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: 2021FA0001

Date: 08 March 2021

Urgent Field Safety Notice

Bander Ureteral Diversion Stent Set

For Attention of: Chief Executive / Risk Management / Purchasing / Urologists

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.

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: 2021FA0001

Urgent Field Safety Notice

Bander Ureteral Diversion Stent Set

Risk Addressed by FSN

1. Information on Affected Devices	
1.	**1. Device Type(s)**
	The Bander Ureteral Diversion Stent Set includes two color-coded radiopaque stents (right and left), a Flexible PTFE-coated stainless steel wire guide, plastic catheter retainers, and an adapter.
1.	**2. Commercial name(s)**
	Bander Ureteral Diversion Stent Set
1.	**3. Primary clinical purpose of device(s)**
	The Bander Ureteral Diversion Stent Set is used for intraoperative placement to stent the ureter during ureteroileal conduit construction and continent urinary diversions.
1.	**4. Device Model/Catalogue/Part Number(s)**
	025227
1.	**5. Affected serial or lot number range**
	13609720

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	Bander Ureteral Diversion Stent Set (025227) Lot 13609720 is missing the left stent component of the set.
2.	**2. Hazard giving rise to the FSCA**
	Potential adverse events that may occur if an affected product is used include increased procedural time and rescheduling or aborting a procedure. If the issue is identified while the procedure is in progress and no replacement devices are readily available, the procedure may be completed without the stent resulting in a need for additional patient monitoring/imaging.
2.	**3. Other information relevant to FSCA**
	At this time, Cook Medical has received 11 customer complaints reporting a missing stent from Lot 13609720. In all complaints, the issue was detected prior to patient contact.

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: 2021FA0001

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	

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.