Getinge / Atrium Medical Corporation Issues Medical Device Correction for Nurse Assist Syringes Provided with Express Drains

On December 13, 2023, Getinge / Atrium Medical Corporation notified affected customers of a nationwide recall (medical device correction) for certain Atrium Express Dry Suction Dry Seal Chest Drains in response to a voluntary medical device recall initiated by a supplier, Nurse Assist. 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 and the patient could potentially be exposed to an infectious pathogen from the water supplied by Nurse Assist. If a patient was already successfully treated with one of the affected Express chest drains, there is no expected negative impact.

The affected Atrium Express Drains are as follows:

Product part number, product name, and UDI Device Identifier:

- 4000-100N, DRAIN, EXPRESS SINGLE W/AC, 00650862115130
- 4050-100N, DRAIN, EXPRESS BRU W/AC, 00650862115147

Affected lot numbers:

4000-100N:
466080, 469402, 474967, 486071, 495193, 466267, 469403, 474982, 487808, 495194, 466455, 469918, 475228, 487809, 495208, 466637, 469919, 475487, 487810, 496207, 466951, 469920, 477950, 489161, 496208, 467193, 470148, 483107, 489877, 496692, 467194, 471069, 483108, 489878, 496774, 467195, 471805, 483180, 490138, 497139, 467352, 471806, 483533, 490744, 498063, 467475, 472581, 483534, 490762, 498578, 467476, 473747, 485228, 492079, 498974, 468395, 474076, 485229, 492644, 499344, 468856, 474077, 485230, 493679, 499805, 468857 474511, 485231, 494224, 499822, 468858, 474950

4050-100N:
466952, 483249, 490139, 492645, 496693, 467477, 487811, 490763, 494226, 498062, 468860, 487849, 492078, 495731, 499345, 470644, 489162

The affected products were manufactured from November 20, 2020, to September 5, 2023, and distributed from December 18, 2020, through November 8, 2023.

Customers who received the affected products were sent notifications with the following instructions:

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 Figures 1 and 2 below.)

Figure 1: Example Label 4000-100N

Figure 2: Example Label 4050-100N

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.

You have the following options:

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 and/or 4050-100N from the above-listed lots, this product can be returned.

i. Please contact your local Atrium/Getinge Customer Support department at (888) 943-8872 (press option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone) 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 provided with the notification to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to atriumexpressdrains2023.qrc@getinge.com or by faxing the form to 1-866-409-8277.

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

Adverse reactions or quality problems experienced with the use of any of the above-listed products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form at 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 (1-800-332-0178)

If you have any questions, please contact your Getinge representative or call Getinge Customer Support at (888) 943-8872 (press option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This Medical Device Recall/Correction is being made with the knowledge of the U.S. Food and Drug Administration.