COOK
MEDICAL

Cook Spectrum® Turbo-Ject®
Over-The-Wire Peripherally Inserted Central Venous Catheters With Micropuncture® Peel-Away® Introducers

Instructions for Use

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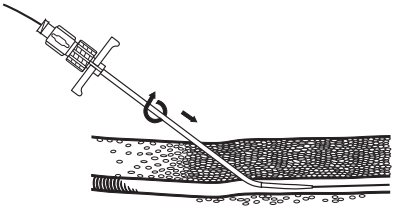


Fig. 1

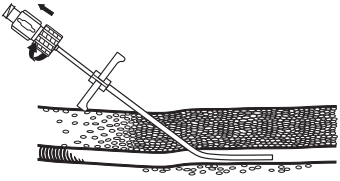


Fig. 2

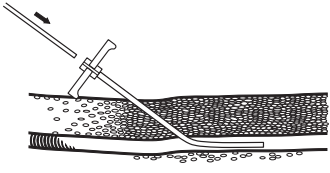


Fig. 3

COOK SPECTRUM® TURBO-JECT® OVER-THE-WIRE PERIPHERALLY INSERTED CENTRAL VENOUS CATHETERS WITH MICROPUNCTURE® PEEL-AWAY® INTRODUCERS

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 Spectrum Turbo-Ject Over-The-Wire Peripherally Inserted Central Venous Catheters feature a soft polyurethane suture wing for secure fixation to the skin. Reinforced polyurethane extensions reduce catheter damage during catheter manipulations. Catheters can be trimmed to fit the patient's anatomy. Plastic clamp(s) help prevent air aspiration due to inadvertent hub dislodgment.

Cook Spectrum Turbo-Ject Over-the-Wire Peripherally Inserted Central Venous Catheters are impregnated with the antimicrobial agents minocycline and rifampin. The highest average concentrations (i.e., for the 6 Fr. triple lumen catheter) are 499 µg/cm and 561 µg/cm respectively. 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 existing infection. The antimicrobial agents, minocycline and rifampin, have a yellow and an orange appearance; therefore, some coloration of the catheter is normal.

Single Lumen Catheters

Catheter	Outer Diameter		Inner Diameter		
French	Inch	Gage	Inch	Gage	Lumen Vol. (mL)
3.0	0.041	19	0.027	19	0.52
4.0	0.053	17	0.030	18	0.71
5.0	0.066	15	0.037	17	0.75

Double Lumen Catheters

Catheter	Outer Diameter		Inner Diameter (each lumen)		
French	Inch	Gage	Inch	Gage	Lumen Vol. (mL)
5.0	.066	15	.022/.044	18	0.72

Triple Lumen Catheters

Catheter	Outer Diameter		Inner Diameter (each lumen)		
French	Inch	Gage	Inch	Gage	Lumen Vol. (mL)
			.031/.053	17	1.04
			.025	19	0.73
6.0	.079	14	.025	19	0.73

INTENDED USE

Cook Spectrum Turbo-Ject Over-The-Wire Peripherally Inserted Central Venous Catheter (PICC) Sets are intended for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSIs). The Spectrum Turbo-Ject Over-The-Wire PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for Power Injectors used with the Spectrum Turbo-Ject PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated, as shown on the following table.

Catheter Size	Maximum Flow Rate*	Injection Pressure Limit Setting
3 Fr Single Lumen	2 mL/sec	325 psi
4 Fr Single Lumen	4 mL/sec	325 psi
5 Fr Single Lumen	7 mL/sec	325 psi
5 Fr Double Lumen	5 mL/sec	325 psi
6 Fr Triple Lumen**	7 mL/sec	325 psi

*Flow rates achieved using room temperature Omnipaque® 300 contrast and verified using a MEDRAD® Stellant® CT injector system. 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.

**Lumen # 1 only.

CONTRAINDICATIONS

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

NOTE: Because the Cook Spectrum Turbo-Ject Over-The-Wire 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 or Spectrum Glide catheters in pregnant women.

