

January 24, 2017

**URGENT FIELD SAFETY NOTICE**  
**ATRIUM THORACIC CATHETERS**  
**Labeling Icon Clarification**  
**All Lot Numbers With Expiration Date Through December 2019**

**Manufacturing Dates: December 2011 to December 2016**

**PLEASE FORWARD THIS INFORMATION TO ALL USERS AND STAFF WHO MAY USE ATRIUM THORACIC CATHETER PRODUCTS.**

**Dear Risk Management Staff,**

This letter is intended to provide clarification about the current labeling on two models of Atrium thoracic catheters. The Atrium thoracic catheters are packaged with a label containing an icon that depicts that product as having multiple eyelets. The graphical icon is designed to represent a generic thoracic catheter, and does not accurately reflect the actual eyelet configuration of the product contained in the package. The packaging is transparent allowing visualization of the actual number of eyelets on the thoracic catheter.

The products affected by this field notification are listed in Table 1, below. All lot numbers are affected.

**Table 1: Affected Products**

<b>Code Number</b>	<b>Product Description</b>	<b>Lot Numbers</b>
8008	8 Fr Thoracic Catheter	All
8010	10 Fr Thoracic Catheter	All

For product code numbers 8008 (8Fr thoracic catheter) and 8010 (10Fr thoracic catheter), the graphical icon depicts a catheter having six (6) eyelets; however the correct number of eyelets on the 8 Fr and 10 Fr thoracic catheters is two (2).

The thoracic catheter labeling is being updated for future production. To date, Atrium has not received any complaints related to this labeling issue.

The Field Safety Notice does not include a removal of the affected thoracic catheter products.

**ACTIONS FOR USERS:**

- Please ensure that all Atrium thoracic catheter users are aware of this Field Notification.
- Customers may continue to use the affected thoracic catheter products with the current labeling.
- Please sign the attached Field Notification Reply Form acknowledging receipt of this Field Notification and return the Field Notification Reply Form to your local Atrium/Maquet/Getinge office.

If you have any questions, please contact your local Maquet/Atrium thoracic catheter representative.

This field action is being conducted in accordance with the supervision of the U.S. Food & Drug Administration.

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax:** 1-800-FDA-0178

Thank you for your continued support of Maquet/Atrium thoracic catheter products.

Sincerely,

Maquet Getinge Group  
45 Barbour Pond Drive  
Wayne, New Jersey 07470

January 24, 2017

**URGENT FIELD SAFETY NOTICE  
FIELD NOTIFICATION REPLY FORM  
ATRIUM THORACIC CATHETERS  
Labeling Icon Clarification  
RETURN THE COMPLETED FORM TO YOUR LOCAL  
MAQUET/ATRIUM/GETINGE OFFICE**

**HOSPITAL:** **[INSERT CUSTOMER NAME]**  
**[INSERT CUSTOMER ADDRESS]**  
**[INSERT CUSTOMER CITY, STATE, ZIP CODE]**

I acknowledge that I have reviewed and understand the Urgent Field Safety Notice – Field Notification for Atrium Thoracic Catheters.

I confirm that all appropriate staff that use and/or maintain Atrium Thoracic Catheters at this facility have been notified accordingly and are aware of the labeling discrepancy.

**Please complete the reply form by entering the required information below, including signature and date.**

Print Name: \_\_\_\_\_

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

Title: \_\_\_\_\_

Telephone: \_\_\_\_\_

Hospital Name: \_\_\_\_\_

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

City and State: \_\_\_\_\_

**RETURN THE COMPLETED FORM TO YOUR LOCAL  
MAQUET/ATRIUM/GETINGE OFFICE**