FSN Ref: FSN_20241119_Packaging FSCA Ref: FSCA_20241119_Packaging

Date: 2024.12.05

URGENT Field Safety Notice
Recall

Foley catheters, Prostatic catheters, Urinary diversion devices, Neoplex® urethral catheters without balloon, Urethral bougies, Urodynamic catheters, Percutaneous nephrostomy catheters, Supra-pubic drainage set and Surgical drainage devices (see Appendix 1 version 3.0).

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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URGENT Field Safety Notice (FSN)
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Risk addressed by FSN

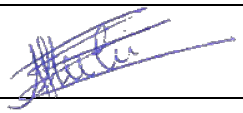
1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The affected devices are: - Foley catheters - Prostatic catheters - Urinary diversion devices - Neoplex® urethral catheters without balloon - Urethral bougies - Urodynamic catheters - Percutaneous nephrostomy catheters - Supra-pubic drainage set - Surgical drainage devices All of these devices are sterile devices.
1.	2. Commercial name(s)*
	See details in Appendix 1 version 3.0
1.	3. Unique Device Identifier(s) (UDI-DI)
	See details in Appendix 1 version 3.0
1.	4. Primary clinical purpose of device(s)*
	Folatex® Foley catheters - Semi-rigid latex (REF. AA32xx, AA36xx and AA38xx) are intended to be used for urethral urinary catheterization and Suprapubic urinary catheterization only for REF. AA32xx, AA36xx. Folysil catheters (REF. AA6xxx, AA7xxx, AA8xxx, AA93xx, HA61xx, HI66xx, HS61xx) are intended to be used for: - Bladder drainage by urethral catheterization, or by suprapubic catheterization (only for non-grooved, straight 2-way Folysil catheters with a maximum balloon volume of 15mL). - Bladder instillation of physiological saline solution. - Post-operative bladder irrigation-lavage by urethral catheterization, only for 3-way Folysil® catheters for neobladder. Prostatic catheters (REF. AB3xxx, AB6xxx, AB7xxx, AM3xxx, XB6xxx) are intended to be used for: - Short-term drainage of bladder urine - Postoperative bladder irrigation-lavage - After prostate surgery: haemostasis of the prostatic fossa Ureterostomy catheters (REF. AC67xx and AC68xx) are intended to be used for ureteral catheterization of a cutaneous ureterostomy Neoplex® catheters without balloon (REF. AD5Dxx and ADN3xx) are intended to be used for urinary catheterisation (urinary drainage). Neoplex® urethral bougies (REF. AG5xxx) are intended to be used for management of urethral stenosis. P.V.C. urethral bougies (REF. AG73xx) are intended to be used for dilation of stricture. Urodynamic catheters Disposable Line (REF. AH2108, AH2309, AH24M9) and Re-usable line (REF. AH5xxx) are intended to be used for: - Cystometry - Urethrocystometry - Urethral Pressure Profile

	Percutaneous nephrostomy balloon catheter in silicone (REF. AJ66xx and AJ67xx) are intended to be used for short-term percutaneous drainage of the upper urinary tract during obstruction, in particular related to lithiasis, a congenital deformity or a tumour of the subjacent urinary tract. Supraflow® Supra-pubic drainage set with silicone balloon catheters (REF. AJ92xx) are intended to be used for supra-pubic drainage of urine from the bladder. Surgical drainage devices - Simple drainage (REF. GA1035, GA50xx, GA62xx, GP60xx) are intended to be used for short-term drainage in the abdominal cavity. Simple drains can drain purulent liquid, blood or other fluids following surgery, traumatism, abscess and wound to help the healing process. Surgical drainage devices - Suction drainage (REF. GA66x, GA67xx and GA68xx) are intended to be used for irrigation and lavage drainage. Surgical drainage devices - Biliary drainage (REF. GD40xx and GD41xx) are intended to be used for cholangiography and short-term drainage of the common bile ducts. Surgical drainage device - Biliary drainage (REF. GD4505) is Coeliodrains intended to be used for cholangiography. Percutaneous Nephrostomy sets with J catheter in Vortek® (REF. RJE1xx) are intended to be used for short-term percutaneous drainage of the upper urinary tract during obstruction, in particular when related to lithiasis, congenital abnormality, or tumour of the underlying urinary tract. Uristil® Supra-pubic drainage set in silicone (REF. AJ89xx) are intended to be used for supra-pubic drainage and irrigation of the bladder by supra-pubic route.
1.	5. Device Model/Catalogue/part number(s)*
	See details in Appendix 1 version 3.0
1.	6. Affected serial or lot number range
	See Appendix 1 version 3.0

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Possible sterility issue was detected in Coloplast's facility on some Coloplast products. This issue on the Coloplast devices packaging has been identified during testing. Defect is not easily visible by the users.
2.	2. Hazard giving rise to the FSCA*
	A device with compromised sterility carries a worst-case of potential harm to cause an infection to the patient. Coloplast initiates a voluntary recall on the for the products and affected lots listed in Appendix 1 version 3.0.
2.	3. Background on Issue
	Coloplast has become aware of a defect on sterile packaging during testing. The defect on these pouches could compromise the device's ability to maintain a sterile barrier.

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 Immediately inspect your internal inventory for the aforementioned packaging defect and quarantine all affected Product pending safe destruction.

	All distributors and customers must ensure that the FSN is sent to treating clinicians at facilities within 24 hours of receipt of this Notice	
3.	2. By when should the action be completed?	January 15th, 2025
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 List of affected devices and lot numbers Certificate of destruction
4.	6. Name/Signature	Magali MERLIN 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.*

Appendix 1 version 3.0 List of affected devices and lot numbers

See attached document: FSN_20241119_Packaging - Appendix 1 version 3.0 List of affected devices and lot numbers