WARNINGS

- **Peripherally Inserted Central Venous Catheters play an important role in treatment of critically ill patients. However, catheter tips can erode or perforate vascular walls. Extreme caution must be used in placement and monitoring of catheters.**
- Catheter 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. (**Reference 1**)
- The safe and effective use of Spectrum Turbo-Ject PICC lines with power injector pressures set above 325 psi has not been established.
- **Do not power inject if maximum injection rate cannot be verified to meet limit printed on catheter hub or extension tube.**
- To safely use Cook Spectrum Turbo-Ject PICC lines with a power injector, the technician/health care professional must verify prior to use that the maximum pressure limit is set at or below 325 psi and that the maximum flow rate is at or below that which is listed on the catheter. Dynamic and static pressure test results are shown in the following table.
- Development of a hypersensitivity reaction should be followed by removal of the catheter and appropriate treatment at the discretion of the physician.
- In rare cases, hepatotoxicity, systemic lupus erythematosus and exacerbation of porphyria have been associated with the systemic use of minocycline and/or rifampin.

NOTE: The Cook Spectrum Turbo-Ject PICC should not supersede strict aseptic techniques as it relates to catheter placement and maintenance.

Cook Spectrum Turbo-Ject Power Injectable PICC Dynamic and Static Pressure Results

French/ Lumen	Priming Volume (mL)	Maximum Labeled Flow Rate (mL/sec)	Average Maximum Catheter Pressure During Maximum Flow (psi)*	Average Static Burst Pressure in 37˚C Water (psi)**	Range of Static Burst Pressure in 37˚C Water (psi)**
3.0/Single	0.52	2	123	249	237-258
4.0/Single	0.61	4	225	382	371-389
5.0/Single	0.75	7	257	418	404-431
5.0/Double	0.72	5	205	267	254-277
6.0/Triple***	1.04	7	140	229	187-198

*Maximum flow rate pressures are determined with pump safety cut-off set at 325 psi, using contrast media with a viscosity of 11.8 cP.

**Static burst pressure is the failure point of the catheter when totally occluded. WARNING: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter.

***Lumen #1 only.

PRECAUTIONS

- This product 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.
- Select puncture site and length of catheter needed by assessing patient anatomy and condition.
- If lumen flow is impeded, do not force injection or withdrawal of fluids. Notify attending physician immediately.
- 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.
- Catheter size should be as small as the use will allow.

NOTE: Prior to insertion, the Cook 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.

NOTE: Controlled clinical trials of Spectrum PICC catheters in pregnant women, pediatric, and neonatal populations have not been conducted. The benefits of the use of Spectrum PICCs should be weighed against possible risks.

CLINICAL STUDIES (Reference 2)

To evaluate efficacy of the Cook Spectrum Silicone Catheter in reducing the incidence of catheter-related bloodstream infection, a prospective, randomized clinical trial was conducted in which 356 patients were enrolled to receive either a Cook Spectrum Silicone Catheter or a non-impregnated silicone control catheter. A total of 182 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 (66 ± 31 days for the Cook Spectrum Silicone Catheter and 63 ± 31 days for the control, p = .003).

Catheters Used in the Clinical Study

Type of Catheter	Control Cohort	Treatment Cohort
Double-Lumen Subclavian	84 (48%)	84 (46%)
Single-Lumen Subclavian	24 (14%)	34 (19%)
PICC Line	66 (38%)	64 (35%)
Total	174 (100%)	182 (100%)

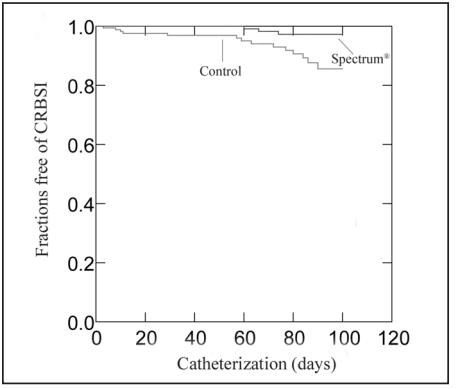
Results from the clinical study showed a statistically significant decrease in the incidence of catheter-related bloodstream infection in patients receiving the Cook Spectrum Silicone Catheter, with infections occurring in 3 of 182 patients (2%) as compared to 14 of 174 patients (8.0%) for the control catheter (p = .005).

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

Blood samples obtained from 9 patients at 1-2 days after insertion of the Cook 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 µg/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 Size and Puncture Site

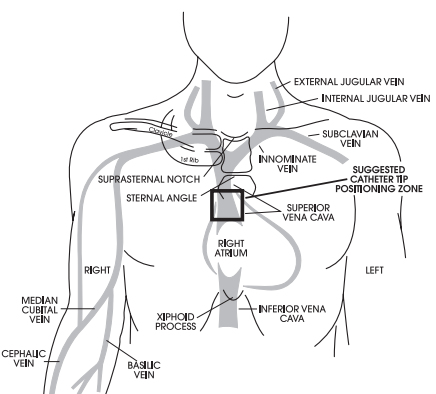
Preliminary reports indicate that catheter size can influence clotting. Larger diameter catheters have more tendency to promote clots. As reported by Amplatz, Gianturco and others, clot formation has less relation to type of catheter material than to size of catheter.

