COOK MEDICAL

Cook Spectrum® Central Venous Catheter Minocycline/Rifampin Antibiotic Impregnated Power Injectable

Instructions for Use

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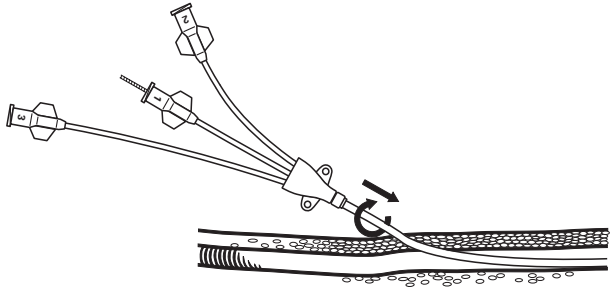


Fig. 1

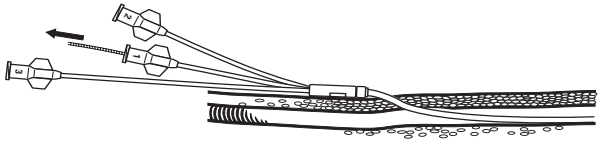


Fig. 2

COOK SPECTRUM® AND SPECTRUM® GLIDE™ CENTRAL VENOUS CATHETERS

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

DEVICE DESCRIPTION

Cook polyurethane central venous catheters incorporate separate, non-communicating vascular access lumens within a single catheter body. Sets and trays also contain an appropriately sized access needle, a wire guide and accessories for use in percutaneous vascular access procedures. **The device and its components are latex-free.**

Cook Spectrum and **Spectrum Glide** catheters are impregnated with antimicrobial agents, minocycline and rifampin (average concentration for 7 Fr catheter: 503 μg/cm minocycline, 480 μg/cm rifampin), to help provide protection against catheter-related bloodstream infections (CRBSI). **Cook Spectrum** catheters are designated by the suffix -ABRM in the order number. The hubs of **Cook Spectrum** and **Spectrum Glide** Catheters are marked "M/R" to help clinicians identify antimicrobial-impregnated catheters after they have been placed in patients.

In addition to the antimicrobial agents described above, **Spectrum Glide** catheters have an EZ-Pass® hydrophilic coating on the distal 10 cm, consisting of polyacrylamide and polyvinylpyrrolidone, to enhance insertion. **Spectrum Glide** catheters are designated by the suffix -HC in the order number.

INTENDED USE

Cook Spectrum and Spectrum Glide central venous catheters are intended for:

- Continuous or intermittent drug infusions
- Central venous blood pressure monitoring (CVP)
- Acute hyperalimentation
- Blood sampling
- Delivery of whole blood or blood products
- Power injection of contrast media*

The activity of the antimicrobial agents, minocycline and rifampin, is localized at the internal and external catheter surface and helps to provide protection against catheter-related bloodstream infections (CRBSI). It is not intended for treatment of existing infection. The device is a short-term use catheter.

* The flow rate may not exceed 10 mL/sec.

CONTRAINDICATIONS

- Allergy or history of allergy to tetracyclines (including minocycline) or rifampin.

  NOTE: The warnings and precautions regarding use of minocycline (a derivative of tetracycline) and rifampin (a derivative of rifamycin B) 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 its use.
- Minocycline and rifampin are agents that do not induce any genotoxic risks except a possible teratogenic effect in pregnant women. We therefore do not recommend the use of **Spectrum** or **Spectrum Glide** catheters in pregnant women.

