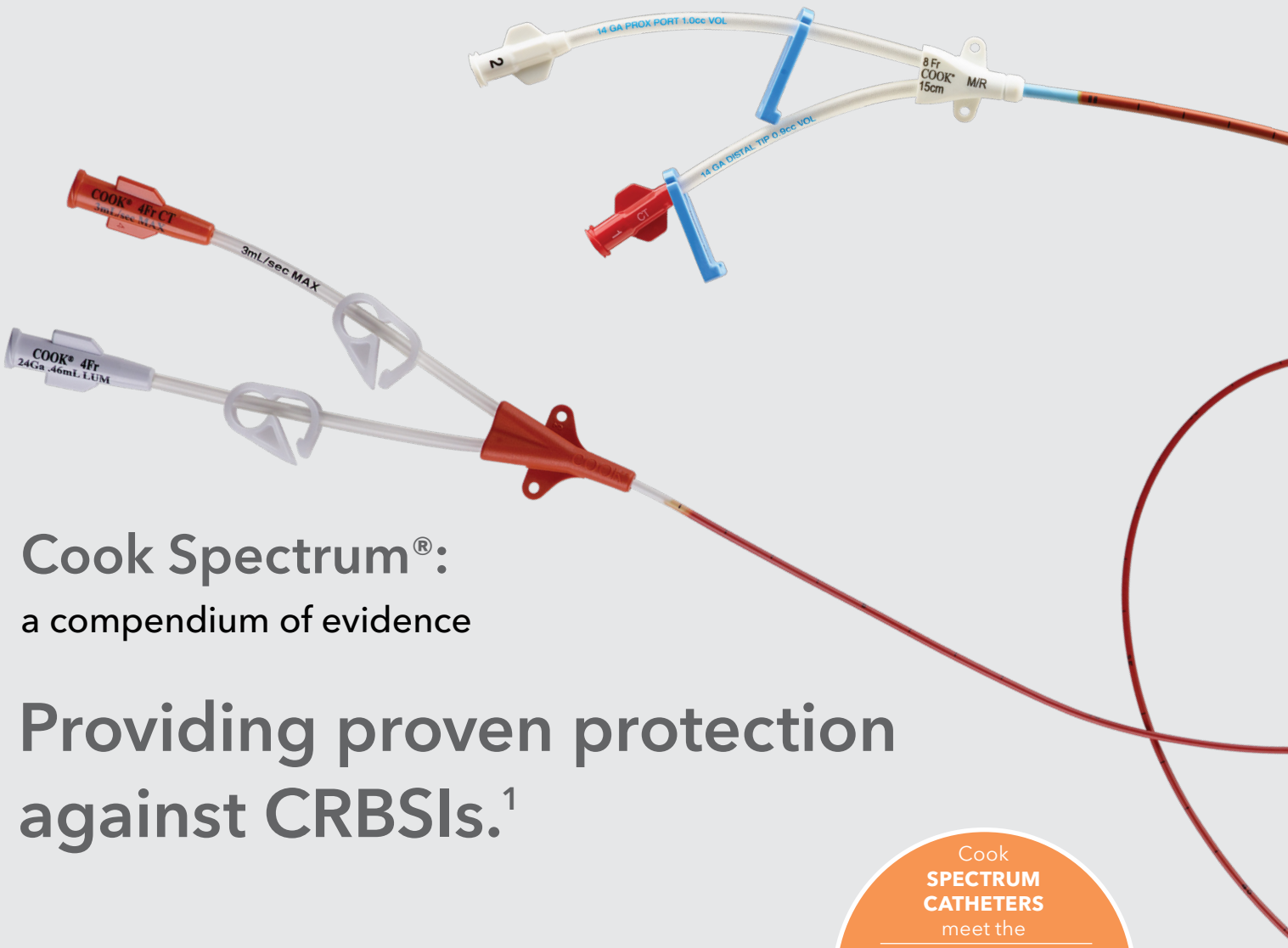

Cook Spectrum®:

a compendium of evidence

Providing proven protection against CRBSIs.[1]

Cook **SPECTRUM CATHETERS** meet the **CDC 1A RECOMMENDATION** as a component of the prevention of CLABSIs.[2]

Cook Spectrum®
TECHNOLOGY

1. Raad I, Darouiche R, Dupuis J, et al. Central venous catheters coated with minocycline and rifampin for the prevention of catheter-related colonization and bloodstream infections: a randomized, double-blind trial. *Ann Intern Med.* 1997;127(4):267-274.

