

# smiths

Smiths Medical International Ltd.

Military Road  
Hythe, Kent, CT21 5BN, UK  
Tel: +44 (0)1303 260551

20 September 2004

## **URGENT: Product Safety and Recall Notification**

### **PORTEX® SWIVEL ADAPTERS, AND 5 ml HYPODERMIC NEEDLE-PRO® SYRINGE WITH NEEDLE SEE ATTACHED CATALOGUE NUMBERS AND LOT NUMBERS**

Dear Customer:

Smiths Medical International Ltd. ("Smiths Medical") is voluntarily recalling the products specified on the attached page as holes in the product packaging have been discovered which may compromise the devices' sterile barrier and therefore we cannot guarantee sterility of the product. This was found during internal testing and we have not received any reports of adverse events from the field. However, as a precautionary measure, and to ensure the highest quality of product is provided to our customers, we are voluntarily recalling these products. **Similar products with Catalogue numbers other than those listed on the attached page are not affected.**

Our records show that you have received the affected product and we request that you take the following actions:

- Promptly inspect your stock for the products on the attached page and quarantine any affected product.
- Complete and fax back the attached **Customer Reply Letter** to the Smiths Medical QA Department at +44 (0)1303 236835. NOTE: Incomplete Reply Letters need to be followed up by telephone and will delay processing your replacement order. A **Returned Goods Authorization (RGA)** will be issued for the return of any affected product, and any credit or replacements will be arranged as requested. Please contact the QA Department at +44 (0)1303 260551 for more information.
- Please return the affected products to your distributor.

It is essential that you complete and return the **Customer Reply Letter** even if you no longer have the affected products in your stock. As much as we do not want to disrupt your day, all letters not returned completed require us to call you.

**Please ensure that a copy of this Product Safety and Recall Notification is provided to all personnel within your organization who use this product.**

Smiths Medical is diligently working to resolve this issue and regrets the inconvenience experienced by our customers due to this action.

Sincerely,

**SMITHS MEDICAL INTERNATIONAL LTD.**

David Poore  
QA Manager

Enclosures: Listing of Catalogue Numbers and Lot Numbers of Affected Products, Customer Reply Letter

**URGENT: Product Safety and Recall Notification**

**PORTEX® SWIVEL ADAPTERS, AND 5 ml HYPODERMIC NEEDLE-PRO® SYRINGE WITH NEEDLE WITH AFFECTED CATALOGUE NUMBERS AND LOT NUMBERS**

PRODUCT DESCRIPTION	PRODUCT CATALOGUE NUMBER	PRODUCT LOT NUMBERS
Hypodermic Needle-Pro® 5 ml Syringe, 20g x 1 ½" Needle	<b>4250</b>	Lot numbers starting with: 1, K1, K51, K52, K53
Hypodermic Needle-Pro® 5 ml Syringe, 20g x 1" Needle	<b>4251</b>	Lot numbers starting with: 1, K1, K2, K50, K51, K52, K53
Hypodermic Needle-Pro® 5 ml Syringe, 21g x 1 ½" Needle	<b>4252</b>	Lot numbers starting with: 1, K1, K2, K50, K51, K52, K53
Hypodermic Needle-Pro® 5 ml Syringe, 22g x 1 ½" Needle	<b>4254</b>	Lot numbers starting with: 1, K1, K2, K50, K51, K52, K53
Dual-Axis Swivel Adapter	<b>525151</b>	Lot numbers starting with: 0, 1, 910, 912, K1, K2, K50, K51, K52
PEEP-KEEP™ Dual-Axis Swivel Adapter	<b>525351</b>	Lot numbers starting with: 0, 1, 912, K1, K2, K50, K52
Fiberoptic Bronchoscope Dual-Axis Swivel Adapter	<b>625191</b>	Lot numbers starting with: 0, 1, 911, 912, K1, K2, K50, K51, K52

**URGENT: CUSTOMER REPLY LETTER**

**SMITHS MEDICAL INTERNATIONAL LTD.  
Military Road, Hythe, Kent, CT21 5BN, UK**

**Product Recall Information: PORTEX® SWIVEL ADAPTERS, AND 5 ml HYPODERMIC NEEDLE-PRO®  
SYRINGE WITH NEEDLE**

**Prevent calls to you from our Administrators by  
completing and faxing immediately to:**

**Fax No.: +44 (0)1303 236835**

Smiths Medical International Ltd. QA Department  
Attention: Complaints Co-ordinator

**SECTION 1 - PLEASE FILL IN REGARDLESS OF STOCK STATUS:**

Printed Name: \_\_\_\_\_ Department: \_\_\_\_\_

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

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

Facility Address: \_\_\_\_\_

Phone Number \_\_\_\_\_ Ext: \_\_\_\_\_ Fax Number: \_\_\_\_\_

**Please check one:**

- We DO NOT have any affected products remaining in stock (Skip Section 2 and fax)**
- We DO have the affected products (Go to Section 2)**

**SECTION 2 - ANSWER ALL ITEMS BELOW**

1.) Returning product for  **REPLACEMENTS**  **CREDIT**

2.) Recalled product you have on hand (use additional sheets to record stock quantities if needed):

Product No. _____	Lot No. _____	Quantity _____	<b>Please check if Qty is by:</b> <input type="checkbox"/> case or <input type="checkbox"/> each
Product No. _____	Lot No. _____	Quantity _____	<b>Please check if Qty is by:</b> <input type="checkbox"/> case or <input type="checkbox"/> each
Product No. _____	Lot No. _____	Quantity _____	<b>Please check if Qty is by:</b> <input type="checkbox"/> case or <input type="checkbox"/> each
Product No. _____	Lot No. _____	Quantity _____	<b>Please check if Qty is by:</b> <input type="checkbox"/> case or <input type="checkbox"/> each
Product No. _____	Lot No. _____	Quantity _____	<b>Please check if Qty is by:</b> <input type="checkbox"/> case or <input type="checkbox"/> each
Product No. _____	Lot No. _____	Quantity _____	<b>Please check if Qty is by:</b> <input type="checkbox"/> case or <input type="checkbox"/> each

Questions should be directed to Customer Service at +44 (0)1303 260551

**For Smiths Medical Use Only**

Customer Account No. \_\_\_\_\_ RGA Number \_\_\_\_\_