COOK MEDICAL EUROPE LTD.
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FSN & FSCA Ref: 2022FA0001

Date: DD:MMM:YYYY.

Urgent Field Safety Notice – Medical Device Recall
Hilal Embolization Microcoil
Nester® Embolization Microcoil
Tornado® Embolization Microcoil

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)**	
	The products are embolization coils made of platinum with spaced synthetic fibers, supplied preloaded in a loading cartridge. They are designed to be delivered to the target vessel using a soft, straight wire guide through an angiographic catheter. They are supplied sterilized by ethylene oxide gas in peel-open packages. They are intended for single use.	
1.	**2. Commercial name(s)**	**3. Primary clinical purpose of device(s)**
	Hilal Embolization Microcoil	Hilal Embolization Microcoils are intended for arterial and venous embolization in the peripheral vasculature.
	Nester® Embolization Microcoil	Nester Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.
	Tornado® Embolization Microcoil	Tornado Embolization Coils are intended for embolization of selective vessel supply to arteriovenous malformations and other vascular lesions. Tornado Embolization Coils are ideally suited for tapering vessel situations.

Please refer to Attachment 1 for affected Part Numbers and Lots.

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	During manufacturing, Cook Medical identified that the loading cartridge included with Hilal Embolization Microcoils, Nester® Embolization Microcoils, and Tornado® Embolization Microcoils may contain a small, unintended, stainless-steel cannula inside. The loading cartridge is manufactured and supplied to Cook Medical by an external supplier.
2.	**2. Hazard giving rise to the FSCA**
	Potential adverse events that may occur if an affected product is used include difficult advancement and/or removal of the device leading to increased procedural time, entrance of the foreign body (small stainless-steel cannula) into the patient, potentially having life-threatening effects, and/or burn (from magnetic resonance imaging if unintended cannula is unnoticed). To date, Cook Medical has not received customer complaints related to the adverse patient effects listed above for the affected lots. However, please be advised that the presence of a small barrel component inside of the loading cartridge cannula 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 their standard patient monitoring following the procedure for an early identification of any complications to mitigate their severity.

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.