IDS Medical Systems (Singapore) Pte Ltd
20 Science Park Road, Teletech Park, #01-23/25
Singapore Science Park II, Singapore 117674
T: 65-6690 7330 F: 65-6690 7380
Email : sgpidsmedicalsystems@idsmed.com
UEN : 201114809E
www.idsmed.com

FIELD SAFETY NOTICE

18 April 2018

<<Customer Name>>
<<Dept>>
<<Address Line 1>>
<<Address Line 2>>
<<Address Line 3>>

IDS REFERENCE:	**2018-009**
SUBJECT: Portex Thoracic Catheter and Connecting Tube (Packaging Seal)	
FOR THE ATTENTION OF: Chairman Medical Board (CMB), BME, Nursing and Medical staff using these devices in the various departments and the relevant Head of Departments.	
DEVICE :	Portex Thoracic Catheter and Connecting Tube

PRODUCT CODE / BATCH NO.:

Description	Identifier	Batch Number
Connecting Tube	800/002/067	3206707, 3228640, 3236592, 3248922, 3300060, 3321419, 3307225
Thoracic Catheter	200/812/160	3324554
Thoracic Catheter	200/812/200	3220281, 3224051
Thoracic Catheter	200/812/240	3211879, 3316279, 3343137, 3324552
Thoracic Catheter	200/812/280	3215823, 3224052, 3229350, 3316278, 3316281, 3321468, 3324557, 3324559, 3335975, 3340753
Thoracic Catheter	200/812/320	3224055, 3232336, 3249019, 3256826, 3307297, 3316283, 3335976, 3343138, 3335978
Thoracic Catheter	200/812/360	3228664, 3232329, 3245495, 3316284, 3335977

PROBLEM:	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.
ACTION TO BE TAKEN:	Our records show that you have purchased the affected product(s) and we request that you read through the letter for more detailed information. 1) Inspect your inventory for the affected product(s) listed in the acknowledgment form and quarantine the affected product(s). 2) Complete and return the acknowledgment form with quantity of the unused affected product(s). Upon receipt of the completed form, an IDS Medical representative shall arrange and collect the affected product(s).

We apologize for any inconvenience caused due to this notice. Meanwhile, should you require further clarification, please do not hesitate to contact Ms Valerie Lee @ +65 9682 8220

Thank you.

With regards,
Kenneth Ow
Regulatory Specialist
IDS Medical Systems (Singapore) Pte Ltd
Email: kennethow@idsmed.com

IDS Medical Systems (Singapore) Pte Ltd
20 Science Park Road, Teletech Park, #01-23/25
Singapore Science Park II, Singapore 117674
T: 65-6690 7330 F: 65-6690 7380
Email : sgpidsmedicalsystems@idsmed.com
UEN : 201114809E
www.idsmed.com

IDS Reference: 2018-009
Device: Portex Thoracic Catheter and Connecting Tube
Subject: **Packaging Seal**

I acknowledge receipt of this letter dated **18 April 2018**.

If you have any questions, please contact Ms Valerie Lee @ +65 9682 8220.

Customer Name:			
Department:			
Address:			
Name:		Tel:	
Designation:			
Signature:		Company Stamp:	

Check the applicable boxes below:	
	I **DO NOT** have affected Portex Thoracic Catheter remaining. All have been used or discarded.
	I **DO** have unused inventory of affected Portex Thoracic Catheter, which I will return for replacement.

Model	**Batch Number**	**Quantity to be Returned (UOM)**

**** Please fax this acknowledgement to IDS Medical Systems at 66907380 or email to kennethow@idsmed.com.***

If there is any discrepancy in the above list, please advise us of the changes.

Thank you.

smiths medical
bringing technology to life

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

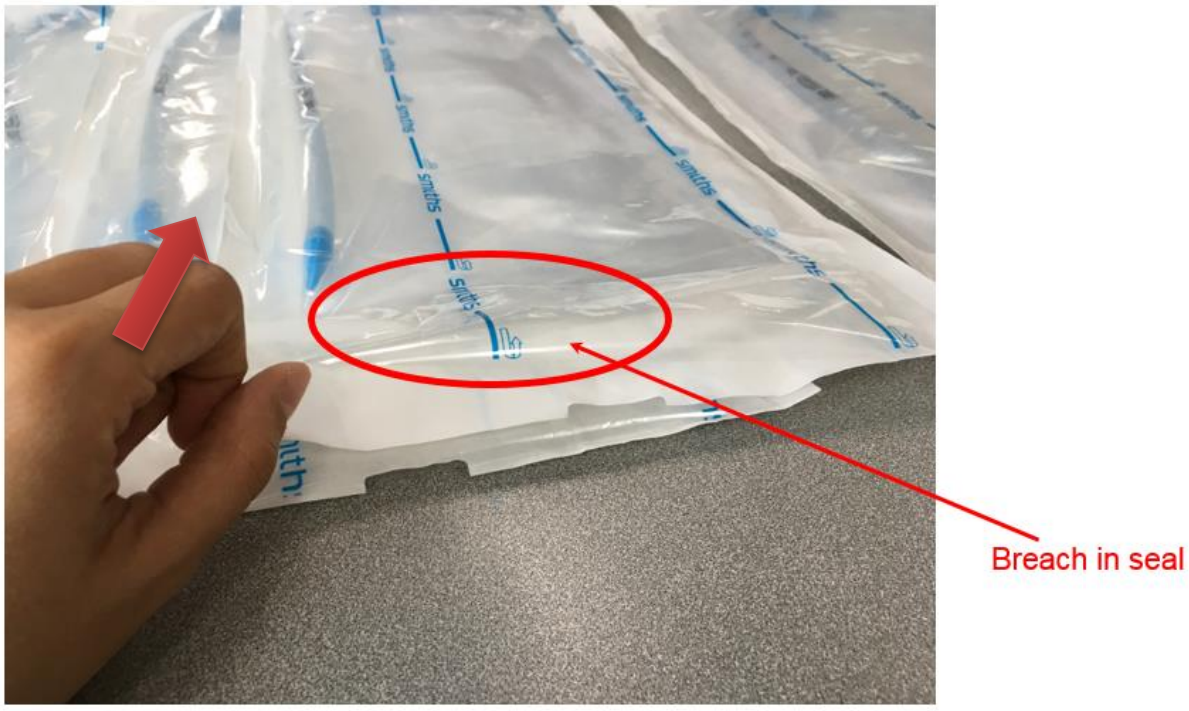
Device Name	Model #	Lot Number
CONNECTING TUBE ID 7.0MM 10/CA	800/002/067	3206707, 3228640, 3236592, 3248922, 3300060, 3321419, 3307225
THORACIC CATHETER 16F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/160	3324554
THORACIC CATHETER 20F ANGLED SOFT, ADULT CONNECTOR, 10/CA	200/812/200	3220281, 3224051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