

[Name and Address - Use F11 to go from one field to another]

12. November 2019

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URGENT FIELD SAFETY NOTICE [FSCA_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 Double Loop Ureteral Stent Kits which include the component ref. ACP215 lot 6692338 (Flush Ureteric Catheter).

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.

Background information and reason for the recall:

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.

Sitz der Gesellschaft:
 Hamburg
 Amtsgericht Hamburg
 HRB 65501
 Geschäftsführer:
 Henning Reichardt

Danske Bank Hamburg:
 BIC: DABADEHH
 IBAN:
 DE30203205004989011502

Zertifiziert nach
 DS/EN ISO 9001 und 13485
 OHSAS18001

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.

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.

Advice on action to be taken by the addressee:

Please review your stock and return any product covered by the list above to this address:

**Coloplast Distribution GmbH
Retourenabteilung / Hr. Scharnberg
Rückruf Urologie: Biosoft & Vortek Ureterschiene Sets
Werner-Schröder-Straße 1
21035 Hamburg**

Expenses for return will be refunded by Coloplast – prior to return of the products, contact us for a collection order. After receipt of the recalled products, you will receive a credit note.

Fill out and return the attached “Confirmation of receipt of FSN”. Please return the confirmation of receipt no later than **11 December 2019**.

Transmission of this Field Safety Notice:

Please forward this message to relevant persons in your organization. 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.

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

We confirm that this notice has been notified to the appropriate Competent Authorities.

Contact person: Ms. Kyra Sievert
E-mail: service@coloplast.com
Telephone: 040 669807-77

Your assistance is appreciated and necessary.

Yours sincerely,

FSN ref.: FSCA_Double Loop Ureteral Stent Kits_20191031

Confirmation of receipt of the FSN

Please return the confirmation of receipt no later than: 11 December 2019

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: service@coloplast.com

Customer ID: _____

Name of customer: _____

Location: _____

Contact person / Profession: _____

- We have checked all the stocks and the products concerned are not on stock.
- We have these products in our stock and will return them:

Kit reference	BCAM75	BCAG75	BCAG74	BCAG73	BCAG65	BCAG63	BCAG64	ACB2C5	ACB455
Lot number	7016473	7023813	7023833	7023863	7036106	7036111	7036761	7035326	7036750
Volume in your stock (no. of pieces)									

Date / Signature: