



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
TEL: +353 61 334440 FAX: +353 61 334441
WWW.COOKMEDICAL.EU

FSN & FSCA Ref: 2026FA0001

Date: 05 March 2026

Urgent Field Safety Notice – Medical Device Removal

**Approach[®] CTO-12 Micro Wire Guide
Blue Rhino[®] G2-Multi Percutaneous Tracheostomy Introducer Set
Cook Staged Extubation Set
NCompass[®] Nitinol Stone Extractor
Spectrum[®] Central Venous Catheter Set
Wayne Pneumothorax Set**

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)

Cook Medical Europe Ltd.
O'Halloran Road
National Technology Park
Limerick, Ireland
E-mail: European.FieldAction@CookMedical.com
Phone: Please refer to the attached Country Contacts List

For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.



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Risk Addressed by FSN

1. Reason for Field Safety Corrective Action (FSCA)	
1.	<p>1. Description of the product problem</p> <p>Cook Medical identified that products from the affected device lots were labelled with expiration dates that exceed the true shelf life. This occurred because the Date By Component calculator did not always include every component's expiry when generating the finished-device label.</p> <p>The issue was identified internally when performing Quality Assurance procedures and IT software validation.</p> <p>You are receiving this letter as Cook Medical records indicate that impacted products were shipped to your facility.</p>
1.	<p>2. Hazard giving rise to the FSCA</p> <p>Potential adverse events that may occur if an affected product is used after its true expiration date include increased procedural time, pain/discomfort, tissue injury, infection, harms associated with device fragmentation/separation, harms associated with a non-biocompatible device, and harms associated with coating flaking off.</p> <p>To date, Cook Medical has not received any customer complaints related to the adverse patient effects listed above for the affected lots.</p>



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2. Information on Affected Devices	
1. Device Type(s)	<p>The Approach[®] CTO Micro Wire Guide is 0.014 inches (0.36 mm) in diameter and is available in a variety of lengths and tip configurations. The product has a TFE-coated stainless steel shaft and distal stainless steel and platinum coils on the tip. The tips' configurations differ in stiffness.</p> <p>The Blue Rhino[®] G2-Multi Percutaneous Tracheostomy Introducer Set/Tray consists of these primary components: an introducer needle, J-tipped wire guide, introducer dilator, guiding catheter, loading dilators, and single-staged Blue Rhino G2-Multi dilator. Dilation takes place in one step with the Blue Rhino G2-Multi dilator using the Seldinger technique.</p> <p>The Cook Staged Extubation Set is a tapered Staged Re-Intubation Catheter, with centimeter markings and a Nitinol Staged Extubation Wire with depth markings. The set is supplied with two Rapi-Fit Adapters (15 mm connector or a Luer lock connector), an extra-firm, soft-tipped, Staged Re-Intubation Catheter, a floppy-tipped Staged Extubation Wire, securing tape, airway wire holder, and securement dressing.</p>
2.	<p>The NCompass[®] Nitinol Stone Extractor is a nitinol basket with an outer sheath diameter of 2.4 French and a 1.5 cm basket diameter when fully expanded. The tipped basket is used under fluoroscopic guidance; the tipless basket is used for procedures utilizing a choledochoscope.</p> <p>Spectrum and Spectrum Glide polyurethane central venous catheters incorporate separate, noncommunicating vascular access lumens within a single catheter body. Spectrum and Spectrum Glide catheters are impregnated with antimicrobial agents, minocycline and rifampin (average concentration 503 µg/cm and 480 µg/cm respectively) to help provide protection against catheter-related bloodstream infections (CRBSI). 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. The Spectrum Glide catheter is designated by the suffix -HC in the reorder number.</p> <p>The Wayne Pneumothorax Set consists of a stainless steel needle obturator with Peel-Away[®] spacer, radiopaque polyurethane catheter, polyvinylchloride connecting tube, plastic three-way stopcock, and latexfree Cook Chest Drain Valve to be used for evacuation of air or fluid.</p>
2. Commercial name(s)	
2.	<p>Approach[®] CTO-12 Micro Wire Guide Blue Rhino[®] G2-Multi Percutaneous Tracheostomy Introducer Set Cook Staged Extubation Set NCompass[®] Nitinol Stone Extractor Spectrum[®] Central Venous Catheter Set Wayne Pneumothorax Set</p>



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2.	<p>3. Primary clinical purpose of device(s)</p> <p>The Approach[®] CTO Microwire Guide is intended for use in facilitating delivery of percutaneous catheters into the peripheral vasculature and is also indicated for the intra-luminal placement of percutaneous catheters or other therapeutic devices beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.</p> <p>Blue Rhino[®] G2-Multi Percutaneous Tracheostomy Introducer Set/Tray is intended for percutaneous dilational tracheostomy for management of the airway in adults only. Tube placement, using the technique described herein, should be performed in a controlled setting (e.g., ICU or operating room) with the assistance of trained personnel.</p> <p>The Cook Staged Extubation Set is intended for staged extubation and subsequent re-intubation.</p> <p>The NCompass[®] Nitinol Stone Extractors are intended for extraction of stones or debris during biliary surgical procedures.</p> <p>The Spectrum[®] 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.</p> <p>The Wayne Pneumothorax Set intended for relief of simple, spontaneous, iatrogenic and tension pneumothorax.</p>
2.	<p>4. Device Model/Catalogue/Part Number(s)</p> <p>Please refer to Attachment 1 – Product Information Table for information on the impacted devices.</p>
2.	<p>5. Affected serial or lot number range</p> <p>Please refer to Attachment 1 – Product Information Table for information on the impacted devices.</p>



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3. Type of Action to Mitigate the Risk	
3.	<p>1. Actions To Be Taken by the User</p> <p><input checked="" type="checkbox"/> Identify Device(s) <input checked="" type="checkbox"/> Quarantine Device(s) <input checked="" type="checkbox"/> Return Device(s) to Cook Medical <input checked="" type="checkbox"/> Other</p> <p>Please complete the enclosed Customer Reply Form. Where devices are indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Reply form.</p> <p>Returned Device(s) should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY</p> <p>Credit will be provided for the returned affected device(s) where applicable.</p>
3.	<p>2. Is Customer Reply Required? Form is attached specifying deadline for return.</p> <p style="text-align: right;">Yes</p>
3.	<p>3. Action Being Taken by the Manufacturer</p> <p><input checked="" type="checkbox"/> Product Removal</p>

4. General Information					
4.	<p>1. FSN Type</p> <p style="text-align: right;">New</p>				
4.	<p>2. Further advice or information already expected in follow-up FSN?</p> <p style="text-align: right;">No</p>				
4.	<p>3. Manufacturer information Refer to page 1 of this FSN for contact details of local representative.</p> <table border="1" style="width: 100%;"> <tr> <td>a. Company Name</td> <td>Cook Incorporated</td> </tr> <tr> <td>b. Address</td> <td>750 Daniels Way Bloomington, IN 47402, United States</td> </tr> </table>	a. Company Name	Cook Incorporated	b. Address	750 Daniels Way Bloomington, IN 47402, United States
a. Company Name	Cook Incorporated				
b. Address	750 Daniels Way Bloomington, IN 47402, United States				
4.	<p>4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.</p>				
4.	<p>5. Name/Signature</p> <p style="text-align: right;"></p> <p style="text-align: right;">Larry D. Pool Director, Post Market Cook Incorporated</p>				



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Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.