January 24, 2017

URGENT FIELD SAFEY 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

Code Number	Product Description	Lot Numbers
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
- **Regular Mail**: Download form 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 CUSOMER 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