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

FSN & FSCA Ref: 2019FA0010

Date: 23 Oct 2019

Urgent Field Safety Notice

Product Removal – Transjugular Intrahepatic 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

Information on Affected Devices	
1.	**1. Device Type(s)**
	The Transjugular Intrahepatic Set is a procedure pack consisting of single CE marked components. The affected component in the procedure pack is a Torcon NB® Advantage Catheter HNB5.0-35-65-P-NS-TIPS
1.	**2. Commercial name(s)**
	Transjugular Intrahepatic Set
1.	**3. Primary clinical purpose of device(s)**
	The Transjugular Intrahepatic Set contains components used to support the procedure for Transjugular Intrahepatic Porto Systemic Shunt. Per the Instructions for Use T_CE_ANGIO088_REV5 the Torcon NB® Advantage Catheter HNB5.0-35-65-P-NS-TIPS is intended for use in angiographic procedures by physicians trained and experienced in angiographic techniques.
1.	**4. Device Model/Catalogue/part number(s)**
	TIPSS-100
1.	**5. Affected serial or lot number range**
	E3892506

Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	The pouch of one of the devices in the procedure pack, the Torcon NB® Advantage Catheter HNB5.0-35-65-P-NS-TIPS, may be undersealed, potentially compromising the sterility of the product. This issue is related specifically to the chevron seal.
2.	**2. Hazard giving rise to the FSCA**
	Use of an affected product could pose significant risk to the patient, as local or systemic infection may occur.

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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?** Form is attached specifying deadline for return.	Yes
3.	**3. Action Being Taken by the Manufacturer** ☒ Product Removal	

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	William Cook Europe
	b. Address	Sandet 6 4632 Bjaeverskov Denmark

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4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. Name/Signature	
		Thomas Hessner Kirk Manager, Regulatory Reporting, Regulatory Affairs William Cook Europe

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. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

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.