

## URGENT FIELD SAFETY NOTICE

Reference: FSCA\_0117\_5779

Silicone 2 way Foley Catheter Kit, 16Fr., Open Tip, Standard.

Date: 13<sup>th</sup> October 2017

Voluntary Medical Device Recall

Attention: Quality Assurance Personnel, Urology Department Management and Healthcare Professionals

### Affected device:

Manufacturer	Description	Product code	LOT number
Mediplus Ltd.	Silicone 2 way Foley Catheter Kit, 16Fr., Open Tip, Standard.	5779	1600425A

### Description of the problem:

Mediplus Ltd. have been made aware that a small number of pouches on product code 5779 from a single LOT were not sealed during manufacture. We therefore cannot guarantee sterility on these affected products.

The affected products are readily identified as the end of the pouch nearest the tip of the catheter has been left open.

As a result of this open pouch, if the product is used there may be increased risk of infection to the patient.

It is only this LOT that has been identified as being affected by this issue.

### Action to be taken by the user:

Our records show that you have been supplied product from the affected LOT between March and October 2017.

The regulatory authorities and the MHRA require reconciliation of recalled product and Mediplus must document your compliance with this voluntary recall.

- Please do not use or further distribute any 5779 product from the LOTs identified above
- Please segregate the units in a secure place pending return to Mediplus Ltd.
- Please forward this Field Safety Notice to all those who need to be aware of it within your organisation.



- Please also forward this Field Safety Notice to any organisation or consignee where potentially affected devices have been transferred. If appropriate please provide Mediplus with details of any affected devices that have been transferred.
- Please fill out the attached Reply Form even if you do not have any product to return. It is extremely important that we receive this information.
- Please email or fax back the Reply Form to report the information.
- If you cannot email or fax the form back please telephone Mediplus on the number provided to report the information verbally.
- Once we have your reply we will contact you to arrange collection and replacement of any affected product.
- Please respond via the Reply Form no later than the **3rd November 2017**

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

Contact reference person:

**Tim Ward**

Operations Manager  
Mediplus Ltd.  
Unit 7, The Gateway Centre  
Cressex Business Park  
High Wycombe  
Bucks, HP12 3SU  
UK

Tel: 00 44 (0)1494 551 200  
quality@mediplus.co.uk

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologise for any inconvenience caused.

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

Yours sincerely



Tim Ward

Enclosed : Urgent Field Safety Notice Reply Form

**Urgent Field Safety Notice Reply Form  
Voluntary Recall of Product**

Reference : **FSCA\_0117\_5779**

Manufacturer : *Mediplus Ltd.*

Product Code : *5779, Silicone 2 way Foley Catheter Kit, 16Fr., Open Tip, Standard.*

Lot Number : *1600425A*

**It is important that you do not use or further distribute any 5779 product from the batch identified above.**

*Only the product code and LOT number listed above are affected.*

- 1) Do you currently possess any of the affected product? (please check both consignment and purchased inventory) Yes/No
- 2) If the answer to 1) is Yes, please list in what quantities : -

Code	Lot	Quantity (units)
5779	1600425A	

- 3) Please PRINT your name and complete all contact information :-

Name : \_\_\_\_\_

Title : \_\_\_\_\_

Account/Hospital : \_\_\_\_\_

Date : \_\_\_\_\_

Contact Phone Number : \_\_\_\_\_

**Please return completed form by 3<sup>rd</sup> November 2017 to :-**

RMA 2695  
**Tim Ward**, Operations Manager  
Mediplus Ltd.  
Unit 7, The Gateway Centre  
Cressex Business Park  
High Wycombe  
Bucks, HP12 3SU  
UK

**Tel : 00 44 (0)1494 551 200**

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