COOK MEDICAL

8 French Double-Lumen Central Venous Catheter

Instructions for Use

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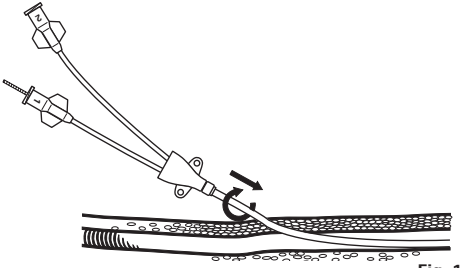


Fig. 1

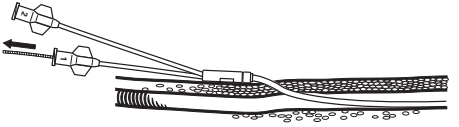


Fig. 2

8 FRENCH DOUBLE-LUMEN CENTRAL VENOUS CATHETER

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

DEVICE DESCRIPTION

8 French Double-Lumen Central Venous Catheters are constructed of polyurethane and incorporate separate, non-communicating, D-shaped vascular access lumens within a single catheter body. Catheters with an "-ABRM-HC" suffix in the product number are Cook Spectrum Glide® catheters.

Cook Spectrum Glide catheters are impregnated with antimicrobial agents, minocycline and rifampin (average of 524 µg/cm and 473 µg/cm respectively) to help provide protection against catheter-related bloodstream infections (CRBSI).

In addition to the antimicrobial agents described above, Cook Spectrum Glide catheters have an EZ-Pass® hydrophilic coating, consisting of polyacrylamide and polyvinylpyrrolidone, on the distal 10 cm to enhance insertion.

INTENDED USE

The central venous catheter is designed for treatment of critically ill patients and is suggested for:

1. Continuous or intermittent drug infusions
2. Central venous blood pressure monitoring (CVP)
3. Acute hyperalimentation
4. Blood sampling
5. Delivery of whole blood or blood products
6. Simultaneous, separate infusion of drugs

The activity of the antimicrobial agents, minocycline and rifampin, is localized at the internal and external catheter surface and is not intended for treatment of systemic infections. The device is a short-term use catheter.

CONTRAINDICATIONS

NOTE: The following contraindications pertain only to Cook Spectrum Glide Central Venous Catheters, which are impregnated with the antimicrobial agents, minocycline and rifampin.

- 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 Cook Spectrum Glide catheters in pregnant women.

WARNINGS

- 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.
- **Do not power inject contrast medium through catheter.** Catheter rupture may result. Use of 10 cc or larger syringe will reduce the risk of catheter rupture.
- 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.
- In rare cases, hepatotoxicity, systemic lupus erythematosus and exacerbation of porphyria have been associated with the systemic use of minocycline and/or rifampin.

PRECAUTIONS

- The catheter is 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. 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.

CLINICAL STUDIES

NOTE: The following information pertains only to Cook Spectrum Central Venous Catheters, which are impregnated with the antimicrobial agents, minocycline and rifampin.

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 Cook 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 Cook Spectrum catheter (0.3% as compared to 3.4% for the control catheter, $p<0.002$). The antimicrobial durability of the Cook 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 Cook Spectrum Catheter and from adjacent skin.[1]

PRODUCT RECOMMENDATIONS

Catheter Tip Position and Puncture Site

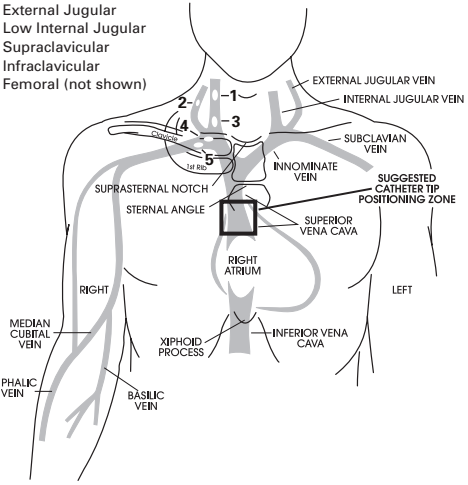
The angle of the catheter tip to the vessel wall should be checked carefully. Blackshear reviewed the medical literature of catheter perforations, which have confirming x-rays, and found that an incident angle of the catheter to the vessel wall greater than 40 degrees was more likely to perforate.[2]

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.[3]

The above discussion is meant to be a guide for puncture site selection. As more data become available, other causal factors may become evident, but present information suggests that left subclavian and left jugular veins should be used only when other sites are not available.

Access Sites of Choice

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



Catheter Selection

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

Length	Access Site
15 cm	Internal and external jugular
20 cm	Right subclavian vein
25 cm	Left subclavian vein

Lumen Information

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

Lumens	Equivalent Gage	Minimum Lumen Volume
#1	14	0.9 cc
#2	14	1.0 cc

Suggested Lumen Utilization

- **#1 Distal exit port** (endhole)– whole blood or blood product delivery and sampling; any situation requiring more flow rate; CVP monitoring; medication delivery. **It is strongly recommended that this lumen be used for all blood sampling.**
- **#2 Proximal exit port** – medication delivery; acute hyperalimentation

Special Patient Group

NOTE: The following information pertains only to Cook Spectrum Glide Central Venous Catheters, which are impregnated with the antimicrobial agents, minocycline and rifampin.

Controlled clinical trials of Cook Spectrum Glide central venous catheters in pregnant women, pediatric and neonatal populations have not been conducted. The benefits of the use of Cook Spectrum Glide central venous catheters should be weighed against possible risks.

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 should be filled with saline solution or heparinized saline solution (100 units of heparin per cc 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.**
- Any unused lumens should be maintained with continuous saline or heparinized saline drip or locked with heparinized saline solution. Heparin-locked lumens should be reestablished at least every 8 hours.
- 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.

- Strict aseptic technique must be adhered to while using and maintaining catheter.

NOTE: Prior to insertion, the Cook 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.

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 Cook Spectrum Glide catheter 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 cc 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.

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. 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.
3. Tocino IM, Watanabe A. "Impending Catheter Perforation of Superior Vena Cava: Radiographic Recognition." *American Journal of Roentgenology,* 1986; 146:487-490.
4. 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.

Keep dry

Keep away from sunlight

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