



Spectrum® Silicone Peripherally Inserted Central Venous Catheters (PICC)

Instructions for Use



C - T - P I C C A B R M - R E V 2



SPECTRUM® SILICONE PERIPHERALLY INSERTED CENTRAL VENOUS CATHETERS (PICC)

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

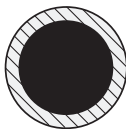
Spectrum Silicone Peripherally Inserted Central Venous Catheters (PICC) are impregnated with the antimicrobial agents minocycline and rifampin, which may minimize the risk of bacterial colonization of the catheter and catheter-related bacteremia bloodstream infection during use. The activity of these antimicrobial agents is localized at the catheter surface and is not intended for treatment of systemic infections. The antimicrobial agents, minocycline and rifampin, have a yellow and an orange appearance; therefore, some coloration of the catheter is normal.

From HPLC assay, the average amount of minocycline contained in a Spectrum Silicone Catheter is approximately 410 µg/cm for a 12.0 French double-lumen catheter and 135 µg/cm for a 7.0 French double-lumen catheter. From HPLC assay, the average amount of rifampin contained in a Spectrum Silicone Catheter is approximately 208 µg/cm for a 12.0 French double-lumen catheter, and 68 µg/cm for a 7.0 French double-lumen catheter. These total amounts of minocycline and rifampin are significantly lower than typical daily systemic pharmacologic doses.

The length of the catheter facilitates placement from an antecubital approach to a central venous location. The catheter with wire guide obturator provides sufficient body to the catheter for advancement through the vasculature. The AQ® hydrophilic coating on the obturator facilitates ease of removal from the catheter after final positioning.

Lumen Diameters & Volumes

SINGLE LUMEN

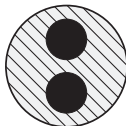


Single-Lumen Round Lumen

French Size	Lumen Diameter	Lumen Volume
4.0	.026 inch	0.6 cc
5.0	.036 inch	0.8 cc

DOUBLE LUMEN

Round Lumens



D-Shaped Lumens



Double-Lumen Round Lumens

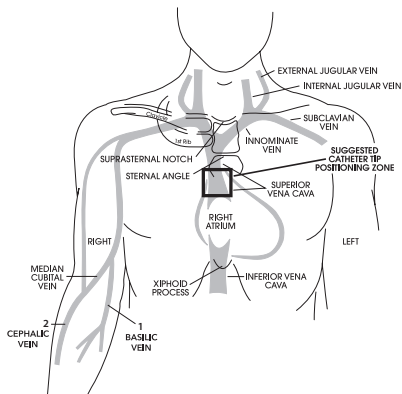
French Size	Small Lumen Diameter	Small Lumen Volume	Large Lumen Diameter	Large Lumen Volume
6.0	.018 inch	0.5 cc	.026 inch	0.6 cc

Double-Lumen D-Shaped Lumens

French Size	Small Lumen Diameter	Small Lumen Volume	Large Lumen Diameter	Large Lumen Volume
7.0	.019 x .045 inch	0.7 cc	.025 x .050 inch	0.8 cc

Access Sites of Choice

1. Basilic Vein
2. Cephalic Vein



INTENDED USE

Spectrum Silicone Peripherally Inserted Central Venous Catheters are intended for the intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSIs). It is not intended to be used as a treatment for existing infections.

CONTRAINDICATIONS

- Allergy or history of allergy to tetracyclines or rifampin

NOTE: Because the Spectrum Silicone Peripherally Inserted Central Venous Catheter is impregnated with a combination of the antimicrobial agents minocycline (a derivative of tetracycline) and rifampin (a derivative of rifamycin B), the contraindications, warnings, and precautions regarding use of these antimicrobials apply and should be adhered to for use of this device, although systemic levels of minocycline and rifampin in patients receiving this device are highly unlikely to result from their use.

- Minocycline and rifampin are agents that do not induce any genotoxic risk except a possible teratogenic effect in pregnant women. We therefore do not recommend the use of Spectrum Silicone Peripherally Inserted Central Venous catheters in pregnant women.

WARNINGS

- Do not power inject contrast medium through catheter. Catheter rupture may result. Use of a 10 ml syringe or larger will reduce the risk of catheter rupture.
- To avoid vascular injury, do not use excessive force when advancing dilator. Use the smallest size dilator catheter placement will allow. Wire guide must always lead dilator by several centimeters. Do not advance dilator more than a few centimeters into the vessel.
- To distend great vessels and to prevent inadvertent air aspiration during catheter insertion, patient should be placed in Trendelenburg position.
- Every effort must be made to ascertain proper tip position in order to prevent erosion or perforation of central venous system. Tip position should be verified by x-ray and monitored on a routine basis. Periodic lateral view x-ray is suggested to assess tip location in relation to vessel wall. Tip position should appear to be parallel to vessel wall.

NOTE: The Spectrum Silicone Peripherally Inserted Central Venous Catheter should not supersede strict aseptic techniques as they relate to catheter placement and maintenance.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in proper positioning of catheters in the central venous system using percutaneous entry (Seldinger) technique. Standard techniques for percutaneous placement of peripherally inserted central venous catheters should be employed.
- Prepare the catheter for insertion by flushing each of the lumens and clamping or attaching the injection caps to the appropriate extensions. Leave the distal extension uncapped for wire guide passage.
- If lumen flow is impeded, do not force injection or withdrawal of fluids. Notify attending physician immediately.
- Select puncture site and length of catheter needed by assessing patient anatomy and condition.
- During blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.
- Patient movement can cause catheter tip displacement. Catheters placed via an antecubital vein have shown tip movement of up to 10 cm with motion of the extremity.
- Development of a hypersensitivity reaction should be followed by removal of the catheter and appropriate treatment at the discretion of the attending physician.

NOTE: Prior to insertion, the Spectrum Catheter shaft should not be wiped with or immersed in ethyl alcohol, isopropyl alcohol, or other alcohols, acetone or other non-polar solvents. These solvents may remove the antimicrobial from the catheter and reduce the catheter's antimicrobial efficacy.

CLINICAL STUDIES

To evaluate efficacy of the Spectrum Silicone Catheter in reducing the incidence of catheter-related bloodstream infection, a prospective, randomized clinical trial was conducted in which 365 patients were enrolled to receive either a Spectrum Silicone Catheter or a non-impregnated silicone control catheter. A total of 191 patients received Spectrum Silicone Catheters, and 174 received control catheters. Patient characteristics (age, sex, underlying disease, degree of immunosuppression, therapeutic interventions, site of insertion, complications, and reason for catheter removal) were comparable for the two groups. Mean catheter dwell time was comparable for the two groups (65 ± 31 days for the Spectrum Silicone Catheter and 62 ± 31 days for the control, $p = 0.3$).

Catheters Used in the Clinical Study

Type of Catheter	Control Cohort	Treatment Cohort
Double-Lumen Subclavian	84 (48.3%)	84 (44%)
Single-Lumen Subclavian	24 (13.8%)	34 (17.8%)
PICC Line	66 (37.9%)	73 (38.2%)
Total	174 (100%)	191 (100%)

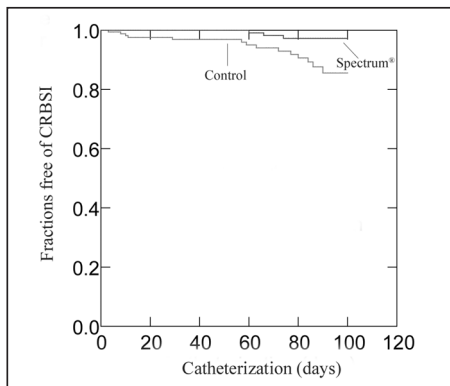
Results from the clinical study showed a statistically significant decrease in the incidence of catheter-related bloodstream infection in patients receiving the Spectrum Silicone Catheter, occurring in 3 of 191 patients (1.6%) as compared to 14 of 174 patients (8.0%) for the control catheter ($p = 0.003$).