2. O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the prevention of intravascular catheter-related infections, 2011. Centers for Disease Control and Prevention website. www.cdc.gov/infectioncontrol/pdf/guidelines/bsi-guidelines.pdf. Updated February 15, 2017. Accessed July 6, 2017. The 1A recommendation from the Centers for Disease Control and Prevention (CDC) is to "Use a chlorhexidine/silver sulfadiazine or minocycline/rifampin -impregnated CVC in patients whose catheter is expected to remain in place >5 days if, after successful implementation of a comprehensive strategy to reduce rates of CLABSI, the CLABSI rate is not decreasing."

COOK® MEDICAL

SPECTRUM + TECHNOLOGY PROCESS BUNDLE

Providing proven protection against CRBSIs.[1]

The science and efficacy of minocycline+rifampin catheters.

This compendium of studies organizes the vast body of research investigating and supporting Cook Spectrum into manageable sections that are easy to understand and quickly reference.

Full-text versions of five of the most commonly requested studies are conveniently included in this booklet (1, 2, 4, 5, 25). If you require any additional resources, please contact your Cook Medical sales representative.

To learn more about Cook Spectrum technology, contact us at spectrum@cookmedical.com.

1. Raad I, Darouiche R, Dupuis J, et al. Central venous catheters coated with minocycline and rifampin for the prevention of catheter-related colonization and bloodstream infections: a randomized, double-blind trial. *Ann Intern Med.* 1997;127(4):267-274.

Spectrum efficacy

1. **Effectiveness of minocycline and rifampin vs chlorhexidine and silver sulfadiazine-impregnated central venous catheters in preventing central line-associated bloodstream infection in a high-volume academic intensive care unit: a before and after trial.**
   Bonne S, Mazuski JE, Sona C, et al.
   Journal of the American College of Surgeons. 2015;221(3):739-747.
   ncbi.nlm.nih.gov/pubmed/26199017

2. **Novel approach using antimicrobial catheters to improve the management of central line-associated bloodstream infections in cancer patients.**
   Chaftari A, Kassis C, El Issa H, et al.
   Cancer. 2011;117(11):2551-2558.
   onlinelibrary.wiley.com/doi/10.1002/cncr.25807/full

3. **The clinical effectiveness of central venous catheters treated with anti-infective agents in preventing catheter-related bloodstream infections: a systematic review.**
   Hockenhull JC, Dwan KM, Smith GW, et al.
   Critical Care Medicine. 2009;37(2):702-712.
   ncbi.nlm.nih.gov/pubmed/19114884

4. **A systematic review comparing the relative effectiveness of antimicrobial-coated catheters in intensive care units.**
   Ramritu P, Halton K, Collignon P, et al.
   American Journal of Infection Control. 2008;36(2):104-117.
   ncbi.nlm.nih.gov/pubmed/18313512

5. **Antimicrobial central venous catheters in adults: a systematic review and meta-analysis.**
   Casey AL, Mermel LA, Nightingale P, et al.
   The Lancet Infectious Diseases. 2008;8(12):763-776.
   ncbi.nlm.nih.gov/pubmed/19022192

6. **Effectiveness of impregnated central venous catheters for catheter related blood stream infection: a systematic review.**
   Gilbert RE, Harden M.
   Current Opinion in Infectious Diseases. 2008;21(3):235-245.
   ncbi.nlm.nih.gov/pubmed/18448967

7. **Rifampicin-impregnated central venous catheters: a meta-analysis of randomized controlled trials.**
   Falagas ME, Fragoulis K, Bliziotis IA, et al.
   Journal of Antimicrobial Chemotherapy. 2007;59(3):359-369.
   jac.oxfordjournals.org/content/59/3/359.full

8. **Comparative in vitro efficacies and antimicrobial durabilities of novel antimicrobial central venous catheters.**
   Hanna H, Bahna P, Reitzel R, et al.
   Antimicrobial Agents and Chemotherapy. 2006;50(10):3283-3288.
   ncbi.nlm.nih.gov/pmc/articles/PMC1610097