WARNINGS

- Complications arising from the use of this device can result in serious injury or death; catheter tip can erode or perforate vascular walls.
- 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.
- 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.
- To distend great vessels and to prevent inadvertent air aspiration during catheter insertion, patient should be placed in Trendelenburg position.
- Development of a hypersensitivity reaction should be followed by removal of the catheter and appropriate treatment at the discretion of the attending physician.
- The safe and effective use of central venous catheters with power injector pressures (safety cut-off) set above 325 psi has not been established.
- **Do not power inject if maximum injection rate cannot be verified to meet limit of 10 mL/sec.**
- To safely use catheters with a power injector, the technician/health care professional must verify prior to use that the maximum safety cut-off pressure limit is set at or below 325 psi and that the maximum flow rate is at or below 10 mL/sec.
- Do not exceed the maximum flow rate of 10 mL/sec. Exceeding the maximum flow rate of 10 mL/sec may result in catheter failure and/or catheter tip displacement.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Power injector machine pressure limiting (safety cut-off) settings may not prevent over-pressurization of an occluded catheter.
- Cook Central Venous Catheter indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- In rare cases, hepatotoxicity, systemic lupus erythematosus and exacerbation of porphyria have been associated with the systemic use of minocycline and/or rifampin.

PRECAUTIONS

- These products are intended for use by physicians trained and experienced in the placement of central venous catheters using percutaneous entry (Seldinger) technique. Standard Seldinger technique for placement of percutaneous vascular access sheaths, catheters and wire guides should be employed during the placement of a central venous catheter.
- Do not re-sterilize catheter.
- Do not cut, trim or modify catheter or components prior to placement or intraoperatively.
- Patient movement can cause catheter tip displacement. Use should be limited to controlled hospital situations. Catheters placed from either a jugular or subclavian vein have demonstrated forward tip movement of 1-3 cm with neck and shoulder motion.
- Catheter should not be used for long-term indwelling applications.
- **If lumen flow is impeded, do not force injection or withdrawal of fluids. Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure. Notify attending physician immediately.**
- Catheter should not be used for chronic hyperalimentation.
- Select puncture site and length of catheter needed by assessing patient anatomy and condition.
- Use of ECG, ultrasound and/or fluoroscopy is suggested for accurate catheter placement.
- Left subclavian and left jugular veins should be used only when other sites are not available.
- Radiographic confirmation of catheter placement prior to each power injection procedure is recommended.
- Trays that include lidocaine also include a lidocaine label, which should be used to label the syringe for lidocaine injection. Any unused lidocaine should be disposed of at the conclusion of the procedure.
- Controlled clinical trials of **Spectrum** and **Spectrum Glide** central venous catheters in pregnant women, pediatric and neonatal populations have not been conducted. The benefits of the use of **Spectrum** and **Spectrum Glide** central venous catheters should be weighed against possible risks.
- Prior to insertion, the **Spectrum** or **Spectrum Glide** 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.
- The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects.

CLINICAL STUDIES

A prospective, randomized, multicenter clinical study was conducted in which 817 patients were enrolled to receive either a 7.0 French triple-lumen **Cook Spectrum** Minocycline/Rifampin Impregnated Catheter or a 7.0 French triple-lumen chlorhexidine gluconate and silver sulfadiazine (CG/SS) coated catheter, with at least 350 patients available for follow-up in each study arm. The patient characteristics (age, sex, underlying disease, degree of immunosuppression, therapeutic interventions, site of insertion, duration of catheterization and reason for catheter removal) were comparable in the two groups. Results from the clinical study showed a statistically significant decrease in the incidence of bacterial colonization of the **Spectrum** catheter (7.9% as compared to 22.8% for the CG/SS catheter, $p<0.001$), and a statistically significant decrease in the incidence of catheter-related bacteremia in patients receiving the **Spectrum** catheter (0.3% as compared to 3.4% for the control catheter, $p<0.002$). The antimicrobial durability of the **Spectrum** catheter against Staphylococcus epidermidis lasted for at least 21 days after catheter insertion in patients (zone of inhibition ≥25 mm). Examination by high-performance liquid chromatography showed that the **Spectrum** catheter contained 11.08 mg (554 µg/cm) and 10.50 mg (525 µg/cm) per catheter of minocycline and rifampin, respectively. Moreover, there were no detectable changes in antibiotic susceptibilities of bacteria cultured from the **Spectrum** Catheter and from adjacent skin.[1]

PRODUCT RECOMMENDATIONS

Catheter Size*	Maximum Power Injection Flow Rate (mL/sec)**	Average Maximum Internal Catheter Pressure During Maximum Flow Rate (psi) ***	Average Maximum Dynamic Burst Pressure (psi)	Average Maximum Static Burst Pressure (psi) ****
7 French, Triple Lumen	10	143.3	289.0	181.6
8 French, Double Lumen	10	55.1	336.9	208.1
9 French, Triple Lumen	10	35.8	321.5	162.8
10 French, Five Lumen	10	32.1	321.3	228.0

All testing performed on the distal lumen of each catheter.

