fittings 1997

Please answer the following questions Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
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? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS? Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

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>
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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>
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Gauging	<input checked="" 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?
4.2.1	Liquid Leakage	<input checked="" 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?
4.2.2	Air Leakage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

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

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SUMMARY REPORT TABLE**

STANDARD TITLE
BS EN 1707 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Lock fittings 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Separation force	<input checked="" 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?
4.4	Unscrewing torque	<input checked="" 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?
4.5	Ease of assembly	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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BS EN 1707 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Lock fittings 1997

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.6	Resistance to overriding	<input checked="" 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?
4.7	Stress Cracking	<input checked="" 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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

BS EN 20594-1:1994; ISO 594-1 Conical fittings with 6% (Lucre) taper for syringes, needles and certain other medical equipment

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 6-11

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

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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
BS EN 20594-1:1994; ISO 594-1 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Gauging	<input checked="" 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?
4.2	Liquid Leakage	<input checked="" 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?
4.3	Air Leakage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Separation force	<input checked="" 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?
4.5	Stress Cracking	<input checked="" 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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

ASTM F 1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 14-229

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ASTM F1980-07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.5	Accelerated Aging Theory	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Adaptation of section 6.5

DESCRIPTION

Accelerated aging duration for antimicrobial testing was calculated taking (b)(7)(C) temperature (b)(4) into consideration.

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.5	Accelerated Aging Theory	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

Accelerated aging duration for mechanical testing is in complete conformance with ASTM F1980-07

JUSTIFICATION

N/A

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

Arrow International Inc. is proposing to add the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable Peripherally Inserted Central Catheters to its family of PICC products. The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is a single or double lumen, radiopaque polyurethane intravascular catheter with antimicrobial treatment on the external catheter surface as well as on the entire fluid pathway. The catheters are available in 4.5 French or 5.5 French sizes with catheter lengths ranging from 40 cm to 55 cm. The devices are supplied sterile and intended for single use.

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICCs are substantially equivalent to the Arrow Pressure Injectable PIC catheters, K061289 and the Arrow 6F Triple Lumen Pressure Injectable PIC catheters, K080604. Table 1 contains a design characteristics comparison between the proposed ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC and the predicate PICC devices.

Table 1: Substantial Equivalence Table - Catheter Design

Design Characteristic	Pressure Injectable PICC (K061289)	6F Triple Lumen Pressure Injectable PICC (K080604)	Proposed ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC
Intended Use	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.
Indications for Use	The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion and power injection of contrast media. The maximum pressure of power injector equipment used with the pressure Injectable PICC may not exceed 300 psi.	The 6F Triple Lumen Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, power injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the pressure Injectable PICC may not exceed 300 psi.	The ARROWg ⁺ ard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWg ⁺ ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.
Catheter OD	4 Fr and 5 Fr	6 Fr	4.5 Fr and 5.5 Fr
Catheter Usable Length	4 Fr. – 60 cm 5 Fr. – 40 cm, 60 cm	6 Fr. – 40 cm to 55 cm	4.5 Fr. – 40, 50, and 55 cm 5.5 Fr. – 40, 50, and 55 cm
Number of Lumens	4 Fr. – 1 lumen 5 Fr. – 2 lumens	6 Fr. – 3 lumens	4.5 Fr. – 1 lumen 5.5 Fr. – 2 lumens
Internal Lumen Configuration	4 Fr. – Round 5 Fr. – Double D	6 Fr. – Round/Round/D	4.5 Fr. – Round 5.5 Fr. – Double D
Catheter Tip Configuration	Trimmable, Blue FlexTip	Blue Flex Tip	Blue FlexTip
Pressure Injection Capabilities	Distal – 4 cc/sec, Power Injectable Proximal – No printing	Distal – 6 mL/sec MAX, Pressure Injectable Proximal – NO CT Medial – NO CT	Distal – 5 mL/sec, Pressure Injectable Proximal – 5 mL/sec, Pressure Injectable

Design Characteristic	Pressure Injectable PICC (K061289)	6F Triple Lumen Pressure Injectable PICC (K080604)	Proposed ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC
Catheter Body Material	(b)(4)		
Catheter Tip Material			
Juncture Hub Material			
Extension Line Material			
Extension Hub Material			
Printing Ink			
Safety and Performance Testing	Mechanical testing to: <ul style="list-style-type: none"> • ISO 10555-1 • ISO 10555-3 Biocompatibility testing	Mechanical testing to: <ul style="list-style-type: none"> • ISO 10555-1 • ISO 10555-3 Biocompatibility testing	Mechanical testing to: <ul style="list-style-type: none"> • ISO 10555-1 • ISO 10555-3 Biocompatibility testing

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICCs are also substantially equivalent to the ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC, K993691 with respect to the antimicrobial agents utilized and application of the agents to the device. Refer to the Substantial Equivalence Discussion section (Section 12) for a more detailed comparison of predicates versus proposed devices.

11. DEVICE DESCRIPTION

11.1 Background

Peripherally inserted central catheters are intended to provide access to the central venous system for purposes such as intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and central venous pressure monitoring.

Although such catheters provide necessary vascular access, their use puts patients at risk for local and systemic infectious complications, including local site infection, CRBSI (Catheter-Related Bloodstream Infection), septic thrombophlebitis, endocarditis, and other metastatic infections (e.g., lung abscess, brain abscess, osteomyelitis, and endophthalmitis).¹

Intravascular devices (IVDs) are now the single most important cause of health care-associated BSI, with an estimated 250,000 to 500,000 IVD-related BSIs occurring each year throughout the United States.² PICCs have gained popularity because they are thought to have specific advantages over central venous catheters. Mainly, PICC was seen as a longer term catheter than CVC; it almost abolished the feared risk of hemorrhage and pneumothorax associated with the insertion of subclavian CVC, and it appeared to be well tolerated by patients.³ Catheter-related BSI rates are generally lower with peripherally inserted central catheters utilized in the out patient setting. However when comparing CRBSI rates of inpatient PICCs with CVC's, the rates are more closely related. Peripherally inserted central catheters used in hospitalized patients (2.4%, 2.1 per 1000 catheter-days) posed risks approaching those seen with short-term conventional CVCs used in the intensive care unit (4.4%, 2.7 per 1000 catheter-days).⁴

¹ Guidelines for the Prevention of Intravascular Catheter-Related Infections. CDC MMWR Morbidity and Mortality Weekly Report. August 9, 2002. Vol. 51 No. RR-10.

² Maki, D., Kluger, D., and Crnich C. The Risk of Bloodstream Infection in Adults with Different Intravascular Devices: A Systematic Review of 200 Published Prospective Studies. Mayo Clin Proc. September 2006; 81(9):1159-1171.

³ Turcotte, S., Dubé, S., and Beauchamp, G. Peripherally Inserted Central Venous Catheters Are Not Superior to Central Venous Catheters in the Acute Care of Surgical Patients on the Ward. World Journal of Surgery (2006) 30: 1605-1619.

⁴ Maki, D., Kluger, D., and Crnich C. The Risk of Bloodstream Infection in Adults with Different Intravascular Devices: A Systematic Review of 200 Published Prospective Studies. Mayo Clin Proc. September 2006; 81(9):1159-1171.

Understanding the pathogenesis of CVC-related BSI's is essential to devising strategies for prevention of these infections.⁵ There are two major sources of intravascular-related bloodstream infection: 1) colonization of the IVD, catheter-related infection, and 2) contamination of the fluid administered through the device, infusate-related infection.⁶ Overall, about 65% of catheter-related infections (CRI's) originate from the skin, 30% from the contaminated hub, and 5% from other pathways.⁷ Catheter contamination is primarily a three step process. First, microorganisms reach and contaminate the catheter segment(s); second microorganisms adhere and proliferate on their surfaces; and third they seed the bloodstream once they have reached a significant number (colonized catheter).⁸

Microorganisms found on patients skin, which gain access to the IVD extraluminally, occasionally intraluminally – coagulase-negative staphylococci (39%), *Staphylococcus aureus* (26%) and *Candida* spp. (11%) – account for 76% of IVD-related BSI's with short-term noncuffed devices of all types; only 14% are caused by gram-negative bacilli.⁹ In contrast, with long term surgically implanted devices, such as cuffed and tunneled catheters, PICCs and subcutaneous central venous ports, gram negative bacilli, which gain access intraluminally and grow rapidly within the infusate in the device, account for nearly half of IVD-related BSI's; only 2% are caused by *Candida* spp.¹⁰

Arrow therefore, has designed and developed the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PIC catheters in response to an overwhelming clinical need for additional infection protection measures.

⁵ Safdar N. and Maki, D. The pathogenesis of catheter-related bloodstream infection with non-cuffed short-term central venous catheters. *Intensive Care Med* (2004) 30:62-67.

⁶ Safdar, N., Mermel, L., Maki, D. The Epidemiology of Catheter-Related Infection in the Critically Ill. *Catheter-Related Infections in the Critically Ill*, 2004 Chapter 1:1-22

⁷ Nitenberg, G., Blot, F. Diagnosis of Catheter-Related Infections. *Catheter-Related Infections in the Critically Ill*, 2004 Chapter 4:59-76.

⁸ Sitges-Serra, A. Epidemiology and Pathogenesis of Catheter-Related Bloodstream Infections. *Catheter-Related Infections in the Critically Ill*, 2004 Chapter 2:23-40.

⁹ Safdar, N., Mermel, L., Maki, D. The Epidemiology of Catheter-Related Infection in the Critically Ill. *Catheter-Related Infections in the Critically Ill*, 2004 Chapter 1:1-22

¹⁰ Safdar, N., Mermel, L., Maki, D. The Epidemiology of Catheter-Related Infection in the Critically Ill. *Catheter-Related Infections in the Critically Ill*, 2004 Chapter 1:1-22

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is a non-tapered, radiopaque polyurethane intravascular catheter with a Blue FlexTip. The Blue FlexTip is a contoured polyurethane tip that is softer than the catheter body and is designed to enhance maneuverability while minimizing vessel trauma. The catheters are available in 4.5 French single lumen and 5.5 French double lumen configurations with usable lengths of 40, 50 and 55 cm. The double lumen catheters have non-communicating lumens with staggered ports designed to reduce solution precipitation during infusion. Depth markings are printed on the catheters in 5 cm increments originating at both the juncture hub and the catheter tip. The indwelling portion of the catheter is connected to the extension line(s) via a soft, pliable juncture hub with suture wings for secure placement to the patient. A slide clamp is provided on each extension line to occlude flow through lumens as needed. Female luer connector hubs on each extension line provide connection for IV administration.

(b)(4)

(b)(4)

A detailed list of the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC catheter components is presented in Table 2. For each component, the materials of construction, whether the component is patient contacting, and if the component is antimicrobially treated is provided.

(Figure 1) was taken with the catheter body guard and catheter tip guard in place. The 5.5 Fr catheter photograph (Figure 2) did not include these components so that the blue Flex tip could be better visualized. Refer to Engineering drawings, located in Attachment 1 for dimensional specifications and additional detail on the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PIC catheters. Attachment 1 contains both coated catheter assembly drawings and uncoated catheter assembly drawings.

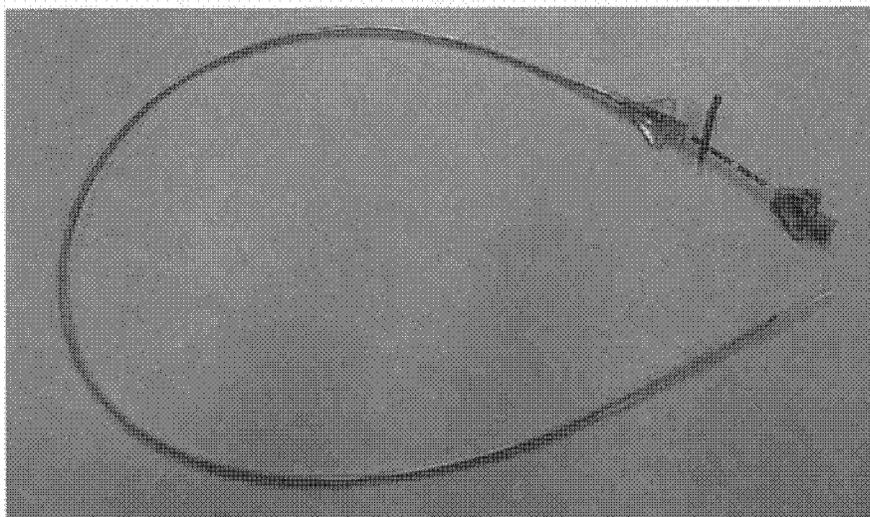


Figure 1: 4.5 French, Single Lumen, 55 cm ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC

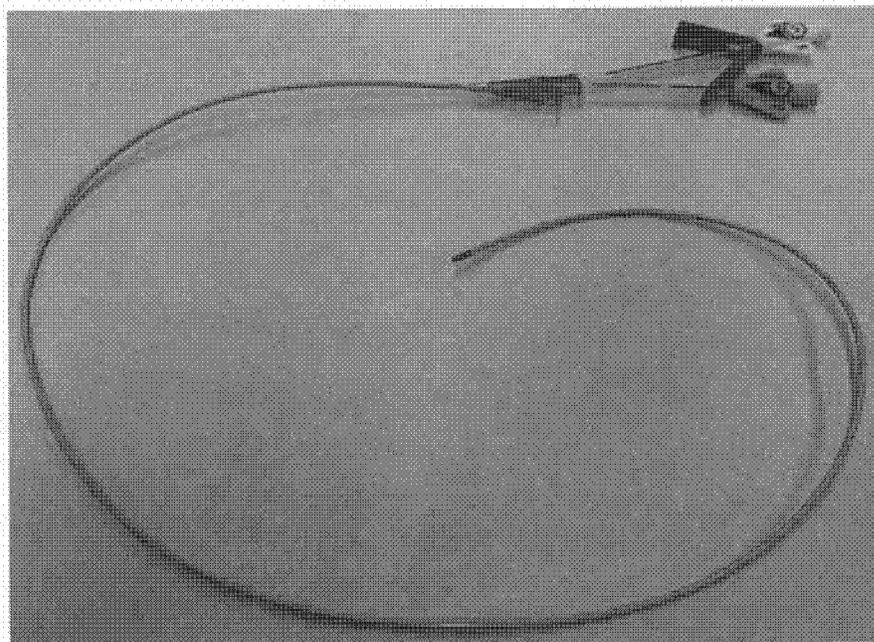


Figure 2: 5.5 French, Double Lumen, 55 cm ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PIC catheters are capable of high pressure injection of contrast media at a maximum infusion rate of 5 mL/sec. The maximum pressure of pressure injectors used with the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Each catheter hub is labeled with the maximum infusion rate as seen in Figure 3 and 4.

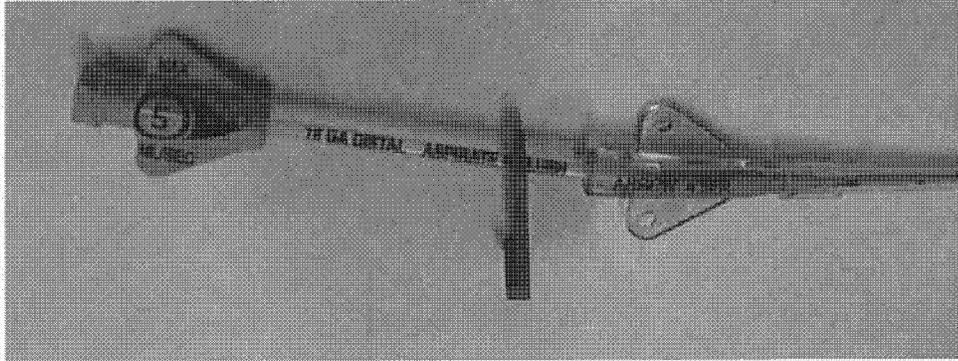


Figure 3: 4.5 French, Single Lumen ARROWg⁺ard Evolution Antimicrobial Catheter showing maximum pressure injectable flow rate

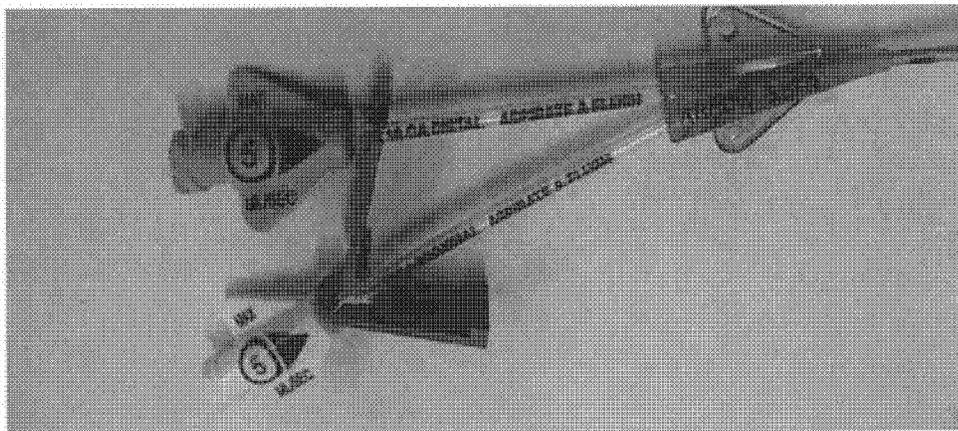


Figure 4: 5.5 French, Double Lumen ARROWg⁺ard Evolution Antimicrobial Catheter showing maximum pressure injectable flow rate

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable catheters are sterile, single use devices that will be available in both nursing and interventional radiology configurations depending upon the end user. Both configurations contain accessories to facilitate catheter insertion. A stylet and T-port connector is part of the catheter assembly provided in the nursing kits to assist in catheter insertion.

All kit components sold with the Pressure Injectable PICC kits were certified under the requirements set forth in FDA's Guidance, Kit Certification for 510(k)s.

I certify that the following components of the subject kit are either:

1. legally marketed pre-Amendments devices
2. exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions for Section 510(k) of the act (e.g. 21 CFR Part 862.9) , or
3. have been found to be substantially equivalent through the premarket notification process for the use(s) for which it is intended (i.e. I am not claiming or causing a new use for the component(s)).

The kit components listed in Table 3 have the corresponding market authorizations listed. The components are packaged with the subject device, labeled and subjected to sterilization via ethylene oxide. Refer to the sterilization section, Section 14, for further information on the Arrow sterilization process.

Table 3: Kit Component Certification

Component	Device Classification	Regulation	Certification
(b)(4)	Class II, DYB	21 CFR 870.1340	(b)(4)
	Class II, DYB	21 CFR 870.1340	
	Class II, DQX	21 CFR 870.1330	
	Class II, DQX	21 CFR 870.1330	
	Class II, FOZ	21 CFR 880.5200	
	Class II, DQX	21 CFR 870.1330	
	Class II, DQY	21 CFR 870.1250	
	Class II, FMF	21 CFR 880.5860	
	Class II, FMI	21 CFR 880.5570	
	Class II, FMF	21 CFR 880.5860	
	N/A - Drug	21 CFR 314	
	Class II, NGT	21 CFR 880.5200	

Component	Device Classification	Regulation	Certification
(b)(4)	N/A – Drug	21 CFR 314	(b)(4)
	N/A – Drug	21 CFR 314	
	N/A – Drug	21 CFR 314	
	Class I, NEC	21 CFR 880.5090	
	Class I, KGZ	21 CFR 878.4200	
	Class I, KGZ	21 CFR 878.4200	
	Class II, FMI	21 CFR 880.5570	
	Class I	21 CFR 878.4800	
	Class I, KGZ	21 CFR 878.4200	
	Class II, FRG	21 CFR 878.6850	
	Class II, IZI	21 CFR 892.1600	
	Class II, FYA	21 CFR 878.4040	
	Class II, KKX	21 CFR 878.4370	
	Class II, KKX	21 CFR 878.4370	
	Class 2, FPA	21 CFR 880.5440	
	Class I, GDX	21 CFR 878.4800	
	Unclassified, FRO	Pre-Amendment	
	Class II, FPA	21 CFR 880.5440	
	Class I, KGX	21 CFR 880.5240	
	Class I, NAB	21 CFR 878.4014	
	Class I, NAB	21 CFR 878.4014	
	Class I, FTY	21 CFR 878.4800	
	Class I, FYF	21 CFR 878.4040	
	Class II, FYA	21 CFR 878.4370	
	Class II, FYA	21 CFR 878.4370	
	Class II, FXX	21 CFR 878.4040	
	Class II, FXX	21 CFR 878.4040	
	Class II, FXX	21 CFR 878.4040	
	Class I, GAX	21 CFR 878.5900	
	Class I, KGX	21 CFR 880.5240	
Class II, DYB/FOZ	21 CFR 870.1340		
Class II, DQX	21 CFR 870.1330		
Class II, FPA	21 CFR 880.5440		

11.2 Identity and Formulation of the Antimicrobial Agent

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PIC catheters are

(b)(4)

(b)(4) is probably the most widely used

biocide in antiseptic products, in particular in hand washing and oral products but also

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

The ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC is substantially equivalent to the Arrow Pressure Injectable PICC (K061289) and the Arrow 6 French Triple Lumen Pressure Injectable PICC (K080604) in terms of catheter design, manufacturing process, materials of construction and principle of operation. The subject device is also substantially equivalent to the Arrow 6 French Triple Lumen Pressure Injectable PICC (K080604) in terms of intended use and indications for use. Refer to the table below for a design characteristic comparison between the ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC and the Arrow predicate PICC devices. Differences between predicates and the proposed device are discussed following the table.

Table 6: Substantial Equivalence Table – Catheter Design

Design Characteristic	Pressure Injectable PICC (K061289)	6F Triple Lumen Pressure Injectable PICC (K080604)	Proposed ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC
Intended Use	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.	The Pressure Injectable Peripherally Inserted Central Catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.
Indications for Use	The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion and power injection of contrast media. The maximum pressure of power injector equipment used with the pressure Injectable PICC may not exceed 300 psi.	The 6F Triple Lumen Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, power injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the pressure Injectable PICC may not exceed 300 psi.	The ARROWg ⁺ ard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWg ⁺ ard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.

Design Characteristic	Pressure Injectable PICC (K061289)	6F Triple Lumen Pressure Injectable PICC (K080604)	Proposed ARROW⁺ard Evolution Antimicrobial Pressure Injectable PICC
Catheter OD	4 Fr and 5 Fr	6 Fr	4.5 Fr and 5.5 Fr
Catheter Usable Length	4 Fr. – 60 cm 5 Fr. – 40 cm, 60 cm	6 Fr. – 40 cm to 55 cm	4.5 Fr. – 40, 50, and 55 cm 5.5 Fr. – 40, 50, and 55 cm
Number of Lumens	4 Fr. – 1 lumen 5 Fr. – 2 lumens	6 Fr. – 3 lumens	4.5 Fr. – 1 lumen 5.5 Fr. – 2 lumens
Internal Lumen Configuration	4 Fr. – Round 5 Fr. – Double D	6 Fr. – Round/Round/D	4.5 Fr. – Round 5.5 Fr. – Double D
Catheter Tip Configuration	Trimable, Blue FlexTip	Blue Flex Tip	Blue FlexTip
Pressure Injection Capabilities	Distal – 4 cc/sec, Power Injectable Proximal – No printing	Distal – 6 mL/sec MAX, Pressure Injectable Proximal – NO CT Medial – NO CT	Distal – 5 mL/sec, Power Injectable Proximal – 5 mL/sec, Power Injectable
Catheter Body Material	(b)(4)		
Catheter Tip Material			
Juncture Hub Material			
Extension Line Material			
Extension Hub Material			
Printing Ink			
Safety and Performance Testing	Mechanical testing to: <ul style="list-style-type: none"> • ISO 10555-1 • ISO 10555-3 Biocompatibility testing	Mechanical testing to: <ul style="list-style-type: none"> • ISO 10555-1 • ISO 10555-3 Biocompatibility testing	Mechanical testing to: <ul style="list-style-type: none"> • ISO 10555-1 • ISO 10555-3 Biocompatibility testing

The differences between the proposed device and the Arrow predicate devices are as follows:

1. (b)(4)

13. PROPOSED LABELING

Draft labeling has been created for the proposed ARROWg⁺ard Evolution Antimicrobial PICC devices. The following standards and guidance's have been utilized in the creation of the labeling.

- BS EN ISO 10555-1:1997, Sterile, single-use intravascular catheters – Part 1: General requirements
- BS EN ISO 10555-3:1997, Sterile, single-use intravascular catheters – Part 3: Central venous catheters
- FDA Draft Guidance for Industry and FDA Staff, Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents
- FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters

The ARROWg⁺ard Evolution Antimicrobial PICC Kits are labeled latex-free. All raw materials that constitute the ARROWg⁺ard Evolution Antimicrobial PICC do not contain latex. (b)(4)

(b)(4)

(b)(4)

The kit components specified in Table 3

have also been determined to meet these requirements.

The tests described in Table 8 were performed to provide data to be used in determining in the final labeling for the device. The actual values to be used on the device labeling will consider the results from all of the available age preconditioning end point data and some calculated values per the method described (b)(4)

(b)(4)

(b)(4)

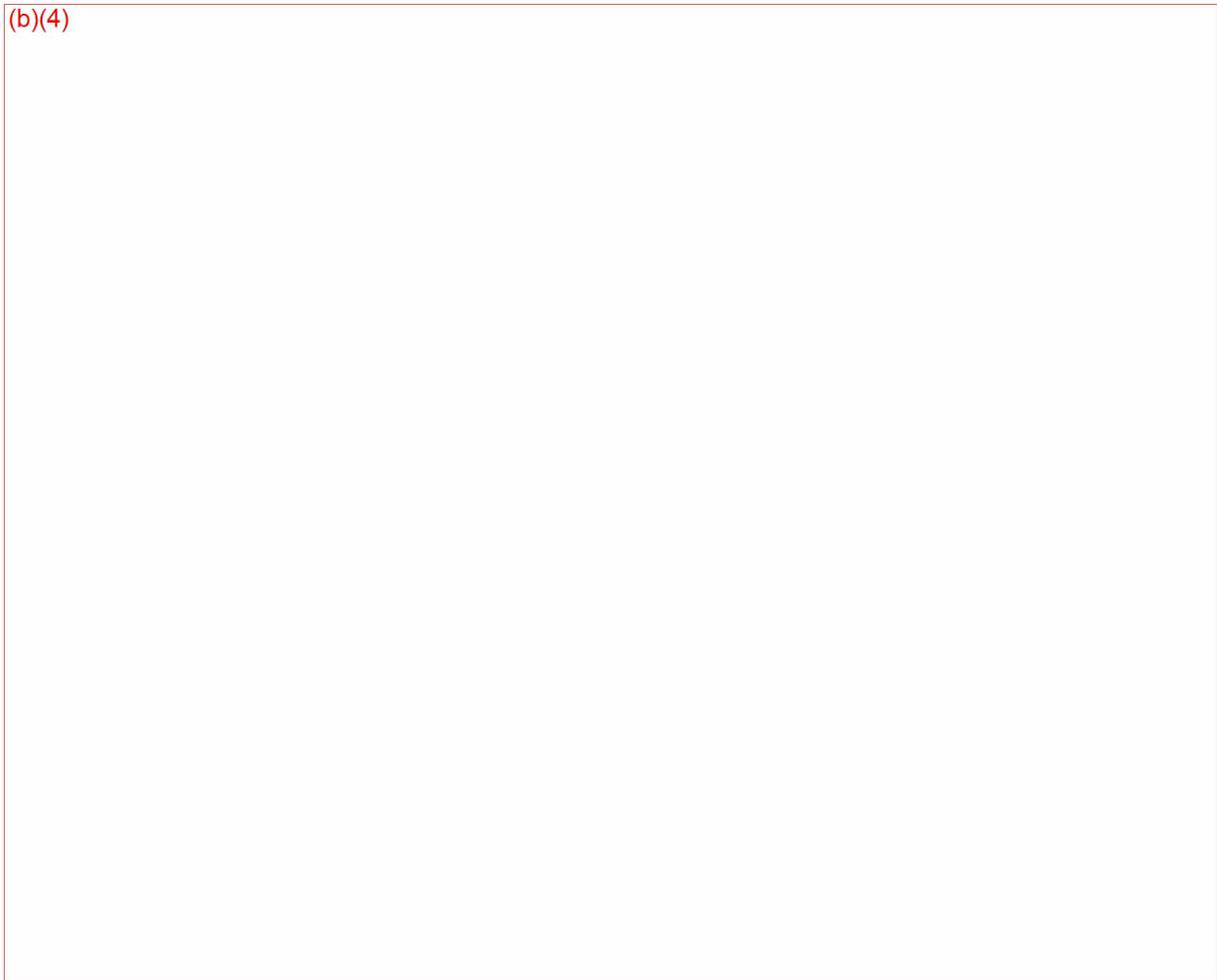
Table 8: Testing performed for proposed device product labeling

Test (Protocol Number)	(b)(4)	Results	Test Report Number
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(b)(4)

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



14. STERILIZATION AND SHELF LIFE

(b)(4)

(b)(4)

16. SOFTWARE

The proposed device does not include software. This section is not applicable.

17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The proposed device does not include an electronic component. This section is not applicable.

18. PERFORMANCE TESTING – BENCH

(b)(4)



21. CERTIFICATION OF COMPLIANCE WITH CLINICALTRIALS.GOV DATA BANK

A completed copy of the Certification of Compliance with ClinicalTrials.gov Data Bank, FDA Form 3674, is provided on the following page.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Arrow International, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Mar 1, 2010
3. ADDRESS (Number, Street, State, and ZIP Code) 2400 Bernville Road Reading, PA 19605	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 610-378-0131 (Fax) 610-374-5360

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Device Common Name: Peripherally Inserted Central Catheter (PICC)

Device Classification: Class II

Device Trade Name: Arrowgard Evolution Antimicrobial Pressure Injectable PICC

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)
1090263 1090263/S001

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) <i>Tracy Maddock</i>	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Tracy Maddock (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 2400 Bernville Road Reading, PA 19605	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 610-378-0131 (Fax) 610-374-5360
15. DATE OF CERTIFICATION 04-Mar-2010	

ATTACHMENTS

- 1 – Engineering drawings
- 2– Test Method Validation Protocols and Reports
- 3 – Analytical Testing
- 4 – Preconditioning Protocols
- 5 – Mechanical Testing Protocols and Reports
- 6 – Proposed Labeling
- 7 – Predicate Device Labeling
- 8 – Aging Documents
- 9 – Biocompatibility Test Reports
- 10 - Biocompatibility Review and Risk Assessment
- 11 – *In Vitro* External Efficacy Testing Protocols and Reports
- 12 – *In Vitro* Internal Efficacy Testing Protocols and Reports
- 13 – *In vivo* Antimicrobial Efficacy Testing Protocols and Reports
- 14 – Clinical Study References
- 15 – MEC Supporting Documentation

ATTACHMENT 1

Engineering Drawings

ATTACHMENT 2

Test Method Validation Protocols and Reports

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ATTACHMENT 3

Analytical Testing Protocols and Reports

FDA CDRH DMC

MAR 05 2010

Received

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ATTACHMENT 4

Preconditioning Protocols

ATTACHMENT 5

Mechanical Testing Protocols and Reports

ATTACHMENT 6

Proposed Labeling

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Attachment 6

List of Documents

1. Instructions for Use
2. Antimicrobial Technology Information Sheet
3. Lidstocks (6)
4. Clip/Checklist(6)
5. Pressure Injectable Information
6. Corrugates (6)

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Pressure Injectable PICC Product

Single, 2-Lumen, or Multi-Lumen

Venous Access | Critical Care

ARROW
1161

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Arrow International, Inc.

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An issued or revision date for these instructions is included for user information. In the event two years have elapsed between this date and product use, the user should contact Arrow International, Inc. to see if additional product information is available.

Issued Date: February 2010

Rx only.

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For convenience, procedural and general Warnings and Precautions are listed at the beginning of the instructions. Please review all content before performing the procedure.

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For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with central venous access refer to Arrow International, Inc. website: www.arrowintl.com

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Pressure Injectable Peripherally Inserted Central Catheter (PICC) Product

Product Description

The Arrow® Pressure Injectable PICC is a peripherally inserted central venous catheter (PICC) manufactured with medical grade, flexible polyurethane. The Arrow® PICC has a non-tapered catheter body with either a blunt tip or a Blue FlexTip® that is softer than a cut tip with a contour design to enhance maneuverability. The Blue FlexTip® also provides visual confirmation of an intact catheter upon removal. The kit components assist the clinician in maintaining maximal sterile barrier precautions.

Indications:

The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the pressure injectable PICC may not exceed 300 psi.

Contraindications:

This device is contraindicated wherever there is presence of device related infections, previous or current thrombosis. Clinical assessment of patient must be completed to ensure no contraindications exists.

Pressure Injection

Warnings and Precautions:

Warnings:

1. Assess each patient for appropriateness of a pressure injection procedure.
2. Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
3. Use an appropriate method to confirm catheter tip position prior to each pressure injection per institutional policy.
4. Ensure patency of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.
5. Discontinue pressure injections at first sign of infiltration / extravasation. Follow hospital protocol for appropriate medical intervention.
6. Use only lumen labeled "Pressure Injectable" for pressure injection to minimize the risk of catheter failure and/or patient complications.

Cautions:

1. Do not exceed the maximum pressure of 300 psi on power injector equipment to minimize the risk of catheter failure and/or tip displacement.
2. Do not exceed the catheter's maximum recommended flow rate located on product labeling to minimize the risk of catheter failure and/or tip displacement.

3. Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.
4. Pressure limit settings on power injector equipment may not prevent over pressurization of an occluded catheter.
5. Use an appropriately rated 60 inch pressure tubing between catheter and power injector equipment to minimize the risk of catheter failure.
6. Follow the specified contrast media manufacturer's instructions for use, warnings, precautions, and contraindications.

Pressure Injection Procedure:

NOTE: Clinicians should use sterile technique when flushing, disconnecting, connecting, and replacing injection/needleless caps.

1. Use an appropriate method to confirm each tip placement prior to each pressure injection per institutional policy.
2. Remove injection cap from the lumen of catheter to be injected.
3. Check for catheter patency:
 - Attach 10 mL syringe, or larger, filled with sterile normal saline.
 - Aspirate catheter until approximately 3 mL of blood enters syringe freely.
 - Vigorously flush catheter.

Warning: Ensure catheter patency prior to pressure injection to minimize the risk of catheter failure and/or patient complications.

4. Detach syringe.
5. Attach pressure injection equipment and extension tubing to lumen of catheter according to manufacturer's recommendations.

Warning: Use only lumen labeled "Pressure Injectable" for pressure injection to minimize the risk of catheter failure and/or patient complications.

Caution: To minimize risk of catheter failure and/or tip displacement:

- Do not exceed the maximum pressure of 300 psi on power injector equipment.
- Do not exceed the catheter's maximum recommended flow rate located on product labeling.

6. Inject contrast media in accordance with hospital protocol.

Caution: Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.

7. Disconnect catheter from power injector equipment.
8. Flush catheter with a 10 mL syringe, or larger, filled with sterile normal saline.
9. Replace sterile injection cap on catheter.

NOTE: Catheter testing included 10 pressure injection cycles. 1165

Central Venous Pressure (CVP) Monitoring

Guidelines:

- Perform chest x-ray or other means of catheter tip placement verification prior to monitoring CVP.
- Flush catheter with sterile normal saline to ensure patency of catheter prior to monitoring CVP.
- It is recommended that injection caps are removed and lines are connected directly.
- Follow hospital/agency protocol for central venous pressure monitoring procedures.
- Ensure the pressure transducer is at the level of the right atrium.
- It is recommended that a continuous infusion of saline (3ml/Hr) is maintained through the catheter while measuring CVP to improve accuracy of CVP results.

Peripherally Inserted Central Catheter

Warnings and Precautions:

Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Figure 1).



Figure 1

General Warnings and Precautions

Warnings:

1. Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
2. Practitioners must be aware of complications associated with central vein catheters including but not limited to: cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, and dysrhythmias.
3. Practitioners must be aware of clinical conditions that may limit use of PICCs including but not limited to: dermatitis,

cellulitis, and burns at or about the insertion site, previous ipsilateral venous thrombosis, radiation therapy at or about insertion site, contractures, mastectomy, and potential use for AV fistula.

4. Do not place central venous catheter (CVC) or peripherally inserted central catheter (PICC) into or allow them to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with hospital protocol must show catheter tip located in right side of mediastinum in the SVC (superior vena cava) above its junction with right atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of guidewire into the heart has also been implicated in causing cardiac perforation and tamponade.
5. Ensure catheter tip has not entered the heart or no longer lies parallel to vessel wall by performing an x-ray exam or other method in compliance with hospital protocol. If catheter position has changed, immediately re-evaluate.
6. Choose appropriate sized catheter for size of vessel to be cannulated.
7. Practitioners must be aware of the potential for entrapment of guidewire by any implanted device in circulatory system (i.e., vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of guidewire inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of guidewire entrapment.
8. Catheter tip must be located in central circulation when administering > 10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with pH less than 5 or greater than 9, and infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
9. Infusion of incompatible drugs through a non "staggered port" may cause precipitation.
10. Be aware of the risk of chemically induced thrombophlebitis when catheter is placed with distal end located in a vessel proximal to the SVC.
11. Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolism can occur with these practices.
12. Use only securely tightened Luer-Lock connections with any Central Venous Access Device (CVAD) to guard against inadvertent disconnect.

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13. Use Luer-Lock connectors to help guard against air embolism and blood loss.

Cautions:

1. The product is designed for single use only.
2. Do not resterilize or reuse.
3. Do not use if package has been previously opened or damaged.
4. Do not alter the catheter, guidewire, or any other kit/set component during insertion, use, or removal (except as instructed).
5. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
6. Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.
7. Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.
8. Temporarily shut off remaining port(s) through which solutions are being infused before blood sampling.
9. Blood aspirate color is not always a reliable indicator of venous access.
10. Do not reinsert needle into introducer catheter to minimize the risk of catheter embolism.
11. Retract scalpel to protected position when not in use to minimize the risk of sharps injury.
12. Perform hand hygiene before and immediately after all clinical procedures and before and after donning and removal of gloves.
13. Properly dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood borne pathogens and/or institutional policy.
14. Hands must remain behind the needle at all times during use and disposal.
15. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.

Catheter Warnings and Precautions

Warnings:

1. For high pressure injection applications, only utilize catheters indicated for such applications. Catheters not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.

2. Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.
3. Do not secure, staple, and/or suture directly to outside diameter of catheter body or extension lines to minimize the risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
4. Do not cut catheter to alter catheter length unless procedure requires it.
5. Catheter clamp and fastener (where provided) must not be attached to catheter until either guidewire or placement wire is removed.
6. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
7. Catheter clamp must be opened prior to infusion to minimize risk of damage to extension line(s) from excessive pressure.
8. Do not attempt to advance or reinsert placement wire (where provided) into catheter, through the septum, if placement wire has been removed prior to catheter insertion. Attempting placement wire advancement or reinsertion increases the risk of damaging catheter or wire.
9. Do not clamp extension line(s) when placement wire is in catheter to minimize the risk of placement wire kinking.
10. Slide clamp(s), where provided, may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove slide clamp(s) when not in use.

Cautions:

1. Check ingredients of prep sprays and swabs before using. Some disinfectants used at catheter insertion site contain solvents which can attack the catheter material. Alcohol and acetone can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.
 - Acetone: Do not use acetone on catheter surface.
 - Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency.
 Take care when instilling drugs containing high concentration of alcohol. Allow insertion site to dry completely prior to applying dressing.
2. Do not use syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi), to minimize the risk of pressure induced damage to catheter.
3. Prior to attempting a catheter exchange procedure, remove catheter clamp and fastener (where provided).

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4. Do not exert excessive force while removing the catheter, to minimize the risk of catheter breakage.
5. Continuously monitor indwelling catheters for:
 - desired flow rate
 - security of dressing
 - adherence of stabilization device to skin and connection to catheter
 - correct catheter position; use centimeter markings to identify if catheter position has changed
 - secure Luer-Lock connection
6. Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.
7. Provide strain relief of catheter under dressing to decrease catheter movement and assist in maintaining proper catheter tip position.
8. Inject a small amount of radiopaque dye to locate catheter tip if difficulty is encountered in visualizing the catheter tip.
9. Remove placement wire and Luer-Lock sidearm assembly as a unit. Failure to do so may result in wire breakage.

Caution:

1. Maintain a firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.

Tissue Dilator Warnings
Warnings:

1. Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.
2. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.

**Placement Wire & Guidewire / SWG
Warnings and Precautions**
Warnings:

1. Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
2. Do not cut guidewire to alter length.
3. Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.
4. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.
5. Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel wall, atrial, or ventricular.
6. Do not apply undue force on guidewire to minimize the risk of possible breakage.
7. Do not apply excessive force in removing guidewire or catheter. If withdrawal cannot be easily accomplished, a visual image should be obtained and further consultation requested.
8. Do not cut guidewire with scalpel.
 - Position cutting edge of scalpel away from guidewire.
 - Retract blade of safety scalpel to protected position once cutaneous puncture site is enlarged, to minimize the risk of cutting the guidewire.

**Peel-Away Sheath over Tissue Dilator
Precaution**
Caution:

1. Do not withdraw dilator until sheath is within vessel to minimize the risk of damage to sheath tip.

Possible Complications:

- cardiac tamponade secondary to vessel wall, atrial or ventricular perforation
- pleural injury
- air embolism
- catheter embolism
- bleeding / hemorrhage
- bacteremia
- thrombosis
- hematoma
- brachial plexus injury
- fibrin sheath formation
- vessel erosion
- mediastinal injury
- nerve injury
- thoracic duct laceration
- occlusion
- septicemia
- inadvertent arterial puncture
- dysrhythmias
- exit site infection
- phlebitis
- catheter tip malposition

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Accessory Component Instructions

Review the list of components that will be utilized before beginning the Arrow® Pressure Injectable PICC insertion procedure. Kits / Sets may not contain all accessory components detailed in this section. Become familiar with instructions for each individual component(s) before beginning the actual PICC insertion procedure.

The following components are listed alphabetically.

Catheter Stabilization Device:

STATLOCK® Catheter Stabilization Device should be used in accordance with manufacturer's instructions for use.

- Cleanse and prep anticipated dressing site per hospital/agency protocol. Skin prep should be applied to coat skin and maximize STATLOCK® adherence. Allow to dry thoroughly. The anchor pad will be placed so center of pad is within 1 to 1-1/2 inches (2.5 to 3.8 cm) of catheter insertion site.
- The catheter can be secured to STATLOCK® by using the primary suture hub.

Caution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.

- Place suture hub wings over STATLOCK® posts and press down (refer to Figure 2). Snap STATLOCK® retainer wings to closed position to secure suture hub (refer to Figure 3).

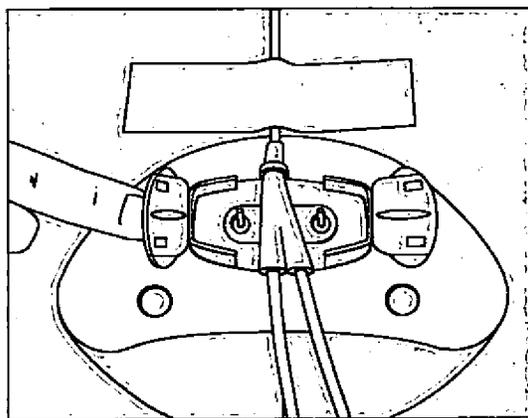


Figure 2

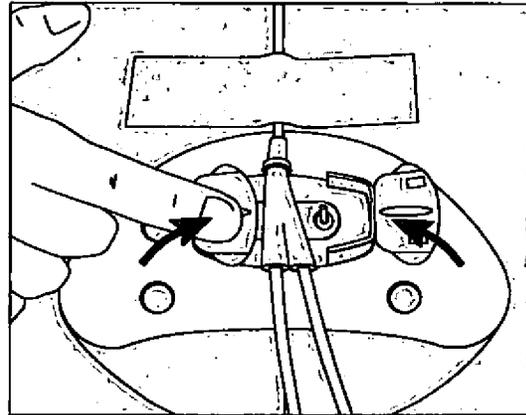


Figure 3

- Remove paper backing from one half of STATLOCK® Catheter Stabilization Device pad and press onto dry, prepared skin. Repeat process for other half of STATLOCK®.
- Complete sterile insertion site dressing according to established hospital/agency protocol.
- Document STATLOCK®/dressing application on patient's chart.
- Replace STATLOCK®/dressing per hospital/agency protocol. STATLOCK® Catheter Stabilization Device should be replaced at least every 7 days to ensure maximum adherence.

