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URGENT MEDICAL DEVICE FIELD ACTION NOTICE

Portex® Thoracic Catheter and Connecting Tube (Packaging Seal)

Type of Action: Removal

Date: April 18, 2018

Attention: Clinicians who oversee the use of the Thoracic Catheter

Affected devices: **Please see Table 1 for a list of affected devices**

Table 1

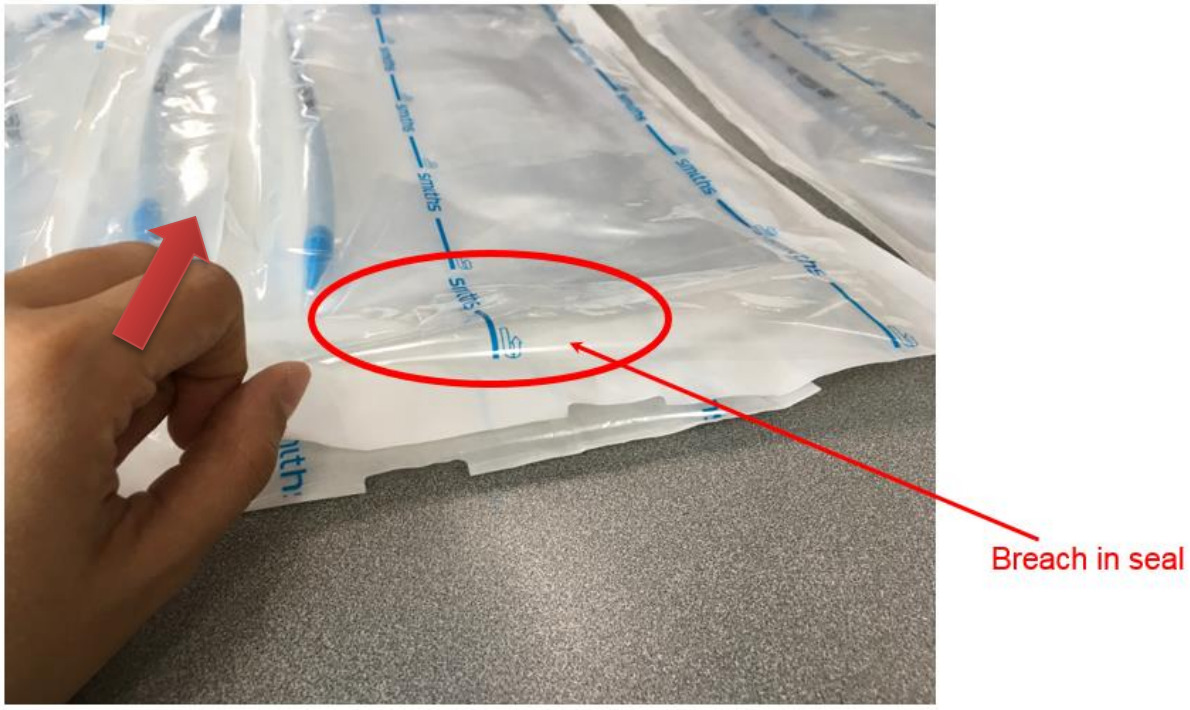
Device Name	Model #	Lot Number
CONNECTING TUBE ID 7.0MM 10/CA	800/002/067	3206707, 3228640, 3236592, 3248922, 3300060, 3321419, 3307225
THORACIC CATHETER 16F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/160	3324554
THORACIC CATHETER 20F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/200	3220281, 3224051
THORACIC CATHETER 24F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/240	3211879, 3316279, 3343137, 3324552
THORACIC CATHETER 28F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/280	3215823, 3224052, 3229350, 3316278, 3316281, 3321468, 3324557, 3324559, 3335975, 3340753
THORACIC CATHETER 32F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/320	3224055, 3232336, 3249019, 3256826, 3307297, 3316283, 3335976, 3343138, 3335978
THORACIC CATHETER 36F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/360	3228664, 3232329, 3245495, 3316284, 3335977

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary field action of certain Portex® Thoracic Catheters and Connecting Tubes due to a potential for the package seal to be compromised, and therefore compromising sterility.

The Portex® Thoracic Catheter is intended to facilitate pleural, medicinal, or pericardial drainage following cardiothoracic or thoracic surgery.

REASON FOR FIELD ACTION:



Example 1 – Package with a breach in the seal for Portex® Thoracic Catheter

Smiths Medical became aware of a potential breach in the seal of the package (see Example 1) on certain packaging lots. These packages were used in the manufacturing of certain Portex® Thoracic Catheters and Connecting Tubes.

This field action is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

If a compromised packaging seal is not identified prior to use, infection and/or the introduction of particulates into the thoracic cavity may possibly occur.

Smiths Medical has not received any reports of deaths or serious injuries related to the packaging seal issue.

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INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS FIELD ACTION

1. If you are a distributor, please immediately notify your customers to whom you have distributed this product.

2. Collect and isolate all Portex® Thoracic Catheters or Connecting Tubes associated with the affected lots identified here:

Device Name	Model #	Lot Number
CONNECTING TUBE ID 7.0MM 10/CA	800/002/067	3206707, 3228640, 3236592, 3248922, 3300060, 3321419, 3307225
THORACIC CATHETER 16F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/160	3324554
THORACIC CATHETER 20F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/200	3220281, 3224051
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THORACIC CATHETER 36F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/360	3228664, 3232329, 3245495, 3316284, 3335977

3. Complete the Urgent Medical Device Field Action Response Form and return to [email address TBD] within 10 days of receiving this letter, even if you no longer have any of the affected product in your possession.

4. Return affected product using the enclosed shipping label. Ensure a copy of the Urgent Medical Device Field Action Response Form is included with the shipment.

5. Upon receipt of Urgent Medical Field Action Response Form and product, you will be sent replacement product or credit.

If you have any questions regarding this notification, please contact Stericycle at [email address TBD]

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

Sincerely,

[redacted]

Global Compliance Manager
Smiths Medical

Consignee ID:

ENCLOSURE 1

URGENT MEDICAL DEVICE FIELD ACTION RESPONSE FORM

Affected Devices: Portex® Thoracic Catheter and Connecting Tube (Packaging Seal)

Please assist us in making this Field action Notification process as efficient and convenient for you as possible by completing and returning this form via email to [Email Address TBD] within 10 calendar days of receipt of this Urgent Medical Device Field action Notice. 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 event. Please return this Urgent Medical Device Field Action Response Form even if you do not have any potentially affected product.

Customer Name
Address
City, State, Zip Code, Country

According to our records, you have purchased the following product affected by this Field action:

Product Number	Product Name	Lot Number	Order Number	Quantity Purchased	Quantity to be Returned	Credit or Replacement

Name and Title (Please Print)	Signature	Date
Email Address	**Telephone Number**	