

## URGENT FIELD SAFETY NOTICE

**Reference:** FSCA\_C19AUG02  
**Product:** 5822, Pump tube set for MMSLibra, Libraplus & Solar urodynamics system  
**Date:** 31<sup>st</sup> October 2019

### Voluntary Medical Device Recall

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

**Affected device:**

Manufacturer	Description	Product code	Affected LOT numbers
Mediplus Ltd.	Pump tube set for MMSLibra, Libraplus & Solar urodynamics system	5822 Unit GTIN: (01)05055140702333 Box GTIN: (01)15055140702330	N002996

**Description of the problem:**

Mediplus has voluntarily initiated a recall of a specific batch of product code 5822, Pump tube set for MMS Libra, Libraplus & Solar urodynamics system.

Internal assessment of the product packaging has confirmed that there is a potential for the sterile barrier to be breached on a limited number of these products resulting in a potential hazard of non-sterile product being used presenting a risk of contamination to the patient. The product is labelled to advise the user not to use if the packaging is damaged.

The potential for this defect is exhibited on the LOT number listed above, however only a single complaint has been received across all LOTs of this product for the past 3 years and 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 in 2019.

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



In order to do this, please undertake the following actions as soon as possible :-

- Please do not use or further distribute any 5822 product from the LOT 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 post, email or fax back the Reply Form to report the information.
- If you cannot post, 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 of any affected product.
- Please respond via the Reply Form no later than the **14/11/2019**

**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\_C19AUG02  
**Manufacturer:** Mediplus Ltd.  
**Product Code:** 5822, Pump tube set for MMSLibra, Libraplus & Solar urodynamics system  
**RMA:** RMA 3384

**It is important that you do not use or further distribute any 5822 product from the LOT number listed below**

Please answer/complete the following two pages:-

- 1) Do you currently possess any of the affected 5822 product? (please check both consignment and purchased inventory) Yes/No
  
- 2) If the answer to 1) is Yes, then please list in what quantities : -

<b>Product Code</b>	<b>Unit GTIN:</b>	<b>Box GTIN:</b>	<b>LOT</b>	<b>Quantity (Units)</b>
<b>5822</b>	(01)05055140702333	(01)15055140702330	<b>N002996</b>	



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

**Reference :** FSCA\_C19AUG19  
**Manufacturer :** Mediplus Ltd.  
**Product Code :** 5822, Pump tube set for MMSLibra, Libraplus & Solar urodynamics system  
**RMA :** RMA 3384

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

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

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

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

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

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

Please return completed form to your distributor by post, fax or email by **14/11/2019** to :-

**Contact:**

**Address:**

**Phone:**

**Email:**