Catheter Trimmer:

NOTE: There should be very limited resistance when cutting catheter with supplied trimmer. Any greater resistance is likely to be caused by the placement wire – which has not been sufficiently retracted. If so, do not use catheter.

Catheter Trimmer is a one time use trimming device.

- To trim catheter with Catheter Trimmer, retract placement wire 1-1/2 inches minimum (4 cm) behind where catheter is to be cut. The placement wire is to be withdrawn through septum (see Figure 4).

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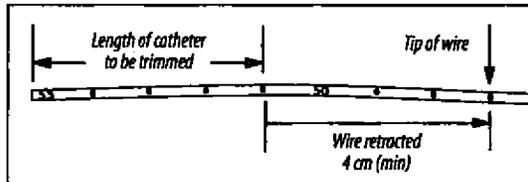


Figure 4

- Kink proximal end of placement wire at connector with side-port (see Figure 5). This minimizes the risk of placement wire extending beyond distal tip of catheter during insertion. (Do not attempt to advance placement wire through septum.)

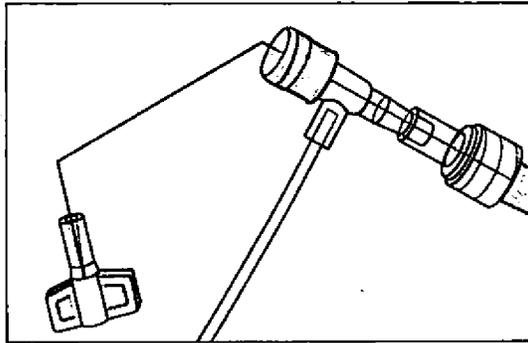


Figure 5

- Peel back contamination guard exposing catheter portion to be trimmed. Using trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Dressing:

Tegaderm™ IV Transparent Dressing:

- Prepare site. Allow all preps to dry completely.
- Peel liner from dressing to expose adhesive.

- Adhere center of transparent window over insertion site, while holding notched portion off the skin (refer to Figure 6).

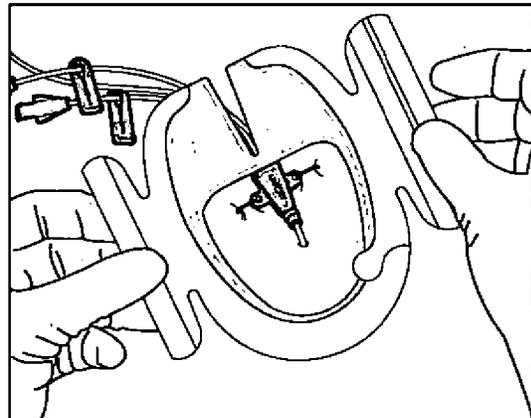


Figure 6

- Overlap softcloth tabs under catheter to form a tight seal around catheter hub and lumens (refer to Figure 7).

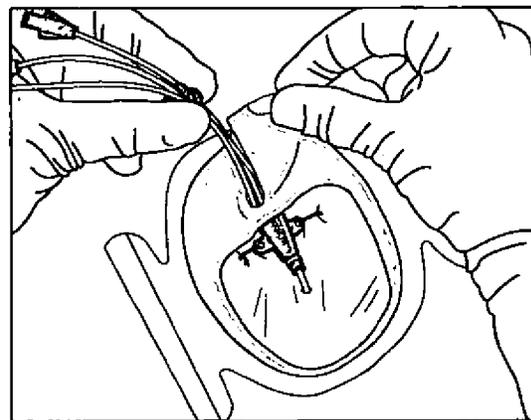


Figure 7

- Press dressing into place.
- Slowly remove frame while smoothing down dressing edges. Smooth dressing from center toward edges, use firm pressure to enhance adhesion (refer to Figure 8).

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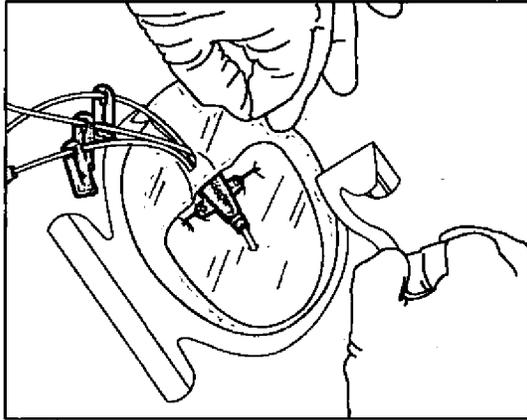


Figure 8

- Use sterile tape strips to secure hub, lumens, and/or tubing (refer to Figure 9).

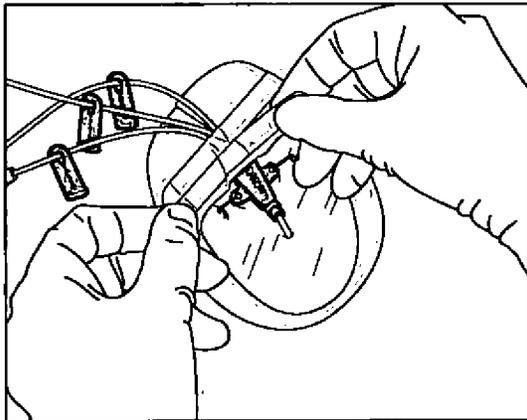


Figure 9

- Label dressing according to protocol.

Refer to individual manufacturer's instructions for more information and specific detailed instructions for dressing removal.

Echogenic Needle:

An echogenic needle is used to provide greater needle visibility under ultrasound. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Filter Straw:

A filter straw is utilized to aspirate solution from glass ampule (5 micron) and minimize the risk of glass particulate from entering the solution.

- Open glass ampule using appropriate sterile and sharps protection technique.
- Attach filter straw to syringe.
- Insert filter straw into ampule.
- Aspirate contents from ampule.
- Remove and discard filter straw.
- Attach appropriate needleless connector or cannula to syringe.
- Purge air from syringe.
- Label syringe appropriately.

Guidewire / SWG Insertion Techniques:

Kits/Sets are available with a variety of Guidewires/SWG. Guidewires are provided in different diameters, lengths, and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique chosen, before beginning the actual PICC insertion procedure.

Image guidance may be used to gain initial venous access.

Catheter Insertion with an 80 cm Guidewire:

Use single 45 cm guidewire for venous access and 80 cm soft tip guidewire for catheter placement. Image guidance or fluoroscopy is used to gain initial venous access; catheter placement with 80 cm guidewire is done under fluoroscopy.

- Gain venous access with 45 cm guidewire and peel-away sheath.
- Load PICC onto 80 cm guidewire until soft tip of wire extends beyond tip of catheter.
- While maintaining control of distal end of guidewire, advance soft tip/catheter tip as a unit through peel-away sheath to desired depth.
- Once catheter is in desired location, remove guidewire.

Catheter Insertion with an 130 cm Guidewire:

Use single 45 cm guidewire for venous access and 130 cm soft tip guidewire for catheter placement. Image guidance or fluoroscopy is used to gain initial venous access; catheter placement with 130 cm guidewire is done under fluoroscopy.

- Gain venous access with 45 cm guidewire.
- Insert soft end of 130 cm guidewire through peel-away sheath to desired depth.
- Thread catheter over guidewire and advance catheter over guidewire through sheath into vessel into correct position.
- Once catheter is in desired location, remove guidewire.

NOTE: Some clinicians will gain access with 130 cm guidewire and thread catheter over guidewire once wire has been correctly positioned in the SVC. This technique is done under fluoroscopy.

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Maximal Barrier Drape:

Drape(s) provide a maximal sterile barrier. Follow CDC Category 1A Recommendation.

- Drape provided is either:
 - Single extra-large drape with fenestration.
 - Two-piece drape consisting of an arm drape with fenestration and a body drape. The body drape is used to appropriately drape torso and upper-lower extremities.
- Unfold the Maximal Barrier Drape:
 - Peel off fenestration backing (refer to Figure 10).

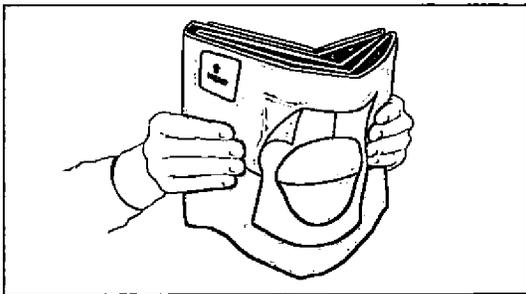


Figure 10

- Position fenestration over intended insertion site (refer to Figure 11).

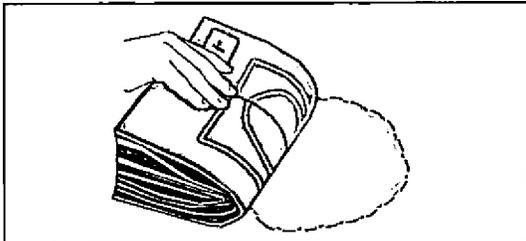


Figure 11

- Unfold width (refer to Figure 12).

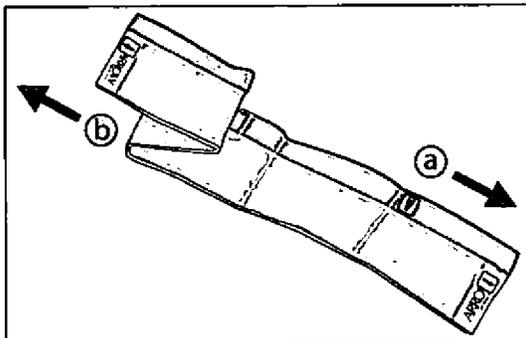


Figure 12

- Unfold towards head (refer to Figure 13).

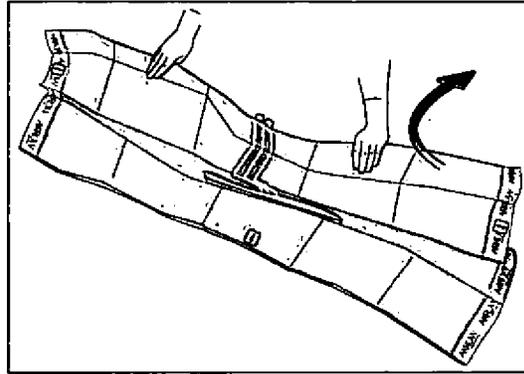


Figure 13

- Unfold towards hand (refer to Figure 14).

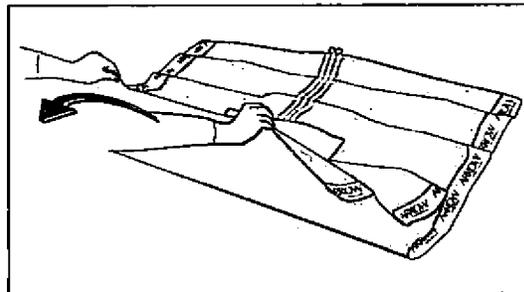


Figure 14

- Perform sterile procedure (refer to Figure 15).

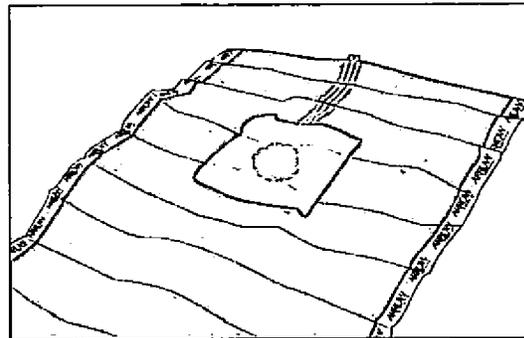


Figure 15

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- Removal procedure: Tear along seam (refer to Figure 16).

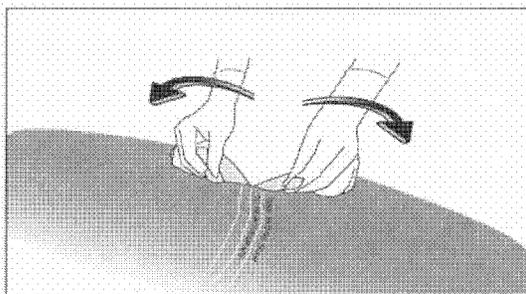


Figure 16

Positive Displacement Valve:

Positive displacement valves are needle-free injection ports utilized to minimize the risk of reflux of blood back into the catheter. Upon disconnection of syringe, a positive displacement of fluid will occur.

- Cleanse connector utilizing an appropriate antiseptic and friction prior to each use.
- Flushing should be done with an appropriately sized syringe.

Refer to individual manufacturer's instructions for specific details for priming volumes, dead space and flow rates.

CLC2000® Connector:

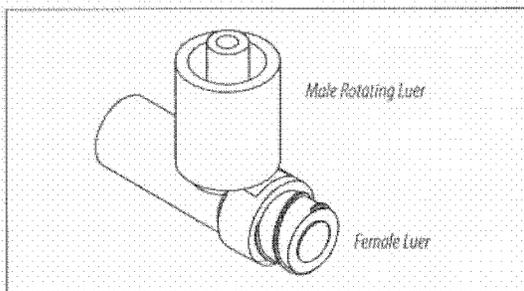


Figure 17

- Using aseptic technique remove CLC2000 from the package. Remove protective cap. Do not contaminate.
- Attach a syringe or administration set to female luer and prime CLC2000 in accordance with facility protocol. Invert device to expel air.
- Attach male rotating luer of CLC2000 to desired extension set or venous access device. Push and twist male rotating luer of CLC2000 into device until tight. Once the CLC2000 is secure, it may be rotated to achieve the most comfortable position on the patient's skin.

- To access CLC2000 swab female luer with desired disinfectant in accordance with facility protocol.
- Attach a fully primed syringe or administration set to CLC2000. Push and twist male luer of device into CLC2000 until tight. If using a rotating luer device, first push and twist Luer-Slip into CLC2000 until tight, then lock down the spin collar. This will ensure a secure connection and optimal flow rates.
- To disconnect from CLC2000, grasp CLC2000 and twist syringe or administration set away from CLC2000 until loose. **DO NOT CLAMP** catheter or extension set while disconnecting syringe or administration set from CLC2000, as it will interrupt the positive displacement.
- Flush the CLC2000 after each use with normal saline or in accordance with facility protocol.
- For subsequent connections repeat from step four.

Caution: **DO NOT USE NEEDLES** in the CLC2000.

Caution: **DO NOT CAP CLC2000, device is closed.**

Caution: **DO NOT CLAMP** the catheter prior to disconnecting a syringe from the CLC2000 as this will interrupt the positive displacement.

*CLC2000 is exclusively manufactured by ICU Medical, Inc.,
San Clement, CA 800-824-7890
949-366-2183 | www.icumed.com*

Protected Needle:

See individual manufacturer's instructions for product use, when used as a single product and not as a kit component.

Warning: **Hands must remain behind needle at all times during use and disposal.**

Caution: **Make sure all needles are used in accordance with OSHA and hospital safety protocols.**

Caution: **Do not attempt to override or defeat the safety locking mechanism of a protected needle.**

Caution: **Discard in an approved sharps collector in accordance with applicable regulations and institutional policy.**

SafetyGlide® Protected Needle:

- Aspirate medication into syringe using aseptic technique.
- If necessary to transport filled syringe to point of administration, use safe, passive recapping technique to cover needle before transport to point of use. In accordance with OSHA standards, such recapping must be accomplished by a one-handed technique, i.e., do not hold needle shield during recapping process.
- Administer injection following established technique.
- Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 18). 1173

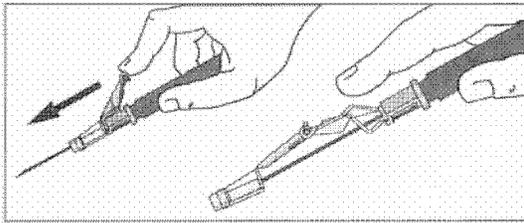


Figure 18

- Visually confirm lever arm has fully advanced and needle tip is covered. If unable to activate, discard immediately into approved sharps collector.
- Activation of protective mechanism may cause minimal splatter of fluid that may remain on needle after injection.
- After single use, discard in an approved sharps collector in accordance with applicable regulations and institutional policy. For greatest safety, use a one-handed technique and activate away from self and others.

SharpsAway II™ Locking Disposal Cup:

The SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. -30 Ga.).

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 19).

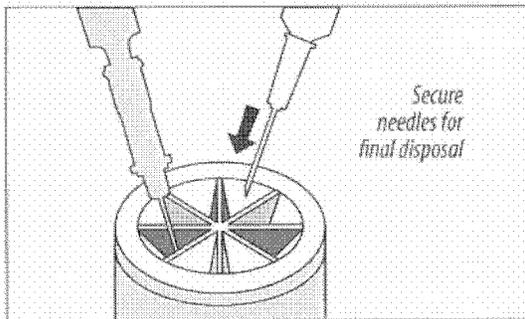


Figure 19

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.
- Discard entire cup, at completion of procedure, into an approved sharps container.

Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

Caution: Do not re-use needles after they have been placed into the foam SharpsAway® system. Particulate matter may adhere to needle tip.

Pre-PICC Insertion & Patient Assessment Activities

Perform hand hygiene as required.

A procedural checklist is included on back of product label.

Procedural Pause:

1. Verify physician order:

- Confirm correct patient.
- Confirm correct diagnosis.
- Confirm correct procedure.

Physician order must include post placement assessment of catheter tip placement (x-ray exam or other method in compliance with hospital protocol).

2. Patient education: Explain procedure to patient. Make sure information is presented with respect to patient's level of understanding, culture, and language.

3. Have informed consent signed, if required.

4. Identify insertion vein:

- Apply tourniquet above anticipated insertion vein.
- Identify appropriate vein for insertion. Use direct visualization technologies, if available, and assess vein health.

NOTE: PICCs are typically inserted into basilic, brachial, or cephalic veins (refer to Figure 20).

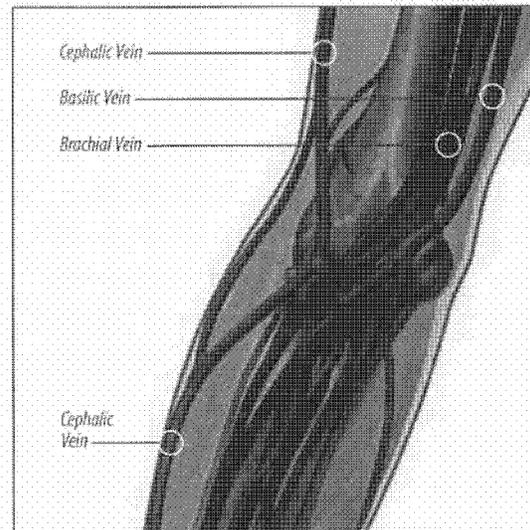


Figure 20

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5. Release tourniquet and leave in place beneath the arm.
6. Measure patient to assure placement of catheter in the SVC:
 - Extend arm laterally 45 to 90 degrees from trunk.
 - Measure distance from insertion site along presumed anatomical course of vessel to be catheterized.
 - Catheter tip should lie in distal one-third of SVC above right atrium and parallel to SVC wall.
 - ◊ If a catheter stabilization device will be used, add 1/2 to 1 inch (1.2 to 2.5 cm) to catheter measurement (STATLOCK®); if another device is used, check manufacturer recommendations.
 - ◊ If using upper arm circumference assessment; for consistency in measurement, measure from an anatomical point and record.
7. Position patient as appropriate for insertion site:
 - Extend arm laterally 45 to 90 degrees from trunk.
8. Prepare work area.

Preparing for PICC Insertion:

- Perform hand hygiene as required:
 - before and immediately after all clinical procedures
 - before and after donning and removal of gloves
- Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.
- Handle and dispose of sharps appropriately in accordance with state/federal OSHA standards for blood borne pathogens and/or institutional policy.
- Clinicians should use sterile technique, maximal sterile barrier precautions throughout the procedure, and dress in protective clothing:
 - mask
 - eye protection
 - sterile gown
 - sterile gloves
 - hair cover

Prep Puncture Site:

1. Prep and drape peripheral puncture site.
2. Perform skin wheal with a local anesthetic as needed.
3. In kits where provided, the SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

Prepare All Equipment:

Prepare Catheter with Placement Wire for Insertion (where provided) (refer to Figure 21).

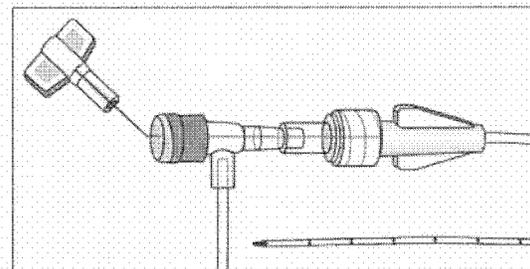


Figure 21

- Remove catheter tip protector.

Trim Catheter:

If necessary, review detailed instructions for Catheter Trimmer device under Accessory Component Instructions section.

1. Identify catheter type:
 - BFT (Blue FlexTip®)
 - Non-BFT
2. Peel back contamination guard exposing catheter portion to be trimmed.
3. Review catheter marking pattern below. The catheter is marked so clinician can easily identify desired amount of catheter to be trimmed; length of catheter that remains or as with BFT catheter – both.
 - BFT double numbering pattern:



Figure 22

- ◊ First number designates centimeters from tip of catheter.
- ◊ Second number designates centimeters from hub of catheter.
- ◊ This double numbering pattern permits clinician to easily identify centimeters of catheter to be trimmed and also identifies centimeters of catheter remaining.
- ◊ Record both numbers.

- Non-BFT numbering pattern:

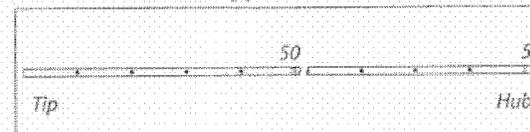


Figure 23

- ◊ Number designates centimeters of catheter to be trimmed and also gives amount of catheter remaining.

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- Using the trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip. **NOTE: There should be very limited resistance when cutting catheter with supplied trimming device. If using a catheter with a placement wire, any greater resistance is likely to be caused by the placement wire which has not been sufficiently retracted. If so, do not use catheter.**

- Inspect cut surface for clean cut and no loose material.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Flush Catheter:

- Use filter straw to withdraw solution from glass ampules.
- Attach syringe to sidearm and flush distal lumen with sterile saline solution. Leave syringe in place.
- Flush remaining lumen(s) with sterile saline. Clamp or attach injection site cap(s) to extension line(s) to contain saline within lumen.

Catheter Insertion Instructions

- Reapply tourniquet and replace sterile gloves.
- Locate vein for insertion:
 - Use image guidance, if available.
 An echogenic needle is included for access.
- Insert introducer needle into vein.
 - Check for pulsatile flow: Pulsatile flow is usually an indicator of inadvertent arterial puncture.

Caution: The color of blood observed is not always a reliable indicator of venous access.

Gain Initial Venous Access:

See specific guidewire instructions, Guidewire Insertion Techniques (page 7) under Accessory Component Instructions section.

- Insert soft tip of guidewire through introducer needle into vein. Advance guidewire to desired depth.

Warning: Do not insert stiff end of soft tip guidewire into vessel as this may result in vessel damage.

Warning: Do not cut guidewire to alter length.

Warning: Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.

- Remove needle:
 - Hold guidewire in place while removing introducer needle.

Caution: Maintain firm grip on guidewire at all times.

- Enlarge puncture site, if necessary:
 - Use scalpel positioned away from the guidewire to enlarge cutaneous puncture site. Do not cut guidewire. Retract scalpel to the protected position.

Sheath Placement:

- Thread tapered tip of peel-away sheath/dilator assembly over guidewire. Grasping near skin advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to further facilitate advancement of sheath into the vessel. A slight twisting motion of the peel-away might help sheath advancement.

Caution: Do not withdraw tissue dilator until the sheath is well within the vessel to minimize the risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

- Check sheath placement by holding sheath in place, withdraw guidewire and dilator sufficiently to allow venous blood flow. Holding sheath in place, remove guidewire and dilator as a unit.

Warning: Do not leave the dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.

Warning: Do not apply undue force on guidewire to minimize the risk of possible breakage.

Catheter Advancement:

Advance catheter according to the guidewire used. Review detailed instructions for 80 cm and 130 cm guidewire usage (page 7) under Accessory Component Instructions section.

Warning: Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.

- Retract catheter guard.
- Insert catheter through peel-away sheath.
 - If resistance is met while advancing catheter, retract and/or gently flush while advancing.
- Stop advancing catheter 5 inches (13 cm) before reaching pre-established insertion length.
- Withdraw peel-away sheath over catheter until free from venipuncture site.
- Grasp tabs of peel-away sheath and pull apart, away from catheter, until sheath splits down entire length.
- Advance catheter to final indwelling position.

Placement Wire (where provided):

Caution: To minimize the risk of placement wire kinking, do not clamp extension line(s) when placement wire is in catheter.

- Complete catheter insertion.
- Remove placement wire.

Warning: Remove placement wire and Luer-Lock sidearm assembly as a unit (see Figure 24). Failure to do so may result in wire breakage.

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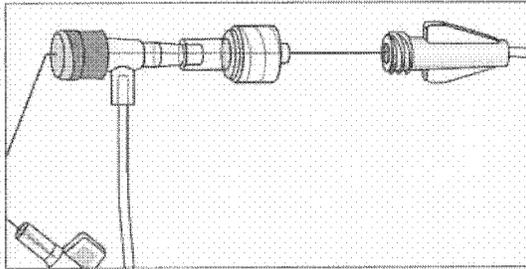


Figure 24

Caution: Catheter clamp and fastener (if provided and used) must not be attached to catheter until either guidewire or placement wire is removed.

Verify Catheter Tip Placement:

1. Examine tip of placement wire after removal to ensure wire has not been altered (see Figure 25).

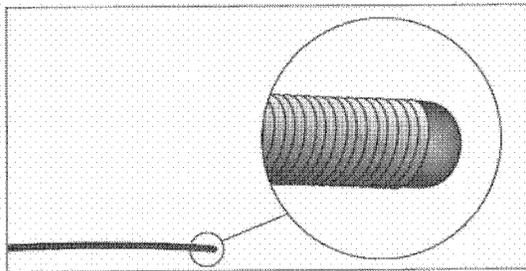


Figure 25

2. If there is any indication placement wire is damaged, catheter and placement wire should be removed together.
3. Check catheter placement with syringe by aspirating through distal lumen until free flow of venous blood is observed.

Caution: The color of blood is not always a reliable indicator of venous access.

Complete Catheter Insertion:

1. Flush lumen(s) to completely clear blood from catheter.
2. Connect extension line(s) to appropriate Luer-Lock line. Alternately, port(s) may be "locked" through injection cap(s) using standard hospital/agency protocol. Slide clamp(s) is provided on extension line to occlude flow through lumen during line and injection cap changes.

Warning: Slide clamp(s), where provided, may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove slide clamp(s) when not in use.

3. Cleanse insertion site per hospital/agency protocol.
- Caution:** Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.
4. Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.
 5. Secure catheter. Where provided, a catheter clamp, fastener, catheter stabilization device or Steri-Strip® may be used.
 6. Assess placement of catheter tip in compliance with hospital protocol.

Documentation

Institutions must establish a permanent medical record that documents the entire procedure, based upon their policy, procedures, and Best Practices. The actual format can differ from institution to institution. Report any product defects/failures to organization risk management, manufacturers, and appropriate regulatory agencies.

Documentation generally includes (but is not limited to) the following information:

1. Device specifics:
 - type, brand and lot number
 - length and size of Vascular Access Device (VAD)
 - internal/external catheter length
 - whether catheter is trimmed
2. Procedure specifics:
 - time out or procedural pause
 - informed consent, as required
 - date, time of insertion, insertion site, number and site attempts, inserter's identification
 - use of visualization and guidance technologies
 - site preparation and technique
3. Patient assessment and response:
 - pertinent dx, assessment, vital signs
 - understanding of procedure, patient's response to procedure
 - complications and barriers to care
4. Therapy specifics:
 - type of therapy, drug dose, rate, time
 - route and method of administration
 - laboratory specimen collected
5. Visual confirmation:
 - verification of appropriate tip location prior to initial use
6. Monitor patient for post catheter insertion complications.

Care and Maintenance

Dressing:

Replace dressing according to organizational policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened, or no longer occlusive.

- Consult manufacturer's recommendations for dressing specifics.
- Transparent semipermeable membrane dressing should be changed every 7 days.
- Gauze and tape should be changed every 48 hours.
- Label dressing with type, size, and length of catheter; date and time; and initials of the clinician performing dressing change.

Maintain Catheter Patency:

Maintaining central venous catheter patency shall be done in accordance with organizational policies, procedures, and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Perform hand hygiene as required.

1. Solution and frequency of flushing a venous access catheter should be established in hospital/agency policy.
2. Catheter patency is established and maintained by:
 - flushing intermittently via syringe with heparinized saline or preservative-free 0.9% sodium chloride (USP)
 - continuous drip
 - positive pressure device
3. The amount of heparin:
 - depends on physician preference.
 - hospital/agency protocol,
 - patient condition

Caution: Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.

4. The volume of flush solution should be:
 - equal to at least twice the priming volume of the catheter and any add-on devices

Catheter priming volume is printed on product packaging.
5. When using any central venous catheter for intermittent infusion therapy, proper flushing (heparinization) using a positive-pressure flushing technique will help prevent occlusion. Neutral as well as positive displacement valve systems have also been shown to help prevent occlusion.
6. All valves need to be properly cleansed with an appropriate antiseptic before being accessed.
7. The SASH or SAS method of flushing will help eliminate occlusions due to incompatible solutions:
 - Saline • Administer drug • Saline • Heparin (if used)

Catheter Removal Procedure

1. PICC removal shall be performed:
 - following order of authorized prescriber
 - in accordance with organizational policies, procedures, and practice guidelines
2. A PICC shall be removed immediately upon patient assessment for:
 - suspected contamination
 - unresolved complication
 - discontinuation of therapy
3. As indicated, place patient in supine position to minimize the risk of potential air embolism.
4. Remove dressing.

Warning: Do not use scissors to remove dressing, to minimize the risk of cutting catheter.

5. Open catheter stabilization device retainer wings and remove catheter from catheter stabilization device posts.
6. Remove catheter by slowly pulling it parallel to skin. If resistance is met when removing the catheter, catheter should not be forcibly removed and the physician should be notified.

Caution: Do not exert excessive force while removing the catheter; to minimize the risk of catheter breakage.

7. Upon removal of catheter:
 - measure and inspect
 - ensure entire catheter length has been removed
8. Direct pressure should be applied at site until hemostasis is achieved.
9. Apply alcohol swab to catheter stabilization device adhesive and gently lift pad off of skin (if applicable).
10. Dress insertion site. Sterile occlusive dressing should be applied and site assessed every 24 hours until site is epithelialized. Residual catheter track may remain an air entry point until completely sealed (usually 24 to 72 hrs); dependent upon amount of time catheter was indwelling.
11. Document catheter removal procedure on patient's chart per hospital/agency protocol.

Include:

 - catheter condition
 - length of catheter removed
 - patient's tolerance of the procedure
 - any nursing interventions needed for removal

For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with central venous access refer to Arrow International, Inc. website: www.arrowintl.com

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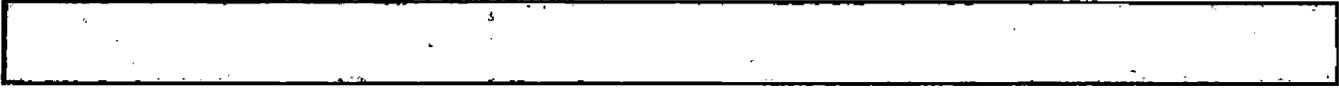
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P-PI PICC draft (2/10)

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ARROW^gard Evolution Antimicrobial Catheter Technology Information

Introduction and Rationale for Antimicrobial Catheters

Infection is the leading complication associated with intravascular devices, and there is a strong need to develop products to help prevent complications and increase safety for patients and providers. The National Nosocomial Infection Surveillance System (NNIS) tracks central line-associated bloodstream infection (BSI) rates in adult and pediatric intensive care units from 300 participating hospitals. This report serves as a benchmark for other hospitals to use in comparing their rates with the national rates. Approximately 90% of catheter-related bloodstream infections (CRBSI) occur with central lines.⁷ Mortality attributable to CRBSI has been reported to be between 4% to 20% with prolonged hospitalization (a mean stay of 7 days) and increased hospital costs. Peripherally Inserted Central Catheters (PICCs) are associated with similar rates of CRBSI as Central Venous Catheters (CVCs), placed in internal jugular or subclavian veins (2 to 5 per 1,000 catheter days).¹⁰

Vascular catheter infections develop for many reasons. They begin when a catheter becomes colonized by microorganisms entering through one or both of two routes: 1) colonization of the outside surface of the catheter or 2) colonization of the inside surface of the catheter. This colonization may be caused by any of five sources: environmental contamination, skin organisms, post-placement subcutaneous tract infection, intraluminal contamination or hematogenous seeding.¹¹

Technology Development:

Antimicrobial central venous catheters (CVCs) were introduced by Arrow International in 1990. The Arrow^gard catheter was the first commercially successful catheter capable of significantly reducing the potential for catheter colonization and subsequent catheter-related bloodstream infections.⁶ The first generation antimicrobial surface treatment, referred to as ARROW^gard Blue^g, consists of two antimicrobial agents (chlorhexidine and silver sulfadiazine) which are impregnated into the indwelling external surface of the catheter. This combination has demonstrated broad spectrum *in vitro* efficacy as well as *in vivo* efficacy through prospective clinical studies.^{1,4,5,7,14}

Due to the need for longer duration of protection as a result of longer dwelling time and in recognition of the role of the intraluminal pathway in catheter colonization by organisms transmitted by the hands of unit personnel,^{6,11,12} two key areas of improvement to the ARROW^gard Blue^g catheter technology were identified: 1) extend the effective duration of action of the external surface coating and 2) provide protection to the internal surfaces of the entire catheter (including extension lines and hubs). The second generation antimicrobial catheter, known as ARROW^gard Blue PLUS^g (AGB^g), was developed to address these needs. This was done by increasing chlorhexidine on the outside surface of the catheter and also by protecting the entire intraluminal path with chlorhexidine. Compared to the original ARROW^gard Blue^g, ARROW^gard Blue PLUS^g catheters produce a significantly longer duration of antimicrobial effect against the most common catheter-related infection-causing microorganisms, including a significant reduction in intraluminal bacterial colonization when compared to untreated catheters.⁸

The third generation of antimicrobial catheter technology is being introduced on PICC products as ARROW^gard Evolution, with slight modification to the clinically proven efficacy of the ARROW^gard Blue PLUS^g technology. Silver sulfadiazine, the secondary antimicrobial agent, has been removed, and the chlorhexidine-to-catheter material processing was optimized to provide longer duration based on the clinical requirements of PICC catheters.

Product Description:

The ARROW^gard Evolution Antimicrobial PICC is a peripherally inserted central venous catheter manufactured with medical grade, radiopaque polyurethane. It has a non-tapered catheter body with a Blue FlexTip^g, designed to be softer than a cut tip. It has a contour design to enhance maneuverability and minimize vessel trauma. The Blue FlexTip^g also provides visual confirmation of an intact catheter upon removal. The catheters are available in usable lengths of 40 to 55 cm and are indicated for 5ml/sec pressure injectability.

The ARROW^gard Evolution Antimicrobial PICC is processed with an external surface treatment that uses the antimicrobial chlorhexidine acetate

on the catheter body and juncture hub nose, as well as an internal lumen impregnation utilizing an antimicrobial combination of chlorhexidine acetate and chlorhexidine base for the catheter body, juncture hub, extension line(s) and extension line hub(s). A maximum total amount of chlorhexidine applied to 40 cm, 50 cm and 55 cm catheters may be up to 13.7mg, 17.0 mg and 18.6 mg respectively.

The ARROWgard Evolution Antimicrobial PICC kit includes essential tools required to:

- Access patients' vasculature
- Promote compliance for reducing risk with an ergonomic, comprehensive design
- Protect patients from five sources of bloodstream infections
- Comply with current evidence-based guidelines for infection reduction and safety

Characterization of Chlorhexidine:

Chlorhexidine is characterized as having a broad antimicrobial activity spectrum, including bacteriostatic and bactericidal effects on gram positive bacteria, gram negative bacteria and fungi. Chlorhexidine also has been shown to be effective against viruses with a lipid component in their coats or with an outer envelope, but these properties have not been evaluated with this product.

Whether chlorhexidine is bacteriostatic or bactericidal depends largely on the concentration of the agent, its pH and the susceptibility of specific organisms. Optimum stability ($C_{26}H_{38}C_{12}N_{10}O_4$) is demonstrated between pH levels of 5.5 and 7.0, which are consistent with pH levels of body surfaces and tissues.²

Chlorhexidine is a cationic compound. Its positively charged molecules are strongly attracted to the negative surface charges of bacterial cells. The outer membrane of gram negative bacteria, cell wall of gram positive bacteria or cytoplasmic membrane of yeasts then becomes weakened from increased permeability caused by chlorhexidine being adsorbed onto the cell surface. Chlorhexidine exhibits bacteriostatic effects at low concentrations due to the release of substances characterized by low molecular weights (i.e., phosphorus and potassium ions) from the cell. This damage is enough to inhibit bacterial cell function. Bactericidal activity of chlorhexidine occurs at higher concentrations by causing precipitation of proteins and nucleic acids.²

Chlorhexidine is poorly absorbed from the gastrointestinal tract. In human and animal studies, the average plasma level peaked at 0.206 ug/g in humans 30 minutes after ingesting 300mg

of chlorhexidine. Excretion occurred primarily through the feces (about 90%), and less than 1% was excreted in urine. Chlorhexidine is metabolized in the same manner as most other foreign substances. The majority will be excreted without being metabolized.²

Preclinical biocompatibility studies support the conclusion that there is a negligible risk of adverse effects from the Antimicrobial PICC products.

Indications for Use:

The ARROWgard Evolution Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ARROWgard Evolution Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. It is not intended to be used for the treatment of existing infections.

Contraindications:

Clinical assessment of the patient must be completed to ensure no contraindications exist. This antimicrobial PICC is contraindicated in the following areas:

- Patients with known hypersensitivity to chlorhexidine.
- In presence of device related infections (not specific to coating technology)
- In presence of previous or current thrombosis (not specific to coating technology)

Warning:

Remove catheter immediately if adverse reactions occur after catheter placement.

NOTE: Perform sensitivity testing to confirm allergy to catheter antimicrobial agents if adverse reaction occurs.

Precaution:

Trimming may decrease effectiveness of coating at trimmed edge.

Refer to enclosed product Instructions for Use (IFU) for additional warnings and precautions. 1182

Hypersensitivity Potential:

Benefits of the use of this catheter should be weighed against any possible risk. Hypersensitivity reactions are a concern with antimicrobial catheters and can be serious and even life-threatening. Since antimicrobial catheters were introduced into the market, there have been some reports of hypersensitivity occurrences outside the United States. This hypersensitivity potential has been reported to occur more frequently in Japan.

Pre-Clinical Evaluations:

The ARROWgard Evolution Antimicrobial PICC has demonstrated microbial colonization reduction against gram-positive, gram-negative and yeast in in-vitro and in-vivo studies for up to 30 days for external surface and in-vitro studies for up to 21 days for fluid pathway.¹³

Clinical Evaluations:

Reduction in colonization or microbial growth on the antimicrobial PICC has not been shown to correlate with a reduction in infections in patients. Clinical studies to evaluate reduction in infection have not been performed on this device. Clinical effectiveness of the Antimicrobial PICC in preventing CRBSIs compared to the ARROWgard Blue PLUS[®] CVC catheters has not been studied. PICC is a type of CVC and centrally inserted CVCs and peripherally inserted CVCs (i.e., PICCs) are used for similar clinical usage. Both are inserted vascularly and are inserted to the same depth near the heart. The PICC products, a subset of CVCs, are generally 4 to 8 inches longer in overall length since they are usually inserted in the upper arm and require extra length in order to reach the same insertion depth. The coating on both products primarily contains the antimicrobial agent chlorhexidine with similar concentration per surface area, which has been shown to be effective in reduction of colonization of catheter surfaces in in-vitro testing. Based on similarities of the Antimicrobial PICC and ARROWgard Blue PLUS[®] catheter technology and clinical usage, the studies performed on ARROWgard Blue PLUS[®] antimicrobial catheters listed below may provide a useful comparison in demonstrating clinical safety and effectiveness of the chlorhexidine based technology in patients.

Clinical Study - France³

A prospective, multi-center, randomized, double-blind clinical study of 397 patients performed at 14 university-affiliated hospital ICUs in France from June 1998 to January 2002 using ARROWgard

Blue PLUS[®] antimicrobial catheters showed use of these catheters was associated with a strong trend toward reduction in infection rates of central venous catheters (colonization rate of 3.7% versus 13.1%, 3.6 versus 11 per 1000 catheter-days, $p=0.01$) and CVC-related infection (bloodstream infection) in 4 versus 11 (2 versus 5.2 per 1000 catheter-days, $p=0.10$).

Clinical Study - Germany⁴

A prospective, randomized, double-blind, controlled clinical study of 184 patients performed at the University Hospital of Heidelberg (Heidelberg, Germany) from January 2000 to September 2001 using ARROWgard Blue PLUS[®] antimicrobial catheters showed these catheters were effective in reducing the rate of significant bacterial growth on either the tip or subcutaneous segment (26%) compared to control catheters (49%). Incidence of catheter colonization was also significantly reduced (12% coated versus 33% uncoated). The number of bloodstream episodes in patients with CHSS catheter was lower than in patients provided with control catheter (3 versus 7 episodes, $p=0.21$).

Clinical Study - United States⁵

A prospective, multi-center, randomized, double-blind, controlled clinical study of 780 patients performed at 9 university-affiliated hospitals in the United States from July 1998 to June 2001 using ARROWgard Blue PLUS[®] antimicrobial catheters showed these catheters were less likely to be colonized at time of removal compared to control catheters (13.3 versus 24.1 colonized catheters per 1000 catheter-days, $p<0.01$). Rate of definitive catheter-related bloodstream infection was 1.24 per 1000 catheter days (CI, 0.26 to 3.26 per 1000 catheter-days) for the control group versus 0.42 per 1000 catheter days (CI, 0.01 to 2.34 per 1000 catheter-days) for the ARROWgard Blue PLUS[®] catheter group ($p=0.06$).

No adverse events were observed from ARROWgard Blue PLUS[®] catheters in any of the clinical studies.

Refer to enclosed product Instructions for Use (IFU) for specific indications, procedural technique(s) and potential complications associated with PICC insertion procedures.

References:

1. Bach A, Bohrer H, Bottiger B, Motsch J, Martin E. Reduction of bacterial colonization of triple-lumen catheters with antiseptic bonding in septic patients. *Anesthesiology*, 1994;81:A261. 1183

2. Block, S.S. 2001. Chlorhexidine. Ch. 15 in Disinfection, Sterilization and Preservation, 5th ed., S.S. Block (Ed.), p. 321-336, 2001.
3. Brun-Buisson C, Doyon F, Sollet J, Cochar J, et al. Prevention of intravascular catheter-related infection with newer chlorhexidine-silver sulfadiazine-coated catheters: a randomized controlled trial. *Intensive Care Medicine*. 2004;30:837-843.
4. Civetta J, Hudson-Civetta J, Ball S. Decreasing catheter related infection and hospital costs by continuous quality improvement. *Crit Care Med*. 1996;24:1660-5.
5. Collin GR. Decreasing catheter colonization through the use of an antiseptic-impregnated catheter: a continuous quality improvement project. *Chest*. 1999;115:1632-1640.
6. Maki DG, Ringer M. Evaluation of dressing regimens for prevention of infection with peripheral intravenous catheters. *JAMA*. 1987;258:2396-2403.
7. Maki DG, Stoiz SM, Wheeler S, Mermel LA. Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter. *Ann Intern Med*. 1997;127:257-266.
8. Ostendorf T, Meinhold A, Harter C, Salwender H, et al. Chlorhexidine and silver sulfadiazine coated central venous catheters in haematological patients -- a double-blind, randomized, prospective, controlled trial. *Support Care Cancer*. 2005;13:993-1000.
9. Rupp M, Lisco S, Lipsett P, Perl T, et al. Effect of a second-generation venous catheter impregnated with chlorhexidine and silver sulfadiazine on central catheter-related infections. *Annals of Internal Medicine*. October 18, 2005;143(8):570-581.
10. Safdar, N and Make DG. Risk of Catheter-Related Bloodstream Infection With Peripherally Inserted Central Venous Catheters Used in Hospitalized Patients. *Chest*. 2005; 285: 489-495.
11. Sherertz RJ. Pathogenesis of vascular catheter-related infections. In: Selfert H, Jansen B, Farr BM, eds. *Catheter-Related Infections*. New York, NY: Marcel Dekker, Inc; 1997:1-29.
12. Sherertz RJ, Heard SO, Raad II. Diagnosis of triple-lumen catheter infection: comparison of roll plate, sonication, and flushing methodologies. *J Clin Microbiol*. 1997;35:641-646
13. Testing Performed by Independent Laboratories (Innovotech and Toxikon): data on file at Arrow International.
14. Veenstra DL, Saint S, Somnath S, Lumley T, Sullivan SD. Efficacy of Antiseptic-impregnated Central Venous Catheters in Preventing Catheter-Related Bloodstream Infection. *JAMA*. 1999;281:261-267.

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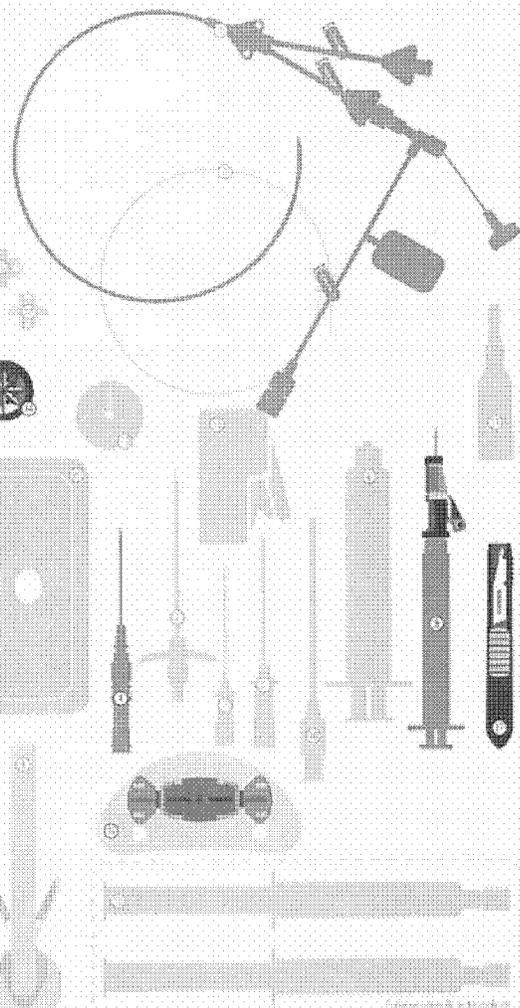
ARROWgard Evolution Antimicrobial PICC Kit

Latex-Free



REF CDC-44052-HPK1A

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Contents:

- 1 Two-lumen indwelling Antimicrobial Catheter, 5.5 Fr. x 175.3 cm (18 cm Radiopaque Pressure Injectable Polyurethane with Blue Flex-Tip[®], Extension Line, Clamps, Contamination Guard and Piercement Wire
- 1 Flexible Sheath 3.5 Fr. x 27.3 cm Radiopaque outer Dilator
- 1 Spring-Loaded Guide, 11 Fr. x 40mm dia x 12-1/4" (35 cm) Straight with Tapered Ends
- 1 Catheter, 20 Ga. x 1-1/8" (2.94 cm) Insite[™] Astoguard[™] Radiopaque over 22 Ga. Introducer Needle
- 1 Introducer Needle, 21 Ga. x 3-1/4" (7.62 cm) TW with Radiopaque Tip
- 1 Syringe, 10 mL, Luer-Lock
- 1 Introducer Needle, 18 Ga. x 1-1/2" (3.81 cm) TW
- 1 Introducer Needle, Safety Glide[™] 25 Ga. x 5/8" (1.6 cm) and 3 mL Luer-Lock Syringe
- 1 1 mL Applicator Patch, 2% CHG and 70% IPA Chlorhexidine One-Step Solution with H-Etix Orange[™] Dye
- 2 10 mL PVA-Filled Saline Syringes[†]
- 1 3 mL Airspike GCP, 1% Lubricose Solution
- 1 Roll Pack, 65% Alcohol Pad Pack
- 1 Antimicrobial Patch, 70% 500 mg Povidone Iodine
- 1 Clamp, Catheter
- 1 Extension Catheter Clamp
- 1 SharpsAway II[™] Locking Disposal Cap
- 1 SharpsAway[™] Disposal Cap
- 1 Catheter Cutter
- 1 CRW Wedge
- 1 Dressing 40" x 40" with 3" x 3" Extension
- 1 Dressing 40" x 24"
- 1 Dressing 100" x 32"
- 1 Towel, 24" x 30"
- 1 Filter, 3" Diameter, In-line
- 1 Safety Scalpel #11
- 1 Clasp Sucker
- 1 Sterile Gauze Pad 4" x 4"
- 1 Sterile Gauze Pad 2" x 2"
- 1 Sterile Gauze Pad 1" x 1"
- 1 Sterile Gauze Pad 1/2" x 1/2"
- 1 Sterile Gauze Pad 1/4" x 1/4"
- 1 Sterile Gauze Pad 1/8" x 1/8"
- 1 Sterile Gauze Pad 1/16" x 1/16"
- 1 Sterile Gauze Pad 1/32" x 1/32"
- 1 Sterile Gauze Pad 1/64" x 1/64"
- 1 Sterile Gauze Pad 1/128" x 1/128"
- 1 Sterile Gauze Pad 1/256" x 1/256"
- 1 Sterile Gauze Pad 1/512" x 1/512"
- 1 Sterile Gauze Pad 1/1024" x 1/1024"
- 1 Sterile Gauze Pad 1/2048" x 1/2048"
- 1 Sterile Gauze Pad 1/4096" x 1/4096"
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- 1 Sterile Gauze Pad 1/2097152" x 1/2097152"
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- 1 Sterile Gauze Pad 1/134217728" x 1/134217728"
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Central Line Insertion Practices (CLIP) Adherence Monitoring Form

*Facility ID: _____ Event #: _____

*Patient ID: _____ Secondary ID: _____ Social Security #: _____ - _____ - _____
 Patient Name, Last: _____ First: _____ Middle: _____
 *Gender: F M *Date of Birth: ____/____/____ (mm/dd/yyyy)
 Ethnicity (specify): _____ Race (specify): _____

*Event Type: CLIP *Location: _____ *Date of Insertion: ____/____/____ (mm/dd/yyyy)
 *Person recording insertion practice data: Inserter Observer
 Central Line Inserter ID: _____ Name, Last: _____ First: _____
 *Occupation of Inserter:
 Fellow IV Team Medical Student Other Medical Staff
 Physician Assistant Attending Physician Intern/Resident Other Student
 Other (specify): _____
 *Reason for Insertion:
 New indication for central line Replace malfunctioning central line
 Suspected central line-associated infection Other (specify) _____
 *Inserter performed hand hygiene prior to central line insertion: Y N
 *Maximal Sterile Barrier Precautions used: Mask Y N Sterile Gown Y N
 Large Sterile Drape Y N Cap Y N Sterile Gloves Y N
 *Skin Preparation (check all that apply): Chlorhexidine Gluconate Povidone Iodine Alcohol
 *Skin preparation agent completely dry at time of first skin puncture: Y N
 *Insertion Site:
 Femoral Jugular Lower Extremity Scalp
 Subclavian Umbilical Upper Extremity
 Antimicrobial Coated Catheter used: Y N
 *Central Line Catheter Type:
 Dialysis Non-Tunneled PICC
 Dialysis Tunneled Umbilical
 Non-Tunneled (other than dialysis) Tunneled (other than dialysis)
 Other (specify): _____
 Number of Lumens (circle one): 1 2 3 ≥ 4
 *Central Line exchanged over a Guidewire: Y N
 Antiseptic ointment applied to site: Y N

Comments: _____

1398



PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Is this a NEW line? YES NO

This procedure is: Elective Emergent Re-position Other: _____

Insertion Procedure Practices

Before Procedure, did the clinician: YES YES N/A
after remainder

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts / forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Estimated vein size: _____ mm
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
 Accelerated Seldinger Technique Other technique used: _____

After Procedure:

- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No
- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was final tip placement ordered / confirmed?

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____ Lot No.: _____

Patient Label

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI Initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

CDC-45541-HPK1A
ARROWgard Evolution
Antimicrobial PICC Kit

ARROW
INTERNATIONAL
C-45541-101A (2/10)

1399

1192

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Is this a NEW line? YES NO

This procedure is: Elective Emergent Re-position Other: _____

Insertion Procedure Practices

Before Procedure, did the clinician: YES YES N/A
after reminder

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts / forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Estimated vein size: _____ mm
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
 Accelerated Seldinger Technique Other technique used: _____

After Procedure:

- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No
- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was final tip placement ordered / confirmed?

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____ Lot No.: _____

Patient Label

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI Initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

CDC-45052-HPK1A
ARROWgard Evolution
Antimicrobial PICC Kit

ARROW
INTERNATIONAL
C-4300101A (2/10)

1193

1400

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Is this a NEW line? YES NO

This procedure is: Elective Emergent Re-position Other: _____

Insertion Procedure Practices

Before Procedure, did the clinician: YES YES N/A
after
reminder

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts / forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Estimated vein size: _____ mm
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
 Accelerated Seldinger Technique Other technique used: _____

After Procedure:

- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No
- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was final tip placement ordered / confirmed?

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____ Lot No.: _____

Patient Label

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI Initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

CDC-45041-HPK1A
ARROWgard Evolution
Antimicrobial PICC Kit

ARROW
INTERNATIONAL
C-45041-01A (2/10)

1194

1401

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Is this a NEW line? YES NO

This procedure is: Elective Emergent Re-position Other: _____

Insertion Procedure Practices

Before Procedure, did the clinician:

YES YES N/A
after reminder

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts / forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Estimated vein size: _____ mm
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
 Accelerated Seldinger Technique Other technique used: _____

After Procedure:

- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No
- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was final tip placement ordered / confirmed?

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____ **Lot No.:** _____

Patient Label

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

CDC-44052-HPK1A
ARROWgard Evolution
Antimicrobial PICC Kit

ARROW
INTERNATIONAL
C-44052-101A (2/10)

1402

1195

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Is this a NEW line? YES NO

This procedure is: Elective Emergent Re-position Other: _____

Insertion Procedure Practices

Before Procedure, did the clinician: YES YES N/A
after reminder

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts / forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Estimated vein size: _____ mm
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
 Accelerated Seldinger Technique Other technique used: _____

After Procedure:

- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No
- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was final tip placement ordered / confirmed?

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____ Lot No.: _____

Patient Label

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI Initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

CDC-44041-HPK1A
ARROWgard Evolution
Antimicrobial PICC Kit

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INTERNATIONAL
C-44041-101A (2/10)

1403

1196

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial **Other:** _____

Is this a NEW line? YES NO

This procedure is: Elective Emergent Re-position **Other:** _____

Insertion Procedure Practices

Before Procedure, did the clinician: YES YES N/A
after remainder

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts / forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Estimated vein size: _____ mm
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
 Accelerated Seldinger Technique **Other technique used:** _____

After Procedure:

- Was the catheter trimmed? Yes No **Length:** _____
- Was a guillotine used? Yes No
- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was final tip placement ordered / confirmed?

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____ **Lot No.:** _____

Patient Label

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

CDC-45552-HPK1A
ARROWgard Evolution
Antimicrobial PICC Kit

ARROW
INTERNATIONAL
C-45552-101A (2/10)

1404

1197

Arrow® Pressure Injectable PICC Information

MAXIMUM injector pressure setting: 300 psi

Catheter size:	Lumen	MAX Indicated Pressure Injection Flow Rate ¹	Maximum Catheter Pressure During MAX Flow Rate ²	Maximum Static Burst Pressure ³
4.5 Fr. 40 cm S-L	Distal	5 mL/sec	210 psi	411 psi
4.5 Fr. 50 cm S-L	Distal	5 mL/sec	248 psi	382 psi
4.5 Fr. 55 cm S-L	Distal	5 mL/sec	257 psi	426 psi
5.5 Fr. 40 cm D-L	Distal	5 mL/sec	206 psi	352 psi
	Proximal	5 mL/sec	207 psi	352 psi
5.5 Fr. 50 cm D-L	Distal	5 mL/sec	220 psi	362 psi
	Proximal	5 mL/sec	220 psi	357 psi
5.5 Fr. 55 cm D-L	Distal	5 mL/sec	230 psi	346 psi
	Proximal	5 mL/sec	227 psi	323 psi

¹ Represents maximum indicated flow rate for pressure injection of contrast media.

² Represents internal catheter pressure during pressure injection with injector safety cut-off at 300 psi, using media of 11.8 Centipose (cP) viscosity.

³ MAX static burst pressure is the failure point of catheter when occluded.

* See Instructions for Use for additional information.

Pressure Injection

Warnings and Precautions:

Warnings:

1. Assess each patient for appropriateness of a pressure injection procedure.
2. Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
3. Use an appropriate method to confirm catheter tip position prior to each pressure injection per institutional policy.
4. Ensure patency of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.
5. Discontinue pressure injections at first sign of infiltration / extravasation. Follow hospital protocol for appropriate medical intervention.
6. Use only lumen labeled "Pressure Injectable" for pressure injection to minimize the risk of catheter failure and/or patient complications.

Cautions:

1. Do not exceed the maximum pressure of 300 psi on power injector equipment to minimize the risk of catheter failure and/or tip displacement.
2. Do not exceed the catheter's maximum recommended flow rate located on product labeling to minimize the risk of catheter failure and/or tip displacement.
3. Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.
4. Pressure limit settings on power injector equipment may not prevent over pressurization of an occluded catheter.
5. Use an appropriately rated 60 inch pressure tubing between catheter and power injector equipment to minimize the risk of catheter failure.
6. Follow the specified contrast media manufacturer's instructions for use, warnings, precautions, and contraindications.

Pressure Injection Procedure:

NOTE: Clinicians should use sterile technique when flushing, disconnecting, connecting, and replacing injection/needleless caps.

1. Use an appropriate method to confirm each tip placement prior to each pressure injection per institutional policy.
2. Remove injection cap from the lumen of catheter to be injected.
3. Check for catheter patency:
 - Attach 10 mL syringe, or larger, filled with sterile normal saline.
 - Aspirate catheter until approximately 3 mL of blood enters syringe freely.
 - Vigorously flush catheter.

Warning: Ensure catheter patency prior to pressure injection to minimize the risk of catheter failure and/or patient complications.

4. Detach syringe.
5. Attach pressure injection equipment and extension tubing to lumen of catheter according to manufacturer's recommendations.

Warning: Use only lumen labeled "Pressure Injectable" for pressure injection to minimize the risk of catheter failure and/or patient complications.

Caution: To minimize risk of catheter failure and/or tip displacement:

- Do not exceed the maximum pressure of 300 psi on power injector equipment.
- Do not exceed the catheter's maximum recommended flow rate located on product labeling.

6. Inject contrast media in accordance with hospital protocol.

Caution: Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.

7. Disconnect catheter from power injector equipment.
8. Flush catheter with a 10 mL syringe, or larger, filled with sterile normal saline.
9. Replace sterile injection cap on catheter.

NOTE: Catheter testing included 10 pressure injection cycles.

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P-44041-100A (2/10)

1198

1405

Pressure Injectable PICC Information

Patient ID: _____ Date of Birth (mm/dd/yy): ____/____/____
 First Name: _____ Male Female
 Last Name: _____ Notes: _____
 Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Kit No.: _____ Date Inserted (mm/dd/yy): ____/____/____

Injection Log

	Date	Lumen	Volume	Flow Rate	Contrast Media
1					
	Notes:				
2					
	Notes:				
3					
	Notes:				
4					
	Notes:				
5					
	Notes:				
6					
	Notes:				
7					
	Notes:				
8					
	Notes:				
9					
	Notes:				
10					
	Notes:				

Patient Label

ARROW
 INTERNATIONAL
 Arrow International, Inc.
 2400 Bernville Road
 Reading, PA 19603 USA

1406

FB-05000-002A (6/98)

Sterile Medical Supplies

ARROW

Arrow International, Inc.
2400 Bernville Road
Rudolph, PA 19605 USA

REF CDC-44041-HPK1A
LATEX-FREE

4.5 Fr. x 15-3/4" (40 cm)

ARROW^gard Evolution Antimicrobial PICC Kit

with Blue FlexTip[®] Catheter, Placement Wire,

Sharps Safety Features and Maximal Barrier Precautions

Qty: 5

Contains Medication

Storage Requirements: Store between 20 - 25 °C (68 - 77 °F).
Avoid freezing, excessive heat above 40 °C (104 °F)
and humidity above 75 % RH.

LOT



STERILE EO



1200

Version 0 (2/10)

Single use — do not re-sterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

1200

1407

Sterile Medical Supplies

ARROW

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605 USA

PB-05000-002A (6/98)

REF CDC-44052-HPK1A

LATEX-FREE

5.5 Fr. x 15-3/4" (40 cm)

ARROWgard Evolution Antimicrobial PICC Kit

with Blue FlexTip® Catheter, Placement Wire,

Sharps Safety Features, and Maximal Barrier Precautions

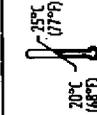
Qty: 5

Contains Medication

Storage Requirements: Store between 20 - 25°C (68 - 77°F).

Avoid freezing, excessive heat above 40°C (104°F) and humidity above 75% RH.

LOT



Single use - do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

1201

Version 0 (2/10)

1201

1408

186902A (6/98)

Sterile Medical Supplies

ARROW

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605 USA

REF CDC-45041-HPK1A

LATEX-FREE

4.5 Fr. x 19-5/8" (50 cm)

ARROWgard Evolution Antimicrobial PICC Kit

with Blue FlexTip® Catheter, Placement Wire,

Sharps Safety Features and Maximal Barrier Precautions

Qty: 5

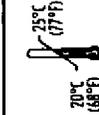
Contains Medication

Storage Requirements: Store between 20 - 25°C (68 - 77°F).

Avoid freezing, excessive heat above 40°C (104°F)

and humidity above 75% RH.

LOT



STERILE



Single use - do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

1202 Version 0 (2/10)

1202

1409

Sterile Medical Supplies

ARROW

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605 USA

PB-05000-002A (6/98)

REF CDC-45052-HPK1A

LATEX-FREE

5.5 Fr. x 19-5/8" (50 cm)

ARROWgard Evolution Antimicrobial PICC Kit

with Blue FlexTip® Catheter, Placement Wire,

Sharps Safety Features and Maximal Barrier Precautions

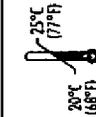
Qty: 5

Contains Medication

Storage Requirements: Store between 20 - 25°C (68 - 77°F).

**Avoid freezing, excessive heat above 40°C (104°F)
and humidity above 75% RH.**

LOT



Single use - do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

1203

Version 0 (2/10)

1203

1410

PG-05000-002A (6/98)

Sterile Medical Supplies

ARROW

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605 USA

REF CDC-45541-HPK1A

LATEX-FREE

4.5 Fr. x 21-21/32" (55 cm)

ARROWgard Evolution Antimicrobial PICC Kit

with Blue FlexTip® Catheter, Placement Wire,

Sharps Safety Features and Maximal Barrier Precautions

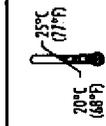
Qty: 5

Contains Medication

Storage Requirements: Store between 20 - 25°C (68 - 77°F).

Avoid freezing, excessive heat above 40°C (104°F) and humidity above 75% RH.

LOT



STERILE



Single use - do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

1204

Version 0 (2/10)

1204 1411

Sterile Medical Supplies

ARROW

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605 USA

FB:05000-002A (6/98)

REF CDC-45552-HPK1A

LATEX-FREE

5.5 Fr. x 21-21/32" (55 cm)

ARROWgard Evolution Antimicrobial PICC Kit

with Blue FlexTip® Catheter, Placement Wire,

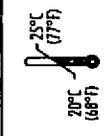
Sharps Safety Features and Maximal Barrier Precautions

Qty: 5

Contains Medication

**Storage Requirements: Store between 20 - 25°C (68 - 77°F).
Avoid freezing, excessive heat above 40°C (104°F)
and humidity above 75% RH.**

LOT



STERILE EO



Single use - do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

1205 Version 0 (2/10)

1205 1412

ATTACHMENT 7

Predicate Device Labeling

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Attachment 7

List of Documents

1. Instructions for Use
3. Lidstocks
4. Checklists
5. Pressure Injectable Information
6. Corrugate Labels

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Attachment 7
Predicate Device Labeling

Single and Double
Lumen Pressure
Injectable PICC
Labeling

1415



Pressure Injectable PICC Product

Venous Access | Critical Care

ARROW.

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An issued or revision date for these instructions is included for user information. In the event two years have elapsed between this date and product use, the user should contact Arrow International, Inc. to see if additional product information is available.

Revised Date: June 2008

Rx only.

1417

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For convenience, procedural and general Warnings and Precautions are listed at the beginning of the instructions. Please review all content before performing the procedure.

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For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with central venous access refer to Arrow International, Inc. website: www.arrowintl.com

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Pressure Injectable Peripherally Inserted Central Catheter (PICC) Product

Product Description

The Arrow® Pressure Injectable PICC is a peripherally inserted central venous catheter (PICC) manufactured with medical grade, flexible polyurethane. The Arrow® PICC has a non-tapered catheter body with either a blunt tip or a Blue FlexTip® that is softer than a cut tip with a contour design to enhance maneuverability. The Blue FlexTip® also provides visual confirmation of an intact catheter upon removal. The kit components assist the clinician in maintaining maximal sterile barrier precautions.

Indications:

The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, and power injection of contrast media. The maximum pressure of power injector equipment used with the pressure injectable PICC may not exceed 300 psi.

Contraindications:

This device is contraindicated wherever there is presence of device related infections, previous or current thrombosis. Clinical assessment of patient must be completed to ensure no contraindications exist.

Pressure Injection

Warnings and Precautions:

Warnings:

1. Assess each patient for appropriateness of a power injection procedure.
2. Power injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
3. Use an appropriate method to confirm catheter tip position prior to each pressure injection per institutional policy.
4. Ensure patency of catheter prior to power injection to minimize the risk of catheter failure and/or patient complications.
5. Discontinue power injections at first sign of infiltration / extravasation. Follow hospital protocol for appropriate medical intervention.

Cautions:

1. Do not exceed the maximum pressure of 300 psi on power injector equipment to minimize the risk of catheter failure and/or tip displacement.
2. Do not exceed the catheter's maximum recommended flow rate located on product labeling to minimize the risk of catheter failure and/or tip displacement.

3. Warm contrast media to body temperature prior to power injection to minimize the risk of catheter failure.
4. Pressure limit settings on power injector equipment may not prevent over pressurization of an occluded catheter.
5. Use an appropriately rated 60 inch pressure tubing between catheter and power injector equipment to minimize the risk of catheter failure.
6. Follow the specified contrast media manufacturer's instructions for use, warnings, precautions, and contraindications.

Pressure Injection Procedure:

NOTE: Clinicians should use sterile technique when flushing, disconnecting, connecting, and replacing injection/needleless caps.

1. Use an appropriate method to confirm each tip placement prior to each pressure injection per institutional policy.
2. Remove injection cap from the lumen of catheter to be injected.
3. Check for catheter patency:
 - Attach 10 mL syringe, or larger, filled with sterile normal saline.
 - Aspirate catheter until approximately 3 mL of blood enters syringe freely.
 - Vigorously flush catheter.

Warning: Ensure catheter patency prior to pressure injection to minimize the risk of catheter failure and/or patient complications.

4. Detach syringe.
5. Attach power injection equipment and extension tubing to lumen of catheter according to manufacturer's recommendations.

Caution: To minimize risk of catheter failure and/or tip displacement:

- Do not exceed the maximum pressure of 300 psi on power injector equipment.
- Do not exceed the catheter's maximum recommended flow rate located on product labeling.

6. Inject contrast media in accordance with hospital protocol.

Caution: Warm contrast media to body temperature prior to power injection to minimize the risk of catheter failure.

7. Disconnect catheter from power injector equipment.
8. Flush catheter with a 10 mL syringe, or larger, filled with sterile normal saline.
9. Replace sterile injection cap on catheter.

NOTE: Catheter testing included 10 pressure injection cycles.

1420

Peripherally Inserted Central Catheter

Warnings and Precautions:

Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Figure 1).



Figure 1

General Warnings and Precautions

Warnings:

1. Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
2. Practitioners must be aware of complications associated with central vein catheters including but not limited to: cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, and dysrhythmias.
3. Practitioners must be aware of clinical conditions that may limit use of PICCs including but not limited to: dermatitis, cellulitis, and burns at or about the insertion site, previous ipsilateral venous thrombosis, radiation therapy at or about insertion site, contractures, mastectomy, and potential use for AV fistula.
4. Do not place central venous catheter (CVC) or peripherally inserted central catheter (PICC) into or allow them to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with hospital protocol must show catheter tip located in right side of mediastinum in the SVC (superior vena cava) above its junction with right atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of guidewire into the heart has also been implicated in causing cardiac perforation and tamponade.
5. Ensure catheter tip has not entered the heart or no longer lies parallel to vessel wall by performing an x-ray exam or other method in compliance with hospital protocol. If catheter position has changed, immediately re-evaluate.
6. Practitioners must be aware of the potential for entrapment of guidewire by any implanted device in circulatory system (i.e., vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of guidewire inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of guidewire entrapment.
7. Catheter tip must be located in central circulation when administering > 10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with pH less than 5 or greater than 9, and infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
8. Infusion of incompatible drugs through a non "staggered port" may cause precipitation.
9. Be aware of the risk of chemically induced thrombophlebitis when catheter is placed with distal end located in a vessel proximal to the SVC.
10. Do not leave open needles or uncapped, undamped catheters in central venous puncture site. Air embolism can occur with these practices.
11. Use only securely tightened Luer-Lock connections with any Central Venous Access Device (CVAD) to guard against inadvertent disconnect.
12. Use Luer-Lock connectors to help guard against air embolism and blood loss.

Cautions:

1. The product is designed for single use only.
2. Do not resterilize or reuse.
3. Do not use if package has been previously opened or damaged.
4. Do not alter the catheter, guidewire, or any other kit/set component during insertion, use, or removal (except as instructed).
5. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
6. Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.
7. Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential

- risk to promote fungal infections and antimicrobial resistance.
8. Temporarily shut off remaining port(s) through which solutions are being infused before blood sampling.
 9. Blood aspirate color is not always a reliable indicator of venous access.
 10. Do not reinsert needle into introducer catheter to minimize the risk of catheter embolism.
 11. Retract scalpel to protected position when not in use to minimize the risk of sharps injury.
 12. Perform hand hygiene before and immediately after all clinical procedures and before and after donning and removal of gloves.
 13. Properly dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood borne pathogens and/or institutional policy.
 14. Hands must remain behind the needle at all times during use and disposal.
 15. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.
8. Do not attempt to advance or reinsert placement wire (where provided) into catheter, through the septum, if placement wire has been removed prior to catheter insertion. Attempting placement wire advancement or reinsertion increases the risk of damaging catheter or wire.
 9. Do not clamp extension line(s) when placement wire is in catheter to minimize the risk of placement wire kinking.
 10. Slide clamp(s), where provided, may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove slide clamp(s) when not in use.

Cautions:

Catheter Warnings and Precautions

Warnings:

1. For high pressure injection applications, only utilize catheters indicated for such applications. Catheters not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.
 2. Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.
 3. Do not secure, staple, and/or suture directly to outside diameter of catheter body or extension lines to minimize the risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
 4. Do not cut catheter to alter catheter length unless procedure requires it.
 5. Catheter clamp and fastener (where provided) must not be attached to catheter until either guidewire or placement wire is removed.
 6. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
 7. Catheter clamp must be opened prior to infusion to minimize risk of damage to extension line(s) from excessive pressure.
1. Check ingredients of prep sprays and swabs before using. Some disinfectants used at catheter insertion site contain solvents which can attack the catheter material. Alcohol and acetone can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.
 - Acetone: Do not use acetone on catheter surface.
 - Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency.
 Take care when instilling drugs containing high concentration of alcohol. Allow insertion site to dry completely prior to applying dressing.
 2. Do not use syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi), to minimize the risk of pressure induced damage to catheter.
 3. Prior to attempting a catheter exchange procedure, remove catheter clamp and fastener (where provided).
 4. Do not exert excessive force while removing the catheter, to minimize the risk of catheter breakage.
 5. Continuously monitor indwelling catheters for:
 - desired flow rate
 - security of dressing
 - adherence of stabilization device to skin and connection to catheter
 - correct catheter position; use centimeter markings to identify if catheter position has changed
 - secure Luer-Lock connection
 6. Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.
 7. Provide strain relief of catheter under dressing to decrease catheter movement and assist in maintaining proper catheter tip position.
 8. Inject a small amount of radiopaque dye to locate catheter tip if difficulty is encountered in visualizing the catheter tip.

Placement Wire & Guidewire / SWG Warnings and Precautions

Warnings:

1. Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
2. Do not cut guidewire to alter length.
3. Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.
4. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.
5. Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel wall, atrial, or ventricular.
6. Do not apply undue force on guidewire to minimize the risk of possible breakage.
7. Do not apply excessive force in removing guidewire or catheter. If withdrawal cannot be easily accomplished, a visual image should be obtained and further consultation requested.
8. Do not cut guidewire with scalpel.
 - Position cutting edge of scalpel away from guidewire.
 - Retract blade of safety scalpel to protected position once cutaneous puncture site is enlarged, to minimize the risk of cutting the guidewire.
9. Remove placement wire and Luer-Lock sidearm assembly as a unit. Failure to do so may result in wire breakage.

Caution:

1. Maintain a firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.

Tissue Dilator Warnings

Warnings:

1. Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.
2. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.

Peel-Away Sheath over Tissue Dilator Precaution

Caution:

1. Do not withdraw dilator until sheath is within vessel to minimize the risk of damage to sheath tip.

Possible Complications:

- cardiac tamponade secondary to vessel wall, atrial or ventricular perforation
- pleural injury
- air embolism
- catheter embolism
- bleeding / hemorrhage
- bacteremia
- thrombosis
- hematoma
- brachial plexus injury
- fibrin sheath formation
- vessel erosion
- mediastinal injury
- nerve injury
- thoracic duct laceration
- occlusion
- septicemia
- inadvertent arterial puncture
- dysrhythmias
- exit site infection
- phlebitis
- catheter tip malposition

Accessory Component Instructions

Review the list of components that will be utilized before beginning the Arrow® Pressure Injectable PICC insertion procedure. Kits / Sets may not contain all accessory components detailed in this section. Become familiar with instructions for each individual component(s) before beginning the actual PICC insertion procedure.

The following components are listed alphabetically.

Catheter Stabilization Device:

STATLOCK® Catheter Stabilization Device should be used in accordance with manufacturer's instructions for use.

- Cleanse and prep anticipated dressing site per hospital/agency protocol. Skin prep should be applied to coat skin and maximize STATLOCK® adherence. Allow to dry thoroughly. The anchor pad will be placed so center of pad is within 1 to 1-1/2 inches (2.5 to 3.8 cm) of catheter insertion site.
- The catheter can be secured to STATLOCK® by using the primary suture hub.

Caution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.

- Place suture hub wings over STATLOCK® posts and press down (refer to Figure 2). Snap STATLOCK® retainer wings to closed position to secure suture hub (refer to Figure 3).

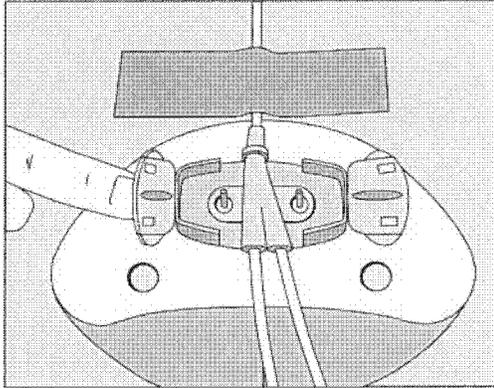


Figure 2

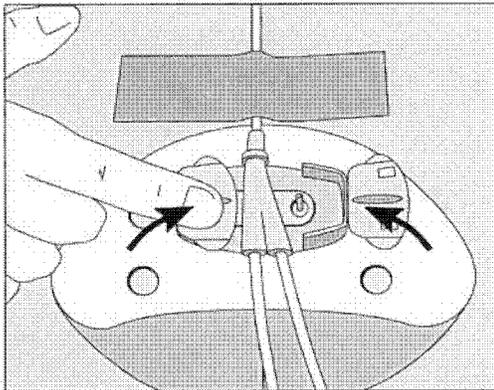


Figure 3

- Remove paper backing from one half of STATLOCK® Catheter Stabilization Device pad and press onto dry, prepared skin. Repeat process for other half of STATLOCK®.
- Complete sterile insertion site dressing according to established hospital/agency protocol.
- Document STATLOCK®/dressing application on patient's chart.
- Replace STATLOCK®/dressing per hospital/agency protocol. STATLOCK® Catheter Stabilization Device should be replaced at least every 7 days to ensure maximum adherence.

Catheter Trimmer:

NOTE: There should be very limited resistance when cutting catheter with supplied trimmer. Any greater resistance is likely to be caused by the placement wire – which has not been sufficiently retracted. If so, do not use catheter.

Catheter Trimmer is a one time use trimming device.

- To trim catheter with Catheter Trimmer, retract placement wire 1-1/2 inches minimum (4 cm) behind where catheter is to be cut. The placement wire is to be withdrawn through septum (see Figure 4).

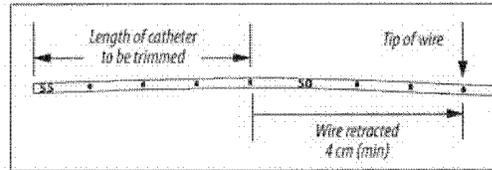


Figure 4

- Kink proximal end of placement wire at connector with side-port (see Figure 5). This minimizes the risk of placement wire extending beyond distal tip of catheter during insertion. (Do not attempt to advance placement wire through septum.)

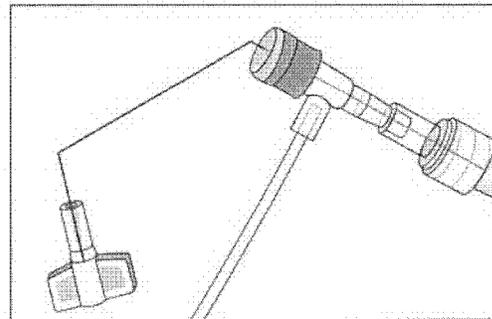


Figure 5

- Peel back contamination guard exposing catheter portion to be trimmed. Using trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

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Dressing:**Tegaderm™ IV Transparent Dressing:**

- Prepare site. Allow all preps to dry completely.
- Peel liner from dressing to expose adhesive.
- Adhere center of transparent window over insertion site, while holding notched portion off the skin (refer to Figure 6).

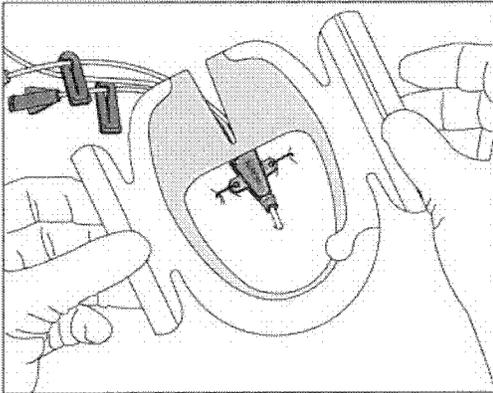


Figure 6

- Overlap softcloth tabs under catheter to form a tight seal around catheter hub and lumens (refer to Figure 7).

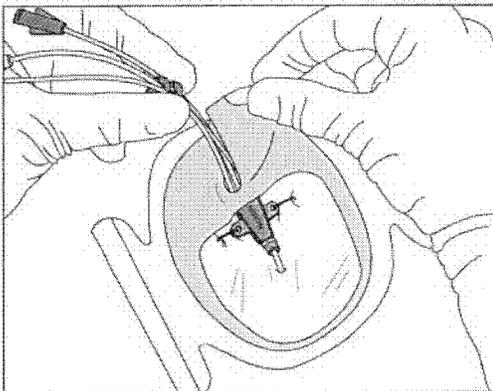


Figure 7

- Press dressing into place.
- Slowly remove frame while smoothing down dressing edges. Smooth dressing from center toward edges, use firm pressure to enhance adhesion (refer to Figure 8).

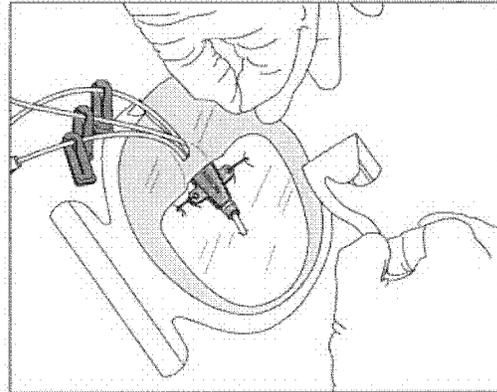


Figure 8

- Use sterile tape strips to secure hub, lumens, and/or tubing (refer to Figure 9).

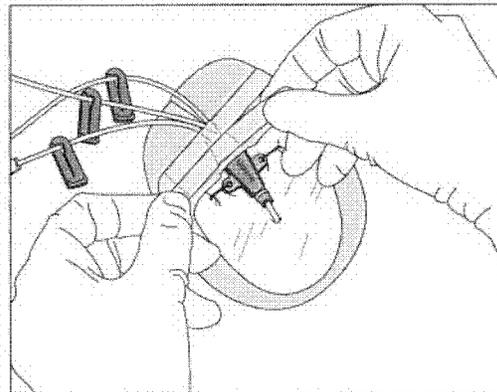


Figure 9

- Label dressing according to protocol.

Refer to individual manufacturer's instructions for more information and specific detailed instructions for dressing removal.

Echogenic Needle:

An echogenic needle is used to provide greater needle visibility under ultrasound. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Filter Straw:

A filter straw is utilized to aspirate solution from glass ampule (5 micron) and minimize the risk of glass particulate from entering the solution.

- Open glass ampule using appropriate sterile and sharps protection technique.
- Attach filter straw to syringe.
- Insert filter straw into ampule.
- Aspirate contents from ampule.
- Remove and discard filter straw.
- Attach appropriate needleless connector or cannula to syringe.
- Purge air from syringe.
- Label syringe appropriately.

Guidewire / SWG Insertion Techniques:

Kits/Sets are available with a variety of Guidewires/SWGs. Guidewires are provided in different diameters, lengths, and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique chosen, before beginning the actual PICC insertion procedure.

Image guidance may be used to gain initial venous access.

Catheter Insertion with an 80 cm Guidewire:

Use single 45 cm guidewire for venous access and 80 cm soft tip guidewire for catheter placement. Image guidance or fluoroscopy is used to gain initial venous access; catheter placement with 80 cm guidewire is done under fluoroscopy.

- Gain venous access with 45 cm guidewire and peel-away sheath.
- Load PICC onto 80 cm guidewire until soft tip of wire extends beyond tip of catheter.
- While maintaining control of distal end of guidewire, advance soft tip/catheter tip as a unit through peel-away sheath to desired depth.
- Once catheter is in desired location, remove guidewire.

Catheter Insertion with an 130 cm Guidewire:

Use single 45 cm guidewire for venous access and 130 cm soft tip guidewire for catheter placement. Image guidance or fluoroscopy is used to gain initial venous access; catheter placement with 130 cm guidewire is done under fluoroscopy.

- Gain venous access with 45 cm guidewire.
- Insert soft end of 130 cm guidewire through peel-away sheath to desired depth.
- Thread catheter over guidewire and advance catheter over guidewire through sheath into vessel into correct position.
- Once catheter is in desired location, remove guidewire.

NOTE: Some clinicians will gain access with 130 cm guidewire and thread catheter over guidewire once wire has been correctly positioned in the SVC. This technique is done under fluoroscopy.

Maximal Barrier Drape:

Drape(s) provide a maximal sterile barrier. Follow CDC Category 1A Recommendation.

- Drape provided is either:
 - Single extra-large drape with fenestration.
 - Two-piece drape consisting of an arm drape with fenestration and a body drape. The body drape is used to appropriately drape torso and upper-lower extremities.
- Unfold the Maximal Barrier Drape:
 - Peel off fenestration backing (refer to Figure 10).

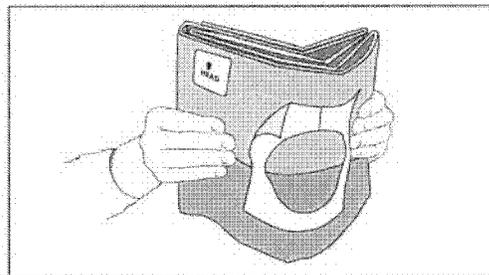


Figure 10

- Position fenestration over intended insertion site (refer to Figure 11).

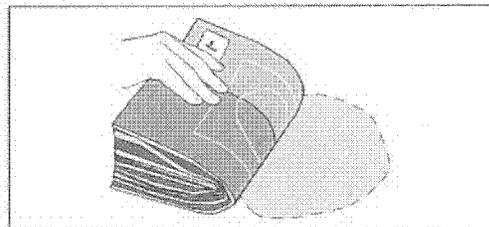


Figure 11

- Unfold width (refer to Figure 12).

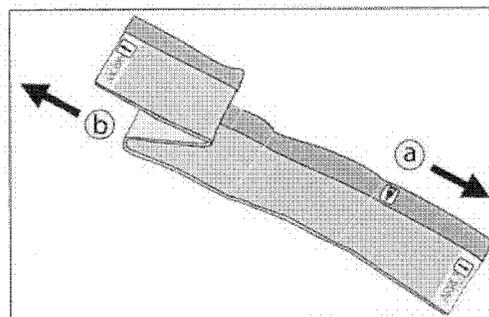


Figure 12

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- Unfold towards head (refer to Figure 13).

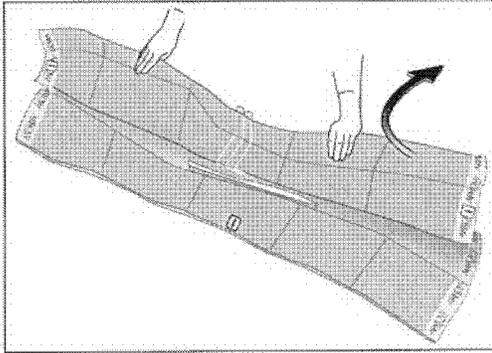


Figure 13

- Unfold towards hand (refer to Figure 14).

