[Month DD, YYYY] via *[Insert method of delivery]*

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION
FSCA 3011175548-12/13/2023-002-C
Atrium Express Dry Suction Dry Seal Chest Drains

Product Description	Product Code / Part Number / REF	UDI Device Identifier (DI)
DRAIN, EXPRESS SINGLE W/AC	4000-100N	00650862115130

Distributed Affected Lot Numbers:	466080, 466267, 466455, 466637, 466951, 467193, 467194, 467195, 467352, 467475, 467476, 468395, 468856, 468857, 468858, 469402, 469403, 469918, 469919, 469920, 470148, 471069, 471805, 471806, 472581, 473747, 474076, 474077, 474511, 474950, 474967, 474982, 475228, 475487, 477950, 483107, 483108, 483180, 483533, 483534, 485228, 485229, 485230, 485231, 486071, 487808, 487809, 487810, 489161, 489877, 489878, 490138, 490744, 490762, 492079, 492644, 493679, 494224, 495193, 495194, 495208, 496207, 496208, 496692, 496774, 497139, 498063, 498578, 498974, 499344, 499805, 499822
Manufacturing Dates for All:	From November 20, 2020 to September 5, 2023
Distribution Dates for All:	February 12, 2021 to October 31, 2023

Dear Hospital Contact,

Getinge/Atrium Medical Corporation is initiating a Medical Device Correction for the above referenced lots of Atrium Express Dry Suction Dry Seal Chest Drain (Product Code: 4000-100N Single Collection).

The Express chest drain (4000-100N) for thoracic drainage is a disposable, dry suction operating system with 2100 mL collection volume, dry suction regulator, and mechanical valves to provide seal protection for the patient. The chest drain is equipped with a patient tube and an in-line connector for system change-out and a graduated air leak monitor with pre-measured sterile water syringe (for air leak detection). The Express chest drain is packaged sterile. The chest drain is for single patient use only.

The Express chest drain was shipped with sterile water from Nurse Assist, which could be used to determine if an active pneumothorax ("air leak") is present.

Identification of the issue:
On November 8, 2023, Getinge received notice from Nurse Assist, LLC that its Sterile Water, USP, 30mL syringes were being recalled because they could not be verified to be sterile. Pre-packaged with every Express chest drain, the 30mL sterile water syringe is intended to fill the air leak monitor chamber for air leak detection during or after initial device set-up, if desired.

During a chest drain knock-over event (device not kept in upright position), the water in the air leak monitor chamber could migrate from the air leak monitor chamber to the drainage fluid collection chamber. The patient could potentially be exposed to an infectious pathogen; therefore, the potential risk to the patient is high.

Risks To Health:
The company's Health Hazard Evaluation (HHE) determined that the Sterile Water, USP, 30mL syringes supplied by Nurse Assist, LLC posed similar patient risk for this Express chest drain. Under normal use, the water within the syringe is non-patient contacting. If the chest drain is knocked over (i.e., device not kept in upright position), the water in the air leak monitor chamber could migrate to the drainage fluid collection chamber. The chest drain fluid collection chamber is connected directly to the patient's indwelling thoracic catheter via the patient tubing, and there is no physical barrier to prevent infectious material from reaching the patient.

- For the Express chest drain (4000-100N), the patient could potentially be exposed to an infectious pathogen from the water supplied by Nurse Assist. Therefore, the potential risk to the patient is high.

If a patient was already successfully treated with one of the affected Express chest drains, there is no expected negative impact.

There have been no adverse events or complaints reported related to this issue for the affected device lot numbers.

Actions to be taken by the customer:

Our records indicate that you have received one or more of the Atrium Express Dry Suction Dry Seal Chest Drains from the affected lots listed on page 1.

I. Please examine your inventory immediately to determine if you have any of the Atrium Express Dry Suction Dry Seal Chest Drains with the REF and LOT numbers listed in this notice.
II. Should you have any affected product, please forward this notification to the clinical area(s) of your facility where this product may be used/stored. The LOT Number (6 digit code) can be found on the product label (illustrated in Figure 1 below.)

Figure 1: Example Label 4000-100N Figure

III. This Medical Device Correction only affects the sterile water syringe (Sterile Water, USP, 30mL) pre-packaged with the Express chest drains. Do not use this syringe, which cannot be guaranteed as having the required Sterility Assurance Level (SAL) of 10^{-6}. When used without the provided syringe, the Express chest drains are safe to use and have no product quality or compliance issues.

