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: 2022FA0003

Date: 18AUG2022

Urgent Field Safety Notice – Medical Device Recall
Vinyl Connecting Tubes
Select models of Wire Guides

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. Information on Affected Devices	
1.	**1. Device Type(s)**
	Please refer to the Tables on Pages 5 - 7 titled "Attachment 1 – Affected Product" for information on the impacted devices.
1.	**2. Commercial name(s)**
	Please refer to the Tables on Pages 5 - 7 titled "Attachment 1 – Affected Product" for information on the impacted devices.
1.	**3. Primary clinical purpose of device(s)**
	Please refer to the Tables on Pages 5 - 7 titled "Attachment 1 – Affected Product" for information on the impacted devices.
1.	**4. Device Model/Catalogue/Part Number(s)**
	Please refer to the Tables on Pages 5 - 7 titled "Attachment 1 – Affected Product" for information on the impacted devices.
1.	5. **Affected serial or lot number range**
	Please refer to the Tables on Pages 5 - 7 titled "Attachment 1 – Affected Product" for information on the impacted devices.

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	Cook Medical identified that devices from the affected device lots may have a complete breach of the chevron seal of the packaging. Therefore, the sterility of affected devices may be compromised.
2.	**2. Hazard giving rise to the FSCA**
	The affected devices may be non-sterile or contaminated with microorganisms. Potential adverse events that may occur if an affected product is used include infection, potentially being life-threatening and/or requiring medical/surgical intervention. To date, Cook Medical has not received any customer complaints related to the adverse patient effects listed above for the affected lots. However, please be advised that compromised device sterility may go undetected by the user.

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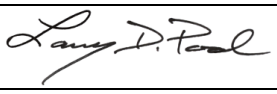
3. Type of Action to Mitigate the Risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☒ Other Please complete the enclosed Customer Reply Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Reply form. Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected products where applicable.
3.	**2. Is Customer Reply Required?** Yes. Form is attached specifying deadline for return.
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal
3.	**4. Is follow-up of patients or review of patients' previous results recommended?** Physicians should practice standard of care patient monitoring following the procedure for early identification of any complications to mitigate their severity. Cook is not recommending additional patient monitoring as infection would likely present physical signs and symptoms abnormal to post-procedural patient recovery and promptly trigger medical intervention.

4. General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information For contact details of local representative refer to page 1 of this FSN.	
	a. Company Name	Cook Incorporated
	b. Address	750 Daniels Way Bloomington, IN 47402, United States
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	
		Larry D. Pool Director, Post Market Cook Incorporated

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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 potentially 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.

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Attachment 1 – Affected Product

COMMERCIAL NAME	MODEL / CATALOGUE /	PART NUMBER(S)	LOT NUMBER	DEVICE TYPES	PRIMARY CLINICAL PURPOSE OF DEVICES
Double Flexible Tipped Wire Guide	TDOC-35-145-0-3	G00362	14793053	Double Flexible Tipped Wire Guides are made with a stainless steel inner mandril and stainless steel outer coil. They come in a variety of diameters, lengths, and tip configurations. These wires are provided with two usable ends. Some devices are provided with a green PTFE coating to ease coaxial use with other devices. Refer to the product label for product specifications.	Double Flexible Tipped Wire Guides are used to facilitate the placement of devices during diagnostic and interventional procedures.
Fixed Core Wire Guide (Safe-T-J® Curved)	TSCF-35-145-3	G00511	14831157	Fixed Core Wire Guides are made with a stainless steel inner mandril and a stainless steel outer coil. They are available in a variety of diameters, lengths, and tip configurations. Some devices are provided with a green PTFE coating to ease coaxial use with other devices. Refer to the product label for product specifications.	Fixed Core Wire Guides are intended to facilitate the placement of devices during diagnostic and interventional procedures.
			14826198		
			14831162		
			14826199		
			14831159		
	TSCF-35-80-3	G00529	14814971		
Fixed Core Wire Guide (Straight)	TSF-35-145	G00650	14833117		
			14809680		
			14821850		
			14827356		
			14833110		
			14827353		

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COMMERCIAL NAME	MODEL / CATALOGUE /	PART NUMBER(S)	LOT NUMBER	DEVICE TYPES	PRIMARY CLINICAL PURPOSE OF DEVICES
Fixed Core Wire Guide (Straight)	TSF-35-145	G00650	14821851 14821849 14821854	Fixed Core Wire Guides are made with a stainless steel inner mandril and a stainless steel outer coil. They are available in a variety of diameters, lengths, and tip configurations. Some devices are provided with a green PTFE coating to ease coaxial use with other devices. Refer to the product label for product specifications.	Fixed Core Wire Guides are intended to facilitate the placement of devices during diagnostic and interventional procedures.
Cope Mandril Wire Guide (Nitinol)	PMG-18SP-60-COPE-NT	G08427 G08428	14816750 14816754	Mandril Guides are made with a core mandril of stainless steel or nitinol material that runs the entire length of the product. Attached at the distal end is a coil of stainless steel , platinum, or palladium of varying length. Mandril Wire Guides come in a variety of lengths, diameters, and tip configurations. Some devices are coated with TFE coating to ease coaxial use with other devices. Some devices are provided with two usable ends. Refer to the product label for product specifications.	Mandril Wire Guides are used to facilitate the placement of devices during diagnostic and interventional procedures.
Vinyl Connecting Tube	CTU14.0-30	G02791	NS14831012 NS14816264 NS14816265	The Vinyl Connecting Tubes are manufactured from 14.0 French vinyl non-radiopaque tubing in length of 30 centimeters. Includes a conical drainage adapter and a male luer lock fitting that enables connection of an external drainage catheter to a drainage bag.	Used for connection of external drainage catheter to drainage pouch.

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COMMERCIAL NAME	MODEL / CATALOGUE /	PART NUMBER(S)	LOT NUMBER	DEVICE TYPES	PRIMARY CLINICAL PURPOSE OF DEVICES
Vinyl Connecting Tube	CTU14.0-40-ST	G02327	NS14818298	The Vinyl Connecting Tubes are manufactured from 14.0 French vinyl non-radiopaque tubing in length of 40 centimeters. Includes a conical drainage adapter and a male luer lock fitting that enables connection of an external drainage catheter to a drainage bag. Manufactured with a one-way stopcock connected to the male luer lock fitting, which allows control of the drainage flow.	Used for connection of external drainage catheter to drainage pouch.
Roadrunner® Hydrophilic PC Wire Guide	RPC-035145-0-5	G34131	14769270X	The Roadrunner PC Wire Guide is coated with AQ (a biocompatible hydrophilic coating), which when activated becomes lubricious. The wire guide is made of a nitinol core with a distal platinum inner spring coil tip, which is completely covered by a bismuth-impregnated polymer jacket.	Used to gain ureteral access, to establish a tract, and to assist in the placement, replacement, and exchange of medical devices during urological procedures. It may also be used for catheter positioning and exchange in a tortuous or kinked ureter, for traversing a large stone en route to the kidney, or in cases demanding enhanced control and high radiopacity. The Roadrunner has a nitinol core, a flexible, platinum tip, and one-to-one torque. The AQ® coating is a microthin layer of hydrophilic polymer that, when activated, attracts and holds water and other liquids to the wire guide, creating a low-friction surface. Choose between standard- and stiff-body options. This product is not intended for PTCA use.
			14828629		
			14818489		
			14802181		
			14818488		
			14816224		
	RPC-035145-5	G34132	14770872		
	RPC-038145-0-5	G34129	14804972		
			14809971		