MEDICAL DEVICES ADVISORY NOTICE

2 December 2024

Coloplast Manufacturing France
C.A. La Boursidière
92357 Le Plessis-Robinson cedex
France
Tel. +33 1 40 83 68 68
Siret 338 864 770 00031

Dear customer,

Coloplast is informing you that the product families listed below in the Interventional Urology portfolio are subject to a voluntary product recall.

These are the affected product families and the full detailed list of references and lot numbers included in the scope of the recall is described in the separate attachment **"FSN_20241119_Packaging - Appendix 1 version 3.0 - List of affected devices and lot numbers"**

- 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

In view of the volume of information, we are sending you, for information purposes, the list in Appendix 2 of batches/products known in our systems as sold to your establishment, and we invite you, in any event, to refer to the complete list in the separate attachment **"FSN_20241119_Packaging - Appendix 1 version 3.0 - List of affected devices and lot numbers"** in order to carry out all the mandatory checks.

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.

Customers affected by this recall are kindly advised to immediately inspect their internal inventory for the aforementioned packaging defect and quarantine all affected products covered by the separate attachment **"FSN_20241119_Packaging - Appendix 1 version 3.0 - List of affected devices and lot numbers"** and then proceed to safe destruction.

All expenses will be refunded by Coloplast A/S upon receipt of the completed **Certificate of Destruction** provided in **Appendix 3**.

Please contact your local Customer Service for any assistance:

Email: gbsurgery@coloplast.com

338 864 770 RCS Bergerac
Capital: 9 371 883 €

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.

Your country competent authority has been notified of this recall.

We apologize for any inconvenience this will cause and we appreciate your understanding and cooperation in this action.

Yours sincerely,

Coloplast Interventional Urology

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.

Appendix 2

See Appendix 2 attached Excel file covering all lot numbers purchased by your organisation.

Appendix 3 - CERTIFICATE OF DESTRUCTION

See attached document: FSN_20241119_Packaging - Appendix 3 - Certificate of Destruction