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: 2021FA0009

Date: 27 September 2021

Urgent Field Safety Notice

Cantata Microcatheter
Dotter Intravascular Retriever Set
Kwart Retro-Inject Ureteral Stent Set
Lunderquist Ring Wire Guide
Miller Double Mushroom Biliary Stent Set
MReye Embolization Coil
Nester Embolization Coil
TAO Brush I.U.M.C. Endometrial Sampler
Thoracentesis Set
Torcon NB Advantage Catheter

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 4 and 5 titled "Attachment 1 – Affected Product" for information on the impacted devices.
1.	**2. Commercial name(s)**
	Please refer to the Tables on Pages 4 and 5 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 4 and 5 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 4 and 5 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 4 and 5 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**
	Specific product lots were distributed throughout Europe, Middle East, and Africa (EMEA) after Cook removed the products from the Declaration of Conformity. The CE Mark should have been removed from the labels and the products should not have been distributed in these regions.
2.	**2. Hazard giving rise to the FSCA**
	There is no health hazard associated with this issue. Products are being removed from the market due to a regulatory/compliance issue.

3. Type of Action to Mitigate the Risk		
3.	**1. Actions 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?** Form is attached specifying deadline for return.	Yes
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal	

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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

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
Kwart Retro-Inject Ureteral Stent Set	003500	G14916	NS13712097	The set includes a radiopaque stent with tether, radiopaque inserter, TFE-coated stainless steel wire guide, radiopaque release sleeve, and an adapter.	Used for retrograde injection during Extracorporeal Shock Wave Lithotripsy (E.S.W.L.) and leaving an indwelling ureteral stent post-E.S.W.L. The stents must not remain indwelling more than six months.
Thoracentesis Set	C-THS-850	G03286	NS10147371 NS10266900 NS13010767 NS13081430 NS13157076	The set includes an access needle, wire guide, centesis catheter, and connecting tubes.	The Thoracentesis Set is intended to remove fluid from the pleural space.
Dotter Intravascular Retriever Set	DRS-100	G03404	10266860 13052339 13296938	The set includes a 4-wire helical loop basket (7cm long, 3cm wide) with a pin vise handle, a catheter and a Check-Flo Introducer Set.	The Dotter Intravascular Retriever Set is intended to snare a foreign body and withdraw it to a peripheral vascular location.
Torcon NB Advantage Catheter	HNB5.0-38-100-P-NS-JR2	G10924	NS13139240 NS13488331 NS13705355	The Torcon NB Advantage angiographic catheters are available in a variety of French sizes, endhole sizes, lengths, materials and designs (e.g., polyethylene or nylon, non-braided or braided with 1:1 torque).	The catheters are intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
MReye Embolization Coil	IMWCE-38-6-10	G42469	NS13480934 NS13480935	The coils are made of Inconel, an MR conditional super alloy with spaced synthetic fibers and are supplied preloaded in a loading cartridge. They are designed to be delivered to the target vessel using a soft, straight wire guide through a standard angiographic catheter.	MReye Embolization Coils are intended for use in peripheral arterial and venous vessel embolization procedures.
TAO Brush I.U.M.C. Endometrial Sampler	J-ES-090500	G17023	13233830 NS13220817 NS13228540 NS13233829 NS13233833 NS13253736 NS13264447 NS13264448 NS13264450 NS13264451 NS13264452	The product includes a stainless steel shaft with brush sampler and a protective sheath with a reference mark.	The Tao Brush I.U.M.C. Endometrial Sampler is used to obtain endometrial cytological and histological samples.

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Cantata Microcatheter	MCS-2.5-NT-100-15-HP	G54529	10112075 10169843 13021067 13025462 13319182 13663468 13795518	Shapeable-tip, braided, kink-resistant microcatheter with hydrophilic coating.	Intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including peripheral and coronary use.
Cantata Microcatheter	MCS-2.8-NT-100-15-HP	G54533	NS10057901 NS10207038	Shapeable-tip, braided, kink-resistant microcatheter with hydrophilic coating.	Intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including peripheral and coronary use.
Nester Embolization Coil	MWCE-35-6-6-NESTER	G27962	NS10162751 NS13034772 NS13497831 NS9766785	Coils made of platinum with spaced synthetic fibers, and are supplied preloaded in a loading cartridge. They are designed to be delivered to the target vessel using a soft, straight wire guide through a standard angiographic catheter.	Nester Embolization Coils are intended for arterial and venous vessel embolization procedures. The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.
Lunderquist Ring Wire Guide	THSF-35-145-THG	G27033	10104825 10109973 10175104 10179302 10215203 13058314 NS10208426 NS13150286	Wire guide made with a stainless steel inner mandril and stainless steel outer coil.	Fixed Core Wire Guides are intended to facilitate the placement of devices during diagnostic and interventional procedures.
Miller Double Mushroom Biliary Stent Set	UBSS-10-7.5-MLR	G03421	9973168X 9984121X	The set includes a radiopaque polyethylene stent, a positioner with inner catheter, and a Peel-Away Introducer Sheath.	The Miller Double Mushroom Biliary Stent Set is intended for internal biliary drainage.