9. **Vancomycin-resistant organisms on a burn unit.**
Still J, Law E, Friedman B, et al.
Southern Medical Journal. 2001;94(8):810-812.
ncbi.nlm.nih.gov/pubmed/11549193

10. **A comparison of two antimicrobial-impregnated central venous catheters.**
Darouiche RO, Raad II, Heard SO, et al.
New England Journal of Medicine. 1999;340(1):1-8.
nejm.org/doi/full/10.1056/NEJM199901073400101

11. **The evolving technology of venous access.**
Wenzel RP, Edmond MB.
New England Journal of Medicine. 1999;340(1):48-50.
ncbi.nlm.nih.gov/pubmed/9878645

12. **The ex vivo antimicrobial activity and colonization rate of two antimicrobial-bonded central venous catheters.**
Marik PE, Abraham G, Careau P, et al.
Critical Care Medicine. 1999;27(6):1128-1131.
ncbi.nlm.nih.gov/pubmed/10397217

13. **Antimicrobial durability and rare ultrastructural colonization of indwelling central catheters coated with minocycline and rifampin.**
Raad I, Darouiche RO, Hachem R, et al.
Critical Care Medicine. 1998;26(2):219-224.
ncbi.nlm.nih.gov/pubmed/9468157

14. **Central venous catheters coated with minocycline and rifampin for the prevention of catheter-related colonization and bloodstream infections: a randomized, double-blind trial.**
Raad I, Darouiche R, Dupuis J, et al.
Annals of Internal Medicine. 1997;127(4):267-274.
annals.org/article.aspx?articleid=710759

Spectrum science

15. **Anti-adherence activity and antimicrobial durability of anti-infective coated catheters against multidrug-resistant bacteria.**
Raad I, Reitzel R, Jiang Y, et al.
Journal of Antimicrobial Chemotherapy. 2008;62(4):746-750.
jac.oxfordjournals.org/content/62/4/746

16. **The broad-spectrum activity and efficacy of catheters coated with minocycline and rifampin.**
Raad I, Darouiche R, Hachem R, et al.
The Journal of Infectious Diseases. 1996;173(2):418-424.
jstor.org/stable/30126138

17. **Antibiotics and prevention of microbial colonization of catheters.**
Raad I, Darouiche R, Hachem R, et al.
Antimicrobial Agents and Chemotherapy. 1995;39(11):2397-2400.
ncbi.nlm.nih.gov/pmc/articles/PMC162954

18. **Antibiotic susceptibility of staphylococcal isolates from patients with vascular catheter-related bacteremia: potential role of the combination of minocycline and rifampin.**
Darouiche RO, Raad II, Bodey GP, et al.
International Journal of Antimicrobial Agents. 1995;6(1):31-36.
ncbi.nlm.nih.gov/pubmed/18611682

Spectrum cost effectiveness

19. **Attributable cost of catheter-associated bloodstream infections among intensive care patients in a nonteaching hospital.**
Warren DK, Quadir WW, Hollenbeak CS, et al.
Critical Care Medicine. 2006;34(8):2084-2089.
ncbi.nlm.nih.gov/pubmed/16763511

20. **Evidence that prevention makes cents: costs of catheter-associated bloodstream infections in the intensive care unit.**
Cosgrove SE.
Critical Care Medicine. 2006;34(8):2243-2244.
ncbi.nlm.nih.gov/pubmed/16883193

21. **Antibiotic-impregnated catheters associated with significant decrease in nosocomial and multidrug-resistant bacteremias in critically ill patients.**
Hanna HA, Raad II, Hackett B, et al.
Chest. 2003;124(3):1030-1038.
ncbi.nlm.nih.gov/pubmed/12970034

22. **New choices for central venous catheters: potential financial implications.**
Shorr AF, Humphreys CW, Helman DL.
Chest. 2003;124(1):275-284.
ncbi.nlm.nih.gov/pubmed/12853534

23. **Which antimicrobial impregnated central venous catheter should we use? Modeling the costs and outcomes of antimicrobial catheter use.**
Marciante KD, Veenstra DL, Lipsky BA, et al.
American Journal of Infection Control. 2003;31(1):1-8.
ncbi.nlm.nih.gov/pubmed/12548250