****Pressurized flow rates are determined with injector safety cut-off set at 325 psi and contrast agent at 11.8 centipoise.***

*****Pressures determined using room temperature Omnipaque 300™ contrast and verified using a Medrad Stellant™ CT injector system with injector safety cut-off at 325 psi. Omnipaque 300™ has a viscosity of 11.8 centipoise at room temperature (20 degrees C). A change in temperature or viscosity of the contrast medium used will result in a change in achievable flow rates. Omnipaque 300™ is a registered trademark of GE Healthcare.***

******Maximum Static/Burst pressure is the static burst pressure failure point of the catheter. When catheter was occluded, failure occurred at these pressures.***

Catheter Size and Puncture Site

Preliminary reports indicate that catheter size can influence clotting; larger diameter catheters tend to promote clots. As reported by Amplatz and others[2], clot formation has less relation to type of catheter material than to size of catheter. The

angle of the catheter tip to the vessel wall should be checked carefully. Blackshear reviewed the medical literature of catheter perforations, which have confirming X-rays, and found that an incident angle of the catheter to the vessel wall greater than 40 degrees was more likely to perforate.[3]

Another critical factor that can cause a catastrophic event is the choice of puncture site. Findings by Tocino and Watanabe indicate that the left subclavian and left jugular veins should be avoided when practical. Eighty percent of the perforations or erosions were found when these vessels were used. In addition, they have observed that the tip curve of a wedged catheter can be detected with lateral view X-ray.[4]

The above discussion is meant to be a guide for catheter size and puncture site. As more data become available, other causal factors may become evident, but present information suggests that:

- The catheter size should be as small as the use will allow.
- Left subclavian and left jugular veins should be used only when other sites are not available.

The following variables should be considered when selecting appropriate catheter and length:

- Patient history
- Size and age of patient
- Access site available
- Unusual anatomical variables
- Proposed use and duration of treatment plan

Standard Catheter Lengths Available for Adult Use

These suggested lengths must be viewed only as a guideline.

French Size	Length	Access Site
7.0, 8.0, 9.0, 10.0	15 cm	Internal and external jugular veins
7.0, 8.0, 9.0, 10.0	20 cm	Right subclavian vein
7.0, 8.0, 9.0, 10.0	25 cm	Left subclavian vein
10.0	30 cm	Femoral vein

Double-Lumen Information

The 8.0 French Double-Lumen Central Venous Catheter has a "double-D" lumen configuration.

French Size	Lumens	Equivalent Gage	Minimum Lumen Volume
8.0	#1 #2	14 14	0.9 mL 1.0 mL

Triple-Lumen Information

French Size	Lumens	Equivalent Gage	Minimum Lumen Volume
7.0	#1 #2 #3	16 18 18	0.6 mL 0.5 mL 0.6 mL
9.0	#1 #2 #3	14 18 18	0.9 mL 0.4 mL 0.5 mL

Five-Lumen Information

French Size	Lumens	Equivalent Gage	Minimum Lumen Volume
10.0	#1 #2 #3 #4 #5	14 17 17 19 19	0.9 mL 0.4 mL 0.4 mL 0.2 mL 0.2 mL

Suggested Lumen Utilization: Double-Lumen

- **#1 Distal exit port (endhole)** — whole blood or blood product delivery and sampling; any situation requiring more flow rate; CVP monitoring; medication delivery; power injection studies. **It is strongly recommended that this lumen be used for all blood sampling.** "CT" labeled on the distal #1 lumen hub indicates that this is the lumen which should be utilized for power injection.
- **#2 Proximal exit port** — medication delivery; acute hyperalimentation.

