

URGENT FIELD SAFETY NOTICE

Reference: C25JUL11

Product: 5775 Silicone 2 Way Foley (open tip) Catheter Kit, 18Fr. 10cc, Standard, 42cm

Date: 31/07/2025

Notification of misinformation on label

Attention: Quality Assurance Personnel, Theatre Managers, Procurement Directors, Clinical Directors of Urodynamics

Affected device:

Manufacturer	Description	Product code	Affected LOT numbers
Mediplus Ltd.	Silicone 2 Way Foley (open tip) Catheter Kit, 18Fr. 10cc, Standard, 42cm	5775 Unit GTIN: (01)05055140703316 Box GTIN: (01)15055140703313	D01110 D01341

Description of the problem:

Mediplus has reported an incident of misinformation on a unit box label.

Internal assessment of the product (see above) has confirmed that the label on the carton box has an incorrect description of 14fr rather than 18fr, however the correct size catheter is in the box and the pouch label and the shipper have the correct description listed. It has been confirmed that the correct size product is in the box. The fit, form, function and safety of the device is not affected by the issue raised.

This defect is exhibited on the LOT number listed above. No patient harm has been reported.

Action to be taken by the user:

Our records show that you have been supplied product from the affected LOT.

Due to this incident being a description error on the label, please forward to the relevant Clinician's and support staff to ensure correct identification of size of the catheter.

This is a notification to confirm that the correct product has been supplied.

The MHRA and other relevant Regulatory Authorities are being notified of this Field Safety Notice

Should you have any questions or require any further assistance, please contact either your local Sales Specialist or myself.

Yours sincerely
Lesley-Anne Gilbert

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