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: 2024FA0001

Date: 28 February 2024

Urgent Field Safety Notice

Dilators - Coons Taper
Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Sets
Chiba Biopsy Needles

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)**
	Dilators are designed with gradual tapers, may include hydrophilic coating, and are available in multiple inner and outer diameter and length combinations. The Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set consists of two or three introducer needles with preloaded anchors and a .035 inch wire guide. The Chiba Biopsy Needle is ideal for initial access and biopsy. The match-ground bevelled tip provides steerability. The Chiba needle that features EchoTip® enhances visibility under ultrasound.
1.	**2. Commercial name(s)**
	Dilators - Coons Taper Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Sets Chiba Biopsy Needles
1.	**3. Primary clinical purpose of device(s)**
	Dilators - Coons Taper are intended to be used for dilating puncture sites or catheter tracts for percutaneous placement of devices for vascular and non-vascular applications such as in the venous, arterial, biliary and renal systems. Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Sets are intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters. Chiba Biopsy Needles are intended for used for aspiration biopsy.
1.	**4. Device Model/Catalogue/Part Number(s)**
	Dilators - Coons Taper Reference Part Number (RPN): JCD22.0-38-20-COONS Order Number (GPN): G04443 Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Sets Reference Part Number (RPN): GIAS-SRM-ADJ-2 Order Number (GPN): G35562 Chiba Biopsy Needles Reference Part Numbers (RPNs): DCHN-22-15.0, DCHN-22-15.0-U Order Numbers (GPNs): G00012, G03314
1.	**5. Affected serial or lot number range**
	Dilators - Coons Taper: 15767086 Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Sets: 15791906 Chiba Biopsy Needles: 15785990, 15784638, 15784722

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	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 packaging seals that do not meet peel strength specifications. This creates a potential of a sterile barrier failure that could result in compromised device sterility. You are receiving this letter as Cook Medical records indicate that impacted products were shipped to your facility.	
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 increased procedural time and 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.	

	3. Type of Action to Mitigate the Risk	
3.	**1. Actions To Be Taken by the User** ☒ Identify Device(s) ☒ Quarantine Device(s) ☒ Return Device(s) to Cook Medical ☒ Other 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. Returned Device(s) should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY Credit will be provided for the returned affected device(s) 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	
3.	**4. Patient Management** Physicians should follow their institution's protocols/guidelines for the standard of patient care after the procedure for identification and treatment(s) of infection or any complications.	

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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 Refer to page 1 of this FSN for contact details of local representative.	
	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.