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 vessel wall greater than 40 degrees was more likely to perforate. (**Reference 3**)

The following variables must also be considered in selecting appropriate catheter and length:

1. Patient history
2. Patient age and size
3. Access site available
4. Unusual anatomical variables
5. Proposed use and duration of treatment plan

Catheter Tip Positioning



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.**

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. (**Reference 4**) Heparin lock should be reestablished after every use, every 24 hours, or in accordance with the approved facility protocol if catheter is 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.

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INSTRUCTIONS FOR USE

NOTE: Prior to placing catheter over the wire, remove stylet (if included) and trim catheter to desired length and flush catheter.

1. After prepping the access site, introduce the access 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 help visualize the tip of the needle during vessel access.
2. Using fluoroscopic guidance, introduce the access wire guide through the needle and advance it 15-20 cm into the vessel.
3. Withdraw the needle, leaving wire guide in place. If necessary, enlarge the puncture site with scalpel blade.
4. Introduce the Peel-Away introducer assembly (sheath and dilator) over the wire guide. With a twisting motion, advance the assembly into the vessel. (**Fig. 1**)
5. Remove the access wire guide. Using fluoroscopic control, insert the longer marked wire guide to determine the correct catheter length by advancing the wire guide to the desired catheter tip location. Once the wire guide tip is in proper position, using the proximal portion of the wire guide that is external to the patient, measure the distance from the triple etch marks to the puncture site. (The distal 60 cm of the wire guide is marked in 5 cm increments, with the triple etch marks positioned proximally at 60 cm.) Trim catheter to the appropriate (60 cm minus X measured cm) length. **NOTE:** Catheters are available in various untrimmed lengths. See packaged label for untrimmed length.
6. Leaving the sheath and wire guide in place, remove the dilator by rotating the locking collar counterclockwise. (**Fig. 2**) **NOTE:** To prevent inadvertent air aspiration after removal of dilator, place thumb and finger around wire guide as it enters the proximal end of the sheath.
7. Introduce the catheter over the wire guide into the sheath as far as possible. (**Fig. 3**) **NOTE:** The last 7 cm of insertable catheter will not pass through the sheath due to an increase in outer diameter.
8. Peel the sheath away from the catheter by grasping the two tabs of the sheath, snapping them down, and pulling outward and upward.
   NOTE: Be sure to maintain stable catheter position while peeling sheath away.
9. Once the sheath is removed, advance the catheter over the wire into final position.
10. Remove wire guide, then cap and flush catheter. Secure catheter to the skin, and dress per protocol.
11. Verify catheter tip radiographically. 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.

Power Injection Procedure

1. Confirm proper catheter tip position radiographically prior to injection.
2. Remove any injection/needleless caps from the Spectrum Turbo-Ject PICC.
3. Attach a 10 mL (or larger) syringe filled with sterile normal saline to the hub of the 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.
6. Conduct study using the power injector, making sure not to exceed the maximum flow rate or pressure limit for the catheter.
7. Disconnect the power injection device and flush the catheter again with 10 mL of sterile normal saline.
8. Place a new injection/needleless cap on the Spectrum Turbo-Ject PICC, flush and lock the catheter with saline or heparinized saline per institutional protocol.
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. Tocino IM, Watanabe A: "Impending Catheter Perforation of Superior Vena Cava: Radiographic Recognition," *American Journal of Roentgenology*, 1986; 146:487-490.
2. 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(15):3163-3171.
3. Welch RH, Gravenstein N, Blackshear RH: "Multilumen Central Venous Catheters in Children: Relative Potential to Perforate Vessels. An In Vitro Study," *Journal of Clinical Monitoring*, 1997;13:75-79.
4. Kelly C, Dumenko L, McGregor SE, McHutchion ME: "Change in Flushing Protocols of Central Venous Catheters," *Oncology Nursing Forum,* 1992; 19:599-605.

Keep dry

Keep away from sunlight

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www.cookmedical.com

2019-11
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