Month DD, 2023

URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE – CORRECTION

Atrium Express Mini 500 Dry Seal Chest Drain

Manufacturer FSCA number 3011175548 -02/15/2023-001-C

Product REF Number:	Express Mini 500 Dry Seal Chest Drain - 16400
UDI Number	00650862164008
Affected Lot Number:	All lots manufactured 3 years prior to correction initiation
Manufacturing Dates:	June 8, 2020 – December 8, 2022
Distribution Dates:	June19, 2020 – January 17, 2023

Dear Risk Manager,

Atrium/Getinge is initiating a voluntary Medical Device Correction for the Atrium Express Mini 500 Dry Seal Chest Drain. The Instructions for Use (IFU) for the Express Mini 500 Dry Seal Chest Drain does not provide sufficient precaution against draining the device for continued use. Additionally, the IFU does not provide sufficient precaution or warning against the use of the device outside the healthcare setting. **No Devices Need to Be Returned.**

Identification of the Issue:
In 17 complaints over about a 3-year period, Atrium/Getinge identified the use of the Express Mini 500 Dry Seal Chest Drain in outpatient (non-healthcare facility) settings and identified the use of the device sampling port to empty the drain for continued use on the same patient. The Express Mini 500 Dry Seal Chest Drain is intended for single use in a healthcare facility setting for patients that require 500mL or less fluid drainage for their intended time using the drain.

Risk to Health:
The identified harms (including anxiety, dyspnea, respiratory distress, hemodynamic instability, infection, and additional medical intervention) and associated risk to the patient are largely due to management of the device in an outpatient setting (ex: home setting) being performed by non-clinical/non-medical personal individuals or by clinical care providers not familiar with management of a thoracic drain. Additionally, the Luer port is not designed or intended to be used as a means of draining fluid from the collection chamber of the device for continued use.

Updated Instructions – New Warning and Precautions:
The facility can continue use of the product with the IFU that was provided along with the consideration of the following:

- **NEW and Applicable Existing Warnings and Precautions for Express Mini 500:**
  - **NEW Warning**: The Express Mini 500 is restricted for use by trained healthcare providers familiar with cardiothoracic surgical procedures and techniques, including the use of chest drains.
  - **NEW Precaution**: The Express Mini 500 is restricted for use in a healthcare facility. The Express Mini 500 should not be used for outpatient drainage.
  - **NEW Precaution**: Use of the Luer port is intended only for sampling patient drainage. Do not use the Luer port or any other means to empty fluid from the collection chamber.
  - **Existing Precaution:** Replace chest drain if damaged or when collection volume meets or exceeds maximum capacity.

Actions to be Taken by the Customer:

- Please ensure that all Atrium Express Mini 500 Dry Seal Chest Drain users at your facility are aware of this Safety Notice and post a copy of the Notice on Page 3 in all inventory locations within your facility where the devices are stored. Your facility can continue use of the device. **No devices need to be returned.**
- Please forward this information to all current and potential Atrium Express Mini 500 Dry Seal Chest Drain 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.
- Please complete and sign the attached URGENT: MEDICAL DEVICE CORRECTION - RESPONSE FORM on Page 4 to acknowledge that you have received this notification. Return the completed form by emailing a scanned copy of the completed form to [INSERT SSU EMAIL] or by faxing the form to [INSERT SSU FAX].

Type of Action Taken by Getinge:
Atrium /Getinge has identified the cause of the issue and has initiated updates to the Express Mini 500 Dry Seal Chest Drain Instructions for Use (IFU).

This voluntary correction only affects the products listed on Page 1; no other products are affected by this voluntary correction.

We apologize for any inconvenience this correction may cause. If you have any questions, please contact your Atrium/Getinge representative or office: [Insert SSU Contact info]

Sincerely,

_____

URGENT: MEDICAL DEVICE – CORRECTION

ATRIUM EXPRESS MINI 500 DRY SEAL CHEST DRAIN

Product Code: 16400
Lots: ALL

PLEASE POST THIS WARNING LABEL NEAR ALL PRODUCT INVENTORY

Inadequate Instructions for Use

Atrium/Getinge is initiating a voluntary Medical Device Correction for the Express Mini 500 Dry Seal Chest Drain due to the Instructions for Use (IFU) not providing sufficient warning/precaution against the use of the device outside the healthcare setting, or sufficient precaution against draining of device for continuous use.

READ PRIOR TO USE OF DEVICE

NEW and Applicable Existing Warnings and Precautions for Express Mini 500 Dry Seal Chest Drain:

1) **NEW Warning:** The Express Mini 500 is restricted for use by trained healthcare providers familiar with cardiothoracic surgical procedures and techniques, including the use of chest drains.

2) **NEW Precaution:** The Express Mini 500 is restricted for use in a healthcare facility. The Express Mini 500 should not be used for outpatient drainage.

3) **NEW Precaution:** Use of the Luer port is intended only for sampling patient drainage. Do not use the Luer port or any other means to empty fluid from the collection chamber.

4) **Existing Precaution:** Replace chest drain if damaged or when collection volume meets or exceeds maximum capacity.

MONTH DD, 2023

URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE CORRECTION RESPONSE FORM

Atrium Express Mini 500 Dry Seal Chest Drain

Product Code: 16400

FAX BACK TO: INSERT SSU FAX#. EMAIL TO: INSERT SSU EMAIL

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

Please acknowledge that you have read and understand this URGENT FIELD SAFETY NOTICE: MEDICAL DEVICE CORRECTION for the Atrium Express Mini 500 Dry Seal Chest Drain. Please ensure that all users of the Atrium Express Mini 500 Dry Seal Chest Drain at this facility have been notified accordingly. **No Devices Need to Be Returned.**

Please complete and return this form whether you have affected product or not.

Facility Representative Information

Signature:_____ Date:_____

Name:_____ Phone:_____

Title:_____ Department:_____

Hospital Name (if different from above):_____

Address, City and State (if different from above):_____

_____

FAX BACK TO: INSERT SSU FAX#. EMAIL TO: INSERT SSU EMAIL