FSN Ref: FSN_In-Ka_20221003 FSCA Ref: FSCA_In-Ka_20221003

Date: 2022:10.05

Field Safety Notice
In-Ka® ureteral balloon dilatation catheter kit

For Attention of*:Healthcare professional

Contact details of local representative (name, e-mail, telephone, address etc.)*
Susanne Heinemann Regional Sales Manager Coloplast ACH, atshei@coloplast.com, Tel +43664 8562651

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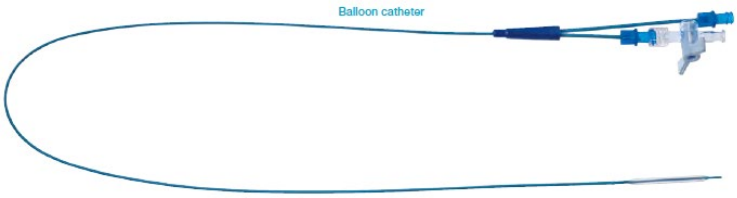
Field Safety Notice (FSN)
Ureteral balloon dilatation catheter kit
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	In-Ka® ureteral balloon dilatation catheter kits REF. BD4144 are system according to the Article 22 of Medical Device Regulation EU 2017/745, containing: - one In-Ka® Ureteral balloon dilatation catheter - one low-volume screw syringe with Luer lock  The kit is composed of single use and sterile devices.
1.	2. Commercial name(s)*
	In-Ka® ureteral balloon dilatation catheter kit
1.	3. Unique Device Identifier(s) (UDI-DI)
	570893262832602R2
1.	4. Primary clinical purpose of device(s)*
	In-Ka® ureteral balloon dilatation catheter kits are intended for dilation of the ureteral meatus and/or ureteral canal during endoscopic procedures and treatment of ureteral stenoses.
1.	5. Device Model/Catalogue/part number(s)*
	BD4144
1.	6. Affected serial or lot number range
	7627304

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The expiration date labelled on the IN-KA® Ureteral balloon dilatation catheter kit is not correct. The shelf life of one component within the kit (syringe) is shorter than the expiration date of the kit.
2.	2. Hazard giving rise to the FSCA*
	The labelling error was identified and reported by one customer. No clinical consequence has been reported within these complaints. Very low clinical risk of infection as the syringe and its content have no contact with patient's body. Coloplast initiates a voluntary recall as the expiration date labelled on the IN-KA® Ureteral balloon dilatation catheter kit is not correct.
2.	3. Background on Issue
	No clinical consequence was reported by the complaining hospital. A review of the complaints database was carried out no similar case has been reported.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device The customers affected by this recall are kindly advised to return any unused product covered by the list in appendix 1 to the address mentioned below: **Distribution center of Coloplast Le Plessis Pate** Att. Blaise Banzouzi Obj: Recall FSCA_In-Ka_20221003 Service Retour 2 Rue Jacqueline Auriol, 91220 Le Plessis-Pâté. France	
3.	2. By when should the action be completed?	November 11th,2022
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	

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	Coloplast A/S
	b. Address	Holtedam 13050 Humlebæk Denmark
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Customer Reply Form
4.	6. Name/Signature	Alexandra Limeul Regulatory Affairs Manager 

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