Organisms isolated from patients having catheter-related bloodstream infection in the treatment cohort included *Candida parapsilosis* and *Klebsiella pneumoniae*. Testing of isolates revealed no evidence of resistance to minocycline or rifampin developed.

Blood samples obtained from nine patients at one to two days after insertion of the Spectrum Silicone Catheter were assayed for minocycline and rifampin by high-performance liquid chromatography (HPLC) analysis. No detectable systemic levels of minocycline or rifampin were observed (limit of detection = $1.0 \mu\text{g/mL}$ for both antimicrobials).

The rates of catheter-related bloodstream infection (calculated according to CDC definition) were 0.24 per 1,000 catheter-days for treatment catheters and 1.30 per 1,000 catheter-days for control catheters. Kaplan-Meier survival analysis indicated that Cook Spectrum Silicone Catheters were, over time, associated with a significantly lower risk of catheter-related bloodstream infection than the control catheters ($p = 0.003$ by log-rank test).

Kaplan-Meier Survival Curves for Freedom from Catheter-Related Bloodstream Infection (CRBSI)



Discussion of Antimicrobial Activity

Antimicrobial activity associated with the Cook Spectrum Silicone Central Venous Catheter over time has been demonstrated in the following way:

The length of activity of the antibiotics was established during *in vitro* zone of inhibition testing after suspension in saline at 37 degrees C. Antimicrobial activity in the 7.0 French double-lumen catheter was demonstrated for at least 28 days against *Staphylococcus epidermidis*, the most common organism implicated in catheter-related infection.

PRODUCT RECOMMENDATIONS

Catheter Site Care

Catheter care and maintenance should be performed in accord with the CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections.

Disinfect clean skin with an appropriate antiseptic before catheter insertion and during dressing changes. Although a 2% chlorhexidine-based preparation is preferred, tincture of iodine, an iodophor, or 70% alcohol can be used. Allow the antiseptic to remain on the insertion site and to air dry before catheter insertion. If using povidone iodine, allow it to remain on the skin for at least 2 minutes or longer if it is not yet dry before insertion. Do not apply organic solvents (e.g., acetone and ether) to the skin before insertion of catheters or during dressing changes.

Catheter Maintenance

Catheter entry site must be prepared and maintained in a manner consistent with standard procedure for central venous catheterization. After catheter placement and prior to use, tip position and lumen patency should be confirmed by free aspiration of venous blood. If blood is not freely aspirated, catheter tip position should be immediately reevaluated by physician. If catheter is not to be used immediately, its lumen should be maintained by continuous saline or heparinized saline drip or locked with heparinized saline solution. **Note:** If CLC-2000, MicroClave or other needleless adapters approved for saline only lock are used, saline only catheter lock may be used. Catheter heparinization should be determined by institutional protocol and clinical judgement. Heparin concentrations of 10 Units/ml to 100 Units/ml have been reported adequate to maintain lumen patency. Heparin lock should be reestablished after every use or at least every 24 hours if unused. Before using catheter lumen already locked with heparin, lumen should be flushed with twice the indicated lumen volume using normal saline. Lumen should be flushed with normal saline between administration of different infusates. After use, lumen should again be flushed with twice the indicated lumen volume using normal saline before reestablishing heparin lock. Strict aseptic technique must be adhered to while using and maintaining catheter.

PATIENT SELECTION

Controlled clinical trials of Spectrum Silicone Central Venous Catheters in pregnant women, pediatric and neonatal populations have not been conducted. The benefits of the use of Spectrum Silicone Central Venous Catheters should be weighed against possible risks.

INSTRUCTIONS FOR USE

Catheter Obturator Preparation: Activating AQ® Hydrophilic Coating

1. Prepare the catheter for insertion by flushing each of the lumens and clamping or attaching the injection caps to the appropriate extensions. Leave the distal extension uncapped for wire guide passage. **NOTE:** The catheter may be trimmed if a shorter length is required.
2. Attach a syringe with heparinized saline solution or sterile water to the Luer lock fitting of the catheter obturator holder.
3. Inject enough solution to wet the obturator surface entirely. This will activate the AQ coating, making the obturator surface very lubricious.
4. Remove the obturator from its holder and insert it into the catheter, locking it into position. If the catheter has been trimmed, only advance the obturator to the distal end of the catheter. **NOTE:** If the surface of the obturator becomes dry after removal from the holder, wetting with additional heparinized saline or sterile water will renew the hydrophilic effect.

Catheter/Obturator Assembly Introduction

The catheter/obturator assembly can now be introduced as described in the following steps:

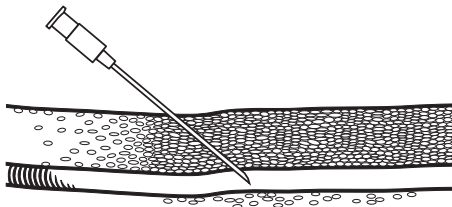


Fig. 1

1. After prepping the access site, introduce the thinwall percutaneous entry needle into the vessel.

NOTE: The use of ultrasound is helpful to determine suitability for vessel access and patency. The Echotip[®] marking on the needle is used to locate the tip of the needle during access into the vessel. If not using ultrasound, venous blood should be easily aspirated to confirm position of the needle tip within vessel. (Fig. 1)

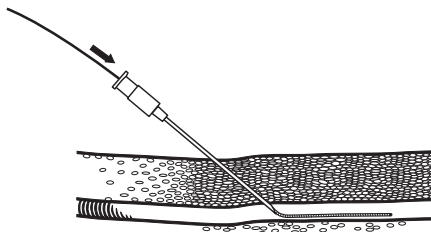


Fig. 2

2. Introduce the wire guide through the needle, and advance it into the vessel. **NOTE:** If using a Safe-T-J[®] wire guide, ensure straightener is over "J" portion of wire guide prior to wire guide insertion. If a straight wire guide is used, always advance the soft, flexible end through the needle hub and into vessel. If resistance is encountered during wire guide insertion, do not force the wire guide. Withdrawal of the wire guide through needle should be avoided; breakage may result. (Fig. 2)

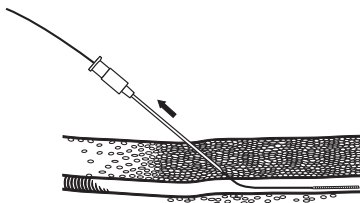


Fig. 3

3. Leaving the wire guide in place, withdraw the needle. (**Fig. 3**) If necessary, enlarge the puncture site with a #11 scalpel blade. If dilation is required, the dilator can be advanced over the wire guide and removed prior to insertion of central venous catheter. **CAUTION: To avoid vascular injury, do not use excessive force when advancing dilators. Use the smallest size dilator catheter placement will allow. Wire guide must always lead dilator by several centimeters. Do not advance dilator more than a few centimeters into the vessel.**

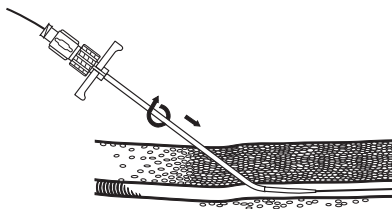


Fig. 4

4. Introduce the sheath-introducer assembly over the wire guide. With a twisting motion, advance the assembly into the vessel. (**Fig. 4**)

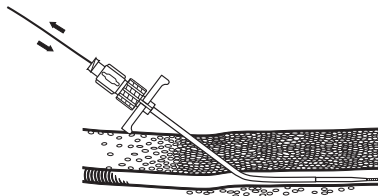


Fig. 5

5a (For Non-Fluoroscopic Placement)

Using a Tyvek® Tape measure, clinical judgment, or other institutional protocol, determine the correct catheter length and trim catheter as needed. **NOTE:** Remove obturator prior to trimming catheter; reinsert for catheter introduction.