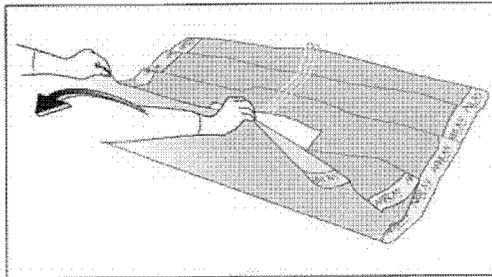


Figure 14

- Perform sterile procedure (refer to Figure 15).

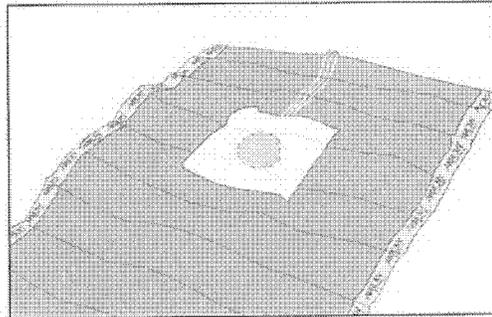


Figure 15

- Removal procedure: Tear along seam (refer to Figure 16).

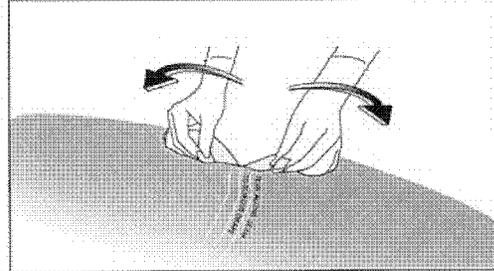


Figure 16

Positive Displacement Valve:

Positive displacement valves are needle-free injection ports utilized to minimize the risk of reflux of blood back into the catheter. Upon disconnection of syringe, a positive displacement of fluid will occur.

- Cleanse connector utilizing an appropriate antiseptic and friction prior to each use.
- Flushing should be done with an appropriately sized syringe.

Refer to individual manufacturer's instructions for specific details for priming volumes, dead space and flow rates.

CLC2000® Connector:

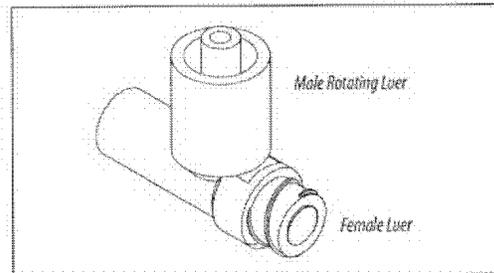


Figure 17

- Using aseptic technique remove CLC2000 from the package. Remove protective cap. Do not contaminate.
- Attach a syringe or administration set to female luer and prime CLC2000 in accordance with facility protocol. Invert device to expel air.
- Attach male rotating luer of CLC2000 to desired extension set or venous access device. Push and twist male rotating luer of CLC2000 into device until tight. Once the CLC2000 is secure, it may be rotated to achieve the most comfortable position on the patient's skin.

- To access CLC2000 swab female luer with desired disinfectant in accordance with facility protocol.
- Attach a fully primed syringe or administration set to CLC2000. Push and twist male luer of device into CLC2000 until tight. If using a rotating luer device, first push and twist Luer-Slip into CLC2000 until tight, then lock down the spin collar. This will ensure a secure connection and optimal flow rates.
- To disconnect from CLC2000, grasp CLC2000 and twist syringe or administration set away from CLC2000 until loose. **DO NOT CLAMP** catheter or extension set while disconnecting syringe or administration set from CLC2000, as it will interrupt the positive displacement.
- Flush the CLC2000 after each use with normal saline or in accordance with facility protocol.
- For subsequent connections repeat from step four.

Caution: **DO NOT USE NEEDLES** in the CLC2000.

Caution: **DO NOT CAP CLC2000**, device is closed.

Caution: **DO NOT CLAMP** the catheter prior to disconnecting a syringe from the CLC2000 as this will interrupt the positive displacement.

CLC2000 is exclusively manufactured by ICU Medical, Inc., San Clement, CA 800-824-7890 949-366-2183 | www.icumed.com

Protected Needle:

See individual manufacturer's instructions for product use, when used as a single product and not as a kit component.

Warning: Hands must remain behind needle at all times during use and disposal.

Caution: Make sure all needles are used in accordance with OSHA and hospital safety protocols.

Caution: Do not attempt to override or defeat the safety locking mechanism of a protected needle.

Caution: Discard in an approved sharps collector in accordance with applicable regulations and institutional policy.

SafetyGlide® Protected Needle:

- Aspirate medication into syringe using aseptic technique.
- If necessary to transport filled syringe to point of administration, use safe, passive recapping technique to cover needle before transport to point of use. In accordance with OSHA standards, such recapping must be accomplished by a one-handed technique, i.e., do not hold needle shield during recapping process.
- Administer injection following established technique.
- Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 18).

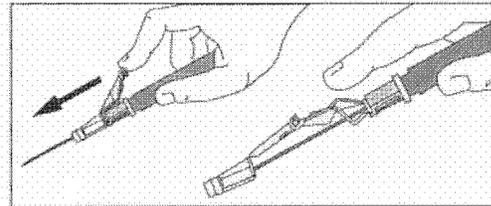


Figure 18

- Visually confirm lever arm has fully advanced and needle tip is covered. If unable to activate, discard immediately into approved sharps collector.
- Activation of protective mechanism may cause minimal splatter of fluid that may remain on needle after injection.
- After single use, discard in an approved sharps collector in accordance with applicable regulations and institutional policy. For greatest safety, use a one-handed technique and activate away from self and others.

SharpsAway II™ Locking Disposal Cup:

The SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 19).

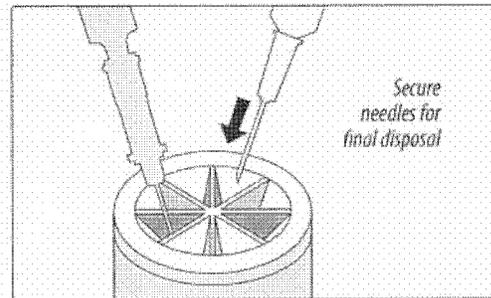


Figure 19

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.
- Discard entire cup, at completion of procedure, into an approved sharps container.

Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

Caution: Do not re-use needles after they have been placed into the foam SharpsAway® system. Particulate matter may adhere to needle tip.

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Pre-PICC Insertion & Patient Assessment Activities

Perform hand hygiene as required.

A procedural checklist is included on back of product label.

Ⓡ Procedural Pause:

1. Verify physician order:

- Confirm correct patient.
- Confirm correct diagnosis.
- Confirm correct procedure.

Physician order must include post placement assessment of catheter tip placement (x-ray exam or other method in compliance with hospital protocol).

2. Patient education: Explain procedure to patient. Make sure information is presented with respect to patient's level of understanding, culture, and language.

3. Have informed consent signed, if required.

4. Identify insertion vein:

- Apply tourniquet above anticipated insertion vein.
- Identify appropriate vein for insertion. Use direct visualization technologies, if available, and assess vein health.

NOTE: PICCs are typically inserted into basilic, brachial, or cephalic veins (refer to Figure 20).

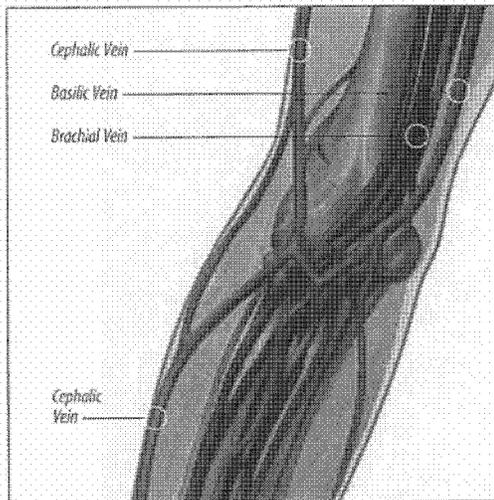


Figure 20

5. Release tourniquet and leave in place beneath the arm.
6. Measure patient to assure placement of catheter in the SVC:
 - Extend arm laterally 45 to 90 degrees from trunk.
 - Measure distance from insertion site along presumed anatomical course of vessel to be catheterized.
 - Catheter tip should lie in distal one-third of SVC above right atrium and parallel to SVC wall.
 - If a catheter stabilization device will be used, add 1/2 to 1 inch (1.2 to 2.5 cm) to catheter measurement (STATLOCK®); if another device is used, check manufacturer recommendations.
 - If using upper arm circumference assessment; for consistency in measurement, measure from an anatomical point and record.
7. Position patient as appropriate for insertion site:
 - Extend arm laterally 45 to 90 degrees from trunk.
8. Prepare work area.

Preparing for PICC Insertion:

- Perform hand hygiene as required:
 - before and immediately after all clinical procedures
 - before and after donning and removal of gloves
- Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.
- Handle and dispose of sharps appropriately in accordance with state/federal OSHA standards for blood borne pathogens and/or institutional policy.
- Clinicians should use sterile technique, maximal sterile barrier precautions throughout the procedure, and dress in protective clothing:
 - mask
 - sterile gown
 - hair cover
 - eye protection
 - sterile gloves

Prep Puncture Site:

1. Prep and drape peripheral puncture site.
2. Perform skin wheal with a local anesthetic as needed.
3. In kits where provided, the SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

Prepare All Equipment:

Prepare Catheter with Placement Wire for Insertion (where provided) (refer to Figure 21).

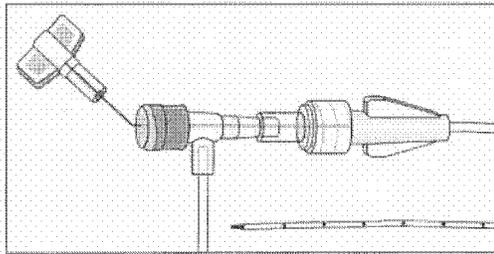


Figure 21

- Remove catheter tip protector.

Trim Catheter:

If necessary, review detailed instructions for Catheter Trimmer device under Accessory Component Instructions section.

1. Identify catheter type:
 - BFT (Blue Flex Tip™)
 - Non-BFT
2. Peel back contamination guard exposing catheter portion to be trimmed.
3. Review catheter marking pattern below. The catheter is marked so clinician can easily identify desired amount of catheter to be trimmed; length of catheter that remains or as with BFT catheter – both.
 - BFT double numbering pattern:

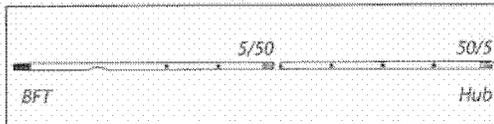


Figure 22

- ◊ First number designates centimeters from tip of catheter.
- ◊ Second number designates centimeters from hub of catheter.
- ◊ This double numbering pattern permits clinician to easily identify centimeters of catheter to be trimmed and also identifies centimeters of catheter remaining.
- ◊ Record both numbers.
- Non-BFT numbering pattern:

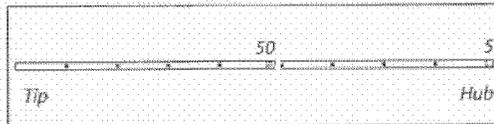


Figure 23

- ◊ Number designates centimeters of catheter to be trimmed and also gives amount of catheter remaining.

4. Using the trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip. **NOTE: There should be very limited resistance when cutting catheter with supplied trimming device. If using a catheter with a placement wire, any greater resistance is likely to be caused by the placement wire which has not been sufficiently retracted. If so, do not use catheter.**

5. Inspect cut surface for clean cut and no loose material.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Flush Catheter:

1. Use filter straw to withdraw solution from glass ampules.
2. Attach syringe to sidearm and flush distal lumen with sterile saline solution. Leave syringe in place.
3. Flush remaining lumen(s) with sterile saline. Clamp or attach injection site cap(s) to extension line(s) to contain saline within lumen.

Catheter Insertion Instructions

1. Reapply tourniquet and replace sterile gloves.
2. Locate vein for insertion:
 - Use image guidance, if available.
 An echogenic needle is included for access.
3. Insert introducer needle into vein. Check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

Caution: The color of blood observed is not always a reliable indicator of venous access.

Gain Initial Venous Access:

See specific guidewire instructions, Guidewire Insertion Techniques (page 7) under Accessory Component Instructions section.

1. Insert soft tip of guidewire through introducer needle into vein. Advance guidewire to desired depth.

Warning: Do not insert stiff end of soft tip guidewire into vessel as this may result in vessel damage.

Warning: Do not cut guidewire to alter length.

Warning: Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.

2. Remove needle: Hold guidewire in place while removing introducer needle.

Caution: Maintain firm grip on guidewire at all times.

3. Enlarge puncture site, if necessary: Use scalpel positioned away from the guidewire to enlarge cutaneous puncture site. Do not cut guidewire. Retract scalpel to the protected position.

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Sheath Placement:

1. Thread tapered tip of peel-away sheath/dilator assembly over guidewire. Grasping near skin advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to further facilitate advancement of sheath into the vessel. A slight twisting motion of the peel-away might help sheath advancement.

Caution: Do not withdraw tissue dilator until the sheath is well within the vessel to minimize the risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

2. Check sheath placement by holding sheath in place, withdraw guidewire and dilator sufficiently to allow venous blood flow. Holding sheath in place, remove guidewire and dilator as a unit.

Warning: Do not leave the dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.

Warning: Do not apply undue force on guidewire to minimize the risk of possible breakage.

Catheter Advancement:

Advance catheter according to the guidewire used. Review detailed instructions for 80 cm and 130 cm guidewire usage (page 7) under Accessory Component Instructions section.

Warning: Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.

1. Retract catheter guard.
2. Insert catheter through peel-away sheath.
 - If resistance is met while advancing catheter, retract and/or gently flush while advancing.
3. Stop advancing catheter 5 inches (13 cm) before reaching pre-established insertion length.
4. Withdraw peel-away sheath over catheter until free from venipuncture site.
5. Grasp tabs of peel-away sheath and pull apart, away from catheter, until sheath splits down entire length.
6. Advance catheter to final indwelling position.

Placement Wire (where provided):

Caution: To minimize the risk of placement wire kinking, do not clamp extension line(s) when placement wire is in catheter.

1. Complete catheter insertion.
2. Remove placement wire.

Warning: Remove placement wire and Luer-Lock sidearm assembly as a unit (see Figure 24). Failure to do so may result in wire breakage.

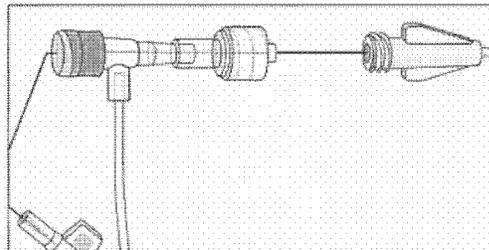


Figure 24

Caution: Catheter clamp and fastener (if provided and used) must not be attached to catheter until either guidewire or placement wire is removed.

Verify Catheter Tip Placement:

1. Examine tip of placement wire after removal to ensure wire has not been altered (see Figure 25).

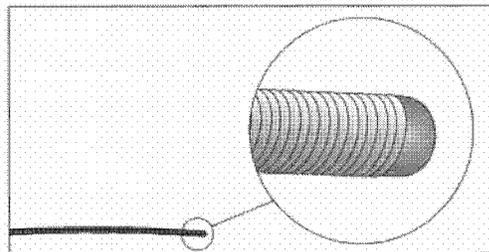


Figure 25

2. If there is any indication placement wire is damaged, catheter and placement wire should be removed together.
3. Check catheter placement with syringe by aspirating through distal lumen until free flow of venous blood is observed.

Caution: The color of blood is not always a reliable indicator of venous access.

Complete Catheter Insertion:

1. Flush lumen(s) to completely clear blood from catheter.
2. Connect extension line(s) to appropriate Luer-Lock line. Alternately, port(s) may be "locked" through injection cap(s) using standard hospital/agency protocol. Slide clamp(s) is provided on extension line to occlude flow through lumen during line and injection cap changes.

Warning: Slide clamp(s), where provided, may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove slide clamp(s) when not in use.

- Cleanse insertion site per hospital/agency protocol.

Caution: Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.

- Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.
- Secure catheter. Where provided, a catheter clamp, fastener, catheter stabilization device or Steri-Strip® may be used.
- Assess placement of catheter tip in compliance with hospital protocol.

Documentation

Institutions must establish a permanent medical record that documents the entire procedure, based upon their policy, procedures, and Best Practices. The actual format can differ from institution to institution. Report any product defects/failures to organization risk management, manufacturers, and appropriate regulatory agencies.

Documentation generally includes (but is not limited to) the following information:

- Device specifics:
 - type, brand and lot number
 - length and size of Vascular Access Device (VAD)
 - internal/external catheter length
 - whether catheter is trimmed
- Procedure specifics:
 - time out or procedural pause
 - informed consent, as required
 - date, time of insertion, insertion site, number and site attempts, inserter's identification
 - use of visualization and guidance technologies
 - site preparation and technique
- Patient assessment and response:
 - pertinent dx, assessment, vital signs
 - understanding of procedure, patient's response to procedure
 - complications and barriers to care
- Therapy specifics:
 - type of therapy, drug dose, rate, time
 - route and method of administration
 - laboratory specimen collected
- Visual confirmation:
 - verification of appropriate tip location prior to initial use
- Monitor patient for post catheter insertion complications.

Care and Maintenance

Dressing:

Replace dressing according to organizational policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened, or no longer occlusive.

- Consult manufacturer's recommendations for dressing specifics.
- Transparent semipermeable membrane dressing should be changed every 7 days.
- Gauze and tape should be changed every 48 hours.
- Label dressing with type, size, and length of catheter; date and time; and initials of the clinician performing dressing change.

Maintain Catheter Patency:

Maintaining central venous catheter patency shall be done in accordance with organizational policies, procedures, and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Perform hand hygiene as required.

- Solution and frequency of flushing a venous access catheter should be established in hospital/agency policy.
- Catheter patency is established and maintained by:
 - flushing intermittently via syringe with heparinized saline or preservative-free 0.9% sodium chloride (USP)
 - continuous drip
 - positive pressure device
- The amount of heparin:
 - depends on physician preference,
 - hospital/agency protocol,
 - patient condition

Caution: Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.

- The volume of flush solution should be:
 - equal to at least twice the priming volume of the catheter and any add-on devices

Catheter priming volume is printed on product packaging.
- When using any central venous catheter for intermittent infusion therapy, proper flushing (heparinization) using a positive-pressure flushing technique will help prevent occlusion. Neutral as well as positive displacement valve systems have also been shown to help prevent occlusion.
- All valves need to be properly cleansed with an appropriate antiseptic before being accessed.
- The SASH or SAS method of flushing will help eliminate occlusions due to incompatible solutions:
 - Saline • Administer drug • Saline • Heparin (if used)

1432

Catheter Removal Procedure

1. PICC removal shall be performed:
 - following order of authorized prescriber
 - in accordance with organizational policies, procedures, and practice guidelines
2. A PICC shall be removed immediately upon patient assessment for:
 - suspected contamination
 - unresolved complication
 - discontinuation of therapy

3. As indicated, place patient in supine position to minimize the risk of potential air embolism.

4. Remove dressing.

Warning: Do not use scissors to remove dressing, to minimize the risk of cutting catheter.

5. Open catheter stabilization device retainer wings and remove catheter from catheter stabilization device posts.

6. Remove catheter by slowly pulling it parallel to skin. If resistance is met when removing the catheter, catheter should not be forcibly removed and the physician should be notified.

Caution: Do not exert excessive force while removing the catheter, to minimize the risk of catheter breakage.

7. Upon removal of catheter:

- measure and inspect
- ensure entire catheter length has been removed

8. Direct pressure should be applied at site until hemostasis is achieved.

9. Apply alcohol swab to catheter stabilization device adhesive and gently lift pad off of skin (if applicable).

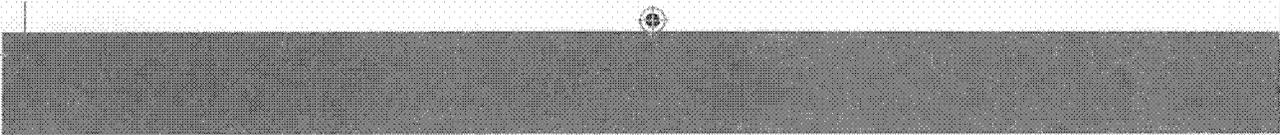
10. Dress insertion site. Sterile occlusive dressing should be applied and site assessed every 24 hours until site is epithelialized. Residual catheter track may remain an air entry point until completely sealed (usually 24 to 72 hrs); dependent upon amount of time catheter was indwelling.

11. Document catheter removal procedure on patient's chart per hospital/agency protocol.

Include:

- catheter condition
- length of catheter removed
- patient's tolerance of the procedure
- any nursing interventions needed for removal

For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with central venous access refer to Arrow International, Inc. website: www.arrowintl.com



2400 Bernville Road, Reading, PA 19605 USA | 1-800-523-8446 1-610-378-0131 | 8 a.m. - 8 p.m. EST | www.arrowintl.com

STERILE EO

A-06041-102D (6/08)

ARROW
INTERNATIONAL

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6/4/2008 11:19:27 AM

1434

1227

Pressure Injectable PICC Kit with Blue FlexTip® Catheter and Placement Wire



INFECTION PROTECTION FEATURES:

- BIOPATCH® Dressing
- ChloroPrep® One-Step skin antiseptic, 2% chlorhexidine gluconate in 70% isopropyl alcohol with Hi-Lite Orange™ Tint
- Drape Sheet
- Impervious Surgical Cap
- Bouffant Surgical Cap
- Surgical Mask with Eye Shield

MAXIMAL BARRIER PRECAUTIONS



SAFETY FEATURES:

- CLC 2000® Positive Displacement Catheter Connector
- SafetyGlide® Protected Needles
- SharpsAway II™ Locking Disposal Cup
- Safety Scalpel
- STATLOCK® Catheter Stabilization Device

PMS 259

40782815

PMS

SharpsAway II™ Locking Disposal Cup

4 Fr. x 21-21/32" (55 cm) Catheter with T-Port Connector and Placement Wire

25 Ga. x 5/8" (1.60 cm) Needle SafetyGlide® 3 mL Luer-Lock Syringe

21 Ga. x 1-1/2" (3.81 cm) RW Needle SafetyGlide®

15 Ga. x 2-3/4" (7 cm) Pre-Flush Sheath over 4 Fr. Dilator

10 mL Luer-Lock Syringe

10 mL Luer-Slip Syringe

0.18" (1.6 mm) dia. x 13-1/4" (35 cm) Spring-Wire Guide

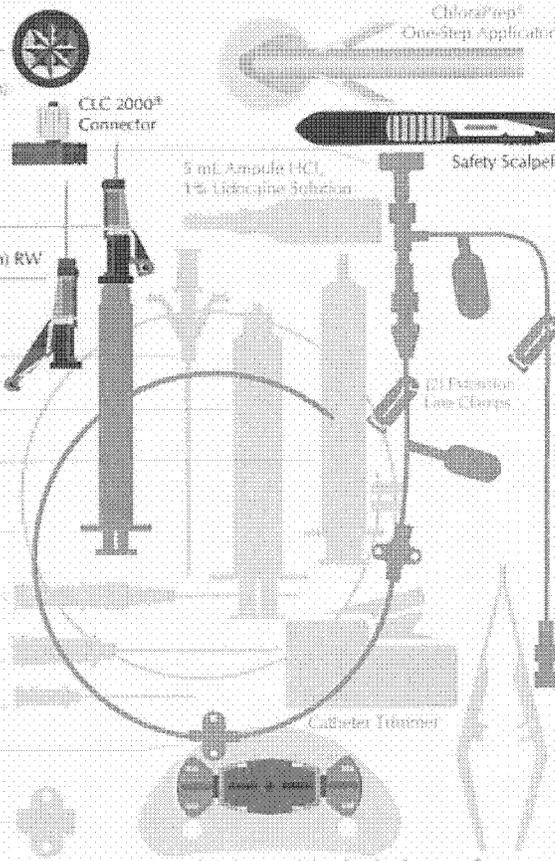
22 Ga. 1-3/4" (4.45 cm) Catheter Assembly

21 Ga. 2-3/4" (7.00 cm) TW Introducer Needle with Echogenic Tip

21 Ga. 1-1/2" (3.81 cm) TW Introducer Needle

Catheter Clamp

Clamp Fastener



STATLOCK® Catheter Stabilization Device

Maximal Barrier ARROW CDC-05541-HPK1A

- Contents:**
- One Indwelling Catheter: 4 Fr. x 21-21/32" (55 cm) Radiopaque Polyurethane with Blue FlexTip®, T-Port Connector, Extension Line Clamps, Injection Site Caps, Contamination Guard and Placement Wire
 - One Pre-Flush Sheath: 15 Ga. x 2-3/4" (7 cm) Radiopaque over 4 Fr. Dilator
 - One Spring-Wire Guide: 0.18" (1.6 mm) dia. x 13-1/4" (35 cm) (Straight Soft Tip on Both Ends)
 - One Catheter: 22 Ga. x 1-3/4" (4.45 cm) Radiopaque over 21 Ga. RW Introducer Needle

- One Injection Needle: SafetyGlide® 21 Ga. x 1-1/2" (3.81 cm) RW Introducer Needle: 21 Ga. x 1-1/2" (3.81 cm) TW
- One Introducer Needle: 21 Ga. x 2-1/4" (7 cm) RW with Echogenic Tip
- One Syringe: 10 mL Luer-Lock
- One Syringe: 10 mL Luer-Slip
- One Injection Needle: SafetyGlide® 25 Ga. x 5/8" (1.60 cm) and 3 mL Luer-Lock Syringe

- One 3 mL Applicator Pouch, 2% CHG and 70% IPA ChloroPrep® One-Step Solution with Hi-Lite Orange™ Tint
- One Pouch: (1) 10 mL Pre-Filled Syringe, 0.9% Sodium Chloride®
- One Sterile Procedure Sign®
- One 5 mL Ampule PCl, 1% Lidocaine Solution
- One Medication Label: 1% Lidocaine
- One Post-Emulsified Pouch 2% Skin Protectant Prep Pad
- One Clamp: Catheter
- One Fastener: Catheter Clamp

- One SharpsAway II™ Locking Disposal Cup
- One Catheter Trimmer
- Three CSR Wraps
- One Drape: 36" x 41" with 3" x 5" Femestration
- One Drape: 60" x 76"
- One Towel: 24" x 36"
- One Filter: 5 Micron Straw
- One Tweezers

- One Safety Scalpel: #11
- One Chart Sticker®
- One Patient ID Card®
- One Patient Information Booklet®
- One Dressing: BIOPATCH®
- One Dressing: STATLOCK® Catheter Stabilization Device

- One Dressing: Tegaderm™ 15.5 cm x 10 cm
- Five Gauze Pads: 2" x 2"
- Two Gauze Pads: 4" x 4"
- Two Paper Tape Measures (one packaged externally)
- One Surgical Apparel: Bouffant Cap
- One Surgical Apparel: Impervious Gown
- One Surgical Apparel: Mask with Eye Shield
- One Surgical Apparel: Mask®
- One Tourniquet®
- One Tape: Steri-Strip™

- One Valve: CLC 2000® Positive Displacement Connector
- One Clear Unit (see inside side)
- * A registered trademark of Becton, Dickinson and Company.
- * A registered trademark of Cardinal Health, Inc. or one of its subsidiaries.
- * U.S. Patent Nos. 5,121,193 and 6,270,727.
- * A registered trademark of Johnson & Johnson Corporation.
- * A registered trademark of 3M, Inc.
- * A registered trademark of 3M Corporation.
- * A registered trademark of ICI Medical, Inc.
- * Packaged separately on the inside kit.

- One Catheter Trimmer
- One Forceps

Rx only.

Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

Sterile. Do not use if package has been previously opened or damaged. Fluid path components are non-pyrogenic. Contains medication. Single use - do not re-sterilize. Sterilized by ethylene oxide.

Arrow International provides the enclosed medication label for your convenience. Please ensure that the label is applied to the correct syringe and corresponding medication.

Store between 20 - 25°C (68 - 77°F). This product contains N.O. natural rubber latex.



www.arrowintl.com

Catheter Diameter: 4 Fr., 1.4 mm
 Priming Volume: 0.5 mL
 Priming volumes are approximate and are done without the CLC 2000® Connector. CLC 2000® Connector priming volume is 0.05 mL.
 Flow Rate: 660 mL/hr
 Flow rates were determined per BS EN ISO 11635-3:1997, Annex A using room temperature water, 100 cm head height and segment appropriate flow characteristics.
 Pump Flow Rate: 4075 mL/hr
 Pump flow rates were determined at room temperature of 30°C.
 Max Pressure Injectable Flow Rate: 4 mL/sec
 Maximum injection flow rates were determined at the site for pressure setting of 300 cm H₂O maximum using fluids of 11.5 centipoise viscosity, with 60" pressure tubing.



4 Fr. | 55 cm catheter length | .018 inch dia. spring-wire guide

CDC-05541-HPK1A Pressure Injectable PICC Kit with Blue FlexTip® Catheter and Placement Wire

PMS 259 (6) (02) (04)

CDC-05541-1028-10002

1495

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____ Date of Birth (mm/dd/yy): ____/____/____
 First Name: _____ Male Female
 Last Name: _____ Notes: _____
 Location (unit/ward/bed): _____
 Insertion Site: Right Left Basilic Cephalic Brachial Other: _____
 Is this a NEW line? YES NO
 This procedure is: Elective Emergent Re-position Other: _____

Insertion Procedure Practices

Before Procedure, did the clinician:

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts/forms)
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands task if unsure?

YES YES N/A
after
reminder

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
- Other technique used: _____
- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No

After Procedure:

- Was sterile technique maintained applying dressing?
- Was dressing dated?

Name of Procedure Clinician (signature if applicable): _____
 Name of Procedure Assistant: _____
 Name of Procedure Auditor: _____
 Today's Date (mm/dd/yy): ____/____/____

Patient Label: _____

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI Initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance.

1436



Specific catheter manufacturer information is provided on reverse side of original document (including product size, description, and product number).

Pressure Injectable PICC Kit with Blue FlexTip® Catheter and Placement Wire



MAXIMAL BARRIER PRECAUTIONS

QUADRO SAFETY

INFECTION PROTECTION FEATURES:

- BIOPATCH® Dressing
- ChloroPrep® One-Step skin antiseptic, 2% chlorhexidine gluconate in 70% isopropyl alcohol with Hi-Lite Orange™ Tint
- Drape Sheet
- Impervious Surgical Gown
- Bouffant Surgical Cap
- Surgical Mask with Eye Shield

SAFETY FEATURES:

- CLC 2000® Positive Displacement Catheter Connectors
- SafetyGlide® Protected Needles
- SharpsAway II™ Locking Disposal Cup
- Safety Scalpel
- STATLOCK® Catheter Stabilization Device

Maximal Barrier

ARROW

CDC-05552-HPK1A

Contents:

- One: ... Two-Lumen Indwelling Catheter: 5 Fr. x 21-21/32" (55 cm) Radiopaque Polyurethane with Blue FlexTip®, T-Port Connector, Extension Line Clamps, Injection Site Cap, Coamination Guard and Placement Wire
- One: ... Pref-Away Sheath: 14 Ga. x 2-1/4" (7 cm) Radiopaque over 5 Fr. Dilator
- One: ... SpringWire Guide: .018" (1.45 mm) dia. x 13-1/8" (34 cm) (Straight Soft Tip on Both Ends)
- One: ... Catheter: 21 Ga. x 1-1/2" (4.45 cm) Radiopaque over 25 Ga. RW Introducer Needle
- One: ... Injection Needle: SafetyGlide® 21 Ga. x 1-1/2" (3.81 cm) RW
- One: ... Introducer Needle: 21 Ga. x 1-1/2" (3.81 cm) RW
- One: ... Introducer Needle: 21 Ga. x 2-1/4" (7 cm) TW with Echogenic Tip
- One: ... Syringe: 10 mL Luer-Lock
- One: ... Syringe: 10 mL Luer-Slip
- One: ... Injection Needle: SafetyGlide® 25 Ga. x 5/8" (1.60 cm) and 3 mL Luer-Lock Syringe
- One: ... 3 mL Applicator Pouch, 2% CHG and 70% IPA ChloroPrep™ One-Step Solution with Hi-Lite Orange™ Tint
- One: ... Pouch: (2) 10 mL Prefilled Syringes, 0.9% Sodium Chloride®
- One: ... Sterile Procedure Sign®
- One: ... Medication Label: 1% Lidocaine
- One: ... 5 mL Ampule HCl, 1% Lidocaine Solution
- One: ... Foil-Laminated Pouch 75% Skin Protectant Prep Pad
- One: ... Clasp Catheter
- One: ... Fastener Catheter Clamp
- One: ... SharpsAway II™ Locking Disposal Cup
- One: ... Catheter Trimmer
- Three: ... CSR Wraps
- One: ... Drape: 60" x 76"
- One: ... Drape: 36" x 41" with 3" x 5" Incision
- One: ... Towel: 24" x 36"
- One: ... Filter: 5 Micron Straw
- One: ... Forceps
- One: ... Safety Scalpel: #11
- One: ... Chart Sticker®
- One: ... Patient ID Card®
- One: ... Patient Information Booklet®
- One: ... Dressing: BIOPATCH®
- One: ... Dressing: STATLOCK® Catheter Stabilization Device
- One: ... Dressing: Tegaderm® 15.5 cm x 10 cm
- Five: ... Gauge Pads: 2" x 2"
- Two: ... Gauge Pads: 4" x 4"
- Two: ... Paper Tape Measures (one packaged externally)
- One: ... Surgical Apparel: Bouffant Cap
- One: ... Surgical Apparel: Impervious Gown
- One: ... Surgical Apparel: Mask with Eye Shield
- One: ... Surgical Apparel: Mask®
- One: ... Antimicrobial
- One: ... Tape: Steri-Strip®
- Two: ... Valves: CLC 2000® Positive Displacement Connector
- One: ... Check list (see reverse side)

1. A registered trademark of Becton, Dickinson and Company.
 2. A registered trademark of Cardinal Health, Inc. or one of its subsidiaries.
 3. U.S. Patent Nos. 5,123,195 and 6,079,577.
 4. A trademark of Johnson & Johnson Corporation.
 5. A registered trademark of C. R. Bard, Inc.
 6. A registered trademark of 3M Company.
 7. A registered trademark of BCI Medical, Inc.
 8. Packaged separately to the sterile kit.

Rx only.
Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

Single: Do not use if package has been previously opened or damaged. Fluid path components are non-pyrogenic. Contains medication. Single use—do not reutilize. Sterilized by ethylene oxide.
Arrow International provides the enclosed medication label for your convenience. Please ensure that the label is applied to the correct syringe and corresponding medication.
 Store between 20 - 25°C (68 - 77°F).
 This product contains **NO** natural rubber latex.

3400 Barnwell Road
 Reading, PA 19605 USA
 www.arrowintl.com

CDC-05552-HPK1A
 Pressure Injectable PICC Kit with Blue FlexTip® Catheter and Placement Wire

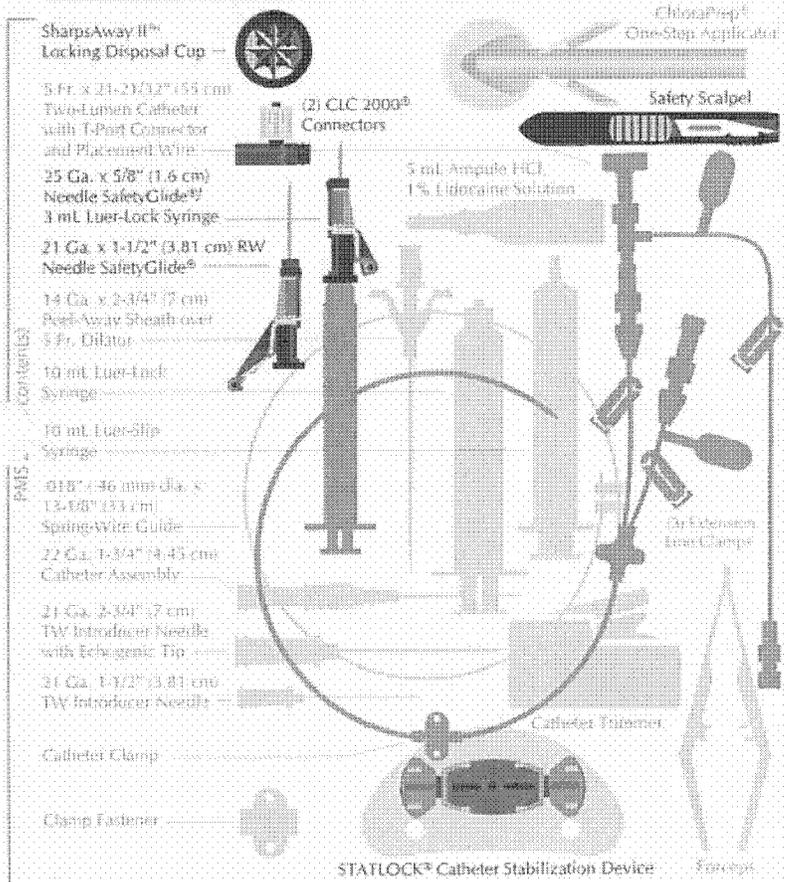
PMS 259

(contents)

PMS

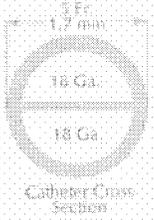
PMS 259 (continued)

CDC-05552-HPK1A (1/1/09)



Lumen	Priming Volume* (mL)	Flow Rate† (mL/hr)	Pump Flow Rate** (mL/hr)	MAX Pressure Injectable Flow Rate†† (mL/sec)
Distal (18 Ga.)	0.5	~80	~934	4
Proximal (18 Ga.)	0.5	~80	~1117	4

* Priming volumes are approximate and are done without the CLC 2000® connector. CLC 2000® Connector priming volume is 0.5 mL.
 † Flow rates were determined per BS EN ISO 10555-1:1997, Annex A using room temperature water, 100 cm head height and reported approximate flow capabilities.
 ‡ Pump flow rates are determined at maximum pump pressure of 10 psi.
 †† Pressure injectable flow rates are determined at the test pressure setting of 300 psi maximum using media of 11.8 mg/mL viscosity, with 60° pressure tubing.



LOT



5 Fr. 2 Lumen 55 cm catheter length .018 inch dia. spring-wire guide

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____ **Date of Birth (mm/dd/yy):** ____/____/____
First Name: _____ Male Female
Last Name: _____ **Notes:** _____
Location (unit/ward/bed): _____
Insertion Site: Right Left Basilic Cephalic Brachial **Other:** _____
Is this a NEW line? YES NO
This procedure is: Elective Emergent Re-position **Other:** _____

Insertion Procedure Practices

	YES	YES <small>after revision</small>	N/A
Before Procedure, did the clinician:			
Perform Procedural Pause:			
Perform patient ID x2?			
Confirm diagnosis, therapy and duration; utilize relevant documents (charts/forms)			
Announce procedure to be performed?			
Mark / assess the site?			
Position patient correctly for procedure?			
Assemble equipment / verify supplies?			
Utilize relevant documents (charts / forms)?			
Order follow-up radiology images (PRN)?			
Cleanse hands (ask if unsure)?			
Prep Procedure Site:			
Use chlorhexidine?			
Other site preparation: _____			
Use large drape to cover patient in sterile fashion?			
During Procedure, did the clinician:			
Wear sterile gloves, cap, mask, and gown?			
Maintain sterile field?			
Venous identification: <input type="checkbox"/> Palpitation <input type="checkbox"/> Fluoroscopy <input type="checkbox"/> Ultrasound <input type="checkbox"/> Other			
Did procedure assistant follow same sterile precautions?			
Did all personnel in the room wear a mask?			
Technique used: <input type="checkbox"/> Modified Seldinger Technique <input type="checkbox"/> Direct puncture			
Other technique used: _____			
Was the catheter trimmed? <input type="checkbox"/> Yes <input type="checkbox"/> No			Length: _____
Was a guillotine used? <input type="checkbox"/> Yes <input type="checkbox"/> No			
After Procedure:			
Was sterile technique maintained applying dressing?			
Was dressing dated?			

Name of Procedure Clinician (signature if applicable): _____
Name of Procedure Assistant: _____
Name of Procedure Auditor: _____
Today's Date (mm/dd/yy): ____/____/____

Patient Label

143P



Specific catheter manufacturer information is provided on reverse side of original document (including product size, description, and product number).

Arrow® International Pressure Injectable PICC Information

MAXIMUM injector pressure setting: 300 psi

Catheter size:	MAX Indicated Pressure Injection Flow Rate ¹	Average Max Catheter Pressure During MAX Flow Rate ²	Average MAX Static Burst Pressure ³	Range of MAX Static Burst Pressure ³
4 Fr. 40 cm S-L	4 mL/sec	232 psi	425 psi	411-435 psi
4 Fr. 50 cm S-L	4 mL/sec	250 psi	413 psi	402-421 psi
4 Fr. 55 cm S-L	4 mL/sec	262 psi	370 psi	359-385 psi
5 Fr. 40 cm D-L	4 mL/sec	208 psi	355 psi	344-371 psi
5 Fr. 50 cm D-L	4 mL/sec	220 psi	334 psi	323-343 psi
5 Fr. 55 cm D-L	4 mL/sec	195 psi	325 psi	313-340 psi
5 Fr. 55 cm D-L ⁴	5 mL/sec	218 psi	336 psi	322-354 psi

¹ Represents maximum indicated flow rate for pressure injection of contrast media.
² Represents internal catheter pressure during pressure injection with injector safety cut-off at 300 psi, using media of 11.8 Centipoise (cP) viscosity.
³ MAX static burst pressure is the failure point of catheter when occluded.
⁴ Non Blue Flex-Tip Catheter
 * See Instructions for Use for additional information.

ARROW
 INTERNATIONAL
 Arrow International, Inc.
 2400 Bernville Road, Reading, PA 19605 USA

XX-15552-100A, Rev. 1 (12/07)

Arrow® International Pressure Injectable PICC Information

MAXIMUM injector pressure setting: 300 psi

Catheter size:	MAX Indicated Pressure Injection Flow Rate ¹	Average Max Catheter Pressure During MAX Flow Rate ²	Average MAX Static Burst Pressure ³	Range of MAX Static Burst Pressure ³
4 Fr. 40 cm S-L	4 mL/sec	232 psi	425 psi	411-435 psi
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4 Fr. 55 cm S-L	4 mL/sec	262 psi	370 psi	359-385 psi
5 Fr. 40 cm D-L	4 mL/sec	208 psi	355 psi	344-371 psi
5 Fr. 50 cm D-L	4 mL/sec	220 psi	334 psi	323-343 psi
5 Fr. 55 cm D-L	4 mL/sec	195 psi	325 psi	313-340 psi
5 Fr. 55 cm D-L ⁴	5 mL/sec	218 psi	336 psi	322-354 psi

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 * See Instructions for Use for additional information.

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 INTERNATIONAL
 Arrow International, Inc.
 2400 Bernville Road, Reading, PA 19605 USA

XX-15552-100A, Rev. 1 (12/07)

Arrow® International Pressure Injectable PICC Information

MAXIMUM injector pressure setting: 300 psi

Catheter size:	MAX Indicated Pressure Injection Flow Rate ¹	Average Max Catheter Pressure During MAX Flow Rate ²	Average MAX Static Burst Pressure ³	Range of MAX Static Burst Pressure ³
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5 Fr. 50 cm D-L	4 mL/sec	220 psi	334 psi	323-343 psi
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5 Fr. 55 cm D-L ⁴	5 mL/sec	218 psi	336 psi	322-354 psi

¹ Represents maximum indicated flow rate for pressure injection of contrast media.
² Represents internal catheter pressure during pressure injection with injector safety cut-off at 300 psi, using media of 11.8 Centipoise (cP) viscosity.
³ MAX static burst pressure is the failure point of catheter when occluded.
⁴ Non Blue Flex-Tip Catheter
 * See Instructions for Use for additional information.

