



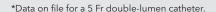




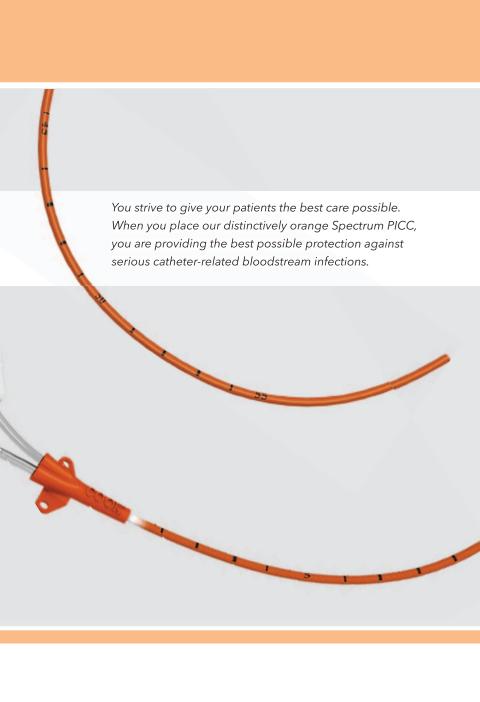
A Guide for Healthcare Providers

Spectrum Technology

This guide is designed to help you understand Cook Medical's Spectrum technology and how it helps in your quest to reduce catheter-related bloodstream infections (CRBSIs). Cook's Spectrum technology is the unique combination of the antibiotics minocycline and rifampin. Minocycline and rifampin are impregnated into the catheter material to provide protection to both the external and internal surfaces of the catheter. Spectrum technology provides superior protection immediately and continues to provide a zone of inhibition of 15 mm for up to 63 days.* It was developed by a team of infectious disease doctors led by Dr. Issam Raad (M.D. Anderson Cancer Center) and Dr. Rabih Darouiche (Baylor College of Medicine) in Houston, Texas.



Section MAX



Catheter-Related Bloodstream Infections

CRBSIs are a concern with any vascular catheter. Bacteria can attach to the surface of a catheter and produce a slimy coating called biofilm. Once biofilm forms, it protects the bacteria from the host's defenses and most systemic antibiotics, including vancomycin.

Bacteria replicate rapidly and grow into large colonies within the biofilm. Over time, the biofilm can begin to shed, sending bacteria-including clumps of bacteria still embedded in biofilm-floating through the bloodstream. The bacteria can then cause infections as they migrate to distant sites such as the kidneys, heart valves and brain. Systemic doses of antibiotics may not be effective against these bacteria that are still coated with protective biofilm.

Bacteria can colonize a catheter in three ways: The external surface can become colonized during insertion or from bacterial migration; the internal surface can become colonized through the hub or from infusate contamination; and the catheter can become seeded with bacteria that travel from a distant site through the bloodstream and attach to the catheter.

The risk of infection increases with dwell time, but infection may begin to breed in as little as two to three days. Multiple catheter lumens may also increase the risk of infection.

Maximal sterile barrier precautions are an essential part of patient care but aren't always enough.

Spectrum catheters are impregnated with an effective combination of minocycline and rifampin antibiotics on both the external and internal areas of the catheter. This impregnation means that patients are protected against infection from all three colonization pathways.

Cook's PICC Procedural Tray provides the essential components for maximal sterile barrier precautions.



Safety and Efficacy

Spectrum technology has been on the market for over 10 years and its safety and efficacy have been well established. The only contraindications in the use of Spectrum are pregnancy and allergy to tetracyclines and rifampin. If allergic reaction does occur, the most common symptom will be a slight skin irritation at the insertion site.

Neither of the antibiotics is detectable in the bloodstream and there have never been any reports of serious complications associated with the antibiotics. In addition, there have been no reports of bacterial resistance developing from the use of Spectrum.¹

Insertion, Maintenance and Removal

All approved protocols set forth by your facility should be followed with insertion, catheter maintenance or removal; a Spectrum catheter requires no additional care or attention. Cook recommends that maximal sterile barrier precautions are followed at placement, as well as all best practices for the care and maintenance of the patient's therapy.

For more information, contact your local Cook representative at **1.800.457.4500** or visit us on our website: www.cookmedical.com/spectrum.

Proven Lowest Infection Rates

Process Alone Cannot Sustain Zero

Antimicrobial catheters are 5 times more effective in reducing catheter-related bloodstream infections than maximal sterile barrier precautions alone.²



The Right Combination

Minocycline/rifampin is the most synergistic antibiotic combination in preventing CRBSIs including MRSA, VRSA and VRE.