Suggested Lumen Utilization: Triple-Lumen

- **#1 Distal exit port (endhole)** — whole blood or blood product delivery and sampling; any situation requiring more flow rate; CVP monitoring; medication delivery; power injection studies. **It is strongly recommended that this lumen be used for all blood sampling.** "CT" labeled on the distal #1 lumen hub indicates that this is the lumen which should be utilized for power injection.
- **#2 Middle exit port** — medication delivery; acute hyperalimentation.
- **#3 Proximal exit port** — medication delivery.

Suggested Lumen Utilization: Five-Lumen

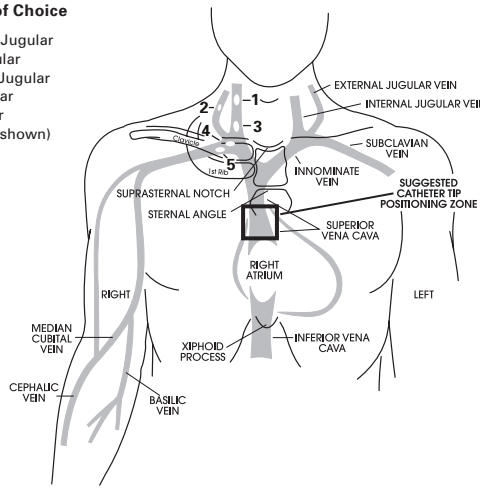
- **#1 Distal exit port (endhole)** — whole blood or blood product delivery and sampling; any situation requiring more flow rate; CVP monitoring; medication delivery; power injection studies. **It is strongly recommended that this lumen be used for all blood sampling.** "CT" labeled on the distal #1 lumen hub indicates that this is the lumen which should be utilized for power injection.
- **#2 Middle exit port** — medication delivery; acute hyperalimentation.
- **#3 Middle exit port** — medication delivery; acute hyperalimentation.
- **#4 Proximal exit port** — medication delivery.
- **#5 Proximal exit port** — medication delivery.

Suggested Catheter Maintenance

- Catheter entry site must be prepared and maintained in a manner consistent with standard procedure for central venous catheterization.
- To prevent clotting or possibility of air embolus, the double-lumen's #2 lumen, the triple-lumen's #2 and #3 lumens, and the five-lumen's #2, #3, #4, and #5 lumens should be filled with saline solution or heparinized saline solution (100 units of heparin per mL of saline is usually adequate), depending on institutional protocol, prior to catheter introduction.
- After catheter is placed and prior to use, tip position and lumen patency should be confirmed by free aspiration of venous blood. **If blood is not freely aspirated, physician should immediately reevaluate catheter tip position. Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.**
- Any unused lumens should be maintained with continuous saline or heparinized saline drip or locked with heparinized saline solution.
- Before using any lumen already locked with heparin, lumen should be flushed with twice the indicated lumen volume using normal saline. Lumens should be flushed with normal saline between administrations of different infusates. After use, lumen should again be flushed with twice the indicated lumen volume using normal saline before reestablishing heparin lock.
- The antimicrobial agents minocycline and rifampin contain yellow/orange pigments. Some coloration of the **Spectrum** or **Spectrum Glide** catheters is normal.
- Strict aseptic technique must be adhered to while using and maintaining the catheter.

Access Sites of Choice

1. High Internal Jugular
2. External Jugular
3. Low Internal Jugular
4. Supraclavicular
5. Infraclavicular
6. Femoral (not shown)



INSTRUCTIONS FOR USE

1. If applicable, remove the Luer-lock end cap from each extension.
2. 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.
3. Introduce thinwall percutaneous entry needle into vessel. Venous blood should be easily aspirated to confirm position of needle tip within vessel.
4. Slide Safe-T-J® wire guide straightener (positioned on distal tip of wire guide) over "J" portion of wire guide. Pass straightened wire guide through needle; advance wire guide 5-10 cm into vessel. If straight wire is used, always advance soft, flexible end through needle hub and into vessel. **If resistance is encountered during wire guide insertion, do not force wire guide. Withdrawal of wire guide through needle should be avoided; breakage may result.**
5. While maintaining wire guide position, withdraw needle and Safe-T-J wire guide straightener.
6. Enlarge puncture site with number 11 scalpel blade, if required. If dilation is required, dilator can be advanced over 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.
7. Measure catheter to be used against patient to determine approximate length of catheter needed from puncture site to central venous tip position.

