COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440
Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product:

FluoroSet® Radiographic Tubal Assessment Set
Kumpe Access Catheter
Selective Salpingography Catheter with Beacon® Tip

Manufacturer : Cook Incorporated
Cook Reference Number: 2016FA0002_CINC
Type of action: Field Safety Corrective Action

Date: DD/MMM/YYYY

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Catalog Identifier	Lot Number
FluoroSet® Radiographic Tubal Assessment Set	J-RTAS-100	All lots
Kumpe Access Catheter	023565-BT	All lots
Selective Salpingography Catheter with Beacon® Tip	J-SSG-504000	All lots

Please see attached complete product listing of all products impacted by this field action which were shipped to your facility.

Description of the problem:
Cook Medical is initiating a voluntary recall of the products listed above. We have identified an increase in reports of polymer degradation of the catheter tip, resulting in tip fracture and/or separation. Our preliminary investigation into this matter has identified that environmental conditions, such as storage temperature, humidity, and the use of Vaporized Hydrogen Peroxide (VHP) for whole-room decontamination within healthcare facilities, may be contributing to the occurrence. We also recognize that there may be other undetermined contributors to this issue and continue to investigate.

These devices are intended for use by physicians who are trained and experienced in each of the procedures for which the following devices are indicated for use.

Product Family	Intended Use
FluoroSet® Radiographic Tubal Assessment Set	Used for instillation of contrast media into the uterine cavity for radiographic evaluation of the uterine cavity and for injection of appropriate contrast media into the fallopian tubes for evaluation of tubal patency.
Kumpe Access Catheter	Used in combination with a HiWire®, Bentson, or other flexible-tipped wire guide to gain difficult ureteral access beyond a redundant or tortuous ureteral segment.
Selective Salpingography Catheter with Beacon® Tip	Used for injection of contrast medium into the fallopian tube(s) for selective salpingography.

Potential adverse events that may occur as a result of catheter polymer degradation could include loss of device function, separation of a device segment leading to medical intervention, or complications resulting from a separated segment. Such complications may include device fragments in the genitourinary system.

This notice is directed to you because our records indicate that you have received product of the listed catalog numbers identified above that have not expired.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected product from your inventory.

2. Please complete the enclosed Customer Response 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 Response form.

   Product should be addressed to:
   Cook Medical EUDC
   Robert-Koch-Straße, 2
   52499 Baesweiler
   GERMANY

   Credit will be provided for the returned devices where applicable.

3. 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 61 334441). Do not enclose the response form with the returned product.

4. Please report any adverse event to Cook Medical Customer Relations by contacting our Customer Services Department.

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.

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.

Contact reference person:

Sinead Burke
Director, Regulatory Affairs
Regulatory Affairs
Cook Ireland
Limerick, IRELAND

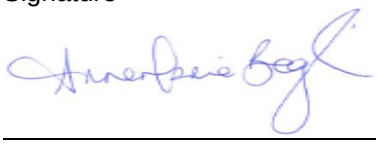
Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

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

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Signature



Annemarie Beglin
Quality Systems Manager