5b (For Fluoroscopic Placement)

Determine the correct catheter length by advancing the wire guide to the desired catheter tip location. Once the wire guide tip is in position, mark the length by clamping forceps onto the wire guide at the skin site. Withdraw the wire guide (**Fig. 5**). Measure the wire guide from the forceps to the distal tip to determine correct catheter length. Trim the catheter if necessary. **NOTE:** Remove the obturator prior to trimming the catheter; reinsert for catheter introduction

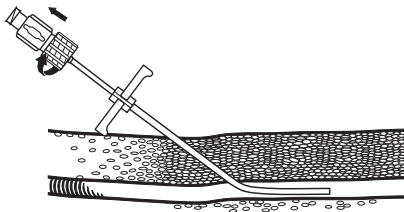


Fig. 6

6. Leaving the sheath in place, remove the dilator by rotating the locking collar counterclockwise. (To prevent inadvertent air aspiration, place thumb or finger over the cuffed proximal end of the sheath after removing the introducer and wire guide.) (Fig. 6)

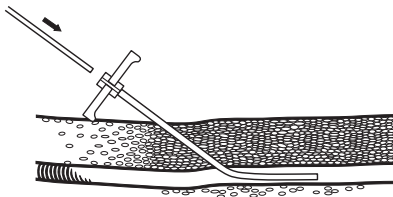


Fig. 7

7. Introduce the catheter/obturator into the sheath; advance the catheter into position. Verify catheter tip position using radiography or appropriate technology. In order to guarantee extrapericardial location, the catheter tip should be located above the SVC-RA junction, within the lower 1/3 of the SVC. Every effort must be made to ascertain proper tip position in order to prevent erosion or perforation of the central venous system and to ensure proper delivery of infusates. (Fig. 7)

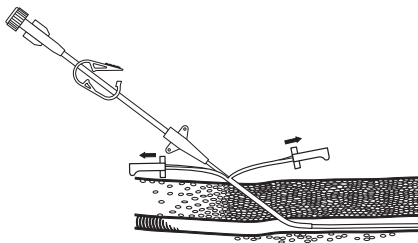


Fig. 8

8. After the catheter is in position, venous blood should be easily aspirated. Remove the sheath by grasping the two tabs of the sheath, snapping them down and pulling outward and upward at the same time to peel the sheath away from the catheter while maintaining stable catheter position. **NOTE:** Remove the obturator after the catheter is in final position. Secure the catheter in place with suture or other securement method. If the catheter is not introduced to its full length, additional

suture should be carefully placed around the catheter and affixed to the skin at entry site. This will help prevent backward or forward catheter movement. Lumens should now be flushed with 5-10 ml normal saline prior to use or establishment of catheter lock. **(Fig. 8)** Verify catheter tip position using radiography or appropriate technology.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

1. Hanna H, Benjamin R, Chatzinikolaou I, *et al.* "Long-term silicone central venous catheters impregnated with minocycline and rifampin decrease rates of catheter-related bloodstream infection in cancer patients: a prospective randomized clinical trial." *Journal of Clinical Oncology*, 2004; 22: 3163-70.



**MANUFACTURER**

COOK INCORPORATED
750 Daniels Way
Bloomington, IN 47404 U.S.A.

www.cookmedical.com
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**EC REPRESENTATIVE**

WILLIAM COOK EUROPE ApS
Sandet 6, DK-4632
Bjæverskov, DENMARK

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