MAQUET
GETINGE GROUP

October 26, 2016

via FedEx

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

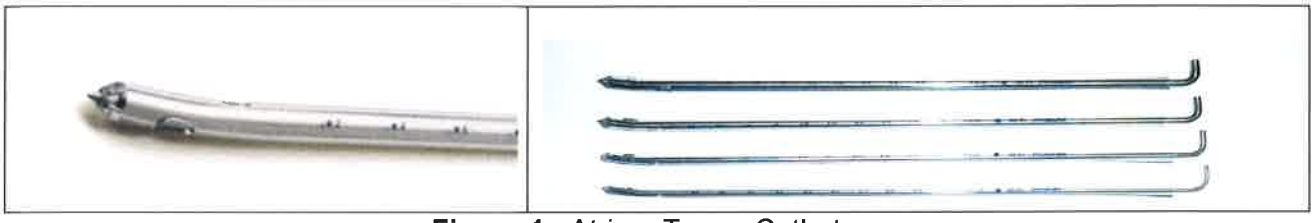

Figure 1: Atrium Trocar Catheters

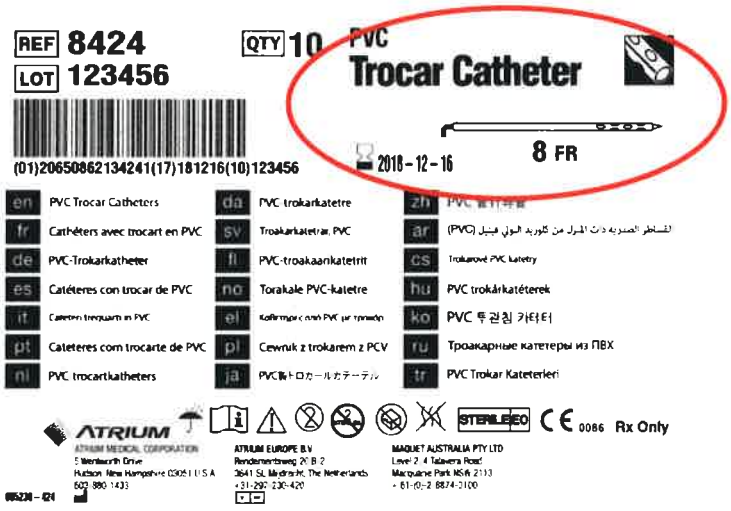

Figure 2: Sample Label

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.

Code Number	Product Description
8408	8 Fr Trocar catheter
8410	10 Fr Trocar catheter
8412	12 Fr Trocar catheter
8416	16 Fr Trocar catheter
8420	20 Fr Trocar catheter
8424	24 Fr Trocar catheter
8428	28 Fr Trocar catheter
8432	32 Fr Trocar catheter

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 Catheters 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.

	Recall Product	Substitute		
Trocar Catheter Size	**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

MAQUET
GETINGE GROUP

October 26, 2016

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: **Customer Number 127925**
CREIGHTON UNIVERSITY
723 N 18TH ST
OMAHA, NE 68178

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

MATERIALS/PURCHASING DEPARTMENT
CREIGHTON UNIVERSITY
723 N 18TH ST
OMAHA, NE 68178

MAQUET
GETINGE GROUP

November 15, 2016 via FEDEX

URGENT MEDICAL DEVICE RECALL - SECOND NOTIFICATION
MAQUET QUADROX OXYGENATORS, ROTAFLOW CENTRIFUGAL PUMPS, HLS SET ADVANCED AND CUSTOM TUBING SETS
POTENTIAL FOR UNEXPECTED INFLAMMATORY RESPONSE

All Product Received Prior to January 1, 2016

PLEASE FORWARD THIS SECOND NOTIFICATION INFORMATION TO ALL USERS, PERFUSIONISTS, AND STAFF WHO MAY USE, OR PREPARE MAQUET QUADROX OXYGENATORS, ROTAFLOW CENTRIFUGAL PUMPS, HLS SET ADVANCED AND CUSTOM TUBING SETS.

Dear Materials/Purchasing Manager or Designee,

This is a second notification. Maquet sent the Risk Manager at your facility, a medical device field correction letter, dated February 23, 2016, for certain Maquet Cardiopulmonary ("MCP") devices regarding a voluntary recall based on the potential risk of exposure to endotoxin with use of the following products delivered prior to January 1, 2016, and requesting that you complete and return the field correction response form to Maquet. Since a signed field correction response form has not been received at Maquet, this second notification is being issued in an attempt obtain acknowledgment from you. Please complete the enclosed field correction response form on page 4 and submit the form to Maquet as soon as possible.

The recall does not include a removal of the devices. Many of the devices listed in this notice do not have an alternative on the market in the U.S.