24. **Making health care safer: a critical analysis of patient safety practices.**
Shojania KG, Duncan BW, McDonald KM, et al.
Evidence Report/Technology Assessment Summary. 2001;(43):1-12.
ncbi.nlm.nih.gov/pubmed/11510252

Spectrum and antibiotic resistance

25. **Clinical effectiveness and risk of emerging resistance associated with prolonged use of antibiotic-impregnated catheters: more than 0.5 million catheter days and 7 years of clinical experience.**
Ramos ER, Reitzel R, Jiang Y, et al.
Critical Care Medicine. 2011;39(2):245-251.
ncbi.nlm.nih.gov/pubmed/21057308

26. **Clinical experience with minocycline and rifampin-impregnated central venous catheters in bone marrow transplantation recipients: efficacy and low risk of developing staphylococcal resistance.**
Chatzinikolaou I, Hanna H, Graviss L, et al.
Infection Control and Hospital Epidemiology. 2003;24(12):961-963.
ncbi.nlm.nih.gov/pubmed/14700414

27. **New technology for reducing infection and resistance in the ICU.**
Crnich CJ, Maki DG.
The Journal of Critical Illness. 2002;17:48-51.
business.highbeam.com/4312/article-1G1-83373440/new-technology-reducing-infection-and-resistance-icu

28. **Comparison of an untreated vs. silver/chlorhexidine vs. rifampin/minocycline central venous catheter in reducing catheter-related bloodstream infections.**
Brooks K, Dauenhauer S, Nelson M.
Abstract presented at: APIC 28th Annual Educational Conference and International Meeting; June 10-14, 2001; Seattle, WA.
No online source.

Spectrum long-term silicone

29. **Comparison of antimicrobial impregnation with tunneling of long-term central venous catheters: a randomized controlled trial.**
Darouiche RO, Berger DH, Khardori N, et al.
Annals of Surgery. 2005;242(2):193-200.
ncbi.nlm.nih.gov/pmc/articles/PMC1357724

30. **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.**
Hanna H, Benjamin R, Chatzinikolaou I, et al.
Journal of Clinical Oncology. 2004;22(15):3163-3171.
ncbi.nlm.nih.gov/pubmed/15284269

COOK SPECTRUM® TURBO-JECT® 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).

INTENDED USE: Cook Spectrum Turbo-Ject 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 Cook Spectrum Turbo-Ject 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 in the complete INSTRUCTIONS FOR USE**.

CONTRAINDICATIONS: Allergy or history of allergy to tetracyclines (including minocycline) or rifampin **NOTE:** Because the Cook Spectrum Turbo-Ject 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 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 complete INSTRUCTIONS FOR USE**. • 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 Spectrum Turbo-Ject PICC should not supersede strict aseptic techniques as it relates to catheter placement and maintenance.

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 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.

See instructions for use for full product information.

AB_T_UPICABRM_REV1

Customer Service

EU Website: cookmedical.eu
EDI: cookmedical.eu/edi
Distributors: +353 61239240, ssc.distributors@cookmedical.com
Austria: +43 179567121, oe.orders@cookmedical.com
Belgium: +32 27001633, be.orders@cookmedical.com
Denmark: +45 38487607, da.orders@cookmedical.com
Finland: +358 972519996, fi.orders@cookmedical.com
France: +33 171230269, fr.orders@cookmedical.com
Germany: +49 6950072804, de.orders@cookmedical.com
Ireland: +353 61239252, ie.orders@cookmedical.com
Italy: +39 0269682853, it.orders@cookmedical.com
Netherlands: +31 202013367, nl.orders@cookmedical.com
Poland: +48 223060159, pl.orders@cookmedical.com
Spain: +34 912702691, es.orders@cookmedical.com
Sweden: +46 858769468, se.orders@cookmedical.com
Switzerland – French: +41 448009609, fr.orders@cookmedical.com
Switzerland – Italian: +41 448009609, it.orders@cookmedical.com
Switzerland – German: +41 448009609, de.orders@cookmedical.com
United Kingdom: +44 2073654183, uk.orders@cookmedical.com

USA Website: cookmedical.com
EDI: cookmedical.com/edi.do
Americas:
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335
E-mail: orders@cookmedical.com
Australia:
Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283
E-mail: cau.custserv@cookmedical.com

COOK MEDICAL

CC, URO-85X11