URGENT MEDICAL DEVICE RECALL (REMOVAL)
ATRIUM TROCAR CATHETERS
LABELING ISSUE - IMMEDIATE ACTION REQUIRED
CODE NUMBERS: 8408, 8410, 8412, 8416, 8420, 8424, 8428, 8432
ALL LOT NUMBERS

Manufacturing Dates: All Trocar Catheters manufactured prior to November 18, 2015

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

Dear Risk Management Staff,

This notification is to inform you of an urgent voluntary medical device recall involving the removal of all lot numbers of Atrium Trocar Catheter products.

The Atrium Trocar Catheters are sterile, single use, disposable devices, and are intended to facilitate the evacuation of air and/or fluid from the chest cavity or mediastinum. Refer to Figure 1, below, for photos of the affected Trocar Catheters. Refer to Figure 2, Sample label

Figure 1: Atrium Trocar Catheters

Figure 2: Sample Label
The product code numbers affected by this recall are listed in the Table 1, below. All lot numbers are affected. All sterile and un-used affected products should be returned to Atrium for credit. Replacement product is not available as all Trocar Catheters have been discontinued.

<table>
<thead>
<tr>
<th>Code Number</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8408</td>
<td>8 Fr Trocar catheter</td>
</tr>
<tr>
<td>8410</td>
<td>10 Fr Trocar catheter</td>
</tr>
<tr>
<td>8412</td>
<td>12 Fr Trocar catheter</td>
</tr>
<tr>
<td>8416</td>
<td>16 Fr Trocar catheter</td>
</tr>
<tr>
<td>8420</td>
<td>20 Fr Trocar catheter</td>
</tr>
<tr>
<td>8424</td>
<td>24 Fr Trocar catheter</td>
</tr>
<tr>
<td>8428</td>
<td>28 Fr Trocar catheter</td>
</tr>
<tr>
<td>8432</td>
<td>32 Fr Trocar catheter</td>
</tr>
</tbody>
</table>

Table 1: Affected Atrium Trocar Catheter Product Codes

REASON FOR RECALL:
Atrium Trocar Catheters are packaged with a label containing an icon that shows more holes (eyelets) than the product actually contains. This graphical icon shows there are 6 side holes on the trocar catheter; however, the correct number of eyelets on the trocar catheter is 2 side holes.

RISK TO HEALTH:
To date, Atrium has received two complaints of insufficient drainage, with injury, as a result of selecting trocar catheters that had fewer eyelets than displayed on the product label. Although the use of a trocar catheter with two eyelets may be effective in most patients, the potential risks related to use of the trocar catheter with 2 eyelets are: incomplete drainage of pleural effusion or pneumothorax, the need for repeat chest tube or pleural drain insertion, and surgical site infection.

ACTION REQUIRED:
Please read the recall letter completely and forward to users and staff who use Atrium Trocar Catheter products.

Please complete the enclosed Recall Reply Form to acknowledge receipt of this notification. Please return the Recall Reply Form to the following e-mail address: trocarrecall@atriummed.com or you may fax the form to 1-603-386-6590.

IF you DO have any of the identified used affected Trocar Catheter devices, remove the product from your supply/inventory and place in quarantine for return.

Replacement product is not available as all Trocar catheters have been discontinued.

Determine if you have a substitution for the affected Atrium Trocar Catheter product. The substitution list provided in Table 2, below, can be referenced for your convenience in identifying a substitute from an alternate supplier.
| Trocar Catheter Size | Recall Product | Substitute | | |
|---------------------|----------------|------------|----------------|
|                     | ATRIUM         | ARGYLE/COVIDIEN | TELEFLEX | AXIOM |
| 8 Fr                | 8408           | 560805     | N/A        | 522208 |
| 10 Fr               | 8410           | 561019     | DTRC-10S  | 522210 |
| 12 Fr               | 8412           | 561027     | DTRC-12S  | 522212 |
| 16 Fr               | 8416           | 561035     | DTRC-16S  | 522216 |
| 20 Fr               | 8420           | 561043     | DTRC-20S  | 522220 |
| 24 Fr               | 8424           | 561050     | DTRC-24S  | 522224 |
| 28 Fr               | 8428           | 561068     | DTRC-28S  | 522228 |
| 32 Fr               | 8432           | 561076     | DTRC-32S  | 522232 |

**Table 2: Trocar Catheter Substitution List – Product Codes**

**ATTENTION DISTRIBUTORS:** Your immediate attention is required if you have shipped any affected Atrium Trocar Catheter products to accounts. Please forward this Urgent Medical Device Recall Notice to your accounts as soon as possible. As outlined in the “ACTION REQUIRED” section on page 2, please ensure that your accounts complete the Recall Reply Form and return the Recall Reply Form to the following e-mail address: trocarrecall@atriummed.com or you may fax the form to 1-603-386-6590. Also, ensure that your accounts remove unused affect product from their supply/inventory and place in quarantine for return.

Please contact Atrium Medical Customer Service at 1-800-370-7899, Monday through Friday between 9:00 am to 5:00 pm, for a Return Goods Authorization to return the product and receive credit.

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

We apologize for any inconvenience that this may cause to you or your patients.

Thank you for your cooperation and immediate assistance.

Sincerely,

Mark Dinger
Senior Regulatory Affairs Specialist
Getinge USA Shared Service
45 Barbour Pond Drive
Wayne, New Jersey 07470
URGENT MEDICAL DEVICE RECALL (REMOVAL) – RECALL REPLY FORM

EMAIL TO: trocarrecall@atriummed.com or
FAX BACK TO: 1-603-386-6590

ATRIUM TROCAR CATHETERS
CODE NUMBERS: 8408, 8410, 8412, 8416, 8420, 8424, 8428, 8432
ALL LOT NUMBERS

HOSPITAL: [INSERT CUSOMER NAME]
[INSERT CUSTOMER ADDRESS]

If you do not have any Atrium Trocar Catheter to return, then please check here ☐ and sign below and return the form.

If you currently have Atrium Trocar Catheters, please enter the quantity of product that you will be returning: _______

If you have affected Trocar Catheter product, please contact Atrium Medical Customer Service at 1-800-370-7899, Monday through Friday between 9:00 am to 5:00 pm, for a Return Goods Authorization to return the product and receive credit. Please enter your Return Goods Authorization number: ____________________________

Please complete the form below by entering the required information, including signature and date, to acknowledge that you have reviewed and understand the Urgent Medical Device Recall (REMOVAL) Notice, have notified all relevant users and staff in your facility and will return all affected Atrium Trocar Catheters.

Print Name: ____________________________
Signature: ____________________________ Date: ____________________________
Title: ____________________________
Phone: ____________________________
Hospital Name: ____________________________
City and State: ____________________________

EMAIL TO: trocarrecall@atriummed.com or FAX BACK TO: 1-603-386-6590