COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: Kwart Retro-Inject™ Stent Set, Salle Intraoperative Pyeloplasty Stent Set
Manufacturer: Cook Incorporated
Cook Reference Number: 2019FA0004
Type of action: Field Safety Corrective Action (FSCA)

Date: 17 Apr 2019

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

PRODUCT BRAND NAME	REFERENCE PART NUMBER (RPN)	ORDER NUMBER	LOT NUMBER
Kwart Retro-Inject™ Ureteral Stent Set	003500	G14916	All Lots
	003600	G14836	
	003700	G14837	
	003800	G14844	
	AQ-003500	G17150	
	AQ-003600	G17151	
	AQ-003700	G17152	
Salle Intraoperative Pyeloplasty Stent Set	SIPSF-040018-56-6	G18168	
	SIPSF-040018-59	G32773	
	SIPSF-050018-59	G32774	

Description of the problem:
Cook Medical is initiating a voluntary correction for the Kwart Retro-Inject™ Stent Set and Salle Intraoperative Pyeloplasty Stent Set. Cook Medical has identified that the Instructions for Use (IFU) do not contain sufficient warning associated with use of these products. The IFUs are currently in process of being updated and will be provided with orders placed following implementation.

The updated IFUs will include the following warning:

> *Formation of knots in multi-length stents may occur. This may result in injury to the ureter during removal and/or the need for additional surgical intervention. The presence of a knot should be considered if significant resistance is encountered during attempts at removal.*

The purpose of this letter is to inform you of the potential for stent knotting to occur and its possible outcomes.

Advise on action to be taken by the user:

1. Understand that stent knotting is a potential complication associated with use of the Kwart Retro-Inject™ Stent Set and Salle Intraoperative Pyeloplasty Stent Set and should be considered if significant resistance is encountered during attempts at removal.

2. Please maintain a copy of this notice with the current IFU or product(s) in your inventory.

3. If you have affected product in inventory, you may continue to use these products. **Cook Medical is not requesting product be returned.**

4. Please complete the enclosed Customer Response Form.

5. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61239294).

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

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

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:
Larry Pool
Post Market Director
Cook Incorporated
750 Daniels Way, PO Box 489, Bloomington, IN 47402, United States

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

Larry Pool
Post Market Director
Cook Incorporated

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2019FA0004
Affected device: Kwart Retro-Inject™ Stent Set, Salle Intraoperative Pyeloplasty Stent Set

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____
(Please Print)

Please confirm the following:

☐ I have received the FSN for the Kwart Retro-Inject™ Stent Set and Salle Intraoperative Pyeloplasty Stent Set, and I understand the warnings associated with use of these products.

☐ I understand that a copy of the FSN should be maintained with the current IFU or product(s) in my inventory.

If you are a distributor, have your customers been notified of this Field Safety Corrective Action?

☐ Yes ☐ No

Signed: _____ Date: _____

Please return the completed Customer Response Form to by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.