URGENT MEDICAL DEVICE RECALL- RC-2024-RN-01113-1

16 December 2024

Coloplast Pty Ltd.
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Dear Customer,

Coloplast Pty Ltd, after consultation with the Therapeutic Goods Administration (TGA), is informing you that the product families listed below from the Interventional Urology portfolio are subject to a medical device recall.

The affected product families included in the scope of this recall are comprehensively described in the attachment: **"Appendix 1: Total list of affected devices and lot numbers"**

This encompasses the following product families:

- 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

Product Problem

A possible sterility problem was detected in our facility impacting some of our products. This problem impacting our packaging has been identified during testing and the defect is not easily visible. The patient is at a significant risk of contracting an infection if the sterility of these products is compromised.

Action

Customers affected by this recall are kindly advised to immediately inspect their inventory for the aforementioned packaging defect and quarantine all affected products covered by the separate attachment **"Appendix 2: Customer specific list of affected devices and lot numbers"** and then proceed to safe destruction.

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

Please complete the **Customer Acknowledgement Form** provided in **Appendix 4** by Friday the 31st of January 2025.

The completed Certificate of Destruction and Customer Acknowledgement Form should be sent our Regulatory Affairs team at:

Email: aureg@coloplast.com

For any further queries, please contact our local Customer Service team at:

Email: auurology@coloplast.com
Phone: 1800 170 009

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

Yours sincerely,

X Kavya Thadani

Kavya Deepak Thadani

Regulatory Affairs Specialist

Appendix 1: Total list of affected devices and lot numbers.

Appendix 2: Customer specific list of affected devices and lot numbers

Appendix 3: Certificate of Destruction

Appendix 4: Customer Acknowledgement Form