COOK MEDICAL EUROPE LTD.
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FSN & FSCA Ref: 2020FA0006

Date: 11 September 2020

Urgent Field Safety Notice

Percutaneous Neonatal Pigtail Nephrostomy Set & Pediatric Nephrostomy Stent Set

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

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 Percutaneous Neonatal Pigtail Nephrostomy Set and Pediatric Nephrostomy Stent Set are sterile, single-use devices. The sets contain a radiopaque pigtail catheter and ancillary devices/components.
1.	**2. Commercial name(s)**
	Percutaneous Neonatal Pigtail Nephrostomy Set Pediatric Nephrostomy Stent Set
1.	**3. Primary clinical purpose of device(s)**
	The Percutaneous Neonatal Pigtail Nephrostomy Set and Pediatric Nephrostomy Stent Set are used for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage.
1.	**4. Device Model/Catalogue/Part Number(s)**
	080106, 080208-S6, 080208-S7
1.	**5. Affected serial or lot number range**
	All lots

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	The indwell time for the Percutaneous Neonatal Pigtail Nephrostomy Set and Pediatric Nephrostomy Stent Set is decreasing from 4 months to 4 weeks.
2.	**2. Hazard giving rise to the FSCA**
	If a catheter is left indwelling longer than 4 weeks, there is an increased potential for breakage, kinking, encrustation, migration, and/or infection to occur. Potential adverse events that may result from these hazards include discomfort, additional intervention, hydronephrosis, pyonephrosis, sepsis, and loss of kidney function. Cook Medical has not received any customer complaints related to the hazards and adverse events listed above for the affected products.
2.	**3. Other information relevant to FSCA**
	The updated IFUs for the affected products are attached to this FSN.

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3. Type of Action to Mitigate the Risk		
3.	**1. Action To Be Taken by the User** ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Follow patient management recommendations ☒ Other • Understand that if an affected product is placed within a patient longer than 4 weeks, there is an increased potential for breakage, kinking, encrustation, migration, and/or infection to occur. • Please maintain a copy of the updated IFUs with product(s) currently in your inventory. • Please complete the enclosed Customer Reply Form. Even if you do not have affected product(s) on hand, you must still complete the Customer Reply Form.	
3.	**2. Particular considerations for: Implantable device** Is follow-up of patients or review of patients' previous results recommended? Yes (see below) • If affected products are currently placed within a patient (less than 4 weeks): – Follow-up with affected patients so that the indwell time does not exceed 4 weeks. – Inform affected patient guardians of the change in the indicated indwell time and potential adverse effects that may occur if a product is indwelling longer than 4 weeks. • If affected products are currently placed within a patient and the indwell time has exceeded 4 weeks: – Consider removing and/or replacing the product. – Inform affected patient guardians of the change in the indicated indwell time and potential adverse effects that may occur if a product is indwelling longer than 4 weeks.	
3.	**3. Is Customer Reply Required?** Form is attached specifying deadline for return.	Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ IFU or labelling change	

4. General Information		
4.	1. FSN Type	Update
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.