[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE CORRECTION

Atrium Pneumostat Chest Drain Valve

Inadequate Precaution/Warnings/Contraindications In Instructions For Use

Product Code/Part Number:	**16100**
Distributed Affected Lot Number:	**All**
Manufacturing Dates:	**July 20, 2018 to October 26, 2020**
Distribution Dates:	**Country specific-** SSUs to fill in using final ship history

PLEASE FORWARD THIS INFORMATION TO ALL CURRENT AND POTENTIAL PNEUMOSTAT CHEST DRAIN VALVE USERS WITHIN YOUR HOSPITAL / FACILITY.

IF YOU ARE A DISTRIBUTOR WHO HAS SHIPPED ANY AFFECTED PRODUCTS TO CUSTOMERS, PLEASE FORWARD THIS DOCUMENT TO THEIR ATTENTION FOR APPROPRIATE ACTION.

Dear Hospital Contact,

Atrium/Getinge is initiating a voluntary Medical Device Correction for the Atrium Pneumostat Chest Drain Valve due to the Instructions for Use (IFU) not providing sufficient precautions/warnings/contraindications related to re-expansion of a collapsed lung due to pneumothorax that may result in an unreasonable risk of harm.

Identification of the issue:

Atrium/Getinge has received a complaint involving an unfortunate event in which a preterm infant required prolonged resuscitation, was intubated and ventilated with difficulty. A resulting left tension pneumothorax subsequently developed and was treated with needle decompression followed by placement of an intercostal catheter (chest tube) which was connected to an Atrium Pneumostat Chest Drain Valve (a 'gravity only' device; no active suction function). The subsequent right tension pneumothorax with subcutaneous emphysema was treated with placement of a right intercostal catheter (chest tube), and was also connected to a Pneumostat Chest Drain Valve. Subsequent follow up chest x-ray showed development of bilateral tension pneumothorax. The infant expired the same day.

The Atrium Pneumostat Chest Drain Valve offers only passive drainage or gravity drainage via natural forces of air and/or fluid from the thoracic cavity. It does not have an active suction feature.

Although use of an Atrium Pneumostat Chest Drain Valve aligns with current medical practice guidelines, when a patient's initial clinical presentation is high risk and their subsequent status appears to be fluctuating and evolving rapidly, an active suction option should be considered.

Atrium/Getinge is in the process of updating the Pneumostat Chest Drain Valve Instructions for Use (IFU); in the meantime, the hospital can continue use of the product that you have with the IFU that was provided (we are not requesting devices be returned), along with the consideration of the following:

REVISED Indication for Use:
Pneumostat is indicated for use with adult patients in a variety of medical conditions in which evacuation of air with or without ancillary fluid is required from the pleural cavity and is also designed to facilitate ambulation. These medical conditions may include pneumothorax, thoracic injury, and other related conditions requiring air evacuation.

NEW Contraindication:
Not for use in pediatric patients.

NEW section for Target Population:
The Pneumostat is intended for adult patients who require gravity drainage.

NEW Warning:
Do not use in situations that require active negative pressure in the pleural space.

NEW Precaution:
The use of the Pneumostat is restricted to the clinical setting.

NEW Precaution:
The use of the Pneumostat is restricted to professional healthcare users familiar with thoracic surgical procedures and techniques, including the use of thoracic chest drains.

Actions to be taken by Customer:

Please examine your inventory immediately to determine if you have any of the Atrium Pneumostat Chest Drain Valves with the product code 16100.

Please ensure that all Pneumostat Chest Drain Valve users at your facility are aware of this notice and post a copy of the Warning Label on **Page 4** in all inventory locations within your facility where the Atrium Pneumostat Chest Drain Valves are stored.

Please complete and sign the attached URGENT FIELD SAFETY NOTICE MEDICAL DEVICE CORRECTION– RESPONSE FORM FORM on **page 5** to acknowledge that you have received this notification. Return the completed form to Atrium/Getinge to INSERT LOCAL SSU EMAIL ADDRESS or by faxing the form to INSERT LOCAL SSU FAX NUMBER.

This voluntary recall only affects the product listed on page 1; no other products are affected by this voluntary recall.

We apologize for any inconvenience this recall may cause. If you have any questions, please contact your local Datascope/Getinge representative

Sincerely,

Maryanna Krivak

Regulatory Affairs and Quality Compliance Field Actions

USA Shared Services

Getinge

45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.getinge.com

URGENT MEDICAL DEVICE – Correction

ATRIUM PNEUMOSTAT CHEST DRAIN VALVE

PN-16100 LOTS-ALL

PLEASE POST THIS WARNING LABEL NEAR ALL PRODUCT INVENTORY

Inadequate Precaution/Warnings/Contraindications in Instructions for Use

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URGENT FIELD SAFETY NOTICE - MEDICAL DEVICE CORRECTION RESPONSE FORM

Atrium Pneumostat Chest Drain Valve

Product Code/Part Number: 16100

Inadequate Precaution/Warnings/Contraindications in Instructions for Use

Return the completed form by FAX to INSERT LOCAL SSU FAX NUMBER **or by EMAIL to** INSERT LOCAL SSU EMAIL ADDRESS

Distribution Date Range: Country specific- SSUs to fill in using final ship history

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS
CITY, STATE, ZIP CODE]

Please acknowledge that you have read and understand this Medical Device Correction Notice for the Pneumostat Chest Drain Valve. Please ensure that all users of the Atrium Pneumostat Chest Drain Valve at this facility have been notified accordingly.

Please provide the required information and signature below.

Facility Representative Information

Signature:_____ Date:_____

Name:_____Phone:_____

Title:_____ Department:_____

Hospital Name:_____

Address, City and State:_____

Return the completed form by FAX to INSERT LOCAL SSU FAX NUMBER **or by EMAIL to** INSERT LOCAL SSU EMAIL ADDRESS

Getinge
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www.getinge.com