Coloplast

Ostomy Care
Continence Care
Wound & Skin Care
Interventional Urology

To Whom it may concern

31 October 2019

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark
Tel: +45 4911 1111
www.coloplast.com

URGENT FIELD SAFETY NOTICE

Ref. FSN_Double Loop Ureteral Stent Kits_20191031

RECALL of all batches below of following devices: BIOSOFT® Duo Double loop ureteral stent kit and VORTEK® Double loop ureteral stent kit

This Field Safety Notice concerns

Catalogue numbers: Double Loop Ureteral Stent Kits refs. BCAM75, BCAG73, BCAG74, BCAG75, BCAG63, BCAG64, BCAG65, ACB2C5 and ACB455 which include the component ref. ACP215 lot 6692338 (Flush Ureteric Catheter).

Lot numbers:

Kit references	Product name	Kit lot
BCAM75	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7016473
BCAG75	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7023813
BCAG74	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7023833
BCAG73	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7023863
BCAG65	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7036106
BCAG63	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7036111
BCAG64	BIOSOFT® Duo Double Loop Ureteral Stent Kit	7036761
ACB2C5	Vortek® Duo Double Loop Ureteral Stent Kit	7035326
ACB455	Vortek® Duo Double Loop Ureteral Stent Kit	7036750

Lot numbers of the Double Loop Ureteral Stent Kits above are subject to a recall from the market.

Description of the problem:

The device ref. ACP215 is a flush ureteric catheter with straight open tip without side eye, radiopaque, CH FR 4.8 and with 73,5 cm of length.

Flush Ureteric Catheters ref. ACP215 can be used for inserting the guidewire, or injecting saline solution or contrast medium. They are made of PEBA (PolyEther Block Amide) and are supplied with a connector fitted with a Luer tip.

They are component of some Double Loop Ureteral Stent Kits of Biosoft® Duo range and Vortek® range.

COLOPLAST has become aware of packaging anomaly on the product ref. ACP215 lot 6692338, which was included in 9 batches of Double Loop Ureteral Stent Kit. The reason of the recall is that there might be some of the pouches of this lot that could be unsealed and compromising the sterility of the device. The non-sterility of device may lead to a risk of infection for the patient.

If the defect is recognized by the healthcare professionals, they would have to change the device and thereby prolong the procedure.

This recall concerns all kits lot numbers mentioned above.

Scope of the recall

Since the packaging integrity for the lot numbers specified above has been questioned, all relevant inventories have been on hold and a failure investigation has been initiated.

This FSN concerns the recall of references:

- BCAM75 lot 7016473
- BCAG75 lot 7023813
- BCAG74 lot 7023833
- BCAG73 lot 7023863
- BCAG65 lot 7036106
- BCAG63 lot 7036111
- BCAG64 lot 7036761
- ACB2C5 lot 7035326
- ACB455 lot 7036750

Advice on action to be taken by the distributors:

The distributors affected by this recall are kindly advised to:

- Return any product covered by the list above to the address mentioned below.
- Fill out and return the attached “confirmation of receipt of FSN”.

Advice on action to be taken by the users:

The customers affected by this recall are kindly advised to:

- Return any product covered by the list above to the address mentioned below.
- Distribute the FSN to all end-users to whom the devices were sold.
- Fill out and return the attached “confirmation of receipt of FSN”

All expenses will be refunded by Coloplast. Please see address below.

Distribution Center of Coloplast Champlan

Recall ACP215
Service Retour
2 bis route du Chemin Blanc
ZAC du Clotais
91160 CHAMPLAN
France

Please contact Supply Chain Customer Service for assistance

e-mail: to be filled in by the relevant subsidiary
phone: to be filled in by the relevant subsidiary

Transmission of this Field Safety Notice:

Please forward this message to relevant persons in your organization.

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

In addition, if you have further distributed this product, please notify the consignees at once of this notification.

Your notification to your customers may be enhanced by including a copy of this notification letter.

This notification should be carried out to the user level. Your assistance is appreciated and necessary.

The undersigned confirms that this notice has been notified to the appropriate Competent Authorities.

If you have any questions, please contact us at:

Contact details:
Subsidiary:
Address:
Contact person:
E-mail:
Telephone:

Yours sincerely,

FSN ref.: FSN_Double Loop Ureteral Stent Kits_20191031

Confirmation of receipt of the FSN

Please fill out the form and send it to the email address given below - even if you do not have the products on your stock please fill out the document.

E-mail: XXXXXXX@coloplast.com

Recall product:

Double Loop Ureteral Stent Kits - ref. : BCAM75; BCAG75; BCAG74; BCAG73; BCAG65; BCAG63; BCAG64; ACB2C5; ACB455.

	Lot numbers								
	7016473	7023813	7023833	7023863	7036106	7036111	7036761	7035326	7036750
Volume in your possession to recall									

- ❑ We have checked all the stocks and the products concerned are not on stock.

Name of customer: _____

Name / Profession: _____

Date / Signature:

Please return the confirmation of receipt no later than: XX-XX-2019