ARROW
 INTERNATIONAL
 Arrow International, Inc.
 2400 Bernville Road, Reading, PA 19605 USA

XX-15552-100A, Rev. 1 (12/07)

1439

Product No.
LATEX-FREE

CDC-05541-HPK1A

4 Fr. x 21-21/32" (55 cm)

Pressure Injectable PICC Kit

**with Blue FlexTip® Catheter, Placement Wire,
Sharps Safety Features and Maximal Barrier Precautions**

Storage Requirements: Store between 20 - 25°C (68 - 77°F).



Qty: 5
Contains Medication

1233

Single use – do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

Version 0 (8/08)

Product No.
LATEX-FREE

CDC-05552-HPK1A

5 Fr. x 21-21/32" (55 cm)

Qty: 5
Contains Medication

Pressure Injectable PICC Kit

with Blue FlexTip® Catheter, Placement Wire,
Sharps Safety Features and Maximal Barrier Precautions

Storage Requirements: Store between 20 - 25°C (68 - 77°F).



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Single use – do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

Version 0 (8/08)

Attachment 7
Predicate Device Labeling

7 French CVC
Labeling

1442

AGB⁺

ARROW[®]

**ARROWgard Blue PLUS[®] Antimicrobial
Multiple-Lumen Central Venous Catheterization Product**

Safety and Efficacy Considerations:

Do not use if package has been previously opened or damaged. Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

The product is designed for single use only. Do not resterilize or reuse. Do not alter the catheter, spring-wire guide, or any other kit/set component during insertion, use, or removal.

Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.

Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Fig. 1).

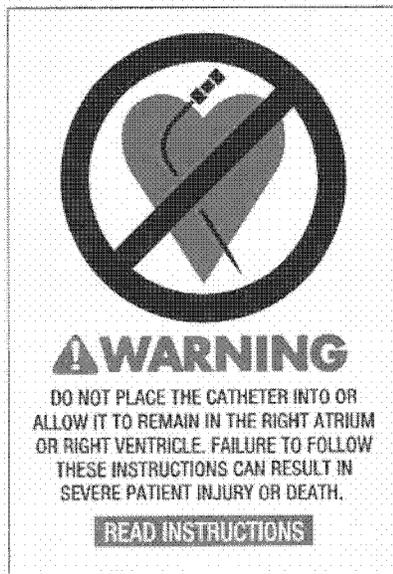


Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice^{4,5,6,7,11,14,39,40} that may lead to cardiac perforation and tamponade.^{4,5,6,11,39,40} Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.⁴³ Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size.

No particular route or catheter type is exempt from this potentially fatal complication.⁵⁰ The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion.^{4,5,11,39,40,47} Central venous catheters should be placed in the superior vena cava^{4,5,6,11,14,39,50} above its junction with the right atrium and parallel to the vessel wall^{22,50} and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

Central venous catheters should not be placed in the right atrium unless specifically required for special relatively short term procedures such as aspiration of air emboli during neurosurgery. Such procedures are, nevertheless, risk prone and should be closely monitored and controlled.

Introduction:

Infection is the leading complication associated with intravascular devices. According to National Nosocomial Infection Surveillance System (NNIS) data, catheter-related bloodstream infections (CRBSIs) rank as the third most common nosocomial infection in intensive care units.³⁴ It has been estimated that over 200,000 of the nosocomial bloodstream infections that occur annually in the United States are associated with the use of intravascular devices, of which approximately 90% are central line related.⁴⁹

Rationale for Antimicrobial Catheters:

Pathogenesis of Catheter-Related Bloodstream Infections:

Vascular catheter infections develop for many reasons, but they begin when a catheter becomes colonized by microorganisms entering through either one of two routes, or both: 1) colonization of the outside of the

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catheter, or 2) colonization of the inside of the catheter.⁴⁶ Colonization of the outside of the catheter can occur from skin microorganisms, contiguous infections, or hematogenous seeding of the catheter from a distant site.⁴⁶ Colonization of the inside of the catheter can happen through the introduction of microorganisms through the catheter hub or contamination of infusion fluid.⁴⁶ A prospective study by Mermel demonstrated that there was a 79% concordance between organisms on the infected catheters and the patient's skin.³¹ Molecular subtyping of the skin organisms and catheter organisms substantiated the link between skin organisms colonizing the external surface of the catheter. It has also been documented that the source of colonization of catheters indwelling less than eight days comes predominantly from the skin (75-90%), followed by the hub, which is the primary source of infection for a catheter in place greater than eight days.⁴⁶

Technology has now been developed to protect the internal as well as the external surfaces of catheters against colonization. The binding of an antimicrobial to the entire indwelling external catheter surface proved to be effective for decreasing the risk of CRBSIs associated with external catheter colonization.^{2,9,12,29,55} As the pathogenesis of catheter-related bloodstream infections becomes more clearly understood, protection of the internal surfaces is viewed as the next step in decreasing the risk of CRBSIs.

Technology Development:

Antimicrobial central venous catheters (CVCs) were introduced by Arrow International in 1990 as the first product capable of significantly reducing the potential for catheter colonization and subsequent catheter-related bloodstream infections. The antimicrobial surface treatment, referred to as ARROWgard[®], consists of two antimicrobial agents, chlorhexidine acetate and silver sulfadiazine, that are impregnated together into the indwelling external surface of the catheter. This combination has demonstrated broad spectrum *in vitro* efficacy when tested using the modified Kirby-Bauer technique.³ In addition, *in vivo* efficacy of the ARROWgard Blue[®] catheter has been demonstrated through several prospective clinical studies.^{2,9,12,29,55}

In spite of an improved understanding of risk factors and aseptic insertion techniques, catheter-related bloodstream infection remains a major concern. Cobb has suggested that central venous catheters should remain in place until there is a clinical indication for a change (i.e. fever without a known source or catheter malfunction), challenging the benefit of scheduled catheter replacements.¹⁰ This recommendation has led

many institutions to routinely leave catheters in place longer than previously accepted catheter exchange protocols of 3 to 4 days. Subsequently, the need for an antimicrobial catheter to provide infection protection for a longer duration has emerged.

It has also been shown that a portion of CRBSIs are due to contamination of the catheter hub and intraluminal catheter colonization by organisms transmitted by the hands of unit personnel.^{28,45,46}

In light of these recent findings, two key areas of improvement to the original ARROWgard Blue[®] catheter technology were identified: 1) extend the effective duration of action of the external surface coating and 2) provide protection to the internal surfaces of the entire catheter (including extension lines and hubs).

Second generation antimicrobial catheters, known as ARROWgard Blue PLUS[®], have been developed to address these needs. Compared to the original ARROWgard Blue[®], ARROWgard Blue PLUS[®] catheters produce a longer duration of antimicrobial effect *in vitro* (modified Kirby-Bauer technique) against a broad range of clinically relevant microorganisms.¹³ In addition, comprehensive *in vitro* luminal adherence assay testing against the most common catheter-related infection-causing microorganisms have shown a significant reduction in intraluminal bacterial colonization when compared to untreated catheters.³²

Product Description:

The ARROWgard Blue PLUS[®] antimicrobial catheter consists of our standard polyurethane catheter with Blue FlexTip[®], plus an external surface treatment of chlorhexidine acetate and silver sulfadiazine and an internal lumen impregnation of chlorhexidine and chlorhexidine acetate to the catheter body, extension lines, and extension line hubs. Compared to the original ARROWgard Blue[®] catheter, this new external surface treatment represents a three-fold increase in the amount of chlorhexidine acetate and an unchanged amount of silver sulfadiazine. The average amount of chlorhexidine, silver, and sulfadiazine applied to the external surface of the 7 Fr. catheter is 425 µg/cm, 24 µg/cm, and 56 µg/cm, respectively. The average amount of chlorhexidine applied to the catheter body and extension line internal lumens is 22 µg/cm. For a 20 cm catheter, the maximum total amount of chlorhexidine, silver, and sulfadiazine applied to the entire catheter is 12.9 mg, 0.80 mg and 1.92 mg, respectively.

Intended Use:

The Multiple-Lumen Catheter permits venous access to the central circulation by way of the femoral, jugular, or subclavian veins.

The ARROWgard® technology is intended to provide protection against catheter-related bloodstream infections. It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use (> 30 days). Superior clinical effectiveness and safety of the ARROWgard Blue PLUS® catheter in preventing CRBSIs compared to the original ARROWgard Blue® catheter has not been demonstrated.

See the Clinical Evaluations section for additional information.

Indications for Use:

The ARROWgard Blue PLUS® antimicrobial catheter is indicated to provide short-term (< 30 days) central venous access for the treatment of diseases or conditions requiring central venous access including, but not limited to:

1. multiple infusions of fluids, medications, or chemotherapy
2. infusion of fluids that are hypertonic, hyperosmolar, or have divergent pH values
3. total parenteral nutrition (TPN) therapy
4. frequent blood sampling or blood/blood component infusions
5. infusion of incompatible medications
6. central venous pressure monitoring
7. lack of usable peripheral IV sites
8. replacement of multiple peripheral sites for IV access

There are no specific guidelines for maximum indwelling times or catheter exchange.^{10,38} Catheters should remain indwelling or should be exchanged per hospital protocol.

Contraindications:

The ARROWgard Blue PLUS® antimicrobial catheter is contraindicated for patients with known hypersensitivity to chlorhexidine, chlorhexidine acetate, silver sulfadiazine and/or sulfa drugs.

Hypersensitivity reactions are a concern with antimicrobial catheters, in that they can be very serious and even life-threatening. The original ARROWgard Blue® antimicrobial catheter was introduced worldwide in 1990, and six years elapsed before the first hypersensitivity reaction was reported in Japan in May, 1996.

To date (July, 2003) the ARROWgard Blue® reported incident rate has been extremely low, at 1 per 487,718 exposures, and the skin test confirmed rate is even lower, at 1 per 1,341,225 exposures. The vast majority of these episodes (17) have been endemic to individuals of Japanese extraction living in Japan. The literature indicates that individuals of Japanese extraction are known to have had similar

hypersensitive reactions following topical chlorhexidine administration.^{20,21,26,27,36,37,48,52} Three (3) incidents have been reported in the UK, and two (2) in the USA. No reactions have been reported with ARROWgard Blue PLUS®. If an adverse reaction occurs after placement, remove the catheter immediately.

Special Patient Populations:

Controlled studies of this product have not been conducted in pregnant women,³³ pediatric or neonatal patients, and patients with known sulfonamide hypersensitivity, erythema multiforme, Stevens-Johnson syndrome,¹⁷ and glucose-6-phosphate dehydrogenase deficiency. The benefits of the use of this catheter should be weighed against any possible risk.

Hypersensitivity Potential:

Although the amount of chlorhexidine acetate has been increased by approximately three-fold compared to the original ARROWgard Blue® catheter, the increase in chlorhexidine concentration is likely to cause only minimal change (whether increased or decreased) in the incidence of hypersensitivity, since the rate of change with dose is usually very slow.⁵³ In addition, the three-fold increase is a very small increment in allergy terms since a ten-fold increase is the standard when performing skin allergy tests.⁵⁴ The risk of hypersensitivity reactions due to the increased antimicrobial concentration of the ARROWgard Blue PLUS® antimicrobial catheter can not be quantified.

See the Warnings and Precautions section for additional information.

Pre-clinical Evaluations:

In vitro

Antimicrobial activity associated with the ARROWgard Blue PLUS® antimicrobial catheter has been demonstrated *in vitro* using the modified Kirby-Bauer technique utilizing the vertical catheter segment placement method, in the following ways:

- ARROWgard Blue PLUS® antimicrobial catheters produced zones of inhibition greater than 7 mm in diameter after 24 hours against¹⁵:

Candida albicans

Staphylococcus aureus

Staphylococcus aureus (methicillin resistant)

Staphylococcus epidermidis

Streptococcus pyogenes

Klebsiella pneumoniae

Xanthomonas maltophilia

Escherichia coli

Escherichia coli (β-lactamase producer)

Pseudomonas aeruginosa
Enterococcal faecalis
Enterobacter cloecae
Enterobacter aerogenes

- ARROWgard Blue PLUS® antimicrobial catheters retained antimicrobial activity (zones of inhibition greater than 5 mm in diameter) after 7 days against¹⁵:
Candida albicans
Staphylococcus epidermidis
Staphylococcus aureus
Staphylococcus aureus (methicillin resistant)
Streptococcus pyogenes
Klebsiella pneumoniae
Pseudomonas aeruginosa
Enterococcal faecalis
Enterobacter cloecae
Enterobacter aerogenes
Escherichia coli
Escherichia coli (β-lactamase producer)
Xanthomonas maltophilia

The 7 Fr. ARROWgard Blue PLUS® antimicrobial catheters have demonstrated a $\geq \log_{10} 2$ decrease in the mean number of adherent bacterial cells to the catheter body and extension line luminal surfaces compared to control catheters *in vitro* against¹²:

Staphylococcus epidermidis
Staphylococcus aureus
Candida albicans
Enterobacter aerogenes

The ARROWgard Blue PLUS® antimicrobial catheter has demonstrated no loss on delivery or interaction of the internal lumen impregnation of chlorhexidine and chlorhexidine acetate when infused with 82 various parenteral drugs tested for compatibility.³¹

In vivo

Antimicrobial activity with the ARROWgard Blue PLUS® antimicrobial catheter has been demonstrated *in vivo* in the following ways:

- After 7 days subcutaneous implantation in a rabbit model for catheter insertion site infections, the 7 Fr. ARROWgard Blue PLUS® catheter demonstrated zones of inhibition diameter greater than 10 mm against *Staphylococcus aureus* using a modified Kirby-Bauer technique.⁴⁴
- After subcutaneous inoculation in a rabbit model for catheter insertion site infections, ARROWgard Blue PLUS® antimicrobial catheters demonstrated a significant decrease ($\geq \log_{10} 3$) in the amount of adherent bacterial

cells of *Staphylococcus aureus* on the external surface of the catheter.^{15,44}

- After removal of subcutaneously implanted catheter segments from a rabbit model for catheter insertion site infections, the *in vivo* antimicrobial activity half-life for 7 Fr. ARROWgard Blue PLUS® catheters was found to persist beyond 7 days.⁴⁴

Clinical Evaluations:

A multi-center, double-blind, randomized, 780 patient clinical study was performed at nine USA hospitals between July 1998 and June 2001. There were no unanticipated adverse device events, nor were there any reports of anaphylaxis/hypersensitivity to the ARROWgard Blue PLUS® antimicrobial catheters. The results of the study are currently being reviewed for possible publication.

- Explanted catheters removed from 111 study patients after up to 46 days (mean 9.48 days, range: 0.125 - 46.2 days) yielded a significant antibacterial effect against *Staphylococcus epidermidis*.¹⁹
- ARROWgard Blue PLUS® catheters were associated with a statistically significant lower rate of microbial colonization per 1000 catheter days compared to control catheters 13.3 vs. 24.1 respectively ($p=0.006$) when three possible colonizations are included, compared to 12.8 vs. 23.5 (0.007) when the three possible colonizations are excluded. ARROWgard Blue PLUS® catheters were associated with fewer bacteremias per 1000 catheter days 2.5 vs. 3.3 ($p=0.8$) when ten possible bacteremias are included, compared to 0.42 vs. 1.2 ($p=0.63$) when the ten possible bacteremias are excluded. ARROWgard Blue PLUS® catheters were not associated with any safety concerns.⁴²

A single-center, double-blind, randomized, 184 patient clinical study was performed in Germany between January 2000 and June 2001. There were no unanticipated adverse device events, nor were there any reports of anaphylaxis/hypersensitivity to the ARROWgard Blue PLUS® antimicrobial catheter. The results of the study are currently being reviewed for possible publication.

A multi-center, double-blind, randomized, 396 patient clinical study was performed at 14 French hospitals between June 1998 and December 2001. There were no unanticipated adverse device events, nor were there any reports of anaphylaxis/hypersensitivity to the ARROWgard Blue PLUS® antimicrobial catheter. The results of the study are currently being reviewed for possible publication.

Prior Clinical Investigations:

Clinical study: The following clinical study was conducted on the original ARROWgard Blue® catheter at the University of Wisconsin²⁹:

- A prospective, randomized, controlled clinical trial of 403 catheter insertions in 158 adult patients in a medical-surgical ICU showed that the original ARROWgard Blue® catheters were 50% less likely to be colonized at removal than the control catheters (13.5 compared to 24.1 colonized catheters per 100 catheters; p=0.005) and were 80% less likely to produce a bloodstream infection (1.0 compared to 4.7 infections per 100 catheters; 1.6 compared to 7.6 infections per 1000 catheter days, p=0.03).
- No adverse effects were seen from the antimicrobial catheter, and none of the isolates obtained from infected catheters in either group showed *in vitro* resistance to chlorhexidine or silver sulfadiazine.

A 191 patient, randomized, prospective clinical trial performed at a community referral center found that the rate of catheter-related infection (CRI) or catheter-related sepsis (CRS) in patients receiving TPN was similar between original ARROWgard® and standard catheters. However, the authors acknowledged that significantly more catheters would be necessary to demonstrate a statistical difference in CRI and CRS.³⁰

Meta-analysis: The following meta-analysis was performed on the original ARROWgard Blue® catheter³¹:

- An independent review of 11 randomized clinical trials on the original ARROWgard Blue® antimicrobial catheters (MEDLINE search from January 1966 to January 1998) concluded that central venous catheters impregnated with a combination of chlorhexidine acetate and silver sulfadiazine are effective in reducing the incidence of both catheter colonization and catheter-related bloodstream infections in patients at high risk for catheter-related infections.

Warnings and Precautions:

Warning: Chlorhexidine-containing compounds have been used as topical disinfectants since the mid-1970's. An effective antimicrobial agent, chlorhexidine found use in many antiseptic skin creams, mouth rinses, and disinfectants used to prepare the skin for surgical procedures. In addition, chlorhexidine has been incorporated into cosmetic products where it reportedly functions as a cosmetic biocide. In the early 1990's, the FDA cleared three types of medical devices containing

chlorhexidine: intravenous catheters, topical antimicrobial skin dressings, and an implanted surgical mesh.³²

Hypersensitivity reactions are a concern with antimicrobial catheters, in that they can be very serious and even life-threatening. The original ARROWgard Blue® antimicrobial catheter was introduced worldwide in 1990, and six years elapsed before the first hypersensitivity reaction was reported in Japan in May, 1996.

To date (July, 2003) the ARROWgard Blue® reported incident rate has been extremely low, at 1 per 487,718 exposures, and the skin test confirmed rate is even lower, at 1 per 1,341,225 exposures. The vast majority of these episodes (17) have been endemic to individuals of Japanese extraction living in Japan. The literature indicates that individuals of Japanese extraction are known to have had similar hypersensitive reactions following topical chlorhexidine administration.^{28,31,32,33,34,35,36,37,38,39} Three (3) incidents have been reported in the UK, and two (2) in the USA. No reactions have been reported with ARROWgard Blue PLUS®. If an adverse reaction occurs after placement, remove the catheter immediately.

1. **Warning:** Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Central vein catheters should be positioned so that the distal tip of the catheter is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel wall. For femoral vein approach, the catheter should be advanced into the vessel so that the catheter tip lies parallel to the vessel wall and does not enter the right atrium.
2. **Warning:** Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, and dysrhythmias.
3. **Warning:** Do not apply excessive force in removing guide wire or catheter. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.
4. **Warning:** The practitioner must be aware of potential air embolism associated with leaving

open needles or catheters in central venous puncture sites or as a consequence of inadvertent disconnects. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. Follow hospital protocol to guard against air embolism for all catheter maintenance.

5. **Warning:** Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block,¹⁰ and a perforation of the vessel wall, atrial or ventricular.
6. **Warning:** Practitioners must be aware of the potential for entrapment of guide wire by any implanted device in the circulatory system (i.e. vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding the length of spring-wire guide inserted.¹¹ It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of guidewire entrapment.
7. **Warning:** Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.
8. **Precaution:** Alcohol and acetone can weaken the structure of polyurethane materials. Check ingredients of prep sprays and swabs for acetone and alcohol content.
Acetone: Do not use acetone on catheter surface. Acetone may be applied to skin but must be allowed to dry completely prior to applying dressing.
Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency. Care should be taken when instilling drugs containing high concentration of alcohol. Always allow alcohol to dry completely prior to applying dressing.
9. **Precaution:** Some disinfectants used at the catheter insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.
10. **Precaution:** Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.
11. **Precaution:** Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies

parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.

12. **Precaution:** For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.
13. **Precaution:** Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture.¹²

A Suggested Procedure:

Use sterile technique.

1. **Precaution:** Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism. If femoral approach is used, place patient in supine position.
2. Prep and drape puncture site as required.
3. Perform skin wheal with desired needle (25 Ga. or 22 Ga. needle). A SharpsAway[®] disposal cup is provided for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. **Precaution:** Do not re-use needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.
4. Prepare the catheter for insertion by flushing each lumen with 30 - 60 mL of dextrose 5% injection or NaCl 0.9% injection or clamping or attaching the injection caps to the appropriate pigtails. Leave the distal pigtail uncapped for guide wire passage. **Warning:** Do not cut the catheter to alter length.

Arrow UserGard[®] Needle-Free Injection Hub

Instructions for Use: (Where provided)

- Attach Luer end of UserGard[®] hub to syringe.
- Prepare injection site with alcohol or betadine per standard hospital protocol.
- Remove red dust cap.
- Press UserGard[®] hub onto injection site and twist to lock on (refer to Fig. 2).

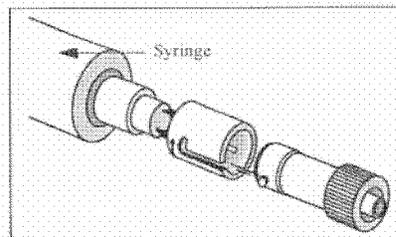


Fig. 2

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- Inject or withdraw fluid as required.
- Disengage UserGard® hub from injection site and discard. **Warning:** To prevent possible air embolism, do not leave UserGard™ hub connected to injection site. Single use only.

5. Insert introducer needle with attached Arrow® Raulerson Syringe into vein and aspirate. (If larger introducer needle is used, vessel may be pre-located with 22 Ga. locator needle and syringe.) Remove locator needle.

Alternate Technique:

Catheter/needle may be used in the standard manner as alternative to introducer needle. If catheter/needle is used, Arrow® Raulerson Syringe will function as a standard syringe, but will not pass spring-wire guide. If no free flow of venous blood is observed after needle is removed, attach syringe to the catheter and aspirate until good venous blood flow is established. **Precaution:** The color of the blood aspirated is not always a reliable indicator of venous access.^{2,3} Do not reinsert needle into introducer catheter.

6. Because of the potential for inadvertent arterial placement, one of the following techniques should be utilized to verify venous access. Insert the fluid primed blunt tip transduction probe into the rear of the plunger and through the valves of the Arrow® Raulerson Syringe. Observe for central venous placement via a wave form obtained by a calibrated pressure transducer. Remove transduction probe (refer to Fig. 3).

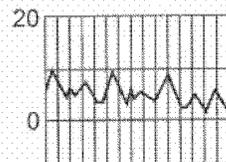


Fig. 3

Alternate Technique:

If hemodynamic monitoring equipment is not available to permit transducing a central venous wave form, check for pulsatile flow by either using the transduction probe to open the syringe valving system or by disconnecting the syringe from the needle. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

7. Using the two-piece Arrow Advancer™, advance spring-wire guide through syringe into vein. **Warning:** Aspiration with spring-wire guide in place will cause introduction of air into syringe. **Precaution:** To minimize the risk of leakage of

blood from syringe cap, do not reinfuse blood with spring-wire guide in place.

Arrow Two-Piece Advancer™ Instructions:

- Using your thumb, straighten the “J” by retracting the spring-wire guide into the Arrow Advancer™ (refer to Figs. 4, 5).

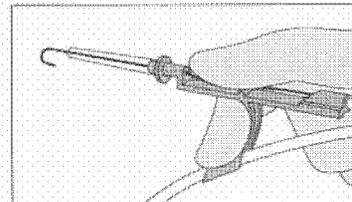


Fig. 4

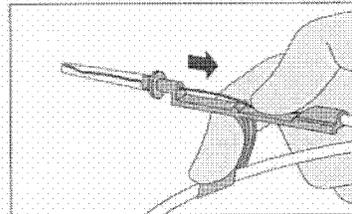


Fig. 5

When the tip is straightened, the spring-wire guide is ready for insertion. Centimeter marks on guide wire are referenced from “J” end. One band indicates 10 cm, two bands 20 cm, and three bands 30 cm.

Introducing the Spring-Wire Guide:

- Place the tip of the Arrow Advancer™ – with “J” retracted – into the hole in the rear of the Arrow® Raulerson Syringe plunger (refer to Fig. 6).

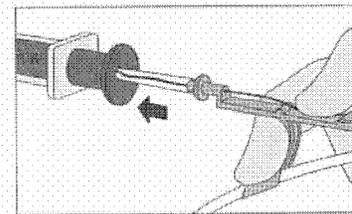


Fig. 6

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the syringe valves (refer to Fig. 7).

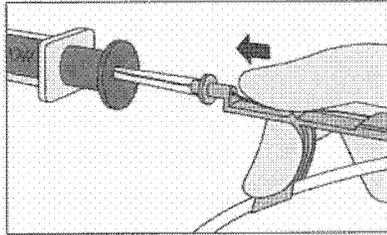


Fig. 7

- Raise your thumb and pull the Arrow Advancer™ approximately 4 cm to 8 cm away from the syringe. Lower thumb onto the Arrow Advancer™ and while maintaining a firm grip on the spring-wire guide, push the assembly into the syringe barrel to further advance the spring-wire guide. Continue until spring-wire guide reaches desired depth (refer to Fig. 8).

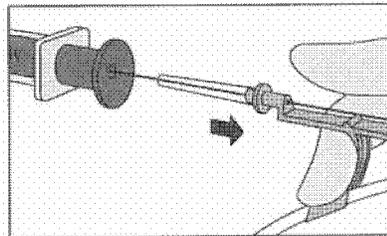


Fig. 8

Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of the Arrow Advancer™ can be disconnected from the unit and used separately.

Separate the Arrow Advancer™ tip or straightening tube from the blue Arrow Advancer™ unit. If the "J" tip portion of the spring-wire guide is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. The spring-wire guide should then be advanced in the routine fashion to the desired depth.

8. Advance guide wire until triple band mark reaches rear of syringe plunger. Advancement of "J" tip may require a gentle rotating motion. **Warning:** Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to minimize the risk of possible severing or damaging of spring-wire guide.
9. Hold spring-wire guide in place and remove introducer needle and Arrow® Raulerson Syringe

(or catheter). **Precaution:** Maintain firm grip on spring-wire guide at all times. Use centimeter markings on spring-wire guide to adjust indwelling length according to desired depth of indwelling catheter placement.

10. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution:** Do not cut guide wire. Use tissue dilator to enlarge site as required. **Warning:** Do not leave tissue dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.
11. Thread tip of multiple-lumen catheter over spring-wire guide. Sufficient guide wire length must remain exposed at hub end of catheter to maintain a firm grip on guide wire. Grasping near skin, advance catheter into vein with slight twisting motion. **Precaution:** Catheter clamp and fastener must not be attached to catheter until spring-wire guide is removed.
12. Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position. All centimeter marks are referenced from the catheter tip. Marking symbology is as follows: (1) numerical: 5, 15, 25, etc.; (2) bands: each band denotes 10 cm intervals, with one band indicating 10 cm, two bands indicating 20 cm, etc.; (3) each dot denotes a 1 cm interval.
13. Hold catheter at desired depth and remove spring-wire guide. The Arrow catheter included in this product has been designed to freely pass over the spring-wire guide. If resistance is encountered when attempting to remove the spring-wire guide after catheter placement, the spring-wire may be kinked about the tip of the catheter within the vessel (refer to Fig. 9).

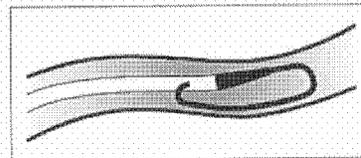


Fig. 9

In this circumstance, pulling back on the spring-wire guide may result in undue force being applied resulting in spring-wire guide breakage. If resistance is encountered, withdraw the catheter relative to the spring-wire guide about 2-3 cm and attempt to remove the spring-wire guide. If resistance is again encountered remove the spring-

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wire guide and catheter simultaneously. **Warning:** Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.

14. Verify that the entire spring-wire guide is intact upon removal.

VitaCuff (where provided)

Instructions for use:

15. Check lumen placement by attaching a syringe to each pigtail and aspirate until free flow of venous blood is observed.
16. Slide cuff and positioner along catheter and use firm manual pressure to push it under skin so that it is no longer visible (refer to Fig. 10). To be effective, the entire collagen (tan) portion of the VitaCuff® device must be beneath skin level. Once *in situ*, the VitaCuff® will absorb fluids and swell to approximately twice its original size, sealing the insertion site. The VitaCuff® device will not prevent inadvertent removal or repositioning of the catheter. Be sure to suture the catheter in place following the instructions detailed below.

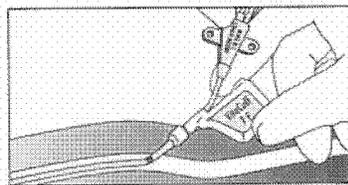


Fig. 10

17. Remove positioner by twisting one quarter turn and pulling parallel to skin (refer to Fig. 11).

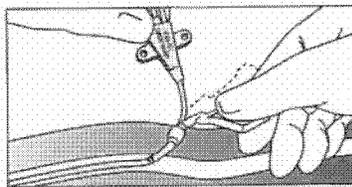


Fig. 11

18. Connect all pigtails to appropriate Luer-Lock line(s) as required. Unused port(s) may be "locked" through injection cap(s) using standard hospital protocol. Slide clamps are provided on pigtails to occlude flow through each lumen during line and injection cap changes. **Precaution:** To minimize the risk of damage to pigtails from excessive

pressure, each clamp must be opened prior to infusing through that lumen.

19. Secure and dress catheter temporarily.
20. Verify catheter tip position by chest x-ray immediately after placement. **Precaution:** X-ray exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized. If catheter tip is malpositioned, reposition and re-verify.
21. Secure catheter to patient. Use triangular junction hub with integral suture ring and side wings as primary suture site. In kits where provided, the catheter clamp and fastener should be utilized as a secondary suture site as necessary. **Precaution:** Do not suture directly to the outside diameter of the catheter to minimize the risk of cutting or damaging the catheter or impeding catheter flow.

Catheter Clamp and Fastener Instructions:

- After spring-wire guide has been removed and the necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location (refer to Fig. 12).

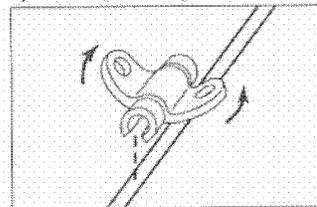


Fig. 12

- Snap rigid fastener onto catheter clamp (refer to Fig. 13).

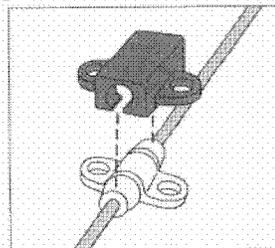


Fig. 13

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- Secure catheter to patient by suturing the catheter clamp and fastener together to the skin, using side wings to minimize the risk of catheter migration (refer to Fig. 14).

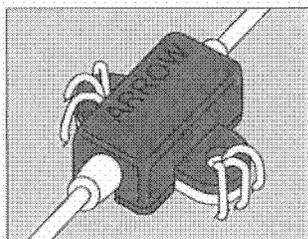


Fig. 14

22. Dress puncture site per hospital protocol. Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.
23. Record on the patient's chart the midwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Catheter Exchange Procedure:

1. Use sterile technique.
2. Precaution: Prior to attempting a catheter exchange procedure, remove the catheter clamp and fasteners.
3. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Procedure:

1. Precaution: Place the patient in a supine position.
2. Remove dressing. Precaution: To minimize the risk of cutting the catheter do not use scissors to remove the dressing.
3. Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system. Remove suture(s) from catheter clamp and primary suture site. Be careful not to cut the catheter. Remove catheter slowly, pulling it parallel to the skin. As catheter exits the site, apply pressure with a dressing impermeable to air, e.g. Vaseline[®] gauze. Because the residual catheter track remains an air entry point until completely sealed, the occlusive dressing should remain in place for at least 24-32 hours

dependent upon the amount of time the catheter was indwelling.^{24,38-41,49}

4. Upon removal of the catheter, inspect it to make sure that the entire length has been withdrawn.
5. Document removal procedure.

References:

1. Andrews RJ, Bova DA, Venbrux AC. How much guidewire is too much? Direct measurement of the distance from subclavian and internal jugular vein access sites to the superior vena cava-atrial junction during central venous catheter placement. *Crit Care Med.* Jan.
2. Bach A, Bohrer H, Bottiger B, Motsch J, Martin E. Reduction of bacterial colonization of triple-lumen catheters with antiseptic bonding in septic patients. *Anesthesiology.* 1994;81:A261.
3. Bach A, Schmidt H, Bottinger B, Schreiber B, Bohrer H, Motsch J, Martin E, Sonntag H. Retention of Antibacterial Activity and Bacterial Colonization of Antiseptic-Bonded Central Venous Catheters. *J Antimicrob Chemother.* 1996;37:315-322.
4. Bar-Joseph G, Galvis AG. Perforation of the heart by central venous catheters in infants: guidelines to diagnosis and management. *J Pediatr Surg.* 1983;18:284-287.
5. Blitt CD, ed. *Monitoring in Anesthesia and Critical Care Medicine: Central venous pressure monitoring.* New York, NY: Churchill Livingstone; 1985:121-165.
6. Brandt RL, Foley WJ, Fink GH, Regan WJ. Mechanism of perforation of the heart with production of hydropericardium by a venous catheter and its prevention. *Am J Surg.* 1970; 119:311-316.
7. Carbone K, Gimenez LF, Rogers WH, Watson AJ. Hemothorax due to vena caval erosion by a subclavian dual-lumen dialysis catheter. *South Med J.* 1987;80:795-796.
8. Ciresi DL, Albrecht RM, Volkens PA, Scholten DJ. Failure of antiseptic bonding to prevent central venous catheter-related infection and sepsis. *Am Surgeon.* 1996;62:641-646.
9. Civetta J, Hudson-Civetta J, Ball S. Decreasing catheter related infection and hospital costs by continuous quality improvement. *Crit Care Med.* 1996;24:1660-5.
10. Cobb DK, High KP, Sawyer RF, Sable CS, Adams RB, Lindley DA, Pruett TL, Schwenzler KJ, Farr BM. A controlled Trial of Scheduled Replacement of Central Venous and Pulmonary-Artery Catheters. *N Engl J Med.* 1992;327:1062-8.

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11. Collier PE, Ryan JJ, Diamond DL. Cardiac tamponade from central venous catheters – report of a case and review of the English literature. *Angiology*. September 1984;35:595-600.
12. Collin GR. Decreasing catheter colonization through the use of an antiseptic-impregnated catheter: a continuous quality improvement project. *Chest*. 1999;115:1632-1640.
13. Conn C. The importance of syringe size when using implanted vascular access devices. *J Vasc Access Nurs*. Winter 1993;3:11-18.
14. Curelaru J, Linder LE, Gustavsson B. Displacement of catheters inserted through internal jugular veins with neck flexion and extension. *Intens Care Med*. 1980;6:179-183.
15. Data on file, ARROW International, Inc.
16. Eissa NT, Kvetan V. Guide wire as a cause of complete heart block in patients with preexisting left bundle branch block. *Anesthesiology*. 1990;73:772-774.
17. Farber T. ARROWgard® antiseptic surface toxicology review. Monograph. Published by Arrow International, Inc. April 1992.
18. FDA Public Health Notice. Potential hypersensitivity reactions to chlorhexidine-impregnated medical devices. Food and Drug Administration Web site. Available at: <http://www.fda.gov/cdrh/chlorhex.html>. Accessed October 26, 1999.
19. Fey PD, Matthews KI, Peterson DK, Iwen PC, Hinrichs SH, Rupp ME. Presented at the 40th ICAAC: Toronto, Ontario, Canada, 2000.
20. Fukui A, Ohsumi A, Takaori M. A case of anaphylactic shock induced by chlorhexidine gluconate. *J Japan Society Clin Anesthesia*. 1989;9:356-360.
21. Harukuni I, Ishizawa Y, Nishikawa T, Takeshima R, Dohi S, Naito H. Anaphylactic shock with ventricular fibrillation induced by chlorhexidine. *Japanese J Anesthesiology*. 1992;41:455-459.
22. Iberti TJ, Katz LB, Reiner MA, Brownie T, Kwun KB. Hydrothorax as a late complication of central venous indwelling catheters. *Surgery*. November 1983;842-846.
23. Jobes DR, Schwartz AJ, Greenhow DE, Stephenson LW, Ellison N. Safer jugular vein cannulation: recognition of arterial punctures and preferential use of the external jugular route. *Anesthesiology*. 1983;59:353-355.
24. Kashuk JL, Penn I. Air embolism after central venous catheterization. *Surg Gynecol Obstet*. September 1984;159:249-252.
25. Kozeny GA, Bansal VK, Vertuno LL, Hano JE. Contralateral hemothorax secondary to chronic subclavian dialysis catheter. *Am J Nephrol*. 1984;4:312-314.
26. Kubo H, Akiyama Y, Honda K, Nakajo N. Anaphylaxis following oral irrigation with chlorhexidine gluconate. *J Japanese Dental Society Anesthesiology*. 1985;13:659-663.
27. Layton GT, Stanworth DR, Amos HE. The incidence of IgE and IgG antibodies to chlorhexidine. *Clin Experimental Allergy*. 1989;19:307-314.
28. Maki DG, Ringer M. Evaluation of dressing regimes for prevention of infection with peripheral intravenous catheters. *JAMA*. 1987;258:2396-2403.
29. Maki DG, Stolz SM, Wheeler S, Mermel LA. Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter. *Ann Intern Med*. 1997;127:257-266.
30. Maschke SP, Rogove HJ. Cardiac tamponade associated with a multilumen central venous catheter. *Crit Care Med*. 1984;12:611-612.
31. Mermel LA, McCormick RD, Springman SR, Maki DG. The pathogenesis and epidemiology of catheter-related infection with pulmonary artery Swan-Ganz catheters: A prospective study utilizing molecular subtyping. *AJM*. 1991;91(suppl 3B):3B-197S-3B-205S.
32. Modak SM. Presented as a slide presentation at the 39th ICAAC: San Francisco, CA, 1999.
33. Modak SM. (Written communication, June 1991).
34. NNIS. National nosocomial infections surveillance (NNIS) system report, data summary from October 1986-April 1998, issued June 1998. *AJIC*. 1998;26:522-533.
35. Norman PS, Peebles RS. *In vivo* Diagnostic Allergy Testing Methods. In: Rose NR, Conway de Macario E, Fields JD, Lane HC, Nakamura RM. *Manual of Clin. Lab. Immunol*. Washington DC: AMS Press; 1997, 5th Edition.
36. Okano M, Nomura, Hata S, et al. Anaphylactic symptoms due to chlorhexidine gluconate. *Arch Dermatol*. 1989;125:50-52.
37. Okano M, Nomura M, Okada N, Sato K, Tashiro M. Four cases presenting anaphylactic reactions due to topical application of Hibitane®. *Skin Research*. 1983;25:587-592.
38. Paskin DL, Hoffman WS, Tuddenham WJ. A new complication of subclavian vein catheterization. *Ann Surg*. March 1974;179:266-268.

39. Pearson ML. Hospital Infection Control Practices Advisory Committee: Guideline for prevention of intravascular-device-related infections. *Infect Control Hosp Epidemiol*. 1996;17:438-473. Special Report.
40. Peters JL, ed. *A Manual of Central Venous Catheterization and Parenteral Nutrition*. Boston, MA: John Wright PSG; 1983;58-61, 155-157.
41. Phifer TJ, Bridges M, Conrad SA. The residual central venous catheter track - an occult source of lethal air embolism: case report. *J Trauma*. 1991;31:1558-1560.
42. Rupp ME, Lisco S, Lipsett P, Perl T, Keating K, Mermel L, Lee D, Dellinger EP, Donahoe M, Giles D, Pfaller M, Sherertz. Presented at the 41st ICAAC: Chicago, IL, 2001.
43. Sheep RE, Guiney WB Jr. Fatal cardiac tamponade. *JAMA*. 1982;248:1632-1635.
44. Sherertz RG. Presented as a poster presentation at the 37th IDSA: Philadelphia, PA, 1999.
45. Sherertz RJ, Heard SO, Raad II. Diagnosis of triple-lumen catheter infection: comparison of roll plate, sonication, and flushing methodologies. *J Clin Microbiol*. 1997;35:641-646.
46. Sherertz RJ. Pathogenesis of vascular catheter-related infections. In: Seifert H, Jansen B, Farr BM, eds. *Catheter-Related Infections*. New York, NY: Marcel Dekker, Inc; 1997:1-29.
47. Sigurdsson J, Riba P, Sigurdsson S. The wandering central venous catheter. *Intensive Care Med*. 1985;11:263-264.
48. Takeda K, Inoue K, Matsuya T, et al. An allergic shock possibly induced by the chlorhexidine; report of a case. *J Osaka Univ Dent Soc*. 1985;30:221-225.
49. Thielen JB, Nyquist J. Subclavian catheter removal. *J Intravenous Nurs*. March/April 1991;14:114-118.
50. Tocino IM, Watanabe A. Impending catheter perforation of superior vena cava: radiographic recognition. *Am J Roentgenology*. March 1986;146:487-490.
51. Trissel L. Presented as a poster presentation at the 39th ICAAC: San Francisco, CA, 1999.
52. Tsuneto S, Watanabe S, Koyama K, Nakayama K, Saito H, Saito K. Anaphylactic shock induced by chlorhexidine mixed in the vial of lidocaine. *J Japan Society Clin Anesthesia*. 1987;7:272-277.
53. Turkeltaub PC, Rastogi SC, Baer H, Anderson MC, Norman PS. Standardized quantitative skin-test assay of allergen potency and stability: Studies on the allergen dose-response curve and effect of wheal, erythema, and patient selection on assay results. *J Allergy Clin Immunol*. 70:343-352. 1982.
54. Vaziri ND, Maksy M, Lewis M, Martin D, Edwards K. Massive mediastinal hematoma caused by a double-lumen subclavian catheter. *Artif Organs*. 1984;8:223-226.
55. Veenstra DL, Saint S, Somnath S, Lumley T, Sullivan SD. Efficacy of Antisepti-Impregnated Central Venous Catheters in Preventing Catheter-Related Bloodstream Infection. *JAMA*. 1999;281:261-267.
56. Wanscher M, Frifelt JJ, Smith-Sivertsen C, et al. Thrombosis caused by polyurethane double-lumen subclavian superior vena cava catheter and hemodialysis. *Crit Care Med*. 1988;16:624-628.

Arrow International, Inc. recommends that the user be acquainted with the reference literature.

