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: 2020FA0010

Date: 06 January 2021

Urgent Field Safety Notice

Kwart Retro-Inject™ Ureteral 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.

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Risk Addressed by FSN

1. Information on Affected Devices	
1.	**1. Device Type(s)**
	The Kwart Retro-Inject™ Ureteral Stent Set includes a radiopaque stent with tether, radiopaque inserter, TFE-coated stainless steel wire guide, radiopaque release sleeve, and an adapter. The stents must not remain indwelling more than six months.
1.	**2. Commercial name(s)**
	Kwart Retro-Inject™ Ureteral Stent Set
1.	**3. Primary clinical purpose of device(s)**
	The Kwart Retro-Inject™ Ureteral Stent Set is used for retrograde injection during Extracorporeal Shock Wave Lithotripsy (E.S.W.L.) and leaving an indwelling ureteral stent post-E.S.W.L.
1.	**4. Device Model/Catalogue/Part Number(s)**
	003700
1.	**5. Affected serial or lot number range**
	NS13089897

2. Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	Cook Medical has identified that the stents from the affected lots were manufactured with incorrect material, which may result in the stent being stiffer and potentially susceptible to degradation.
2.	**2. Hazard giving rise to the FSCA**
	If a stent is stiffer and/or susceptible to degradation, this could potentially lead to breakage/fragmentation. Potential adverse events that may occur if an affected product is used include patient discomfort, additional intervention to remove a fragmented stent, and hydronephrosis. While biocompatibility testing has been completed for the affected material to support limited contact duration (≤ 24hr), biocompatibility testing has not been completed for long-term indwelling use. Therefore, potential adverse events resulting from long-term exposure to affected product has not been characterized.
2.	**3. Other information relevant to FSCA**
	At this time, Cook Medical has not received customer complaints for the affected lots.

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3. Type of Action to Mitigate the Risk		
3.	**1. Actions To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☒ Follow patient management recommendations ☒ 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. 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 indwelling in a patient, consider scheduling a follow-up with the patient to remove and/or replace the product, based on the status and preferences of each individual patient.	
3.	**3. Is Customer Reply Required?** Form is attached specifying deadline for return.	Yes
3.	**4. 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

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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.

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Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2020FA0010
FSN Date	06 January 2021
Product/Device name	Kwart Retro-Inject™ Ureteral Stent Set
Product Part Number(s)	003700
Batch/Serial Number(s)	NS13089897

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation
Please mark boxes below to indicate actions have been completed.
If action is not applicable, please write N/A in the column on the right.

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I have affected devices to return - enter Lot number and quantities in table below.	
☐	No affected devices remain in our organisation's inventory	

Print Name	
Signature	
Date	

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4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt, even if you do not have any of the affected product(s).
Customer Helpline	Please refer to the attached Country Contacts List

If you are returning any affected product, please indicate the part number, lot number and quantity:

Product Part Number	**Product Lot Number**	**Quantity**

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.