Atrium Medical Corporation

Notification Guide & Certificate of Medical Necessity Form

FEBRUARY 3, 2015

FOR US CUSTOMERS ONLY

Contents

1. Overview

This Notification Guide provides information about changes in the availability of certain products made by Atrium Medical Corporation (Atrium) as a result of our entry into a civil Consent Decree (Decree) with the U.S. Department of Justice (DOJ) on behalf of the U.S. Food and Drug Administration (FDA).

This guide also provides information on how to maintain continued supply of the Atrium products you are currently using, including how to submit a Certificate of Medical Necessity (CMN), see Section 5 on page 7.

If you have questions about the availability of Atrium products, please call your local sales representative. In addition, because we have created a website for you to be kept informed about this issue, please visit www.atriummed.com/consentdecree for more information.

Background

Atrium, along with three other affiliated MAQUET companies, entered into a Decree with the U.S. Government that was approved by the Court on February 3, 2015. The Decree addresses concerns raised by FDA during inspections of Atrium and other MAQUET manufacturing facilities conducted in 2013. The government concluded that Atrium and MAQUET had violated the Federal Food, Drug, and Cosmetic Act by manufacturing and selling devices that were not in conformity with FDA's current Good Manufacturing Practices and quality system regulations. We started making corrections to our facilities in 2013 and they are well underway.

Under the Decree, manufacturing operations at Atrium facilities in Hudson, New Hampshire will be temporarily suspended with regard to certain products while corrections are being made. Atrium specializes in manufacturing medical devices for the treatment of coronary and vascular disease, tracheal bronchial management, chest trauma, hernia and soft tissue injury.

Atrium may continue to distribute certain products inside and outside of the U.S. that are deemed medically necessary under the Decree, provided that the authorized representatives of U.S. and International customers have signed the attached CMN form certifying that, after learning from this Notification Guide of the FDA findings at the Atrium Hudson manufacturing facility, and evaluating the relevant risks and benefits, there is an immediate medical need for the continued use and purchase of these products. Some other products manufactured by Atrium will be temporarily unavailable, once existing inventory located at our distribution facilities has been exhausted.

Other MAQUET companies inside and outside of the U.S. will continue to produce and distribute products globally without interruption.

2. Restricted Products

Under the terms of the Decree, the following products manufactured at Atrium's Hudson, New Hampshire facilities will be unavailable until further notice, except to the extent that these products are in current inventory at our distribution facilities.

We regret the inconvenience caused by the temporary unavailability of these products. We are committed to helping you serve your patients, and our sales representatives will work with you to identify other products that can provide the same or a similar service until the products below are available again.

Restricted products include:

Product Area	***Product Name***
BioSurgery	Prolite
	Prolite Self-Forming Plug
	Prolite Ultra
	Prolite Ultra Self-Forming Plug
	ProLoop
	C-QUR
	C-QUR V-Patch
	C-QUR Tacshield
	C-QUR FX
	C-QUR CentriFX
	C-QUR Mosaic
	C-QUR Film
Vascular Grafts	FLIXENE
	FLIXENE with IFG
	Advanta VXT
	Advanta VS
	Advanta SuperSoft
	Advanta SST
	Advanta SST Large Diameter
Vascular Graft Accessories	Tunneler
	Vein Graft Tunneling System
Vascular Patch	Ivena Vascular Patch

3. Restricted Products Available with Certificate of Medical Necessity

Certain products manufactured at Atrium's Hudson facilities, but not those listed in Section 2 on page 4, have been deemed **medically necessary under the Decree** and will continue to be made available to customers inside and outside of the U.S, provided that the authorized representatives of U.S. and International customers have signed the attached CMN form certifying that, after learning from this Notification Guide of the FDA findings at the Atrium Hudson manufacturing facility, and evaluating the relevant risks and benefits, there is an immediate medical need for the continued use and purchase of these products.

Restricted products available with a Certificate of Medical Necessity include:

Product Area	***Product Name***	***Accessories***
Oasis Dry Suction Water Seal Drains, including accessories	Oasis Chest Drain	Pneumostat PVC Catheters PVC Firm Catheters Silicone Catheters ATS Blood Bags Pleuraguide Kit
Ocean Wet Suction Water Seal Drains, including accessories	Ocean Chest Drain	
Express Dry Suction Dry Seal Drains, including accessories	Express Chest Drain	
	Express Mini-500 Chest Drain	
Local Therapeutic Infusion Catheters	ClearWay RX Catheter	
	ClearWay OTW Catheter	
Covered Stents	iCAST Covered Stent	

4. Other MAQUET Company Products Available without Restriction

All other MAQUET companies inside and outside of the U.S. will continue to produce and distribute products globally without interruption. This includes all products manufactured and distributed by:

- MAQUET Cardiac Assist
- MAQUET Cardiopulmonary
- MAQUET Cardiovascular
- MAQUET Critical Care
- MAQUET Medical Systems
- MAQUET Surgical Workplaces

5. Submitting a Certificate of Medical Necessity

Atrium, along with three other affiliated MAQUET companies, have entered into a civil Consent Decree with the DOJ on behalf of FDA. The Decree permits Atrium to continue to distribute certain products identified on page 5 of this Notification Guide to customers inside and outside of the U.S.

Below is a summary of the steps that you, as the customer, need to take to obtain the products deemed medically necessary under the Decree.

To continue to receive medically necessary products:

- The Certificate of Medical Necessity (CMN) form included in Appendix 1 on page 8 must be completed and signed by an authorized representative of the customer certifying that, s/he is aware of FDA's findings and deems the product necessary.
- Customers must provide the completed CMN form to Atrium as soon as possible in order to continue receiving medically necessary restricted products.
- Please return the completed CMN form to Atrium in one of three ways:
  - *PDF:* cmn@atriummed.com
  - *U.S. Fax:* 1-800-880-6976
  - *Mail:*

    Office of Medical Affairs
    Atrium Medical Corporation
    5 Wentworth Drive
    Hudson, NH 03051 U.S.A.

Your Atrium sales representatives will be contacting you to assist in completing the CMN form, and to discuss any additional questions you may have.

Appendix 1: Certificate of Medical Necessity (CMN) Form

Please provide the following information:

Customer name:_____

Address: _____

_____

City: _____ State: _____

Zip/Postal Code: _____ Country: _____

After reading the attached Notification Guide regarding the FDA findings at the Atrium Hudson manufacturing facility, I certify that I evaluated the relevant risks and benefits and concluded that there is an immediate medical need for the continued use and purchase of the Atrium products checked below and their associated parts, components, and accessories.

- ☐ Chest Drains (Ocean/Oasis/Express)
- ☐ Local Therapeutic Infusion Catheters (ClearWay RX/OTW)
- ☐ Covered Stents (iCAST)

Signature: _____

Customer name: _____

Name (print): _____

Title: _____

Date: _____

Telephone: _____

E-mail (if available): _____

Please return the completed CMN form to Atrium in one of three ways:

- *PDF:* cmn@atriummed.com
- *US Fax:* 1-800-880-6976
- *Mail:*
  Office of Medical Affairs
  Atrium Medical Corporation
  5 Wentworth Drive
  Hudson, NH 03051 U.S.A.

Appendix 2: Atrium Contact Information

Country	*Contact Information*
United States	**Atrium Medical Corporation** Office of Medical Affairs 5 Wentworth Drive Hudson, NH, 03051 U.S.A Tel: 1-603-880-1433 Fax: 1-800-880-6976 Email: cmn@atriummed.com