*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

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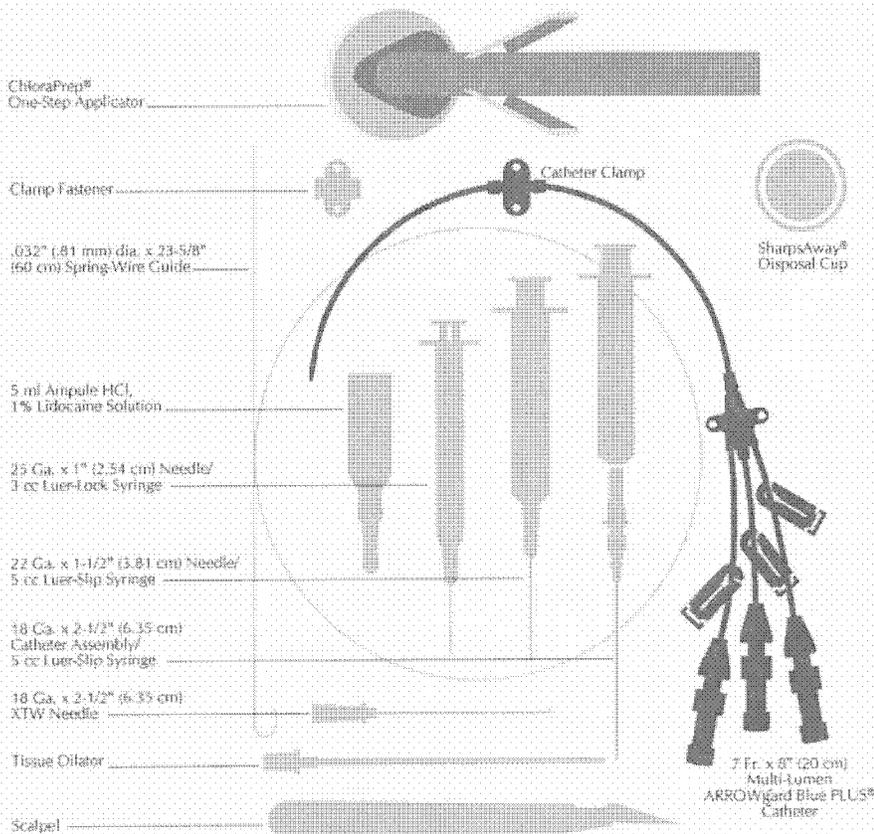
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Hi-Lite Orange[™]

Antimicrobial surfaces utilizing
chlorhexidine, chlorhexidine acetate
and silver sulfadiazine

AK-45703

Latex-
Free



Contents:

- One: ... Multi-Lumen Indwelling Catheter: 7 Fr. x 8" (20 cm) Radiopaque Polyurethane with Blue FlexTip[®], ARROWgard Blue PLUS[®] Antimicrobial Surface Treatment[†], Extension Line Clamps, Injection Site Caps
- One: ... Spring-Wire Guide: .032" (0.81 mm) dia. x 23-5/8" (60 cm) (Straight Soft Tip on One End - "T" Tip on Other)
- One: ... Introducer Needle: 18 Ga. x 2-1/2" (6.35 cm) XTW
- One: ... Catheter: 18 Ga. x 2-1/2" (6.35 cm) Radiopaque over 20 Ga. RW Introducer Needle with 5 cc Luer-Slip Syringe
- One: ... Injection Needle: 22 Ga. x 1-1/2" (3.81 cm) and 5 cc Luer-Slip Syringe
- One: ... Injection Needle: 25 Ga. x 1" (2.54 cm) and 3 cc Luer-Lock Syringe
- One: ... Tissue Dilator
- One: ... 3 ml Applicator Pouch, 2% CHG and 70% IPA ChloroPrep[®] One-Step Solution with Hi-Lite Orange[™] Tint
- One: ... 5 ml Ampule HCl, 1% Lidocaine Solution
- One: ... Suture: 3-0 Braided Silk with Straight Needle
- One: ... Clamp: Catheter
- One: ... Fastener: Catheter Clamp
- One: ... SharpsAway[®] Disposal Cup
- One: ... Drape: 24" x 36" with 4" fenestration
- One: ... CSR Wrap
- One: ... Scalpel: # 11
- Two: ... Gauze Pads: 2" x 2"
- Five: ... Gauze Pads: 4" x 4"

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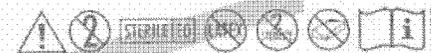
By only.
Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

Contraindications: The ARROWgard Blue PLUS[®] antimicrobial catheter is contraindicated for patients with known hypersensitivity to chlorhexidine, chlorhexidine acetate, silver sulfadiazine and/or sulfa drugs (refer to product instructions for references).

Sterile. Do not use if package has been previously opened or damaged. Fluid path components are non-pyrogenic. Contains medication. Single use - do not re-sterilize. Sterilized by ethylene oxide.

Store between 20 - 25°C (68 - 77°F). Avoid freezing and excessive heat above 40°C (104°F).

This product contains NO natural rubber latex.



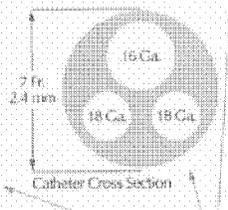
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AK-45703-100F, Rev. 1 (1/2007)

INFECTION PROTECTION FEATURE:
*AGB⁺ catheters now include internal lumen protection & enhanced external surface activity



Lumen	Priming Volume [†] (cc)	Flow Rate [‡] (cc/hr)
Distal (16 Ga.)	0.44	3100
Medial (18 Ga.)	0.39	1500
Proximal (18 Ga.)	0.39	1600

[†]Priming volumes are approximate and are done without the injection cap. Injection cap priming volume is 0.17 cc.
[‡]Flow rates are done with normal saline, room temperature, 100 cm head height and represent approximate flow capabilities.

LOT [] PMS 3005 Shadowgraph, X-sec., Outline, "Infection Protection" & statement

1455

AGB⁺

ARROWgard Blue PLUS[®] Multi-Lumen CVC Kit

Latex-
Free

7 Fr. / 3 Lumen / 20 cm catheter / .032 inch dia. spring-wire guide

AK-45703

Peel to Open

Product No. AK-45703
LATEX-FREE

Qty: 5
Contains Medication

**7 Fr. x 8" (20 cm) Multi-Lumen Central Venous Catheterization Kit
with ARROWgard Blue PLUS® Catheter**

**Storage Requirements: Store between 20 - 25°C (68 - 77°F).
Avoid freezing and excessive heat above 40°C (104°F).**

LOT



Single use – do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

Version 0 (10/07)

1456

Attachment 7
Predicate Device Labeling

6 French Triple Lumen
Pressure Injectable
PICC
Labeling

1457

1250



Pressure Injectable Multi-Lumen PICC Product

Venous Access | Critical Care

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An issued or revision date for these instructions is included for user information. In the event two years have elapsed between this date and product use, the user should contact Arrow International, Inc. to see if additional product information is available.

Revised Date: October 2008

Rx only.

Table of Contents

For convenience, procedural and general Warnings and Precautions are listed at the beginning of the instructions. Please review all content before performing the procedure.

For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with central venous access refer to Arrow International, Inc. website: www.arrowintl.com

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Pressure Injectable Peripherally Inserted Central Catheter (PICC) Product

Product Description

The Arrow® Pressure Injectable PICC is a peripherally inserted central venous catheter (PICC) manufactured with medical grade, flexible polyurethane. The Arrow® PICC has a non-tapered catheter body with either a blunt tip or a Blue FlexTip® that is softer than a cut tip with a contour design to enhance maneuverability. The Blue FlexTip® also provides visual confirmation of an intact catheter upon removal. The kit components assist the clinician in maintaining maximal sterile barrier precautions.

Indications:

The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, power injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of power injector equipment used with the pressure injectable PICC may not exceed 300 psi.

Contraindications:

This device is contraindicated wherever there is presence of device related infections, previous or current thrombosis. Clinical assessment of patient must be completed to ensure no contraindications exists.

Pressure Injection

Warnings and Precautions:

Warnings:

1. Assess each patient for appropriateness of a power injection procedure.
2. Power injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
3. Use an appropriate method to confirm catheter tip position prior to each pressure injection per institutional policy.
4. Ensure patency of catheter prior to power injection to minimize the risk of catheter failure and/or patient complications.
5. Discontinue power injections at first sign of infiltration / extravasation. Follow hospital protocol for appropriate medical intervention.
6. Use only lumen labeled "Pressure Injectable" for power injection to minimize the risk of catheter failure and/or patient complications.

Cautions:

1. Do not exceed the maximum pressure of 300 psi on power injector equipment to minimize the risk of catheter failure and/or tip displacement.
2. Do not exceed the catheter's maximum recommended flow rate located on product labeling to minimize the risk of catheter failure and/or tip displacement.

3. Warm contrast media to body temperature prior to power injection to minimize the risk of catheter failure.
4. Pressure limit settings on power injector equipment may not prevent over pressurization of an occluded catheter.
5. Use an appropriately rated 60 inch pressure tubing between catheter and power injector equipment to minimize the risk of catheter failure.
6. Follow the specified contrast media manufacturer's instructions for use, warnings, precautions, and contraindications.

Pressure Injection Procedure:

NOTE: Clinicians should use sterile technique when flushing, disconnecting, connecting, and replacing injection/needleless caps.

1. Use an appropriate method to confirm each tip placement prior to each pressure injection per institutional policy.
2. Remove injection cap from the lumen of catheter to be injected.
3. Check for catheter patency:
 - Attach 10 mL syringe, or larger, filled with sterile normal saline.
 - Aspirate catheter until approximately 3 mL of blood enters syringe freely.
 - Vigorously flush catheter.

Warning: Ensure catheter patency prior to pressure injection to minimize the risk of catheter failure and/or patient complications.

4. Detach syringe.
5. Attach power injection equipment and extension tubing to lumen of catheter according to manufacturer's recommendations.

Warning: Use only lumen labeled "Pressure Injectable" for power injection to minimize the risk of catheter failure and/or patient complications.

Caution: To minimize risk of catheter failure and/or tip displacement:

- Do not exceed the maximum pressure of 300 psi on power injector equipment.
- Do not exceed the catheter's maximum recommended flow rate located on product labeling.

6. Inject contrast media in accordance with hospital protocol.

Caution: Warm contrast media to body temperature prior to power injection to minimize the risk of catheter failure.

7. Disconnect catheter from power injector equipment.
8. Flush catheter with a 10 mL syringe, or larger, filled with sterile normal saline.
9. Replace sterile injection cap on catheter.

NOTE: Catheter testing included 10 pressure injection cycles.

Central Venous Pressure (CVP) Monitoring

Guidelines:

- Perform chest x-ray or other means of catheter tip placement verification prior to monitoring CVP.
- Flush catheter with sterile normal saline to ensure patency of catheter prior to monitoring CVP.
- It is recommended that injection caps are removed and lines are connected directly.
- Follow hospital/agency protocol for central venous pressure monitoring procedures.
- Ensure the pressure transducer is at the level of the right atrium.
- It is recommended that a continuous infusion of saline (3ml/Hr) is maintained through the catheter while measuring CVP to improve accuracy of CVP results.

Peripherally Inserted Central Catheter

Warnings and Precautions:

Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Figure 1).



Figure 1

General Warnings and Precautions

Warnings:

1. Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
2. Practitioners must be aware of complications associated with central vein catheters including but not limited to: cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, and dysrhythmias.
3. Practitioners must be aware of clinical conditions that may limit use of PICCs including but not limited to: dermatitis, cellulitis, and burns at or about the insertion site, previous ipsilateral venous thrombosis, radiation therapy at or about insertion site, contractures, mastectomy, and potential use for AV fistula.
4. Do not place central venous catheter (CVC) or peripherally inserted central catheter (PICC) into or allow them to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with hospital protocol must show catheter tip located in right side of mediastinum in the SVC (superior vena cava) above its junction with right atrium and parallel to vessel wall and its distal tip positioned at a level above either azygos vein or carina of the trachea, whichever is better visualized. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it. Improper advancement of guidewire into the heart has also been implicated in causing cardiac perforation and tamponade.
5. Ensure catheter tip has not entered the heart or no longer lies parallel to vessel wall by performing an x-ray exam or other method in compliance with hospital protocol. If catheter position has changed, immediately re-evaluate.
6. Choose appropriate sized catheter for size of vessel to be cannulated.
7. Practitioners must be aware of the potential for entrapment of guidewire by any implanted device in circulatory system (i.e., vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of guidewire inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of guidewire entrapment.
8. Catheter tip must be located in central circulation when administering > 10% glucose solution, total parenteral nutrition, continuous vesicant therapy, infusates with pH less than 5 or greater than 9, and infusates with an osmolality above 600 mOsm/L, or any medication known to be irritating to vessels proximal to the vena cava.
9. Infusion of incompatible drugs through a non "staggered port" may cause precipitation.
10. Be aware of the risk of chemically induced thrombophlebitis when catheter is placed with distal end located in a vessel proximal to the SVC.
11. Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolism can occur with these practices.
12. Use only securely tightened Luer-Lock connections with any Central Venous Access Device (CVAD) to guard against inadvertent disconnect.

13. Use Luer-Lock connectors to help guard against air embolism and blood loss.

Cautions:

1. The product is designed for single use only.
2. Do not resterilize or reuse.
3. Do not use if package has been previously opened or damaged.
4. Do not alter the catheter, guidewire, or any other kit/set component during insertion, use, or removal (except as instructed).
5. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
6. Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.
7. Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.
8. Temporarily shut off remaining port(s) through which solutions are being infused before blood sampling.
9. Blood aspirate color is not always a reliable indicator of venous access.
10. Do not reinsert needle into introducer catheter to minimize the risk of catheter embolism.
11. Retract scalpel to protected position when not in use to minimize the risk of sharps injury.
12. Perform hand hygiene before and immediately after all clinical procedures and before and after donning and removal of gloves.
13. Properly dispose of sharps in sharps container in accordance with US OSHA or other governmental standards for blood borne pathogens and/or institutional policy.
14. Hands must remain behind the needle at all times during use and disposal.
15. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.

Catheter Warnings and Precautions

Warnings:

1. For high pressure injection applications, only utilize catheters indicated for such applications. Catheters not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.

2. Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.
3. Do not secure, staple, and/or suture directly to outside diameter of catheter body or extension lines to minimize the risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.
4. Do not cut catheter to alter catheter length unless procedure requires it.
5. Catheter clamp and fastener (where provided) must not be attached to catheter until either guidewire or placement wire is removed.
6. Do not use scissors to remove dressing to minimize the risk of cutting catheter.
7. Catheter clamp must be opened prior to infusion to minimize risk of damage to extension line(s) from excessive pressure.
8. Do not attempt to advance or reinsert placement wire (where provided) into catheter, through the septum, if placement wire has been removed prior to catheter insertion. Attempting placement wire advancement or reinsertion increases the risk of damaging catheter or wire.
9. Do not clamp extension line(s) when placement wire is in catheter to minimize the risk of placement wire kinking.
10. Slide clamp(s), where provided, may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove slide clamp(s) when not in use.

Cautions:

1. Check ingredients of prep sprays and swabs before using. Some disinfectants used at catheter insertion site contain solvents which can attack the catheter material. Alcohol and acetone can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.
 - Acetone: Do not use acetone on catheter surface.
 - Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency.
 Take care when instilling drugs containing high concentration of alcohol. Allow insertion site to dry completely prior to applying dressing.
2. Do not use syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi), to minimize the risk of pressure induced damage to catheter.
3. Prior to attempting a catheter exchange procedure, remove catheter clamp and fastener (where provided).

4. Do not exert excessive force while removing the catheter, to minimize the risk of catheter breakage.
5. Continuously monitor indwelling catheters for:
 - desired flow rate
 - security of dressing
 - adherence of stabilization device to skin and connection to catheter
 - correct catheter position; use centimeter markings to identify if catheter position has changed
 - secure Luer-Lock connection
6. Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.
7. Provide strain relief of catheter under dressing to decrease catheter movement and assist in maintaining proper catheter tip position.
8. Inject a small amount of radiopaque dye to locate catheter tip if difficulty is encountered in visualizing the catheter tip.
9. Remove placement wire and Luer-Lock sidearm assembly as a unit. Failure to do so may result in wire breakage.

Caution:

1. Maintain a firm grip on guidewire at all times. Keep sufficient guidewire length exposed at hub for handling purposes. A non-controlled guidewire can lead to wire embolism.

Tissue Dilator Warnings

Warnings:

1. Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.
2. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.

Placement Wire & Guidewire / SWG Warnings and Precautions

Warnings:

1. Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
2. Do not cut guidewire to alter length.
3. Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.
4. Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation and bleeding.
5. Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel wall, atrial, or ventricular.
6. Do not apply undue force on guidewire to minimize the risk of possible breakage.
7. Do not apply excessive force in removing guidewire or catheter. If withdrawal cannot be easily accomplished, a visual image should be obtained and further consultation requested.
8. Do not cut guidewire with scalpel.
 - Position cutting edge of scalpel away from guidewire.
 - Retract blade of safety scalpel to protected position once cutaneous puncture site is enlarged, to minimize the risk of cutting the guidewire.

Peel-Away Sheath over Tissue Dilator Precaution

Caution:

1. Do not withdraw dilator until sheath is within vessel to minimize the risk of damage to sheath tip.

Possible Complications:

- cardiac tamponade secondary to vessel wall, atrial or ventricular perforation
- pleural injury
- air embolism
- catheter embolism
- bleeding / hemorrhage
- bacteremia
- thrombosis
- hematoma
- brachial plexus injury
- fibrin sheath formation
- vessel erosion
- mediastinal injury
- nerve injury
- thoracic duct laceration
- occlusion
- septicemia
- inadvertent arterial puncture
- dysrhythmias
- exit site infection
- phlebitis
- catheter tip malposition

Accessory Component Instructions

Review the list of components that will be utilized before beginning the Arrow® Pressure Injectable PICC insertion procedure. Kits / Sets may not contain all accessory components detailed in this section. Become familiar with instructions for each individual component(s) before beginning the actual PICC insertion procedure.

The following components are listed alphabetically.

Catheter Stabilization Device:

STATLOCK® Catheter Stabilization Device should be used in accordance with manufacturer's instructions for use.

- Cleanse and prep anticipated dressing site per hospital/agency protocol. Skin prep should be applied to coat skin and maximize STATLOCK® adherence. Allow to dry thoroughly. The anchor pad will be placed so center of pad is within 1 to 1-1/2 inches (2.5 to 3.8 cm) of catheter insertion site.
- The catheter can be secured to STATLOCK® by using the primary suture hub.

Caution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.

- Place suture hub wings over STATLOCK® posts and press down (refer to Figure 2). Snap STATLOCK® retainer wings to closed position to secure suture hub (refer to Figure 3).

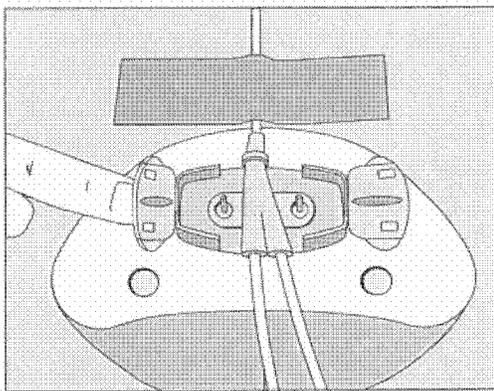


Figure 2

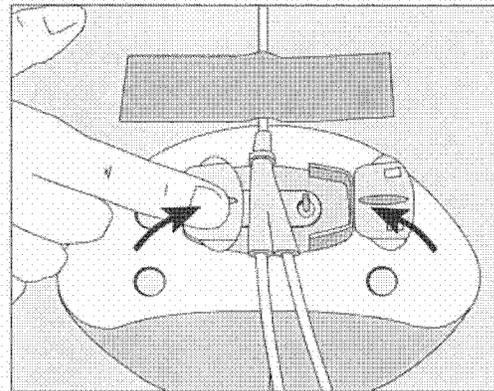


Figure 3

- Remove paper backing from one half of STATLOCK® Catheter Stabilization Device pad and press onto dry, prepared skin. Repeat process for other half of STATLOCK®.
- Complete sterile insertion site dressing according to established hospital/agency protocol.
- Document STATLOCK®/dressing application on patient's chart.
- Replace STATLOCK®/dressing per hospital/agency protocol. STATLOCK® Catheter Stabilization Device should be replaced at least every 7 days to ensure maximum adherence.

Catheter Trimmer:

NOTE: There should be very limited resistance when cutting catheter with supplied trimmer. Any greater resistance is likely to be caused by the placement wire – which has not been sufficiently retracted. If so, do not use catheter.

Catheter Trimmer is a one time use trimming device.

- To trim catheter with Catheter Trimmer, retract placement wire 1-1/2 inches minimum (4 cm) behind where catheter is to be cut. The placement wire is to be withdrawn through septum (see Figure 4).

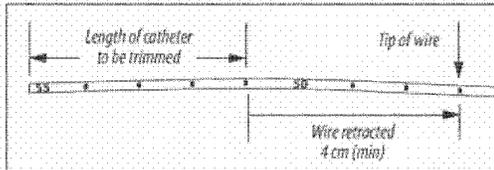


Figure 4

- Kink proximal end of placement wire at connector with side-port (see Figure 5). This minimizes the risk of placement wire extending beyond distal tip of catheter during insertion. (Do not attempt to advance placement wire through septum.)

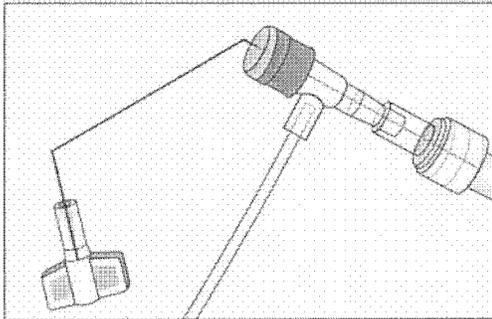


Figure 5

- Peel back contamination guard exposing catheter portion to be trimmed. Using trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Dressing:

Tegaderm™ IV Transparent Dressing:

- Prepare site. Allow all preps to dry completely.
- Peel liner from dressing to expose adhesive.

- Adhere center of transparent window over insertion site, while holding notched portion off the skin (refer to Figure 6).

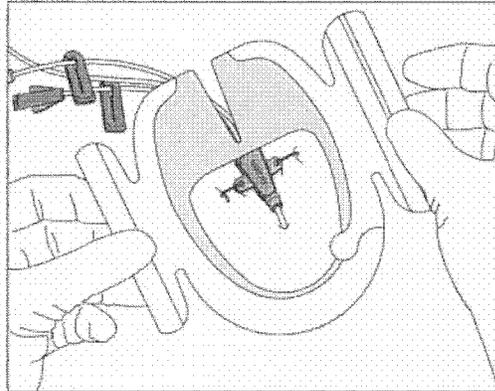


Figure 6

- Overlap softcloth tabs under catheter to form a tight seal around catheter hub and lumens (refer to Figure 7).

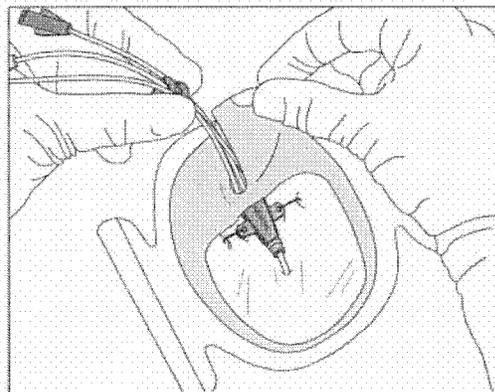


Figure 7

- Press dressing into place.
- Slowly remove frame while smoothing down dressing edges. Smooth dressing from center toward edges, use firm pressure to enhance adhesion (refer to Figure 8).

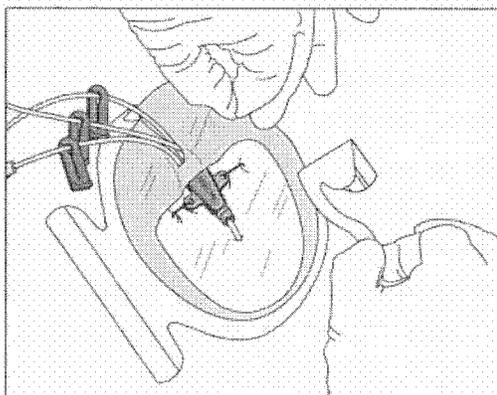


Figure 8

- Use sterile tape strips to secure hub, lumens, and/or tubing (refer to Figure 9).

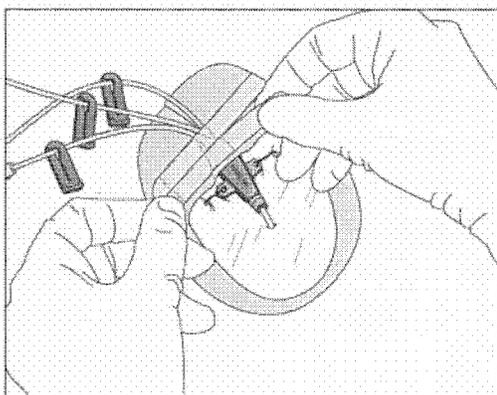


Figure 9

- Label dressing according to protocol.

Refer to individual manufacturer's instructions for more information and specific detailed instructions for dressing removal.

Echogenic Needle:

An echogenic needle is used to provide greater needle visibility under ultrasound. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Filter Straw:

A filter straw is utilized to aspirate solution from glass ampule (5 micron) and minimize the risk of glass particulate from entering the solution.

- Open glass ampule using appropriate sterile and sharps protection technique.
- Attach filter straw to syringe.
- Insert filter straw into ampule.
- Aspirate contents from ampule.
- Remove and discard filter straw.
- Attach appropriate needleless connector or cannula to syringe.
- Purge air from syringe.
- Label syringe appropriately.

Guidewire / SWG Insertion Techniques:

Kits/Sets are available with a variety of Guidewires/SWGs. Guidewires are provided in different diameters, lengths, and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique chosen, before beginning the actual PICC insertion procedure.

Image guidance may be used to gain initial venous access.

Catheter Insertion with an 80 cm Guidewire:

Use single 45 cm guidewire for venous access and 80 cm soft tip guidewire for catheter placement. Image guidance or fluoroscopy is used to gain initial venous access; catheter placement with 80 cm guidewire is done under fluoroscopy.

- Gain venous access with 45 cm guidewire and peel-away sheath.
- Load PICC onto 80 cm guidewire until soft tip of wire extends beyond tip of catheter.
- While maintaining control of distal end of guidewire, advance soft tip/catheter tip as a unit through peel-away sheath to desired depth.
- Once catheter is in desired location, remove guidewire.

Catheter Insertion with an 130 cm Guidewire:

Use single 45 cm guidewire for venous access and 130 cm soft tip guidewire for catheter placement. Image guidance or fluoroscopy is used to gain initial venous access; catheter placement with 130 cm guidewire is done under fluoroscopy.

- Gain venous access with 45 cm guidewire.
- Insert soft end of 130 cm guidewire through peel-away sheath to desired depth.
- Thread catheter over guidewire and advance catheter over guidewire through sheath into vessel into correct position.
- Once catheter is in desired location, remove guidewire.

NOTE: Some clinicians will gain access with 130 cm guidewire and thread catheter over guidewire once wire has been correctly positioned in the SVC. This technique is done under fluoroscopy.

Maximal Barrier Drape:

Drape(s) provide a maximal sterile barrier. Follow CDC Category 1A Recommendation.

- Drape provided is either:
 - Single extra-large drape with fenestration.
 - Two-piece drape consisting of an arm drape with fenestration and a body drape. The body drape is used to appropriately drape torso and upper-lower extremities.
- Unfold the Maximal Barrier Drape:
 - Peel off fenestration backing (refer to Figure 10).

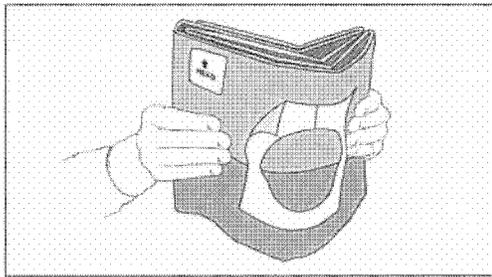


Figure 10

- Position fenestration over intended insertion site (refer to Figure 11).

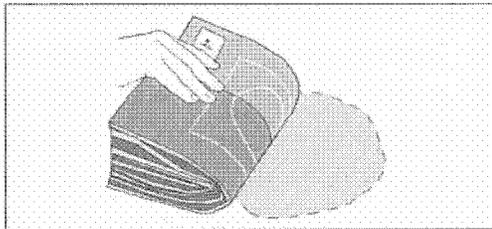


Figure 11

- Unfold width (refer to Figure 12).

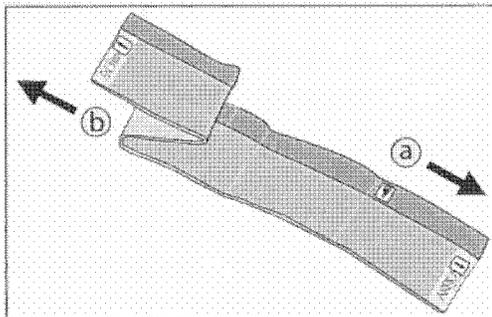


Figure 12

- Unfold towards head (refer to Figure 13).

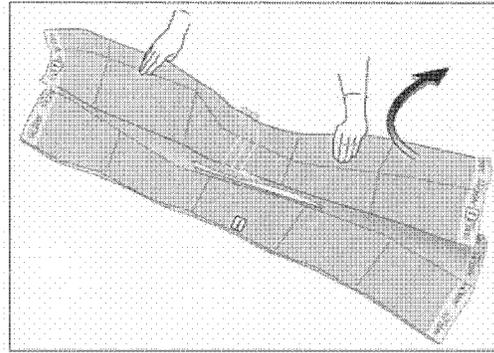


Figure 13

- Unfold towards hand (refer to Figure 14).

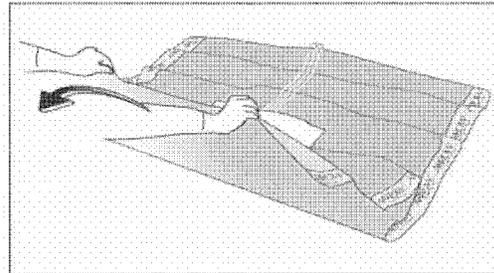


Figure 14

- Perform sterile procedure (refer to Figure 15).

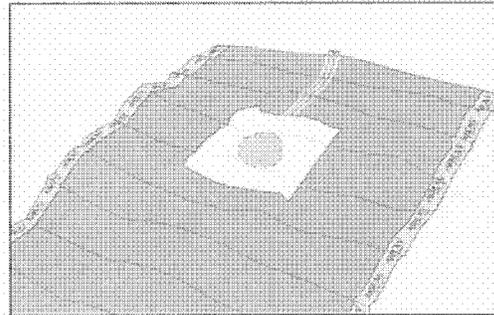


Figure 15

- Removal procedure: Tear along seam (refer to Figure 16).

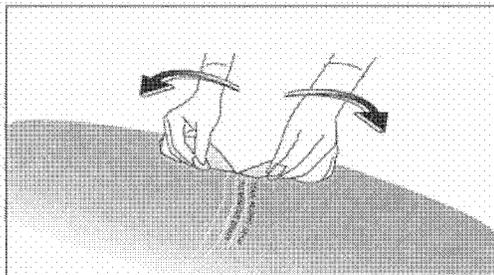


Figure 16

Positive Displacement Valve:

Positive displacement valves are needle-free injection ports utilized to minimize the risk of reflux of blood back into the catheter. Upon disconnection of syringe, a positive displacement of fluid will occur.

- Cleanse connector utilizing an appropriate antiseptic and friction prior to each use.
- Flushing should be done with an appropriately sized syringe.

Refer to individual manufacturer's instructions for specific details for priming volumes, dead space and flow rates.

CLC2000® Connector:

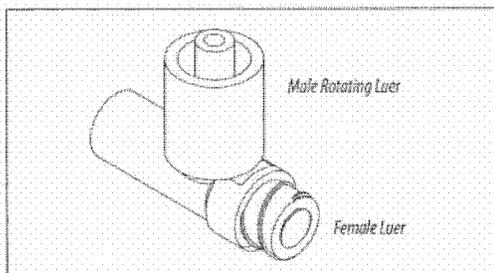


Figure 17

- Using aseptic technique remove CLC2000 from the package. Remove protective cap. Do not contaminate.
- Attach a syringe or administration set to female luer and prime CLC2000 in accordance with facility protocol. Invert device to expel air.
- Attach male rotating luer of CLC2000 to desired extension set or venous access device. Push and twist male rotating luer of CLC2000 into device until tight. Once the CLC2000 is secure, it may be rotated to achieve the most comfortable position on the patient's skin.

- To access CLC2000 swab female luer with desired disinfectant in accordance with facility protocol.
- Attach a fully primed syringe or administration set to CLC2000. Push and twist male luer of device into CLC2000 until tight. If using a rotating luer device, first push and twist Luer-Slip into CLC2000 until tight, then lock down the spin collar. This will ensure a secure connection and optimal flow rates.
- To disconnect from CLC2000, grasp CLC2000 and twist syringe or administration set away from CLC2000 until loose. **DO NOT CLAMP** catheter or extension set while disconnecting syringe or administration set from CLC2000, as it will interrupt the positive displacement.
- Flush the CLC2000 after each use with normal saline or in accordance with facility protocol.
- For subsequent connections repeat from step four.

Caution: **DO NOT USE NEEDLES** in the CLC2000.

Caution: **DO NOT CAP CLC2000**, device is closed.

Caution: **DO NOT CLAMP** the catheter prior to disconnecting a syringe from the CLC2000 as this will interrupt the positive displacement.

CLC2000 is exclusively manufactured by ICU Medical, Inc.,
San Clement, CA 800-824-7890
949-366-2183 | www.icumed.com

Protected Needle:

See individual manufacturer's instructions for product use, when used as a single product and not as a kit component.

Warning: **Hands must remain behind needle at all times during use and disposal.**

Caution: **Make sure all needles are used in accordance with OSHA and hospital safety protocols.**

Caution: **Do not attempt to override or defeat the safety locking mechanism of a protected needle.**

Caution: **Discard in an approved sharps collector in accordance with applicable regulations and institutional policy.**

SafetyGlide® Protected Needle:

- Aspirate medication into syringe using aseptic technique.
- If necessary to transport filled syringe to point of administration, use safe, passive recapping technique to cover needle before transport to point of use. In accordance with OSHA standards, such recapping must be accomplished by a one-handed technique, i.e., do not hold needle shield during recapping process.
- Administer injection following established technique.
- Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 18).

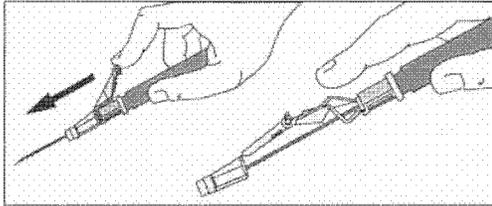


Figure 18

- Visually confirm lever arm has fully advanced and needle tip is covered. If unable to activate, discard immediately into approved sharps collector.
- Activation of protective mechanism may cause minimal splatter of fluid that may remain on needle after injection.
- After single use, discard in an approved sharps collector in accordance with applicable regulations and institutional policy. For greatest safety, use a one-handed technique and activate away from self and others.

SharpsAway II™ Locking Disposal Cup:

The SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 19).

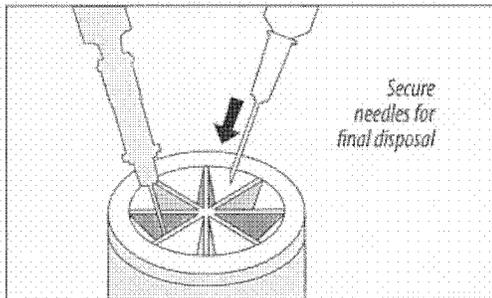


Figure 19

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.
- Discard entire cup, at completion of procedure, into an approved sharps container.

Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

Caution: Do not re-use needles after they have been placed into the foam SharpsAway® system. Particulate matter may adhere to needle tip.

Pre-PICC Insertion & Patient Assessment Activities

Perform hand hygiene as required.

A procedural checklist is included on back of product label.

Procedural Pause:

1. Verify physician order:
 - Confirm correct patient.
 - Confirm correct diagnosis.
 - Confirm correct procedure.

Physician order must include post placement assessment of catheter tip placement (x-ray exam or other method in compliance with hospital protocol).
2. Patient education: Explain procedure to patient. Make sure information is presented with respect to patient's level of understanding, culture, and language.
3. Have informed consent signed, if required.
4. Identify insertion vein:
 - Apply tourniquet above anticipated insertion vein.
 - Identify appropriate vein for insertion. Use direct visualization technologies, if available, and assess vein health.

NOTE: PICCs are typically inserted into basilic, brachial, or cephalic veins (refer to Figure 20).

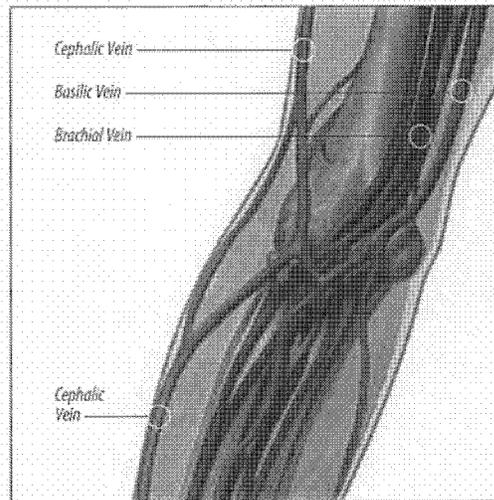


Figure 20

5. Release tourniquet and leave in place beneath the arm.
6. Measure patient to assure placement of catheter in the SVC:
 - Extend arm laterally 45 to 90 degrees from trunk.
 - Measure distance from insertion site along presumed anatomical course of vessel to be catheterized.
 - Catheter tip should lie in distal one-third of SVC above right atrium and parallel to SVC wall.
 - ◊ If a catheter stabilization device will be used, add 1/2 to 1 inch (1.2 to 2.5 cm) to catheter measurement (STATLOCK®); if another device is used, check manufacturer recommendations.
 - ◊ If using upper arm circumference assessment, for consistency in measurement, measure from an anatomical point and record.
7. Position patient as appropriate for insertion site:
 - Extend arm laterally 45 to 90 degrees from trunk.
8. Prepare work area.

Preparing for PICC Insertion:

- Perform hand hygiene as required:
 - before and immediately after all clinical procedures
 - before and after donning and removal of gloves
- Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens.
- Handle and dispose of sharps appropriately in accordance with state/federal OSHA standards for blood borne pathogens and/or institutional policy.
- Clinicians should use sterile technique, maximal sterile barrier precautions throughout the procedure, and dress in protective clothing:
 - mask
 - eye protection
 - sterile gown
 - sterile gloves
 - hair cover

Prep Puncture Site:

1. Prep and drape peripheral puncture site.
2. Perform skin wheal with a local anesthetic as needed.
3. In kits where provided, the SharpsAway II™ Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

Caution: Do not attempt to remove needles that have been placed into SharpsAway II™ Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.

Prepare All Equipment:

Prepare Catheter with Placement Wire for Insertion (where provided) (refer to Figure 21).

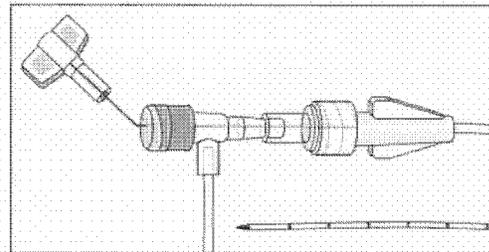


Figure 21

- Remove catheter tip protector.

Trim Catheter:

If necessary, review detailed instructions for Catheter Trimmer device under Accessory Component Instructions section.

1. Identify catheter type:
 - BFT (Blue Flex Tip®)
 - Non-BFT
2. Peel back contamination guard exposing catheter portion to be trimmed.
3. Review catheter marking pattern below. The catheter is marked so clinician can easily identify desired amount of catheter to be trimmed; length of catheter that remains or as with BFT catheter – both.
 - BFT double numbering pattern:



Figure 22

- ◊ First number designates centimeters from tip of catheter.
- ◊ Second number designates centimeters from hub of catheter.
- ◊ This double numbering pattern permits clinician to easily identify centimeters of catheter to be trimmed and also identifies centimeters of catheter remaining.
- ◊ Record both numbers.

- Non-BFT numbering pattern:

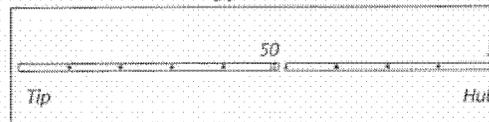


Figure 23

- ◊ Number designates centimeters of catheter to be trimmed and also gives amount of catheter remaining.

1472

- Using the trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip. **NOTE: There should be very limited resistance when cutting catheter with supplied trimming device. If using a catheter with a placement wire, any greater resistance is likely to be caused by the placement wire which has not been sufficiently retracted. If so, do not use catheter.**

- Inspect cut surface for clean cut and no loose material.

Warning: Do not cut placement wire when trimming catheter to minimize the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter segment, after trimming catheter. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.

Flush Catheter:

- Use filter straw to withdraw solution from glass ampules.
- Attach syringe to sidearm and flush distal lumen with sterile saline solution. Leave syringe in place.
- Flush remaining lumen(s) with sterile saline. Clamp or attach injection site cap(s) to extension line(s) to contain saline within lumen.

Catheter Insertion Instructions

- Reapply tourniquet and replace sterile gloves.
- Locate vein for insertion:
 - Use image guidance, if available.
 An echogenic needle is included for access.
- Insert introducer needle into vein.
 - Check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

Caution: The color of blood observed is not always a reliable indicator of venous access.

Gain Initial Venous Access:

See specific guidewire instructions, *Guidewire Insertion Techniques* (page 7) under Accessory Component Instructions section.

- Insert soft tip of guidewire through introducer needle into vein. Advance guidewire to desired depth.

Warning: Do not insert stiff end of soft tip guidewire into vessel as this may result in vessel damage.

Warning: Do not cut guidewire to alter length.

Warning: Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.

- Remove needle:
 - Hold guidewire in place while removing introducer needle.

Caution: Maintain firm grip on guidewire at all times.

- Enlarge puncture site, if necessary:
 - Use scalpel positioned away from the guidewire to enlarge cutaneous puncture site. Do not cut guidewire. Retract scalpel to the protected position.

Sheath Placement:

- Thread tapered tip of peel-away sheath/dilator assembly over guidewire. Grasping near skin advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to further facilitate advancement of sheath into the vessel. A slight twisting motion of the peel-away might help sheath advancement.

Caution: Do not withdraw tissue dilator until the sheath is well within the vessel to minimize the risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

- Check sheath placement by holding sheath in place, withdraw guidewire and dilator sufficiently to allow venous blood flow. Holding sheath in place, remove guidewire and dilator as a unit.

Warning: Do not leave the dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.

Warning: Do not apply undue force on guidewire to minimize the risk of possible breakage.

Catheter Advancement:

Advance catheter according to the guidewire used. Review detailed instructions for 80 cm and 130 cm guidewire usage (page 7) under Accessory Component Instructions section.

Warning: Do not apply excessive force in placing or removing catheter. Failure to do so can result in catheter breakage. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.

- Retract catheter guard.
- Insert catheter through peel-away sheath.
 - If resistance is met while advancing catheter, retract and/or gently flush while advancing.
- Stop advancing catheter 5 inches (13 cm) before reaching pre-established insertion length.
- Withdraw peel-away sheath over catheter until free from venipuncture site.
- Grasp tabs of peel-away sheath and pull apart, away from catheter, until sheath splits down entire length.
- Advance catheter to final indwelling position.

Placement Wire (where provided):

Caution: To minimize the risk of placement wire kinking, do not clamp extension line(s) when placement wire is in catheter.

- Complete catheter insertion.
- Remove placement wire.

Warning: Remove placement wire and Luer-Lock sidearm assembly as a unit (see Figure 24). Failure to do so may result in wire breakage.

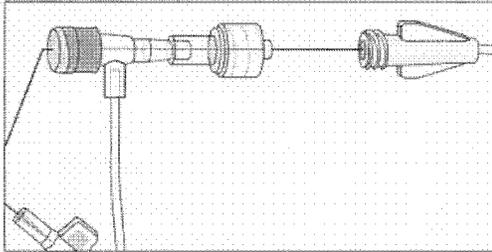


Figure 24

Caution: Catheter clamp and fastener (if provided and used) must not be attached to catheter until either guidewire or placement wire is removed.