<u>You have the following options:</u>

a. If visualization of active pneumothorax is not needed, keep the affected Express chest drains and set up without water.

i. To use Express chest drains without water, first dispose the pre-packaged sterile water syringe. Set up the chest drain per the Instructions for Use but omit Step 4, Air Leak Monitor, instructing to fill the air leak monitor. The Express chest drains contain a Vacuum Protection Valve (VPV), which functions as the water seal and does not require the use of water.

b. Use the Express chest drain as intended by replacing the sterile water syringe provided with the drain with a new syringe filled with sterile water using aseptic technique.

i. Dispose the pre-packaged sterile water syringe provided with the affected Express chest drain

ii. The steps to set up the chest drain with locally sourced sterile water are:

a. Obtain necessary supplies for device set-up:

i. (1) New Luer-lock syringe (30mL or greater in size)

ii. (1) Sterile Water bottle (Minimum of 30mL of sterile water)

iii. Fill new syringe with sterile water (30mL required for initial set-up) using aseptic technique

iv. Screw syringe onto Luer-lock port on back of Express chest drain and add 30mL into the air leak monitor

v. Verify sufficient volume of sterile water in the Express chest drain by checking the fluid level to ensure it reaches the dotted fill line of the air leak monitor (as required by the Instructions for Use)

vi. Unscrew syringe from Luer-lock port

vii. Drain is set up and ready for use

c. Return the affected Express chest drains to Getinge/Atrium Medical Corporation via Return Good Authorization (RGA). If you have any affected Express 4000-100N from the lots listed on page 1, this product can be returned.

i. Please contact your local Atrium/Getinge Customer Service at *[INSERT LOCAL SSU CUSTOMER SERVICE TELEPHONE NUMBER]* between the hours of *[INSERT APPLICABLE LOCAL SSU CUSTOMER SERVICE HOURS OF OPERATION]* to request a return authorization and shipping instructions to return any affected unused/unexpired product. You will receive credit upon your acknowledgement that you have affected product for return.

IV. Whether or not you have affected product(s) with the REF and LOT numbers listed in this notice, please complete and sign the attached MEDICAL DEVICE – CORRECTION RESPONSE FORM (page 6) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to *[INSERT LOCAL SSU EMAIL ADDRESS]* or by faxing the form to *[INSERT LOCAL SSU FAX NUMBER]*.

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

Actions to be taken by Getinge:

If requested, Getinge will facilitate the removal of affected Express chest drain 4000-100N products from your facility and provide credit for your return of these products.

This Medical Device Correction only affects the Express chest drain 4000-100N products listed on page 1; no other products are affected.

We apologize for any inconvenience this Medical Device Removal may cause. If you have any questions, please contact your Maquet/Getinge representative.

Sincerely,

_____

[INSERT PRINTED NAME HERE AND SIGN ABOVE]
[INSERT TITLE]

[Month DD, YYYY]

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION – RESPONSE FORM
FSCA 3011175548-12/13/2023-002-C
Atrium Express Dry Suction Dry Seal Chest Drains

DISTRIBUTION DATES: February 12, 2021 to October 31, 2023

ADD ACCOUNT#
[FACILITY NAME
STREET ADDRESS

CITY, STATE, ZIP CODE]

Please complete this entire form where applicable, whether or not you have product to return.

I acknowledge that I have read and understand this Medical Device Correction notice for the affected Atrium Express Dry Suction Dry Seal Chest Drains (REF 4000-100N) with affected lots identified on Page 1 of this letter.

I have ensured that all affected recipients and users of the affected Atrium Express Dry Suction Dry Seal Chest Drains (REF 4000-100N) with affected lots identified on Page 1 of this letter, have been notified accordingly.

If you have no affected product at your facility, check here _____

If you have affected product at your facility, but are choosing to use it, check here _____

If you have affected product (REF 4000-100N) to return, please report it below after calling Customer Support for your RGA#:

Affected Lot Number:	Quantity to Return:	Getinge Return RGA #:

Facility Representative Information:

Signature: _____ Date: _____

Name: _____

Phone: _____ Email: _____

Title: _____ Department: _____

Hospital Name (if different than above): _____
Address, City and State (if different than above): _____

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