- **All sizes and membrane types of QUADROX-i oxygenators,**
  - **QUADROX –i(D) Adult, Small Adult, Pediatric and Neonatal with SOFTLINE and BIOLINE Coating; BE-HMOD xxxxx, BEQ-HMO xxxxx, BEQ-HMOD xxxxx, BO-VKMO xxxxx, HMO xxxxx, HMOD xxxxx, VKMO xxxxx, X HMO xxxxx U, X HMOD 30000 U, X VKMO xxxxx U, and X 1895.**
  - **QUADROX-iR with SOFTLINE and BIOLINE Coating; XVIVO HMO 70100 U.**
- **Rotaflow pumps BIOLINE/SOFTLINE Coating; BEQ-RF32, BEQ-RF-32-USA, BO-RF-32, BO-RF-32 USA, RF-32, RF-32 USA, RF-32u.**
- **HLS Set Advanced**
  - **Small Adult 5.0 with BIOLINE Coating BEQ-HLS 5050, 70105.2797**
  - **Adult 7.0 with BIOLINE Coating BEQ-HLS 7050, 70105.2794**
  - **Adult 7.0 with SOFTLINE Coating BO-HLS 7050, 70105.2786**
- **Custom Tubing Packs containing products listed above; T xxxxx, TOP xxxxx, BE-TOP xxxxx, BO-TOP xxxxx, BO-T xxxxx, BEQ-T xxxxx, and BEQ-TOP xxxxx.**

NOTE: (A lower case "x" was used to represent variations of catalog numbers)

Reason for the Recall:

MCP has determined that listed products may possess levels of endotoxin that exceed regulatory limits. You are being contacted because you have been identified as one the recipients of an affected unit or units.

Risk to Health:

Endotoxins are part of the outer membrane of the cell wall of Gram-negative bacteria. Endotoxins are invariably associated with Gram-negative bacteria whether the organisms are pathogenic or not. Endotoxins stimulate the immune system cells to release proteins called cytokines. This cascade of inflammatory mediators leads to symptoms that may include fever, general body aches, and sepsis.

To date, MCP has not received reports of systemic issues or unexpected inflammatory responses relating to device endotoxins.

MCP has become aware that its sampling plans for endotoxin testing on products labeled "non-pyrogenic" were not compliant with USP Requirements for Endotoxin on Medical Devices and *ANSI/AAMI ST72: 2011 Bacterial Endotoxins – Test Methods, routine monitoring, and alternatives to batch testing.* While Maquet has not received any complaints of adverse events related to endotoxin exposure, Maquet cannot ensure devices labeled "non-pyrogenic" are without endotoxin based on a statistically valid sampling plan.

Since the lapse in testing was discovered, MCP has performed a gap assessment and implemented a statistically valid sampling plan. In addition to this sampling plan, MCP continues to monitor endotoxin levels in the water system at the manufacturing facility.

Actions to be taken by the Device User:

- Review the above referenced list of products to determine if you have any affected product.
- MCP has determined that the product will not be removed from the field. As such please ensure you monitor the following:
  - Monitor patients for signs of Systemic Inflammatory Response Syndrome (SIRS)
    - Monitor and treat signs of SIRS/sepsis according to your facility's protocols and clinical judgment.
  - Support shock symptoms and maintain circulatory and hemodynamics per your facility's protocols and care guidelines.

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

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

Please acknowledge receipt of the Urgent Recall Medical Device Notice by completing and returning the enclosed response form. Please either fax the completed form to 1-973-629-1518 or send via email to MCPrecall2016@maquet.com.

We apologize for any inconvenience that this may cause to you or your patients. For any questions, please contact your Maquet sales representative or Maquet Customer Service at 1-888-627-8383 (press option 2, followed by option 2) Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. EST.

Thank you for your cooperation and immediate assistance.

Sincerely,

Karen LeFevere

Karen LeFevere
Director of Regulatory Affairs and Field Action Compliance
MAQUET Medical Systems
45 Barbour Pond Drive
Wayne, New Jersey 07470

MAQUET
GETINGE GROUP

November 15, 2016

SECOND NOTIFICATION
URGENT MEDICAL DEVICE RECALL- Response Form
EMAIL TO: MCPrecall2016@maquet.com or
FAX BACK TO: 1-973-629-1518

MAQUET QUADROX OXYGENATORS, ROTAFLOW CENTRIFUGAL PUMPS, HLS SET ADVANCED AND CUSTOM TUBING SETS POTENTIAL FOR UNEXPECTED INFLAMMATORY RESPONSE

HOSPITAL: **CREIGHTON UNIVERSITY**
723 N 18TH ST
OMAHA, NE 68178

Your timely response to the Second Notification, Urgent Medical Device Recall Notice is requested. Please complete and email/fax this form to MCPrecall2016@maquet.com or 1-973-629-1518 within three (3) business days.

Acknowledgment: I acknowledge receipt of MAQUET's Second Notification Urgent Medical Device Recall Notice, dated November 15, 2016 and have notified users in my facility:

_____
Initial

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 Notice and have notified all relevant users and staff in your facility.

Print Name: _____

Signature: _____ Date: _____

Title: _____

Phone: _____

Hospital Name _____

City and State _____

EMAIL TO: MCPrecall2016@maquet.com or FAX BACK TO: 1-973-629-1518