Verify Catheter Tip Placement:

1. Examine tip of placement wire after removal to ensure wire has not been altered (see Figure 25).

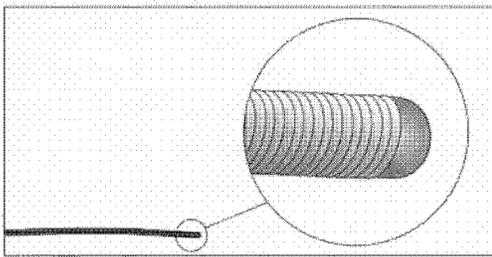


Figure 25

2. If there is any indication placement wire is damaged, catheter and placement wire should be removed together.
3. Check catheter placement with syringe by aspirating through distal lumen until free flow of venous blood is observed.

Caution: The color of blood is not always a reliable indicator of venous access.

Complete Catheter Insertion:

1. Flush lumen(s) to completely clear blood from catheter.
2. Connect extension line(s) to appropriate Luer-Lock line. Alternately, port(s) may be "locked" through injection cap(s) using standard hospital/agency protocol. Slide clamp(s) is provided on extension line to occlude flow through lumen during line and injection cap changes.

Warning: Slide clamp(s), where provided, may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove slide clamp(s) when not in use.

3. Cleanse insertion site per hospital/agency protocol.

Caution: Do not routinely apply prophylactic topical antimicrobial or antiseptic ointment or cream to the insertion site of peripheral venous catheters because of the potential risk to promote fungal infections and antimicrobial resistance.

4. Ensure insertion site is dry before applying dressing. Apply skin protectant as needed.
5. Secure catheter. Where provided, a catheter clamp, fastener, catheter stabilization device or Steri-Strip® may be used.
6. Assess placement of catheter tip in compliance with hospital protocol.

Documentation

Institutions must establish a permanent medical record that documents the entire procedure, based upon their policy, procedures, and Best Practices. The actual format can differ from institution to institution. Report any product defects/failures to organization risk management, manufacturers, and appropriate regulatory agencies.

Documentation generally includes (but is not limited to) the following information:

1. Device specifics:
 - type, brand and lot number
 - length and size of Vascular Access Device (VAD)
 - internal/external catheter length
 - whether catheter is trimmed
2. Procedure specifics:
 - time out or procedural pause
 - informed consent, as required
 - date, time of insertion, insertion site, number and site attempts, inserter's identification
 - use of visualization and guidance technologies
 - site preparation and technique
3. Patient assessment and response:
 - pertinent dx, assessment, vital signs
 - understanding of procedure, patient's response to procedure
 - complications and barriers to care
4. Therapy specifics:
 - type of therapy, drug dose, rate, time
 - route and method of administration
 - laboratory specimen collected
5. Visual confirmation:
 - verification of appropriate tip location prior to initial use
6. Monitor patient for post catheter insertion complications.

Care and Maintenance

Dressing:

Replace dressing according to organizational policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised e.g. dressing becomes damp, soiled, loosened, or no longer occlusive.

- Consult manufacturer's recommendations for dressing specifics.
- Transparent semipermeable membrane dressing should be changed every 7 days.
- Gauze and tape should be changed every 48 hours.
- Label dressing with type, size, and length of catheter; date and time; and initials of the clinician performing dressing change.

Maintain Catheter Patency:

Maintaining central venous catheter patency shall be done in accordance with organizational policies, procedures, and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Perform hand hygiene as required.

1. Solution and frequency of flushing a venous access catheter should be established in hospital/agency policy.
2. Catheter patency is established and maintained by:
 - flushing intermittently via syringe with heparinized saline or preservative-free 0.9% sodium chloride (USP)
 - continuous drip
 - positive pressure device
3. The amount of heparin:
 - depends on physician preference,
 - hospital/agency protocol,
 - patient condition

Caution: Assess patient for heparin sensitivity. Heparin-induced thrombocytopenia (HIT) has been reported with the use of heparin flush solutions.

4. The volume of flush solution should be:
 - equal to at least twice the priming volume of the catheter and any add-on devices

Catheter priming volume is printed on product packaging.
5. When using any central venous catheter for intermittent infusion therapy, proper flushing (heparinization) using a positive-pressure flushing technique will help prevent occlusion. Neutral as well as positive displacement valve systems have also been shown to help prevent occlusion.
6. All valves need to be properly cleansed with an appropriate antiseptic before being accessed.
7. The SASH or SAS method of flushing will help eliminate occlusions due to incompatible solutions:
 - Saline • Administer drug • Saline • Heparin (if used)

Catheter Removal Procedure

1. PICC removal shall be performed:
 - following order of authorized prescriber
 - in accordance with organizational policies, procedures, and practice guidelines
2. A PICC shall be removed immediately upon patient assessment for:
 - suspected contamination
 - unresolved complication
 - discontinuation of therapy
3. As indicated, place patient in supine position to minimize the risk of potential air embolism.

4. Remove dressing.

Warning: Do not use scissors to remove dressing, to minimize the risk of cutting catheter.

5. Open catheter stabilization device retainer wings and remove catheter from catheter stabilization device posts.
6. Remove catheter by slowly pulling it parallel to skin. If resistance is met when removing the catheter, catheter should not be forcibly removed and the physician should be notified.

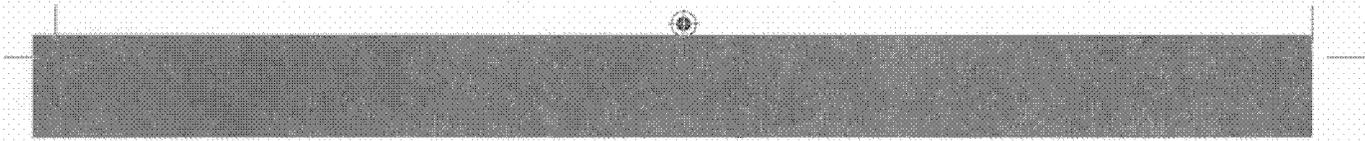
Caution: Do not exert excessive force while removing the catheter; to minimize the risk of catheter breakage.

7. Upon removal of catheter:
 - measure and inspect
 - ensure entire catheter length has been removed
8. Direct pressure should be applied at site until hemostasis is achieved.
9. Apply alcohol swab to catheter stabilization device adhesive and gently lift pad off of skin (if applicable).
10. Dress insertion site. Sterile occlusive dressing should be applied and site assessed every 24 hours until site is epithelialized. Residual catheter track may remain an air entry point until completely sealed (usually 24 to 72 hrs); dependent upon amount of time catheter was indwelling.
11. Document catheter removal procedure on patient's chart per hospital/agency protocol.

Include:

 - catheter condition
 - length of catheter removed
 - patient's tolerance of the procedure
 - any nursing interventions needed for removal

For reference literature concerning patient assessment, clinician education, insertion techniques and potential complications associated with central venous access refer to Arrow International, Inc. website: www.arrowintl.com



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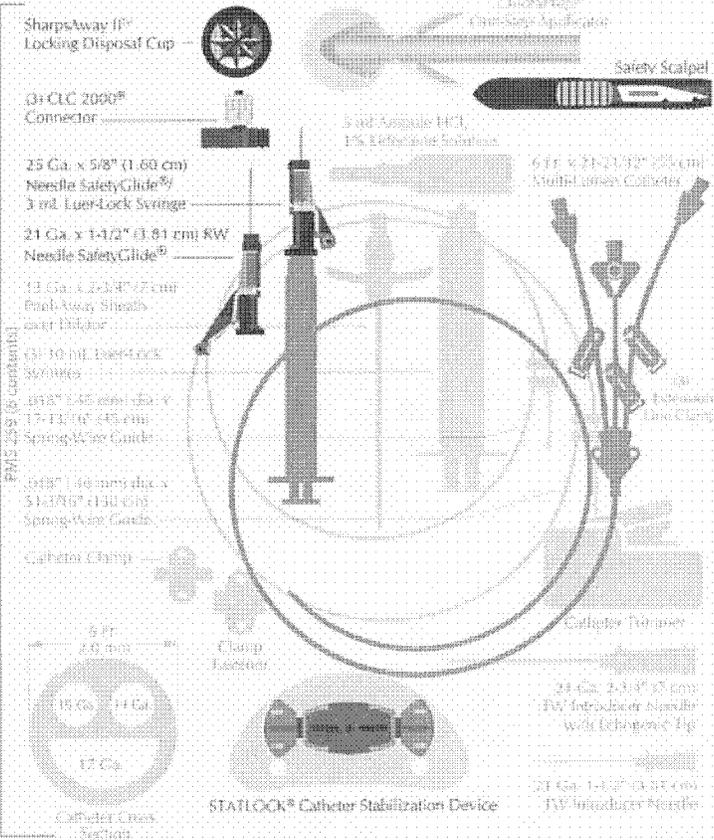
1476

Dimensions: 7 x 9

Pressure Injectable Multi-Lumen PICC Kit
with Blue FlexTip® Catheter



- INFECTION PROTECTION FEATURES:**
- BIORAPID™ Dressing
 - ChlorPrep® One-Step skin antisepsis; 2% chlorhexidine gluconate in 70% isopropyl alcohol with Hi-Low Challenge™ Test
- SAFETY FEATURES:**
- CLC 2000® Positive Displacement Catheter Connector
 - SafetyGlide® Protected Needles
 - SharpsAway II™ Locking Disposal Cup
 - Safety Scalpel
 - STATLOCK® Catheter Stabilization Device



Lumen	Priming Volume* (mL)	Flow Rate† (mL/hr)	Pump Flow Rate** (mL/hr)	MAX Pressure Injectable Flow Rate†† (mL/sec)
Distal (17 Ga.)	0.71	1070	1976	6
Medial (19 Ga.)	0.46	360	2246	n/a
Proximal (19 Ga.)	0.49	350	2467	n/a

* Priming volumes are approximate and are done without the CLC 2000® Connector. CLC 2000® Connector priming volume is 2.06 mL.
 † Flow rates were determined using room temperature water, 100 cm head height and represent approximate flow capabilities.
 ** Pump flow rates are determined at maximum pump pressure of 10 psi and represent approximate flow capabilities.
 †† Pressure injection flow rates are determined at injector pressure settings of 300 psi maximum using media of 1.18 centipoise viscosity, with 60" extension tubing.

Extreme Safety **ARROW**
PR-05563-HPX

- Contents:**
- One Multi-Lumen Inwelling Catheter 6 fr. x 21-2/32" (5.5 cm)
 - One **Pressure Injectable** Radiopaque Polyurethane with Blue FlexTip® and Extension Line Clamps
 - One Peel-Away Sheath: 13 Ga. x 1-1/2" (3.81 cm) Radiopaque over Dilator
 - One Spring-Wire Guide, Matched: #15" (3.81 mm dia. x 51-1/16" (130 cm) (Both Ends Straight) - Saw Tip on Distal End
 - One Spring-Wire Guide: #18" (4.6 mm dia. x 37-1/16" (95 cm) (Straight Saw Tip on Both Ends)
 - One **Injection Needle: SafetyGlide® 21 Ga. x 1-1/2" (3.81 cm) RW**
 - One Introducer Needle: 24 Ga. x 1-1/2" (3.81 cm) RW
 - One Introducer Needle: 24 Ga. x 3/4" (1.91 cm) RW with Echogenic Tip
 - Three Syringes: 10 mL Luer-Lock
 - One **Injection Needle: SafetyGlide® 25 Ga. x 5/8" (1.60 cm) and 3 mL Luer-Lock Syringe**
 - One 3 mL Applicator Pouch, 2% CHG and 70% IPA ChlorPrep® One-Step Solution with Hi-Low Challenge™ Int.
 - One 10 mL Ampule: 0.9% Saline Solution
 - One Medication Label: 0.9% Saline
 - One 5 mL Ampule: 1% Lidocaine Solution
 - One Medication Label: 1% Lidocaine
 - One Fast-Accessed Pouch: 29% Skin Protectant Prep Pad
 - One Clamp: Catheter
 - One Fastener: Catheter Clamp
 - One **SharpsAway II™ Locking Disposal Cup**
 - One Catheter Trimmer
 - One QSR Wrap
 - One Towel: 24" x 36"
 - One Filter: 3 Micron Straw
 - One **Safety Scalpel: #11**
 - One Chart Sticker
 - One Patient ID Card
 - One Patient Information Booklet
 - One Dressing: BIORAPID™
 - One **Dressing: STATLOCK® Catheter Stabilization Device**
 - One Dressing: Tegaderm™ 13.3 cm x 11 cm
 - Five Gauze Pads: 2" x 2"
 - Two Gauze Pads: 4" x 4"
 - Two Paper Tape Measures
 - One FoamSquee
 - One Tape: Steri-Strip™
 - Three **Valves: CLC 2000® Positive Displacement Connector**
 - One Checklist and course rider
 - Two registered trademarks of Becton Dickinson and Company
 - Two registered trademarks of Cardinal Health, Inc. or one of its subsidiaries
 - One registered trademark of C. R. Bard, Inc.
 - One registered trademark of Johnson & Johnson Corporation
 - One registered trademark of C. R. Bard, Inc.
 - One registered trademark of The Company
 - One registered trademark of B.D. Medical, Inc.

Ex only.
 Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

Do not use if package has been previously opened or damaged. Check that components are not expired, C.O.D. expires application, single use - discard after use. Sterilized by irradiation only.
 Arrow International provides the original instructions labels for your convenience. Please ensure that these labels are applied to the correct syringe and compatible medication.
 Store between 20° - 25°C (68° - 77°F).
 This product contains **NO** natural rubber latex.

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 www.arrow-intl.com

6 fr. | 3 Lumen | 55 cm catheter length | .018 inch dia. spring-wire guide

PR-05563-HPX
Pressure Injectable Multi-Lumen PICC Kit
 with Blue FlexTip® Catheter
 PMS 259

1479

PICC Line Insertion Checklist

Indication: To document procedural practices related to insertion technique for Central Venous Catheters.

Patient ID: _____

Date of Birth (mm/dd/yy): ____/____/____

First Name: _____

Male Female

Last Name: _____

Notes: _____

Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Is this a NEW line? YES NO

This procedure is: Elective Emergency Re-position Other: _____

Before Procedure, did the clinician:

Perform Procedural Pause:

- Perform patient ID x2?
- Confirm diagnosis, therapy and duration; utilize relevant documents (charts/forms)?
- Announce procedure to be performed?
- Mark / assess the site?
- Position patient correctly for procedure?
- Assemble equipment / verify supplies?
- Utilize relevant documents (charts / forms)?
- Order follow-up radiology images (PRN)?
- Cleanse hands (ask if unsure)?

YES YES
 offer
 consider

Prep Procedure Site:

- Use chlorhexidine?
- Other site preparation: _____
- Use large drape to cover patient in sterile fashion?

During Procedure, did the clinician:

- Wear sterile gloves, cap, mask, and gown?
- Maintain sterile field?
- Vein identification: Palpitation Fluoroscopy Ultrasound other
- Did procedure assistant follow same sterile precautions?
- Did all personnel in the room wear a mask?
- Technique used: Modified Seldinger Technique Direct puncture
- Other technique used: _____

After Procedure:

- Was sterile technique maintained applying dressing?
- Was dressing dated?
- Was the catheter trimmed? Yes No Length: _____
- Was a guillotine used? Yes No

--	--

Patient Label

Insertion Procedure Practices

Name of Procedure Clinician (signature if applicable): _____

Name of Procedure Assistant: _____

Name of Procedure Auditor: _____

Today's Date (mm/dd/yy): ____/____/____

This form is provided as an option for recording basic best practice procedures as recommended by the CDC Guidelines, INS Standards and IHI Initiatives. A hospital specific checklist may be in use. Consult your hospital insertion line protocol for guidance. Specific catheter manufacture identification is provided on reverse side of original document (including product size, description and product lot number).



149P

Arrow® Pressure Injectable PICC Information

MAXIMUM injector pressure setting: 300 psi

Catheter size:	MAX Indicated Pressure Injection Flow Rate ¹	Average Max Catheter Pressure During MAX Flow Rate ²	Average MAX Static Burst Pressure ³	Range of MAX Static Burst Pressure ³
4 Fr. 40 cm S-L	4 mL/sec	232 psi	425 psi	411-435 psi
4 Fr. 50 cm S-L	4 mL/sec	250 psi	413 psi	402-421 psi
4 Fr. 55 cm S-L	4 mL/sec	262 psi	370 psi	359-385 psi
5 Fr. 40 cm D-L	4 mL/sec	208 psi	355 psi	344-371 psi
5 Fr. 50 cm D-L	4 mL/sec	220 psi	334 psi	323-343 psi
5 Fr. 55 cm D-L	4 mL/sec	195 psi	325 psi	313-340 psi
5 Fr. 55 cm D-L ⁴	5 mL/sec	218 psi	336 psi	322-354 ps
6 Fr. 40 cm T-L	6 mL/sec	183 psi	355 psi	335-374 psi
6 Fr. 50 cm T-L	6 mL/sec	197 psi	327 psi	309-353 psi
6 Fr. 55 cm T-L	6 mL/sec	204 psi	364 psi	351-373 psi

¹ Represents maximum indicated flow rate for pressure injection of contrast media. ² Represents internal catheter pressure during pressure injection with injector safety cut-off at 300 psi, using media of 11.8 Centipoise (cP) viscosity. ³ MAX static burst pressure is the failure point of catheter when occluded. ⁴ Non Blue Flex-Tip Catheter.
* See Instructions for Use for additional information.

Pressure Injection

Warnings and Precautions:

Warnings:

1. Assess each patient for appropriateness of a power injection procedure.
2. Power injection procedures must be performed by trained personnel well versed in safe technique and potential complications.
3. Use an appropriate method to confirm catheter tip position prior to each pressure injection per institutional policy.
4. Ensure patency of catheter prior to power injection to minimize the risk of catheter failure and/or patient complications.
5. Discontinue power injections at first sign of infiltration / extravasation. Follow hospital protocol for appropriate medical intervention.
6. Use only lumen labeled "Pressure Injectable" for power injection to minimize the risk of catheter failure and/or patient complications.

Cautions:

1. Do not exceed the maximum pressure of 300 psi on power injector equipment to minimize the risk of catheter failure and/or tip displacement.
2. Do not exceed the catheter's maximum recommended flow rate located on product labeling to minimize the risk of catheter failure and/or tip displacement.
3. Warm contrast media to body temperature prior to power injection to minimize the risk of catheter failure.
4. Pressure limit settings on power injector equipment may not prevent over pressurization of an occluded catheter.
5. Use an appropriately rated 60 inch pressure tubing between catheter and power injector equipment to minimize the risk of catheter failure.
6. Follow the specified contrast media manufacturer's instructions for use, warnings, precautions, and contraindications.

Pressure Injection Procedure:

NOTE: Clinicians should use sterile technique when flushing, disconnecting, connecting, and replacing injection/needless caps.

1. Use an appropriate method to confirm each tip placement prior to each pressure injection per institutional policy.
2. Remove injection cap from the lumen of catheter to be injected.
3. Check for catheter patency:
 - Attach 10 mL syringe, or larger, filled with sterile normal saline.
 - Aspirate catheter until approximately 3 mL of blood enters syringe freely.
 - Vigorously flush catheter.

Warning: Ensure catheter patency prior to pressure injection to minimize the risk of catheter failure and/or patient complications.

4. Detach syringe.
5. Attach power injection equipment and extension tubing to lumen of catheter according to manufacturer's recommendations.

Warning: Use only lumen labeled "Pressure Injectable" for power injection to minimize the risk of catheter failure and/or patient complications.

Caution: To minimize risk of catheter failure and/or tip displacement:

- Do not exceed the maximum pressure of 300 psi on power injector equipment.
- Do not exceed the catheter's maximum recommended flow rate located on product labeling.

6. Inject contrast media in accordance with hospital protocol.
- Caution:** Warm contrast media to body temperature prior to power injection to minimize the risk of catheter failure.
7. Disconnect catheter from power injector equipment.
8. Flush catheter with a 10 mL syringe, or larger, filled with sterile normal saline.
9. Replace sterile injection cap on catheter.

NOTE: Catheter testing included 10 pressure injection cycles.

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Reading, PA 19605 USA

C-04063-103A (10/08)

1272

1999

Pressure Injectable PICC Information

Patient ID: _____ Date of Birth (mm/dd/yy): ____/____/____
 First Name: _____ Male Female
 Last Name: _____ Notes: _____
 Location (unit/ward/bed): _____

Insertion Site: Right Left Basilic Cephalic Brachial Other: _____

Kit No.: _____ Date Inserted (mm/dd/yy): ____/____/____

Injection Log

	Date	Lumen	Volume	Flow Rate	Contrast Media
1					
	Notes:				
2					
	Notes:				
3					
	Notes:				
4					
	Notes:				
5					
	Notes:				
6					
	Notes:				
7					
	Notes:				
8					
	Notes:				
9					
	Notes:				
10					
	Notes:				

Patient Label

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 INTERNATIONAL
 Arrow International, Inc.
 2400 Bernville Road
 Reading, PA 19605 USA

1273 1490

Product No.
LATEX-FREE

PR-05563-HPX

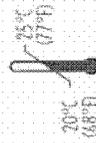
6 Fr. x 21-21/32" (55 cm)

Pressure Injectable PICC Kit

with Blue FlexTip® Catheter and Sharps Safety Features

Storage Requirements: Store between 20 - 25°C (68 - 77°F).

Qty: 5
Contains Medication



1274

Single use – do not resterilize. Sterilized by ethylene oxide.
Fluid path components are non-pyrogenic.

Version 01101084

1481

1274

FDA CDRH DMC

MAR 05 2010

Received

ATTACHMENT 8

Aging Documents

1482

1275

ATTACHMENT 9

Biocompatibility Test Reports

1499

1292

ATTACHMENT 10

Biocompatibility Review and Risk Assessment

1788

1581

ATTACHMENT 11

In Vitro External Efficacy Testing Protocol and Report

1812

1605

FDA CDRH DMC

MAR 05 2010

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ATTACHMENT 12

In Vitro Internal Efficacy Testing Protocol and Reports

1891

1684

ATTACHMENT 13

In Vivo Antimicrobial Efficacy Testing Protocols and Reports

2145

1938

ATTACHMENT 14

ARROWg⁺ard Blue PLUS[®] Clinical Study References

Attachment 14

List of Documents

1. Brun-Buisson C, Doyon F, Sollet J, Cochard J, et al. Prevention of intravascular catheter-related infection with newer chlorhexidine-silver sulfadiazine-coated catheters: a randomized controlled trial. *Intensive Care Medicine*. 2004;30:837-843.
2. Ostendorf T, Meinhold A, Harter C, Salwender H, et al. Chlorhexidine and silver sulfadiazine coated central venous catheters in haematological patients – a double-blind, randomized, prospective, controlled trial. *Support Care Cancer*. 2005;13:993-1000.
3. Rupp M, Lisco S, Lipsett P, Perl T, et al. Effect of a second-generation venous catheter impregnated with chlorhexidine and silver sulfadiazine on central catheter-related infections. *Annals of Internal Medicine*. October 18, 2005;143(8):570-581.

Christian Brun-Buisson
Françoise Doyon
Jean-Pierre Sollet
Jean-François Cochard
Yves Cohen
Gérard Nitenberg

Prevention of intravascular catheter-related infection with newer chlorhexidine-silver sulfadiazine-coated catheters: a randomized controlled trial

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Participants of the Catheter Infection Prevention Study Group, co-authors of this article, are listed in the Appendix (electronic supplementary material). This work was presented in part at the International Conference of Antimicrobial Agents and Chemotherapy, San Francisco, October 2002.

Electronic Supplementary Material
Supplementary material is available in the online version of this article at <http://dx.doi.org/10.1007/s00134-004-2221-9>.

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Abstract Background: The indication of antiseptic-coated catheters remains debated. **Objective:** To test the ability of the new generation of chlorhexidine-silver and sulfadiazine-coated catheters, with enhanced antiseptic coating, to reduce the risk of central venous catheter (CVC)-related infection in ICU patients. **Design:** Multicentre randomized double-blind trial. **Patients and setting:** A total of 397 patients from 14 ICUs of university hospitals in France. **Intervention:** Patients were randomized to receive an antiseptic-coated catheter (ACC) or a standard non-coated catheter (NCC). **Measurements:** Incidence of CVC-related infection. **Results:** Of 367 patients having a successful catheter

insertion, 363 were analysed (175 NCC and 188 ACC). Patients had one (NCC=162, ACC=180) or more (NCC=13, ACC=11) CVC inserted. The two groups were similar for insertion site [subclavian (64 vs 69)] or jugular (36 vs 31%), and type of catheters (single-lumen 18 vs 18%; double-lumen 82 vs 82%), and mean (median) duration of catheterisation [12.0±11.7 (9) vs 10.5±8.8 (8) days in the NCC and ACC groups, respectively]. Significant colonisation of the catheter occurred in 23 (13.1%) and 7 (3.7%) patients, respectively, in the NCC and ACC groups (11 vs 3.6 per 1000 catheter-days; $p=0.01$); CVC-related infection (bloodstream infection) occurred in 10 (5) and 4 (3) patients in the NCC and CC groups, respectively (5.2 vs 2 per 1000 catheter days; $p=0.10$). **Conclusions:** In the context of a low baseline infection rate, ACC were associated with a significant reduction of catheter colonisation and a trend to reduction of infection episodes, but not of bloodstream infection.

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Chlorhexidine and silver-sulfadiazine coated central venous catheters in haematological patients—a double-blind, randomised, prospective, controlled trial

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Abstract Background: Central venous catheters (CVCs) are essential for the intensive care of patients with haematological illness. Catheter-related infections (CRI) are an important problem in modern medicine, which may lead to life-threatening situations, to prolonged hospitalisation and increased cost. In immunocompromised patients suffering from haemato-oncological diseases, CRI is a significant factor for adverse outcome. Several clinical studies have shown that CVCs coated with antiseptics such as chlorhexidine and silver-sulfadiazine (CHSS) reduce the risk of catheter-related bacteraemia. Most studies, however, were performed on intensive care patients not suffering from chemotherapy-induced immunosuppression. **Patients and methods:** A prospective double-blind, randomised, controlled trial was performed to investigate the effectiveness of CHSS-coated catheters in haemato-oncological patients. A total number of 184 catheters (median duration of placement, 11 days) were inserted into 184 patients (male 115, female 69), of which 90 were antiseptically coated. After removal, all catheters were

investigated for bacterial growth. **Main results:** Catheters coated with CHSS were effective in reducing the rate of significant bacterial growth on either the tip or subcutaneous segment (26%) compared to control catheters (49%). The incidence of catheter colonisation was also significantly reduced (12% coated vs 33% uncoated). Data obtained show a significant reduction of catheter colonisation in CHSS catheters. There was no significant difference in the incidence of catheter-related bacteraemia (3% coated vs 7% uncoated). However, due to the overall low rate of CRI, we could not observe a significant reduction in the incidence of catheter-related bacteraemia. **Conclusion:** Our data show that the use of CHSS catheters in patients with haematological malignancy reduces the overall risk of catheter colonisation and CRI, although the incidence of catheter-related bacteremia was similar in both groups.

Keywords Central venous catheter · Chlorhexidine · Silver sulfadiazine · Catheter-related infection · Haematologic–oncologic patients

Copyrighted Material

2345

Effect of a Second-Generation Venous Catheter Impregnated with Chlorhexidine and Silver Sulfadiazine on Central Catheter-Related Infections

A Randomized, Controlled Trial

Mark E. Rupp, MD; Steven J. Lisco, MD; Pamela A. Lipsett, MD; Trish M. Perl, MD, MSc; Kevin Keating, MD; Joseph M. Civetta, MD; Leonard A. Mermel, DO, ScM; David Lee, MD; E. Patchen Dellinger, MD; Michael Donahoe, MD; David Giles, MD; Michael A. Pfaller, MD; Dennis G. Maki, MD; and Robert Sherertz, MD

Background: Central venous catheter-related infections are a significant medical problem. Improved preventive measures are needed.

Objective: To ascertain 1) effectiveness of a second-generation antiseptic-coated catheter in the prevention of microbial colonization and infection; 2) safety and tolerability of this device; 3) microbiology of infected catheters; and 4) propensity for the development of antiseptic resistance.

Design: Multicenter, randomized, double-blind, controlled trial.

Setting: 9 university-affiliated medical centers.

Patients: 780 patients in intensive care units who required central venous catheterization.

Intervention: Patients received either a standard catheter or a catheter coated with chlorhexidine and silver sulfadiazine.

Measurements: The authors assessed catheter colonization and catheter-related infection, characterized microbes by molecular typing, and determined their susceptibility to antiseptics. Patient tolerance of the catheter was monitored.

Results: Patients with the 2 types of catheters had similar demographic features, clinical interventions, laboratory values, and risk factors for infection. Antiseptic catheters were less likely to be

colonized at the time of removal compared with control catheters (13.3 vs. 24.1 colonized catheters per 1000 catheter-days; $P < 0.01$). The center-stratified Cox regression hazard ratio for colonization controlling for sampling design and potentially confounding variables was 0.45 (95% CI, 0.25 to 0.78). The rate of definitive catheter-related bloodstream infection was 1.24 per 1000 catheter-days (CI, 0.26 to 3.62 per 1000 catheter-days) for the control group versus 0.42 per 1000 catheter-days (CI, 0.01 to 2.34 per 1000 catheter-days) for the antiseptic catheter group ($P = 0.6$). Coagulase-negative staphylococci and other gram-positive organisms were the most frequent microbes to colonize catheters. Noninfectious adverse events were similar in both groups. Antiseptic susceptibility was similar for microbes recovered from either group.

Limitations: The antiseptic catheter was not compared with an antibiotic-coated catheter, and no conclusion can be made regarding its effect on bloodstream infection.

Conclusions: The second-generation chlorhexidine-silver sulfadiazine catheter is well tolerated. Antiseptic coating appears to reduce microbial colonization of the catheter compared with an uncoated catheter.

Ann Intern Med. 2005;143:570-580.
For author affiliations, see end of text.

www.annals.org

Copyrighted Material

ATTACHMENT 15

MEC Supporting Documentation

2365

2158

Attachment 15

List of Documents

1. Schaadt R, Sweeney D, Activity of silver sulfadiazine and chlorhexidine in combination against representative strains of bacteria and *Candida albicans*, Report 03-23-2007-Arrow6, 23 March 2007.
2. Block, S.S. 2001. Chlorhexidine. Ch. 15 in Disinfection, Sterilization and Preservation, 5th ed., S.S. Block (Ed.), p. 321-336, 2001.

2366

CHAPTER 15

Chlorhexidine

Graham W. Denton

Copyrighted Material



COVER SHEET MEMORANDUM

From: Reviewer Name William M. Burdick
Subject: 510(k) Number K100635/S2
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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20202%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	X	
510(k) Summary	510(k) Statement Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
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)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674; Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674; Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days - < 2 years old)			X
Child (2 years - < 12 years old)			X
Adolescent (12 years - < 18 years old)			X
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.)			X

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old) X
 Nanotechnology X
 Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC. X

Regulation Number: 880.5970 Class*: II Product Code: ~~F333~~ LJS
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____
 Review: *[Signature]* Acting for RICHARD CHAPMAN GHDB 8/27/2010
(Branch Chief) (Branch Code) (Date)

Final Review: *[Signature]* 8/27/10
(Division Director) (Date)

5



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

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

K100635/S002

Date: August 26, 2010

To: The Record

From: William M. Burdick

Office: HFZ-480

Division: DAGID/GHDB

510(k) Holder: Arrow International, Inc.

Device Name: Arrow Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter
[a.k.a ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC]

Contact #1: Tracy Maddock, RAC
Regulatory Affairs Specialist

Phone: (610) 378-0131 extension 3384

Email: tracy.maddock@teleflexmedical.com

I. Purpose and Submission Summary

(b)(4)

[Redacted content]

Burdick, William M.

From: Panguluri, Ramesh K
Sent: Thursday, August 26, 2010 1:46 PM
To: Burdick, William M.
Cc: Chapman, Richard; Runner, Susan

(b)(4),(b)(5)

From: Burdick, William M.
Sent: Wednesday, August 25, 2010 6:31 PM
To: Panguluri, Ramesh K

(b)(4),(b)(5)

William M. Burdick
Biomedical Engineer/Physicist
ODE/DAGID/GHDB
WO66, Room 2522
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Ph #: 301-796-6286
FAX #: 301-847-8109
E-Mail: william.burdick@fda.hhs.gov

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FDA - Teleflex Medical Conference Call Meeting Minutes

Date: August 3, 2010

Re: Antimicrobial PICC 510(k) Submission (K100635)

Attendees:	Tracy Maddock, RAC	Regulatory Affairs Specialist
	Robin Fatzinger, RAC	Director, Regulatory Affairs
	Robert Phillips	V.P, QA/RA
	William Burdick	Lead Reviewer
	Kapil Panguluri, Ph.D.	Consulting Reviewer

(b)(4),(b)(5)



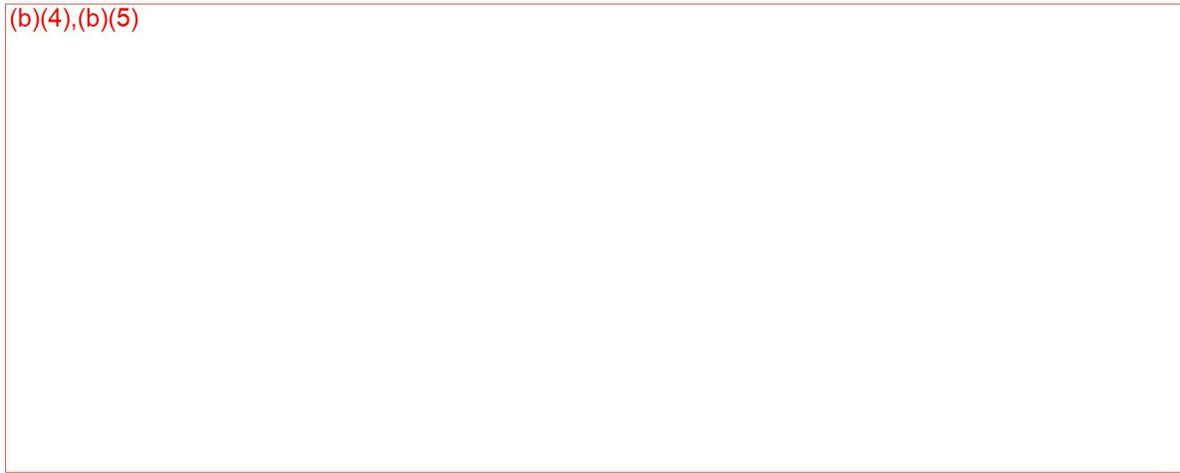
41

FDA - Teleflex Medical Conference Call Meeting Minutes

Date: August 3, 2010

Re: Antimicrobial PICC 510(k) Submission (K100635)

(b)(4),(b)(5)



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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf	X		
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080275.htm	X		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm	X		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm	X		
Class III Summary and Certification	Class III Summary and Certification Form http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf Financial Disclosure by Clinical Investigators http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm			X

Title	Related Information	Present	Inadequate	N/A
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm FDA Standards program http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm			X
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm	X		
Proposed Labeling	Device Advice "Content of a 510(k)" Section H http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072783.htm 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm	X		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm			X

Title	Related Information	Present	Inadequate	N/A
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/default.htm See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			X
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm	X		
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 http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf			X
FORM FDA 3654, Standards Data Report for 510(k)s - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf	Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity – Yes Standards Form Required 3: Standard but no declaration – Yes Standards Form Required	X		
Kit Certification	Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080213.htm			X

Last Updated: 9/3/08 – Brandi Stuart

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PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)	(b)(4),(b)(5)	
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?)	(b)(4),(b)(5)	
3. Does this device type require a PMA by regulation? (Please see management.)	(b)(4),(b)(5)	
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20%202007.doc)	(b)(4),(b)(5)	
5. a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)	(b)(4),(b)(5)	
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)	(b)(4),(b)(5)	



COVER SHEET MEMORANDUM

From: Reviewer Name

William M. Budnick

Subject: 510(k) Number

12100635/51

To: The Record

Please list CTS decision code TH

Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_5631/Screening%20Checklist%207%202%2007.doc)

Hold (Additional Information or Telephone Hold) AI E-Mail

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		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/O_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
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.)			

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From: Burdick, William M.
Sent: Thursday, June 24, 2010 6:53 PM
To: 'Maddock, Tracy'
Cc: Burdick, William M.
Subject: K100635/S001 - ARROWg⁺ard Evolution Antimicrobial Pressure Injectable
PICC

**K100635/S001: ARROWg⁺ard Evolution Antimicrobial
Pressure Injectable PICC**

(b)(4),(b)(5)

(b)(4),(b)(5)

Sincerely,

William M. Burdick
Biomedical Engineer/Physicist
ODE/DAGID/GHDB
WO66, Room 2522

12/

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Ph #: 301-796-6286
FAX #: 301-847-8109
E-Mail: william.burdick@fda.hhs.gov

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

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

K100635/S001

Date: June 23, 2010

To: The Record

From: William M. Burdick

Office: HFZ-480

Division: DAGID/GHDB

510(k) Holder: Arrow International, Inc.

Device Name: ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC

Contact #1: Tracy Maddock, RAC
Regulatory Affairs Specialist

Phone: (610) 378-0131 extension 3384

Email: tracy.maddock@teleflexmedical.com

I. Purpose and Submission Summary

(b)(4),(b)(5)

[Redacted content]

(b)(4),(b)(5)

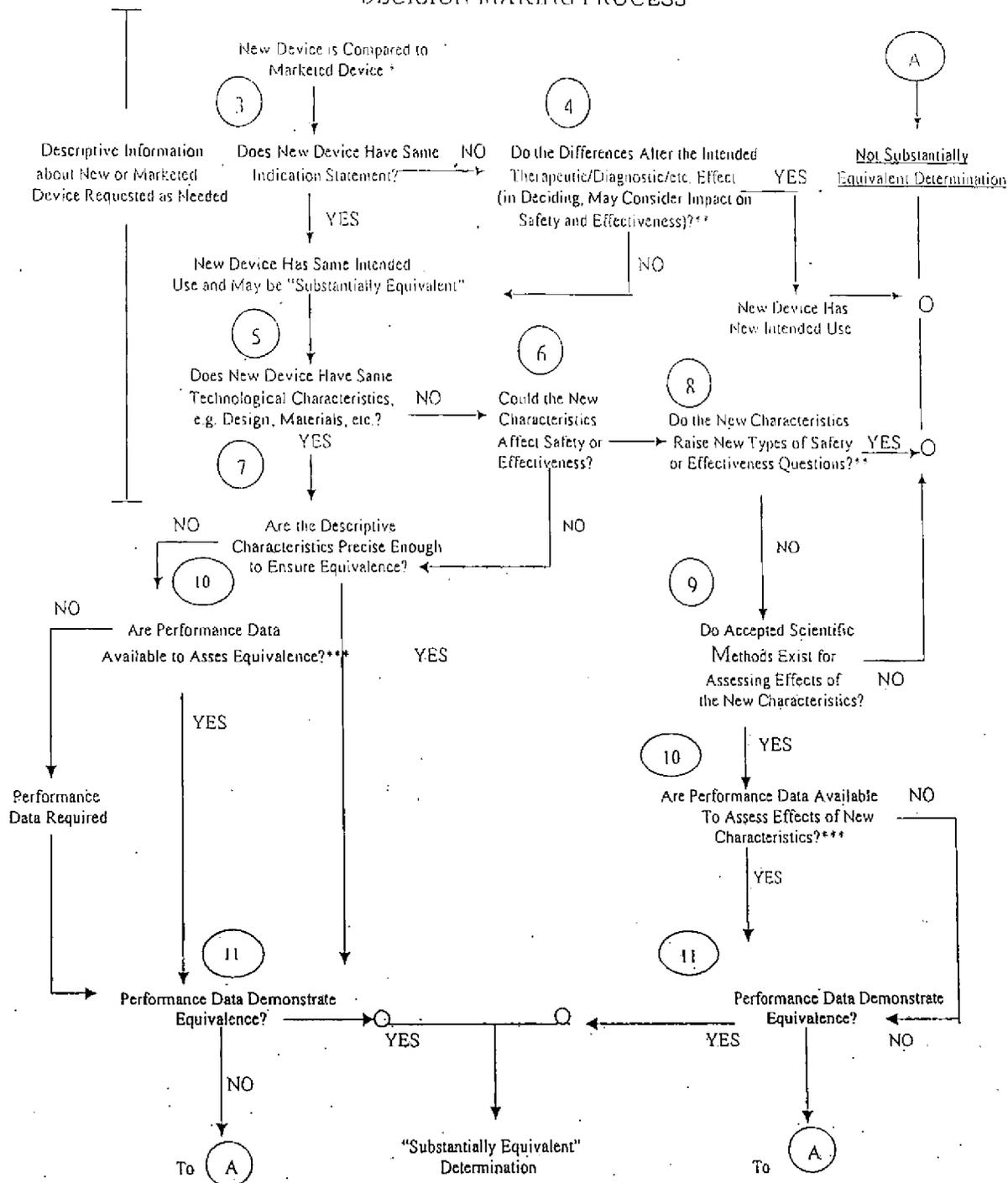
II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	(b)(4),(b)(5)		
Truthful and Accuracy Statement			
510(k) Summary or 510(k) Statement (Summary is incomplete. AI will be requested.)			
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?	(b)(4),(b)(5)		
Is the device an implant (implanted longer than 30 days)?			
Does the device design use software?			
Is the device sterile?			
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?			

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



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.



COVER SHEET MEMORANDUM

From: Reviewer Name William M. Burdick
Subject: 510(k) Number K100635
To: The Record

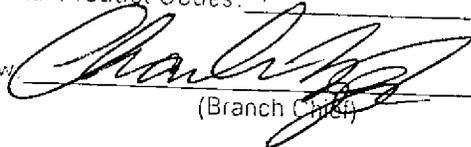
Please list CTS decision code TH
 Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/D_5631/Screening%20Checklist%20202%2007.doc)
 Hold (Additional Information of Telephone Hold E-Mail)
 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		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/D_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
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.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)
Nanotechnology
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

Regulation Number _____ Class* _____ Product Code _____

Additional Product Codes: _____ (*If unclassified, see 510(k) Staff)

Review:  (Branch Chief) 110 (Branch Code) 5/10/10 (Date)

Final Review: _____ (Division Director) _____ (Date)

From: Burdick, William M.
Sent: Friday, May 07, 2010 4:31 PM
To: 'Maddock, Tracy'
Cc: Stevens, Alan M; Syed, Sajjad H; Burdick, William M.
Subject: K100635-Arrowgard Antimicrobial PICC: Request for Additional Information

**K100636: ARROWg⁺ard Evolution Antimicrobial Pressure
Injectable PICC**

(b)(4),(b)(5)



(b)(4),(b)(5)

Sincerely,

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William M. Burdick
Biomedical Engineer/Physicist
ODE/DAGID/GHDB
WO66, Room 2522
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Ph #: 301-796-6286
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Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

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

K100635

Date: May 4, 2010

To: The Record

From: William M. Burdick

Office: HFZ-480

Division: DAGID/GHDB

510(k) Holder: Arrow International, Inc.