   NOTE: The **Spectrum Glide** catheter with EZ-Pass hydrophilic coating may be wetted with sterile water or saline prior to insertion to activate the coating.
8. Introduce the central venous catheter over wire guide. While maintaining wire guide position, advance catheter into vessel with a gentle twisting motion. (**Fig. 1**)

   NOTE: Do not advance catheter tip beyond distal tip of wire guide. Always have wire guide leading during catheter placement. 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.
9. After catheter is in position, remove wire guide. (**Fig. 2**) **Venous blood should be easily aspirated.** Winged hub can now be sutured into place. If catheter is not introduced to its full length, additional suture should be carefully placed around catheter and affixed to the skin at entry site (if movable suture wing is not included). 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 heparin lock.

   NOTE: A wire guide that is at least twice as long as the catheter is recommended for catheter exchange procedure.

Power Injection Procedure

1. Confirm proper catheter tip position radiographically prior to injection.
2. Remove any injection/needleless caps from the catheter.
3. Attach a 10 mL (or larger) syringe filled with sterile normal saline to the hub of the distal (#1) extension tube to be used for power injection.
4. Ensure adequate blood return and flush catheter vigorously with the entire 10 mL of sterile normal saline to ensure lumen patency.

   WARNING: Failure to ensure patency of the catheter lumen prior to injection may result in catheter failure.
5. Remove syringe and attach power injection device to the catheter using the manufacturer's recommendations.

NOTE: Refer to power injector manufacturer's recommendations regarding connecting tubes.

6. Conduct study using the power injector, making sure not to exceed the maximum flow rate of 10 mL/sec or pressure limit safety cut-off of 325 psi for the catheter.
7. Disconnect the power injection device and flush the catheter again with 10 mL of sterile normal saline.
8. Replace injection/needleless cap on the catheter.
9. Confirm proper catheter tip position radiographically following power injection.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or 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. Darouiche R, Raad I, Heard S, et al. "A Comparison of Two Antimicrobial-impregnated Central Venous Catheters." N Engl J Med, 1999; 340:1-8.
2. Amplatz K. "A Simple Non-thrombogenic Coating." Investigative Radiology, 1971; 6:280-289.
3. Blackshear RH, Gravenstein N. "Critical Angle of Incidence for Delayed Vessel Perforation by Central Venous Catheter: A Study of *In Vivo* Data." Annals of Emergency Medicine, 1992; 21:242.
4. Tocino IM, Watanabe A. "Impending Catheter Perforation of Superior Vena Cava: Radiographic Recognition." American Journal of Roentgenology, 1986; 146:487-490.
5. Darouiche RO, Smith JA, Hanna H, et al. "Efficacy of Antimicrobial-impregnated Bladder Catheters in Reducing Catheter-associated Bacteriuria: A Prospective, Randomized, Multicenter Clinical Trial." Urology, 1999; 54:976-981.
6. Oropello JM , Leibowitz AB, Manasia A, Guidice RD, Benjamin E. "Dilator-Associated Complications of Central Vein Catheter Insertion: Possible Mechanisms of Injury and Suggestions for Prevention," Journal of Cardiothoracic and Vascular Anesthesia, 1996; 10:634-637.

This symbol on the label indicates that this device contains phthalates. Specific phthalates contained in the device are identified beside or below the symbol by the following acronyms:

- **BBP: Benzyl butyl phthalate**
- **DBP: Di-n-butyl phthalate**
- **DEHP: Di(2-ethylhexyl) phthalate**
- **DIDP: Diisodecyl phthalate**
- **DINP: Diisononyl phthalate**
- **DIPP: Diisopentyl phthalate**
- **DMEP: Di(methoxyethyl) phthalate**
- **DNOP: Di-n-Octyl phthalate**
- **DNPP: Di-n-pentyl phthalate**

MANUFACTURER

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