

<b>URGENT MEDICAL DEVICE RECALL <u>PRODUCT REMOVAL</u></b> <b>ATRIUM PVC THORACIC CATHETER</b> <b>PRODUCTS' STERILE BARRIER POUCH WAS NOT PROPERLY SEALED AT THE BOTTOM</b>	
<b>Product:</b>	ATRIUM PVC Thoracic Catheter
<b>Product Code:</b>	<b>REF</b> 8128
<b>Affected Lot Number:</b>	<b>LOT</b> ME221275
<b>Manufacturing Date:</b>	March 5, 2018
<b>Distribution Date:</b>	From June 13, 2018 to August 22, 2018

**PLEASE READ, FOLLOW THE INSTRUCTIONS AND FORWARD THIS NOTICE TO ALL CUSTOMERS WHO POTENTIALLY RECEIVED AFFECTED ATRIUM THORACIC CATHETER PRODUCTS.**

**Dear Purchasing Manager or Designee,**

Getinge/Atrium is initiating a voluntary product recall involving one lot number of Atrium 28Fr. PVC Right Angle Thoracic Catheter as listed above.

**Reason for the recall:**

This recall has been initiated in response to a seal defect found in certain sterile barrier pouches containing the device. Affected pouches are un-sealed at the bottom.

**Risk to Health:**

If the pouch defect is not detected it could represent a serious hazard to the patient. A sterility breach could potentially lead to product contamination. The potentially affected device is used in contact with critical anatomical structures and deep into the body. If contaminated, the consequences for the patient could be severe. The severity of the possible clinical complications depends on the degree of contamination of the device, the microorganisms involved and the patient's risk factors. To date, Getinge/Atrium has not received any reports of patient injury related to this issue.

**Identification of the issue:**

The Part and Lot number (location on labels circled in red) are printed on the device labeling as shown in Figure 1 below:



Figure 1: Representative Case Label, Carton Label and Sterile Pouch Label

Affected devices can be identified by grasping the Chevron seal to open the pouch as directed in the Instructions for Use. The device will drop through the bottom of any affected pouches.

**Actions required:**

Our records indicate that you have purchased 28 Fr PVC Right Angle Thoracic Catheter **REF** 8128 **LOT** ME221275. Please read and complete the following steps 1 through 4:

- 1. Examine your inventory to determine if you have the affected product listed in this Notification. If so, remove affected products, quarantine them, and place in a secure location.**
- 2. If you are a DISTRIBUTOR who has shipped any affected products to your customers, immediately forward copies of this notification including the form to their attention for appropriate action.**
- 3. If you have affected product, please contact [fathima.nuskiya@getinge.com](mailto:fathima.nuskiya@getinge.com) to request return authorization and shipping instructions to return any affected product for credit or exchange. Pack the product to be returned with the appropriate return documents, using the shipping instructions provided.**
- 4. Please complete and sign the response form to acknowledge that you have received this notification. Return the completed form to Maquet/Getinge by e-mailing a scanned copy to [mubashir.javed@getinge.com](mailto:mubashir.javed@getinge.com)**

We apologize for any inconvenience that this may cause. If you have any questions, please contact [mubashir.javed@getinge.com](mailto:mubashir.javed@getinge.com)

Thank you for your cooperation and immediate assistance.

Sincerely,

**URGENT MEDICAL DEVICE RECALL PRODUCT REMOVAL-RESPONSE FORM**  
**ATRIUM PVC THORACIC CATHETER**  
**PRODUCTS' STERILE BARRIER POUCH WAS NOT PROPERLY SEALED AT THE BOTTOM**

**EMAIL TO:** mubashir.javed@getinge.com

**Facility Name:** [INSERT NAME]  
**Facility Address** [INSERT ADDRESS]  
 [INSERT ADDRESS]

I acknowledge that I have read and understand the [INSERT DATE] Medical Device Recall Notification for the PVC Thoracic Catheter. I confirm that I have followed the instructions in the letter and have forwarded this notification including the response form to any potential customers.

**Product Code** [REF] **8128**    **Lot Number** [LOT] **ME221275**

- Check this box if you have **NO AFFECTED PRODUCT**. Complete this form and send to your local Maquet/Getinge representative at the email address or FAX number above.
- Check this box if you have **AFFECTED PRODUCT**. If you have any affected product, please contact first at fathima.nuskiya@getinge.com or +97144470963 to request return authorization and shipping instructions. Then, complete this form and send to your local Maquet/Getinge representative at mubashir.javed@getinge.com.

<b>Quantity Returning:</b>	<b>Enter RA number:</b>	
<b>Print Name:</b>	<b>Title:</b>	
<b>Signature:</b>	<b>Date:</b>	
<b>Phone:</b>	<b>Comments:</b>	
<b>Facility Name:</b>		
<b>Facility Street Address:</b>		
<b>City:</b>	<b>State:</b>	<b>Zip Code:</b>