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URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Portex® Loss of Resistance Device with Missing Label Information

Affected Device: Portex® Loss of Resistance Device

Type of Action: Removal

Date: December, 03 2020

Attention: Clinical Users of, and Distributors of the Portex® Loss of Resistance Device

Affected Devices: **The following Product Number and Lot Numbers are potentially affected by this issue:**

Table 1: List of Affected Devices

Model Number	Name	Lot Number
100/398/000	Portex® Loss of Resistance Device	3980977 3986734 3994302 3994303 4001003

Dear Customer,

The purpose of this Field Safety Notice is to advise you that Smiths Medical has initiated a Field Safety Corrective Action for specific lots of Portex® Loss of Resistance Devices listed in Table 1: List of Affected Devices.

REASON FOR FIELD SAFETY CORRECTIVE ACTION

Smiths Medical became aware that a specific model number of Portex® Loss of Resistance Devices may have a pouch label that is missing symbols and associated text. The label with the missing symbols and text is illustrated in Figure 1.

This Field Safety Corrective Action is being performed with the knowledge of the appropriate regulatory authorities.

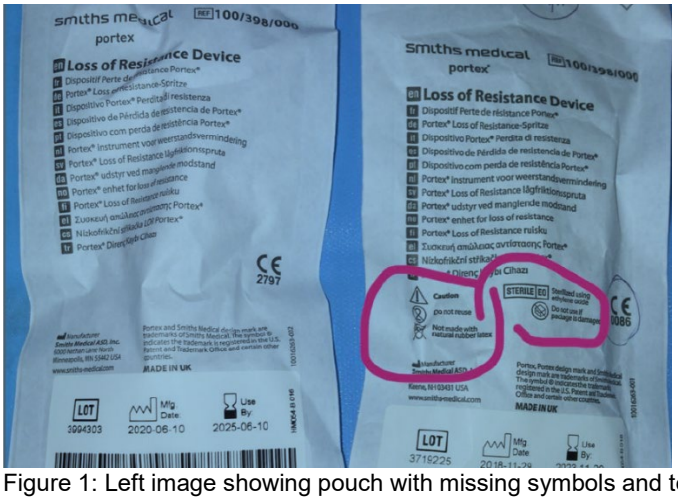

Figure 1: Left image showing pouch with missing symbols and text. Right image showing correct pouch with symbols and text.

RISK TO HEALTH:

The information missing from the label includes sterilization information and prohibition of reuse. If information is missing from the label this may potentially cause therapy to be delayed or exposure to infectious agents if the device was reused.

Smiths Medical has received no reports of deaths or serious injuries related to this issue.

INSTRUCTIONS TO CUSTOMERS AND DISTRIBUTORS:

1. Identify and quarantine affected product in your possession by referring to Table 1: List of Affected Devices included on page 1 this Field Safety Notice.

2. Complete the Field Safety Notice Response Form (Attachment 1). Return the completed response form to fieldactions@smiths-medical.com within 10 days of receipt. The form must be returned even if you do not have any affected Portex® Loss of Resistance Devices in your possession.

3. After the completed Field Safety Response Form has been submitted to fieldactions@smiths-medical.com ,you will be contacted to arrange the return of any affected product.

4. DISTRIBUTORS, if you have distributed potentially affected product to your customers, please immediately notify them of this Field Safety Corrective Action.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Smiths Medical via email at fieldactions@smiths-medical.com.

Sincerely,

Dave Halverson
Director Global Compliance
Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442
fieldactions@smiths-medical.com

Enclosure: Attachment 1 – Field Safety Notice Response Form

ATTACHMENT 1

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MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Portex® Loss of Resistance Device with Missing Label Information

Please assist us in making this Medical Device Field Safety Corrective Action efficient and convenient for you by completing and returning this form as soon as possible. This will serve as confirmation that you have received and understand the notification, and will allow us to ensure that we have reached all customers who may be affected by this Field Safety Notice.

Please acknowledge receipt of this Urgent Field Safety Notice by completing and returning this Field Safety Notice Response Form to fieldactions@smiths-medical.com within 10 days.

DISTRIBUTORS - Please provide a copy of this Response Form and the accompanying Field Safety Notice to any of your customers to whom you distributed affected product, and complete page 2 of this Response Form.

Affected Product Information		
Product Number	**Lot Number**	**Quantity to be Returned (individual units)**

I certify that I have read and understand the information in the attached Field Safety Notice:

Name and Title (Please Print)	**Signature and Date**	**Customer Number**	**Facility Name and Ship To Address***
Email Address	**Telephone Number**		

*If you are submitting a response form for multiple locations, please include the address for each facility you are responding for on the form or in an attachment.

For Distributors Only

I have identified and notified my customers that were shipped or may have been shipped this product

Distributor Name_____

Distributor Address_____

Distributor Email Address/Phone Number_____