Device Name: ARROWg⁺ard Evolution Antimicrobial Pressure Injectable PICC

Contact #1: Tracy Maddock, RAC
Regulatory Affairs Specialist

Phone: (610) 378-0131 extension 3384

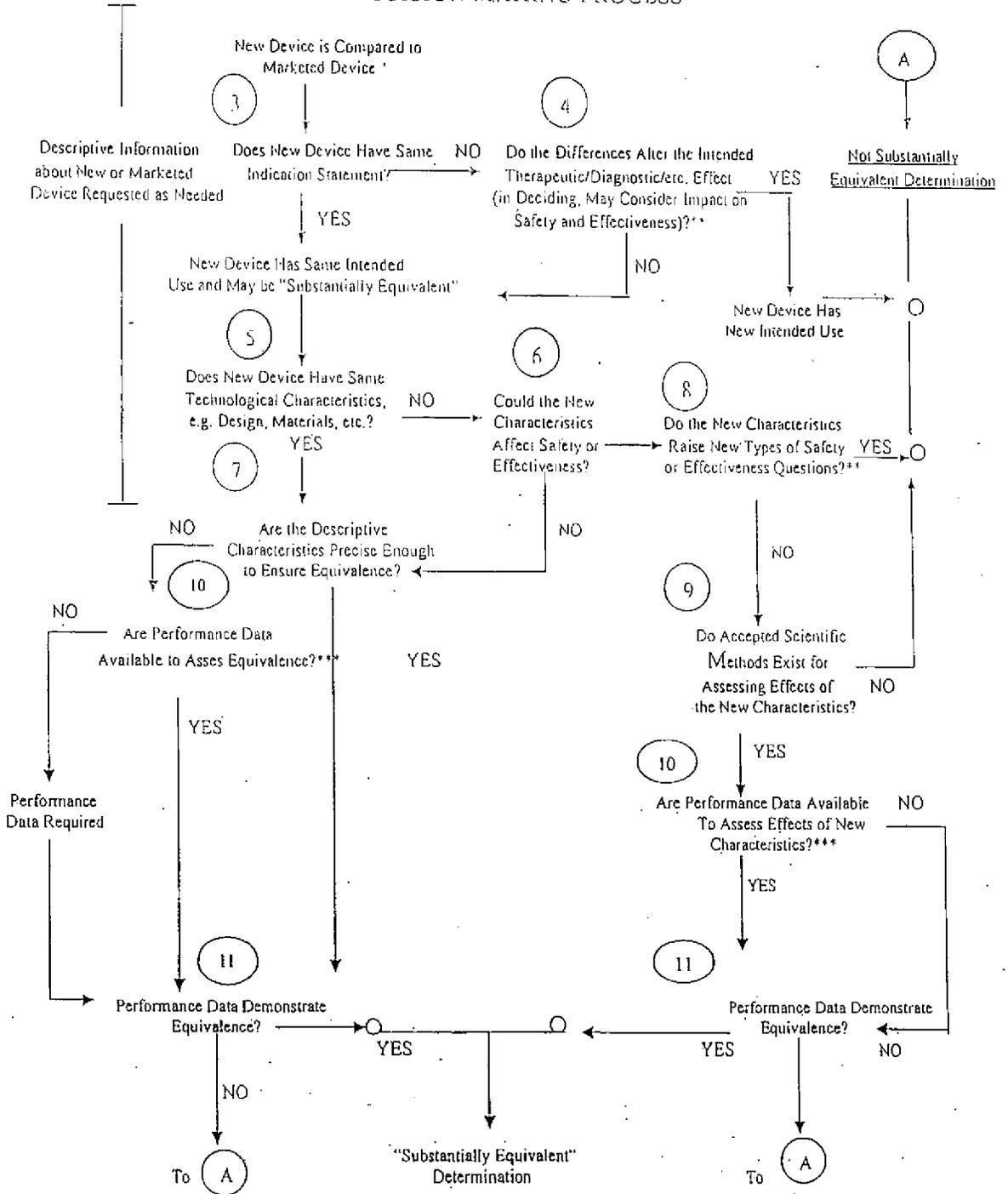
Email: tracy.maddock@teleflexmedical.com

I. Purpose and Submission Summary

(b)(4),(b)(5)

[Redacted content]

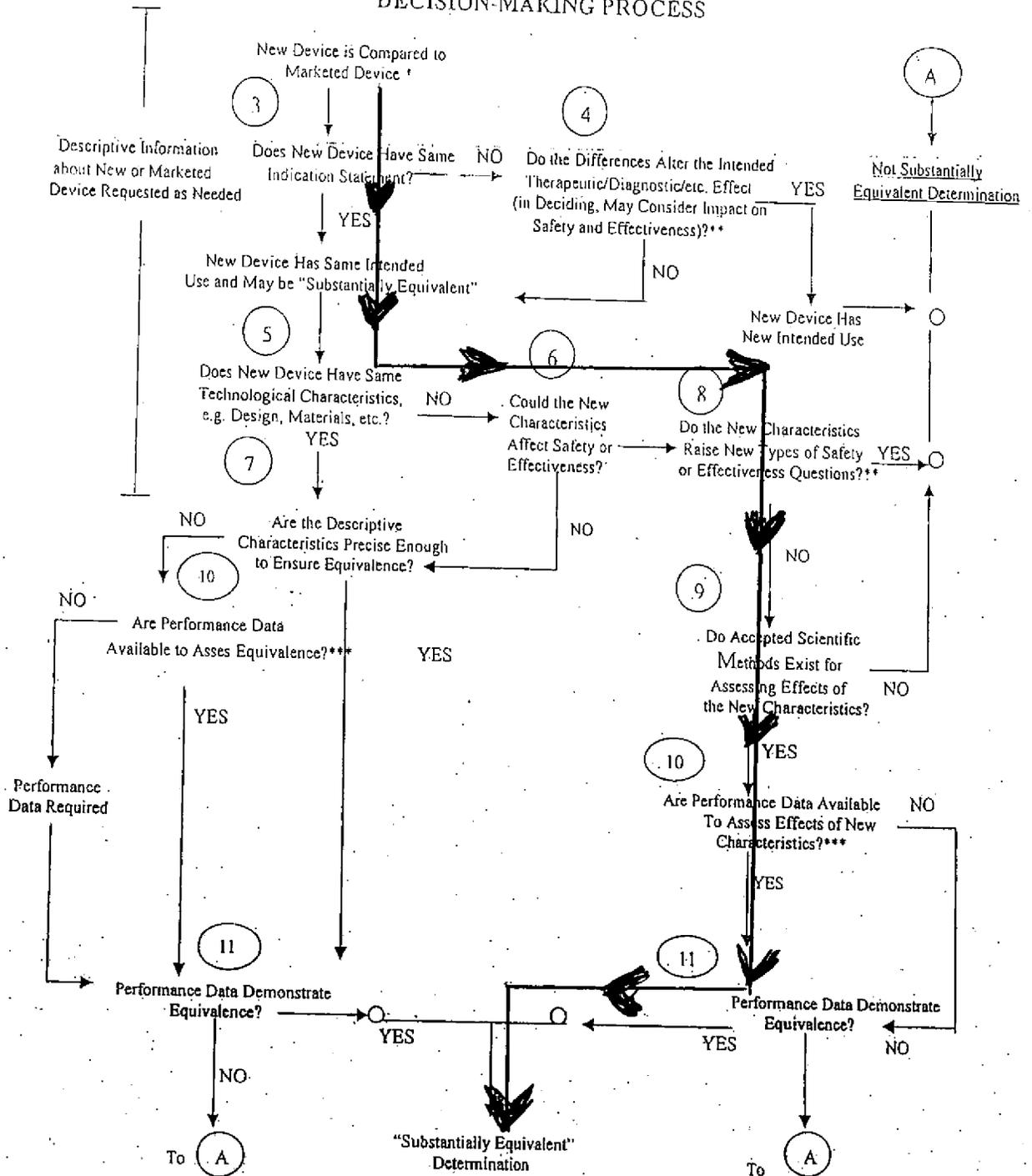
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

194

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



- ❖ 510(k) Submissions compare new devices to marketed devices; FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

June 4, 2010

K100635/5'



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

**Subject: 510(k) Premarket Notification - K100635
Arrow Antimicrobial Pressure Injectable PICC**

Dear Sir or Madam:

The following information is being submitted in response to the request for additional information regarding Premarket Notification K100635, sent via e-mail on May 7, 2010. Two copies are being submitted to the Agency for review.

(b)(4),(b)(5)

(b)(4),(b)(5)

Please find the responses to the Agency's questions on the following pages. Supporting documentation is provided in Attachments 1 – 11.

FDA CDRH DMC

JUN 07 2010

Received

K-22



If you have any questions regarding this additional information, please contact me at (610) 378-0131 Extension 3384 or by email at tracy.maddock@teleflexmedical.com.

Sincerely,

A handwritten signature in black ink that reads "Tracy Maddock". The signature is written in a cursive, flowing style.

Tracy Maddock
Regulatory Affairs Specialist

Arrow
Antimicrobial Pressure
Injectable PICC

KI00635

Additional Information Submitted
04 June 2010

Arrow International, Inc.
2400 Bernville Rd.
Reading, PA 19605

June 4,2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: 510(k) Premarket Notification - KI00635
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If you have any questions regarding this additional information, please contact me at (610) 378-0131 Extension 3384 or by email atracey.maddock@teleflexmedical.com.

Sincerely,

A handwritten signature in black ink that reads "Tracy Maddock". The signature is written in a cursive, flowing style.

Tracy Maddock
Regulatory Affairs Specialist

ATTACHMENT 1:

Arrow (b)(4)
Biocompatibility and Risk
Assessment

ATTACHMENT 2:

Arrow (b)(4) **Clinical**
Studies

Christian Brun-Buisson
Françoise Doyon
Jean-Pierre Sollet
Jean-François Cochard
Yves Cohen
Gérard Nitenberg

Prevention of intravascular catheter-related infection with newer chlorhexidine-silver sulfadiazine-coated catheters: a randomized controlled trial

Received: 19 July 2003
Accepted: 29 January 2004
Published online: 2 April 2004
© Springer-Verlag 2004

Participants of the Catheter Infection Prevention Study Group, co-authors of this article, are listed in the Appendix (electronic supplementary material). This work was presented in part at the International Conference of Antimicrobial Agents and Chemotherapy, San Francisco, October 2002.

Electronic Supplementary Material
Supplementary material is available in the online version of this article at <http://dx.doi.org/10.1007/s00134-004-2221-9>.

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G. Nitenberg
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Institut Gustave Roussy,
Villejuif, France

Abstract Background: The indication of antiseptic-coated catheters remains debated. **Objective:** To test the ability of the new generation of chlorhexidine-silver and sulfadiazine-coated catheters, with enhanced antiseptic coating, to reduce the risk of central venous catheter (CVC)-related infection in ICU patients. **Design:** Multicentre randomized double-blind trial. **Patients and setting:** A total of 397 patients from 14 ICUs of university hospitals in France. **Intervention:** Patients were randomized to receive an antiseptic-coated catheter (ACC) or a standard non-coated catheter (NCC). **Measurements:** Incidence of CVC-related infection. **Results:** Of 367 patients having a successful catheter

insertion, 363 were analysed (175 NCC and 188 ACC). Patients had one (NCC=162, ACC=180) or more (NCC=13, ACC=11) CVC inserted. The two groups were similar for insertion site [subclavian (64 vs 69)] or jugular (36 vs 31%), and type of catheters (single-lumen 18 vs 18%; double-lumen 82 vs 82%), and mean (median) duration of catheterisation [12.0 ± 11.7 (9) vs 10.5 ± 8.8 (8) days in the NCC and ACC groups, respectively]. Significant colonisation of the catheter occurred in 23 (13.1%) and 7 (3.7%) patients, respectively, in the NCC and ACC groups (11 vs 3.6 per 1000 catheter-days; $p=0.01$); CVC-related infection (bloodstream infection) occurred in 10 (5) and 4 (3) patients in the NCC and CC groups, respectively (5.2 vs 2 per 1000 catheter days; $p=0.10$). **Conclusions:** In the context of a low baseline infection rate, ACC were associated with a significant reduction of catheter colonisation and a trend to reduction of infection episodes, but not of bloodstream infection.

Keywords Intensive care · Catheter-associated infection · Bacteraemia · Prevention · Antiseptics

Effect of a Second-Generation Venous Catheter Impregnated with Chlorhexidine and Silver Sulfadiazine on Central Catheter-Related Infections

A Randomized, Controlled Trial

Mark E. Rupp, MD; Steven J. Lisco, MD; Pamela A. Lipsett, MD; Trish M. Perl, MD, MSc; Kevin Keating, MD; Joseph M. Civetta, MD; Leonard A. Mermel, DO, ScM; David Lee, MD; E. Patchen Dellinger, MD; Michael Donahoe, MD; David Giles, MD; Michael A. Pfaller, MD; Dennis G. Maki, MD; and Robert Sherertz, MD

Background: Central venous catheter-related infections are a significant medical problem. Improved preventive measures are needed.

Objective: To ascertain 1) effectiveness of a second-generation antiseptic-coated catheter in the prevention of microbial colonization and infection; 2) safety and tolerability of this device; 3) microbiology of infected catheters; and 4) propensity for the development of antiseptic resistance.

Design: Multicenter, randomized, double-blind, controlled trial.

Setting: 9 university-affiliated medical centers.

Patients: 780 patients in intensive care units who required central venous catheterization.

Intervention: Patients received either a standard catheter or a catheter coated with chlorhexidine and silver sulfadiazine.

Measurements: The authors assessed catheter colonization and catheter-related infection, characterized microbes by molecular typing, and determined their susceptibility to antiseptics. Patient tolerance of the catheter was monitored.

Results: Patients with the 2 types of catheters had similar demographic features, clinical interventions, laboratory values, and risk factors for infection. Antiseptic catheters were less likely to be

colonized at the time of removal compared with control catheters (13.3 vs. 24.1 colonized catheters per 1000 catheter-days; $P < 0.01$). The center-stratified Cox regression hazard ratio for colonization controlling for sampling design and potentially confounding variables was 0.45 (95% CI, 0.25 to 0.78). The rate of definitive catheter-related bloodstream infection was 1.24 per 1000 catheter-days (CI, 0.26 to 3.62 per 1000 catheter-days) for the control group versus 0.42 per 1000 catheter-days (CI, 0.01 to 2.34 per 1000 catheter-days) for the antiseptic catheter group ($P = 0.6$). Coagulase-negative staphylococci and other gram-positive organisms were the most frequent microbes to colonize catheters. Noninfectious adverse events were similar in both groups. Antiseptic susceptibility was similar for microbes recovered from either group.

Limitations: The antiseptic catheter was not compared with an antibiotic-coated catheter, and no conclusion can be made regarding its effect on bloodstream infection.

Conclusions: The second-generation chlorhexidine-silver sulfadiazine catheter is well tolerated. Antiseptic coating appears to reduce microbial colonization of the catheter compared with an uncoated catheter.

Ann Intern Med. 2005;143:570-580.
For author affiliations, see end of text.

www.annals.org

(b)(4),(b)(5)

ATTACHMENT 3:

(b)(4)

Evaluation

(b)(4)

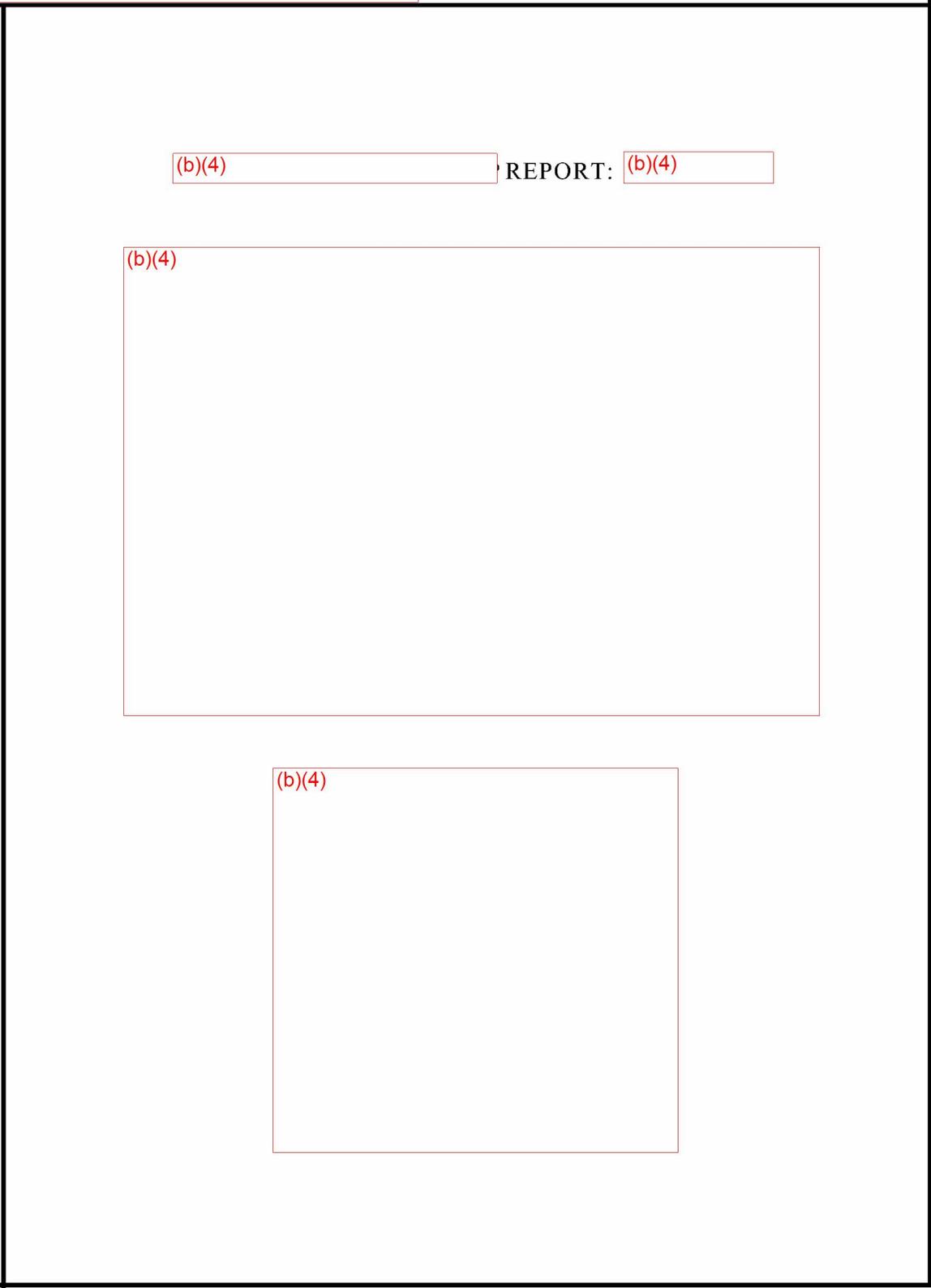
ATTACHMENT 4:

(b)(4)

Evaluation

(b)(4)

(b)(4)



(b)(4) REPORT: (b)(4)

(b)(4)

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(b)(4)

STERILIZATION REQUEST FORM

(b)(4)

(b)(4)

ATTACHMENT 5:

(b)(4)

the Antimicrobial PICC

ATTACHMENT 6:

(b)(4)

(b)(4)

Results

(b)(4)

(b)(4)

Protocol

ATTACHMENT 7:

(b)(4)



ATTACHMENT 8:

Antimicrobial PICC Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: Arrow Antimicrobial Pressure Injectable Peripherally Inserted Central Catheter (PICC)

Indications for Use:

The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi.

Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

ATTACHMENT 9:
510(k) Summary

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
ARROW ANTIMICROBIAL PRESSURE INJECTABLE PICC

1. Submitter Information

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)
Address: 2400 Bernville Road
Reading, PA 19605-9607
Telephone Number: (610) 378-0131
Contact Person: Tracy Maddock
Regulatory Affairs Specialist
Telephone Number: (610) 378-0131 Extension 3384
Fax Number: (610) 374-5360
Email: tracy.maddock@teleflexmedical.com
Date Prepared: June 4, 2010

2. Device Name

Device Trade Name: Arrow Antimicrobial Pressure Injectable Peripherally
Inserted Central Catheter (PICC)
Common Name: Peripherally Inserted Central Catheter
Classification Name: Percutaneous, implanted, long-term intravascular catheter

3. Predicate Devices

Predicate 1: Pressure Injectable PICC (K061289)
Predicate 2: 6 French Triple Lumen Pressure Injectable PICC (K080604)
Predicate 3: ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691)

4. Device Description

The Arrow Antimicrobial Pressure Injectable PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in 4.5 Fr. single lumen and 5.5 Fr. double lumen configurations with usable lengths of 40 – 55 cm. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based antimicrobial technology.

The catheters will be packaged sterile in both nursing and radiology configurations. Both configurations will include components to facilitate insertion.

5. Indications for Use

The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using *in vitro* methods, and no correlation between *in vitro* and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

6. Summary Comparing Technological Modifications

Modifications to existing Arrow products include:

- Inclusion of 4.5 Fr. single lumen and 5.5 Fr double lumen catheters to those ARROW PICCs already marketed. The increase in OD of the catheters allow for the subject devices to achieve 5 mL/sec pressure injection and to accommodate external / internal treatment.
- The catheter body material for the subject devices consist of a blending of two durometers of polyurethane resin. A blue colorant was added to the catheter body resins to differentiate from non-antimicrobial PIC catheters.
- A blue colorant was added to the juncture hub material of the subject devices to further differentiate the antimicrobial catheters.
- The catheter tip material of the subject devices includes a different radiopacifier for enhanced radiopacity.
- Antimicrobial treatment has been applied to the external catheter body surface and the entire fluid path of the device.
- The antimicrobial treatment present on the external catheter body of the subject devices consist of chlorhexidine only as opposed to chlorhexidine and silver sulfadiazine present on currently marketed Arrowgard Blue Plus central venous catheters.

7. Nonclinical Testing

Bench testing was performed on the Arrow Antimicrobial Pressure Injectable PICC in accordance with ISO 10555-1, 10555-3 and FDA Guidance on Premarket Notification [510(k)] Submission for Short- Term and Long- Term Intravascular Catheters. *In vitro* and *in vivo* testing was performed to assess the safety and efficacy of the proposed device. Testing included biocompatibility, *in vitro* antimicrobial efficacy, and *in vivo* animal infection study.

8. Summary of Verification Activities

Test	Acceptance Criteria	Results														
Air Leakage during aspiration	<p>There shall be no air leakage in the form of an air bubble in the syringe connected to the PICC after the first 5 seconds when tested per BS EN ISO 10555-1:1997 Annex D.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
Collapse Resistance	<p>The catheter shall not collapse during aspiration as evidenced by water being able to be pulled out of the catheter when vacuum is applied by a minimum of a 10 cc syringe. The extension line clamps, if present, shall be in the fully constrained position.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
Liquid Leakage under pressure	<p>There shall be no liquid leakage in the form of a falling drop of water at 300-320 kPa (43.5 -46.4) for 30 sec when tested per BS EN ISO 10555-1:1997 Annex C.</p> <p>All catheters must pass to achieve a 5% LTPD with 95% confidence</p>	Pass														
Force at break -Tensile Testing and Catheter Elongation	<p>There must be a 95% confidence level that 95% of the population meets the specification.</p> <table border="1"> <thead> <tr> <th>Tensile attribute</th> <th>Requirement per BS EN ISO 10555-1 and 10555-3</th> </tr> </thead> <tbody> <tr> <td>Catheter Body Force at Break</td> <td>≥ 10N</td> </tr> <tr> <td>Blue Flex Tip to Catheter Body Force at Break</td> <td>≥ 4N</td> </tr> <tr> <td>Catheter Body to Juncture Hub Force at Break</td> <td>≥ 10N</td> </tr> <tr> <td>Extension Line to Juncture Hub Force at Break</td> <td>≥ 15N</td> </tr> <tr> <td>Extension Line to Luer Hub Force at Break</td> <td>≥ 15N</td> </tr> <tr> <td>Catheter Body Elongation</td> <td>> 100%</td> </tr> </tbody> </table>	Tensile attribute	Requirement per BS EN ISO 10555-1 and 10555-3	Catheter Body Force at Break	≥ 10N	Blue Flex Tip to Catheter Body Force at Break	≥ 4N	Catheter Body to Juncture Hub Force at Break	≥ 10N	Extension Line to Juncture Hub Force at Break	≥ 15N	Extension Line to Luer Hub Force at Break	≥ 15N	Catheter Body Elongation	> 100%	Pass
Tensile attribute	Requirement per BS EN ISO 10555-1 and 10555-3															
Catheter Body Force at Break	≥ 10N															
Blue Flex Tip to Catheter Body Force at Break	≥ 4N															
Catheter Body to Juncture Hub Force at Break	≥ 10N															
Extension Line to Juncture Hub Force at Break	≥ 15N															
Extension Line to Luer Hub Force at Break	≥ 15N															
Catheter Body Elongation	> 100%															
Radio-Detectability	The optical density contrast must be at least 0.1.	Pass														
Catheter Body Kink	Does not kink at a radius greater than 0.5 inch when tested per BS EN 13868:2002 Annex A under simulated <i>in vivo</i> conditions. This requirement shall be met with 95% assurance.	Pass														

Test	Acceptance Criteria	Results
Central Venous Pressure Monitoring	The average amplitude difference between input and output signals shall be less than or equal to 1 mmHg when tested using a 1 Hz sinusoidal input signal. This requirement shall be met with 95% assurance.	Pass
Column Strength and Tip Stiffness	<p>For catheters having a tip of different construction to the catheter body, the tip shall be constructed in accordance with the requirement 5.1.6 and shall be made of lower durometer material than that of the catheter body.</p> <p>Design of tip shall ensure that the average force required to deflect or compress the tip is no greater than the average force required to deflect or compress the catheter body.</p> <p>NOTE: Requirement 5.1.6 referenced above is taken from an internal Arrow requirements document. Requirement 5.1.6 is identical to the requirement found in ISO 10555-3 Section 4.3.</p>	Pass
Static Burst Pressure	The maximum internal static pressure during pressure injection shall not exceed the static burst pressure.	Pass
Static Burst Pressure	The maximum internal static pressure during pressure injection shall not exceed the static burst pressure.	Pass
Rate Limited Injection Testing	Each pressure injectable lumen shall withstand at least 5 repeat injections without rupture or visually evident yielding of the catheter when injected at the maximum indicated flow rate using 125 mL of contrast media or equivalent (maximum viscosity of 11.8 ± 0.2 cP) at $37 \pm 2^\circ\text{C}$.	Pass
Pressure Limited Injection Testing	The average flow rate of each catheter lumen shall be at least 90% of the maximum indicated flow rate.	Pass
Ink Adhesion Testing	The catheter shall remain legible when examined without magnification with exposure to ChloroPrep and Iodine for 1 minute each, then application and removal of semi-permeable adhesive dressing and Biopatch after 7 days. The acceptance criteria for meeting this requirement will be a legible marking.	Pass
Step Stress Testing	The catheters shall pass the first 10 injections at the maximum flow rate without visually evident yielding or rupture.	Pass
Trim Tool	<p>After trimming with the provided trimming tool and visualized under 2.5X magnification, the indwelling catheter shall terminate at the distal end with a square tip that:</p> <ul style="list-style-type: none"> • Has no points • Produces a clean, smooth surface <p>With a sample size of n=60, zero failures are required to show a 95% confidence level and LTPD=5% in an attribute test.</p>	Pass

Test	Acceptance Criteria	Results
<p>Luer Hub Slip</p>	<p><u>Luer Hub Slip</u></p> <p>The hub shall meet the following Luer slip requirements with 95% confidence and a LTPD of 10% when tested per BS EN 20594-1:1994, ISO 594-1:1986 Clauses 5.1 through 5.5:</p> <p>Gauging: The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.</p> <p>Liquid Leakage: No liquid leakage shall occur in the form of one or more falling drops of water.</p> <p>Air Leakage: There shall be no signs of continued formation of air bubbles.</p> <p>Separation force: The Luer hub shall remain attached to the reference fitting.</p> <p>Stress cracking: There shall be no evidence of stress cracking of the fitting.</p>	<p>Pass</p>
<p>Luer Hub Lock</p>	<p><u>Luer Hub Lock</u></p> <p>The hub shall meet the following Luer lock requirements with 95% confidence and a LTPD of 10% when tested per BS EN 1707:1997 Clauses 5.2 through 5.8:</p> <p>Gauging: When tested with the appropriate gauge, the conical part of the lock fitting shall have the plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge. Rocking shall not be evident between the gauge and the fitting made of rigid material undergoing test.</p> <p>Liquid Leakage: No liquid leakage shall occur in the form of one or more falling drops of water.</p> <p>Air Leakage: There shall be no signs of continued formation of air bubbles.</p> <p>Separation force: The Luer hub shall remain attached to the reference fitting.</p> <p>Unscrewing torque: The Luer hub shall remain attached to the reference fitting.</p> <p>Ease of Assembly to Male Fitting: No resistance shall be observed until the taper of the fitting under test and the reference fitting fit together securely.</p> <p>Resistance to Overriding Male to Female Luer Connection: The reference fitting shall not override the threads or lugs of the fitting under test.</p> <p>Stress cracking: There shall be no evidence of stress cracking of the fitting</p>	<p>Pass</p>
<p>Catheter Securement</p>	<p>The catheter shall include a feature that enables the catheter to be secured to the patient's skin.</p> <p>Demonstrate a 95% confidence level and LTPD=5% by having the suture holes for all catheters fit over the Securement posts with zero failures and the retainer wings from all catheters lock into place with zero failures.</p>	<p>Pass</p>

Test	Acceptance Criteria	Results
First Article Inspection	<p>If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5cm. (BS EN ISO 10555-3: 1997 Section 4.4 and JIS T 3218:2005, Section 5.7)</p> <p>For multilumen catheters, identification of each lumen shall be apparent to the user (BS EN ISO 10555-3:1997, Item 4.5 and JIS T 3218:2005, Item 5.8)</p> <p>The French size of the catheter shall be printed on the integral juncture hub or in a location that can be seen after the catheter has been inserted.</p> <p>The tradename and/or name of the manufacturer of the catheter shall be printed on the integral juncture hub or in a location that can be seen after the catheter has been inserted.</p>	Pass
Clamp Closure Efficacy	The clamp closure capability shall be such that when the clamps are in the fully constrained position, there shall be no flow through the lumen being tested when tested in accordance with BS EN ISO 10555-3 Annex A or JIS T 3218 Annex C.	Pass
Flow restriction after clamping	The extension lines shall not be permanently deformed from the use of extension line clamps during the maximum expected clamp duration of the catheter to the point where a restriction in the extension line decreases the gravity flow through the catheter below the minimum gravity flow rate requirement (i.e. 90 mL/hr)	Pass
<i>In vitro</i> efficacy testing – external antimicrobial treatment	<p>The antimicrobial agent release rate will be sufficiently slow to provide efficacy against gram (+), gram (-) and fungi for a minimum of 7 days.</p> <p>Note: Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.</p>	Pass
<i>In vitro</i> efficacy testing – internal antimicrobial treatment	<p>The antimicrobial agent release rate will be sufficiently slow to provide efficacy against gram (+), gram (-) and fungi for a minimum of 7 days.</p> <p>Note: Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.</p>	Pass
<i>In vivo</i> animal infection study	The product shall exhibit efficacy against Staphylococcus aureus at minimum 7 days for <i>in-vivo</i> studies. Efficacy will be based upon a minimum 4 log reduction of adherent biomass (microbial colonization) when compared to the initial inoculum concentration.	Pass

9. Conclusions

The Arrow Antimicrobial Pressure Injectable PICCs are substantially equivalent to the Arrow Pressure Injectable PICCs (K061289) and the Arrow 6 French Triple Lumen Pressure Injectable PICCs (K080604). The subject devices have the same intended use, principles of operation and technological characteristics as the predicates. The indications for use, for the proposed catheters, are the same as the

Arrow PICC predicate device K080604 with the addition of the proposed catheter's effectiveness in reducing microbial colonization.

The antimicrobial agent for the proposed device is a similar Chlorhexidine-based solution used for the ARROWg⁺ard Blue PLUS[®] Multi-Lumen CVC (K993691). The process of application of the antimicrobial agent is also similar to that of the predicate device.

The results of the testing performed have demonstrated that the Arrow Antimicrobial Pressure Injectable PICC devices are safe and perform as intended. The differences, between subject devices and predicate devices, do not raise any new issues of safety and effectiveness. Thus, the Arrow Antimicrobial Pressure Injectable PICCs are substantially equivalent to the predicate devices.

ATTACHMENT 10:
Antimicrobial PICC Tech Sheet

ATTACHMENT 11:
Antimicrobial PICC Unit Labeling



August 23, 2010

K100635/S2

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

FDA CDRH DMC
AUG 24 2010
Received

**Subject: 510(k) Premarket Notification - K100635
Arrow Antimicrobial Pressure Injectable PICC**

Dear Sir or Madam:

The following information is being submitted in response to the request for additional information regarding Premarket Notification K100635. This documentation was originally supplied to the reviewer via e-mail subsequent to a teleconference held between the Agency and Arrow International on August 3, 2010. Two copies of the additional information are being submitted to the Agency for review. In addition to a paper copy of the submission, an electronic copy, an exact duplicate of the paper copy, is provided to facilitate the review.

If you have any questions regarding this additional information, please contact me at (610)378-0131 Extension 3384 or by e-mail at tracy.maddock@teleflexmedical.com.

Sincerely,

Tracy Maddock, RAC
Regulatory Affairs Specialist

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 08/23/2010	User Fee Payment ID Number MD 6047509-956733	FDA Submission Document Number (if known) K100635
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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 type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE 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):
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	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? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Arrow International, Inc. (subsidiary of Teleflex Inc.)		Establishment Registration Number (if known) 2518433	
Division Name (if applicable) Critical Care		Phone Number (including area code) (610) 378-0131	
Street Address 2400 Bernville Road		FAX Number (including area code) (610) 374-5360	
City Reading	State / Province PA	ZIP/Postal Code 19605	Country USA
Contact Name Tracy Maddock			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address tracy.maddock@teleflexmedical.com	

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

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

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

<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 (<i>specify below</i>)	<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 (<i>specify below</i>)	<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 (<i>specify below</i>)	<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

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"/> Repose 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		

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
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Other Reason (*specify*):
 Response to request for additional information.

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	FOZ	3	
5		6		7	
				<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	K061289	1	Pressure Injectable PICC	1	ARROW INTL, Inc
2	K080604	2	6F Triple Lumen Pressure Injectable PICC	2	ARROW INTL, Inc
3	K993691	3	ARROWg+ard Blue Plus Multi-Lumen CVC	3	ARROW INTL, Inc
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Peripherally Inserted Central Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Arrow Evolution Antimicrobial Peripherally Inserted Central Catheter (PICC)	1	S-44041-002, S-45041-002, S-455041-002
2	Arrow Evolution Antimicrobial Peripherally Inserted Central Catheter (PICC)	2	MC-44052-003, MC-45052-003, MC-45552-003
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1	1090263	2	1090263/S001	3	
7		8		9	
				10	
				11	
				12	

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LJS	C.F.R. Section (if applicable) 21 CFR 880.5970	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General Hospital and Personal Use Devices		

Indications (from labeling)
 The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using in vitro methods, and no correlation between in vitro and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of 

<i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number <i>(if known)</i>	
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 checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name ARROW INTL, Inc (Subsidiary of Teleflex Inc.)		Establishment Registration Number 1036844	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> (336) 498-4153	
Street Address 312 Commerce Place		FAX Number <i>(including area code)</i> (336) 495-1642	
City Asheboro	State / Province NC	ZIP/Postal Code 27203	Country USA
Contact Name Matt Winton	Contact Title Quality Assurance Manager	Contact E-mail Address Matt.Winton@teleflexmedical.com	

(b)(4)

<input 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 type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> ()	
Street Address		FAX Number <i>(including area code)</i> ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control



August 23, 2010

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

**Subject: 510(k) Premarket Notification - K100635
Arrow Antimicrobial Pressure Injectable PICC**

Dear Sir or Madam:

The following information is being submitted in response to the request for additional information regarding Premarket Notification K100635. This documentation was originally supplied to the reviewer via e-mail subsequent to a teleconference held between the Agency and Arrow International on August 3, 2010. Two copies of the additional information are being submitted to the Agency for review. In addition to a paper copy of the submission, an electronic copy, an exact duplicate of the paper copy, is provided to facilitate the review.

If you have any questions regarding this additional information, please contact me at (610)378-0131 Extension 3384 or by e-mail at tracy.maddock@teleflexmedical.com.

Sincerely,

A handwritten signature in cursive script that reads "Tracy Maddock".

Tracy Maddock, RAC
Regulatory Affairs Specialist

From: Phillips, Robert
Sent: Wednesday, August 11, 2010 12:49 PM
To: William.Burdick@fda.hhs.gov
Cc: Maddock, Tracy
Subject: K100635 - Arrow International - Antimicrobial PICC - Additional Information

Importance: High

(b)(4)

(b)(4)

Sincerely,

Robert Z. Phillips

VP, QA/RA - Critical/Cardiac Care

Arrow International, Inc. (a wholly-owned subsidiary of Teleflex Medical)

2400 Bernville Road, Reading, PA 19605

rphillips@teleflexmedical.com

Office: +1-610-478-3138

Cell: +1-510-996-8074

Fax: +1-610-478-3179

(b)(4)

(b)(4) **REPORT:** (b)(4)

(b)(4)

(b)(4)

(b)(4) TEST PROTOCOL
(b)(4)

(b)(4)

(b)(4)

ORIGINAL

(b)(4)



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

August 25, 2010

ARROW INTL., INC.
2400 BERNVILLE RD.
READING, PENNSYLVANIA 19605
UNITED STATES
ATTN: TRACY MADDOCK

510k Number: K100635

Product: ARROWGARD EVOLUTION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 08/23/2010	User Fee Payment ID Number MD 6047509-956733	FDA Submission Document Number (if known) K100635
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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 type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE 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):
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	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? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Arrow International, Inc. (subsidiary of Teleflex Inc.)	Establishment Registration Number (if known) 2518433		
Division Name (if applicable) Critical Care	Phone Number (including area code) (610) 378-0131		
Street Address 2400 Bernville Road	FAX Number (including area code) (610) 374-5360		
City Reading	State / Province PA	ZIP/Postal Code 19605	Country USA
Contact Name Tracy Maddock			
Contact Title Regulatory Affairs Specialist	Contact E-mail Address tracy.maddock@teleflexmedical.com		

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

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

K-9

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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 (<i>specify below</i>)	<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 (<i>specify below</i>)	<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 (<i>specify below</i>)	<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 (<i>specify</i>):					

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"/> Repose 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 (<i>specify</i>):					

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 checked="" type="checkbox"/> Other Reason (<i>specify</i>): Response to request for additional information.					

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 <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1 LJS	2 FOZ	3	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed (if known)			
	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K061289	1 Pressure Injectable PICC	1 ARROW INTL, Inc
2	K080604	2 6F Triple Lumen Pressure Injectable PICC	2 ARROW INTL, Inc
3	K993691	3 ARROWg+ard Blue Plus Multi-Lumen CVC	3 ARROW INTL, Inc
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Peripherally Inserted Central Catheter

	Trade or Proprietary or Model Name for This Device	Model Number
1	Arrow Evolution Antimicrobial Peripherally Inserted Central Catheter (PICC)	1 S-44041-002, S-45041-002, S-455041-002
2	Arrow Evolution Antimicrobial Peripherally Inserted Central Catheter (PICC)	2 MC-44052-003, MC-45052-003, MC-45552-003
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)					
1 1090263	2 1090263/S001	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

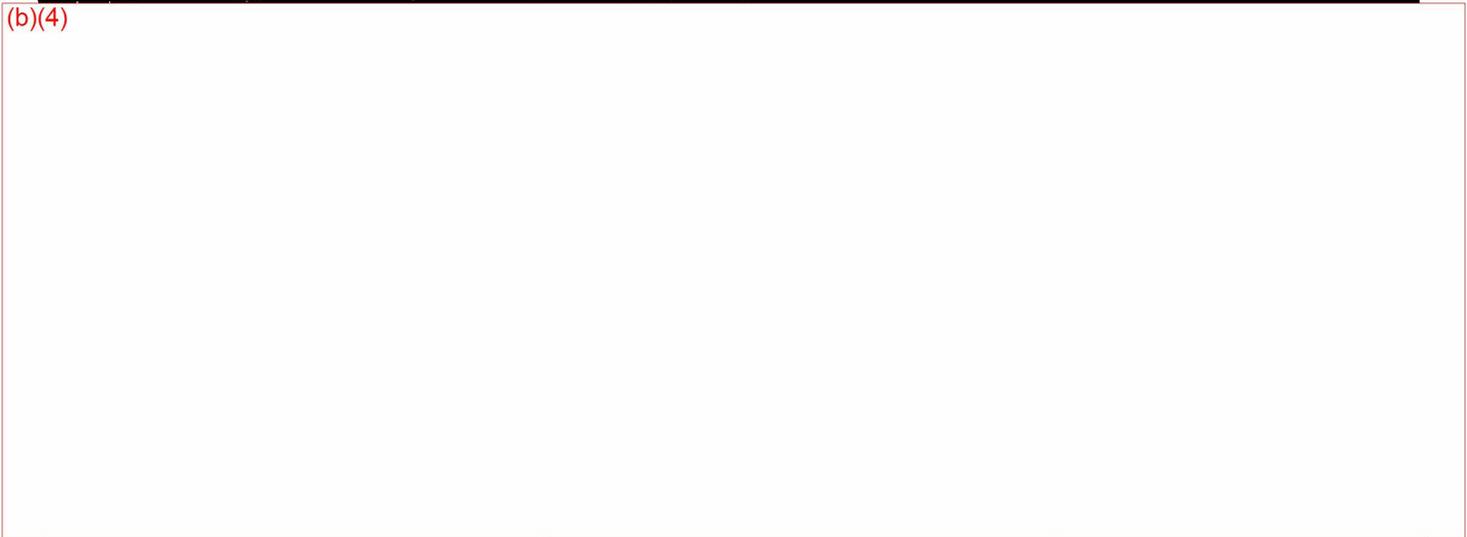
Product Code LJS	C.F.R. Section (if applicable) 21 CFR 880.5970	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General Hospital and Personal Use Devices		

Indications (from labeling)
 The Arrow Antimicrobial Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial Pressure Injectable PICC may not exceed 300 psi. Antimicrobial treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization. Antimicrobial effectiveness was evaluated using in vitro methods, and no correlation between in vitro and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of

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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 checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name ARROW INTL, Inc (Subsidiary of Teleflex Inc.)		Establishment Registration Number 1036844	
Division Name (if applicable)		Phone Number (including area code) (336) 498-4153	
Street Address 312 Commerce Place		FAX Number (including area code) (336) 495-1642	
City Asheboro		State / Province NC	ZIP/Postal Code 27203
Contact Name Matt Winton		Contact Title Quality Assurance Manager	Contact E-mail Address Matt.Winton@teleflexmedical.com

(b)(4)



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

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
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7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

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(b)(4) Study

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(b)(4) Test

4

(b)(4) Study

5

(b)(4)

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August 23, 2010

K100635/S2

FDA CDRH DMC
AUG 24 2010
Received

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

Subject: 510(k) Premarket Notification - K100635
Arrow Antimicrobial Pressure Injectable PICC

Dear Sir or Madam:

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If you have any questions regarding this additional information, please contact me at (610)378-0131 Extension 3384 or by e-mail at tracy.maddock@teleflexmedical.com.

Sincerely,

Tracy Maddock, RAC
Regulatory Affairs Specialist

From: Phillips, Robert

Sent: Wednesday, August 11, 2010 12:49 PM

William.Burdick@fda.hhs.gov

Cc: Maddock, Tracy

Subject: K100635 - Arrow International - Antimicrobial PICC - Additional Information

Importance: High

(b)(4),(b)(5)

(b)(4),(b)(5)

Sincerely,

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(b)(4)

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REPORT: (b)(4)

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(b)(4) TEST PROTOCOL
(b)(4)
(b)(4)

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(b)(4) PROTOCOL NUMBER: (b)(4)

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ORIGINAL

(b)(4)

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ArrowEVOLUTION™ Chloragard Technology Information

(b)(4)