Unmatched Evidence

Over 21 peer-reviewed studies and meta-analyses about minocycline/rifampin catheters provide evidence no other process or technology can match.



Decreased Resistance

No evidence of bacterial resistance. Decreased need for systemic antibiotic use.

Frequently Asked Questions

How long does Spectrum last and when should it be removed?

The Spectrum Turbo-Ject PICC line is cleared by the FDA for both short- and long-term use. In vitro studies of the 5 Fr double-lumen catheter show a 15 mm zone of inhibition for up to 63 days. This does not mean that the catheter needs to be removed at 63 days; the catheter should be removed as soon as therapy is complete or when the physician orders it removed.

What is Spectrum effective against?

Spectrum is effective against a broad spectrum of bacteria that commonly cause CRBSI, including MRSA, VRSA and VRE. The antibiotic combination of minocycline and rifampin works synergistically to provide protection against gram-negative and gram-positive organisms.³

Are there any resistance issues?

Over 10 years of clinical use have shown no evidence that minocycline and rifampin impregnated catheters lead to bacterial resistance, and a seven-year study of over 500,000 catheter days confirms these results.⁴ Data indicate that facilities using minocycline and rifampin catheters have a decreased need for systemic antibiotic use due to a lower rate of CRBSI.⁵

Which types of catheters are available with the Spectrum technology?

Cook Medical provides several central venous catheters in various sizes with Spectrum technology. These include PICC lines, hyperalimentation catheters and acute central venous catheters. Please contact your Cook representative at 1.800.457.4500 or visit www.cookmedical.com/spectrum for more information.

Where can I find the studies that support the use of Spectrum?

Your Cook representative can provide you with numerous clinical studies. Over 21 peer-reviewed studies and meta-analyses have been published regarding Spectrum technology including, but not limited to, examinations of its effectiveness, science and economics; its use with pediatric, oncology and burn patients; and its safety relative to the development of bacterial resistance.

Can antiseptic dressings be used with a Spectrum catheter?

Yes. If your institution uses antiseptic dressings, they will be compatible with the Spectrum catheter. Spectrum technology provides protection on both the external and internal surfaces of the catheter; additional efficacy with the use of antiseptic dressings has not been studied.

Will the Spectrum catheter treat a current infection?

No. Spectrum catheters are only for the prevention of CRBSI, not to treat an active infection.

Is minocycline or rifampin detectable in the bloodstream?

No. The antibiotics are impregnated into the material and released slowly over time. Due to the minimal amount of antibiotics on the catheter, minocycline and rifampin are never detectable in the patient's blood. The maximum amount of antibiotic present in one Spectrum catheter is less than 1/10 of one daily systemic dose for normal therapies.⁶

- 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.
- Maki DG, Stolz SM, Wheeler S, et al. Prevention of central venous catheterrelated bloodstream infection by use of an antiseptic-impregnated catheter. Ann Intern Med. 1997;127(4):257-266.
- 3. Raad I, Darouiche R, Hachem R, et al. The broad-spectrum activity and efficacy of catheters coated with minocycline and rifampin. *J Infect Dis.* 1996;173(2):418-424.
- 4. Ramos E, Jiang Y, Hachem R, et al. Is the prolonged use of minocycline/ rifampin coated catheters (M+R CVC) associated with increased resistance: a seven year experience in a tertiary cancer center. Paper presented at: The Society of Healthcare and Epidemiology of America 18th Annual Scientific Meeting; April 5-8, 2008; Orlando, FL.
- Brooks K, Dauenhauer S, Nelson M. Comparison of an untreated vs. silver/chlorhexidine vs. rifampin/minocycline central venous catheter in reducing catheter-related bloodstream infections. Abstract of paper presented at: APIC 28th Annual Educational Conference and International Meeting; June 10-14, 2001; Seattle, WA.
- Raad II, Darouiche RO, Hachem R, et al. Antimicrobial durability and rare ultrastructural colonization of indwelling central catheters coated with minocycline and rifampin. Crit Care Med. 1998;26(2):219-224.

Dr. Raad is the co-inventor of the synergistic pairing of the antibiotics minocycline and rifampin that are impregnated within the catheter material of the Cook Spectrum catheter. His institution receives a royalty payment based upon Cook Medical's license to use this patented technology.



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