Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 219 **dated** 23/10/2023 **Regarding NCMDR FSCA of Atrium Ocean, Oasis, and Express Chest Drains from (mfr: Atrium Medical Corp).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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سلطنة عُمان
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مسقط

Circular No. 219 **/ 2023**

08 -04-1445 H
23 -10-2023

Field Safety Corrective Action of Atrium Ocean, Oasis, and Express Chest Drains from Atrium Medical Corp

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19725
Product	Atrium Ocean, Oasis, and Express Chest Drains.
Description	Chest drainage systems.
Manufacturer	Atrium Medical Corp.
The affected products	Multiple REF numbers of the affected products, please refer to the attachment; Lot: All lots within labeled product expiry; Manufacturing Dates: Any product manufactured on and after July 21, 2020; Distribution Dates: Any product shipped on and after August 6, 2020
Reason	The Instructions for Use (IFU) for the above chest drains do not provide sufficient precaution instruction for proper set up of catheter(s) and patient line connections with single collection chamber chest drains.
Action	1. Your facility can continue use of the device by following " Updated Instructions – New Precaution" in the attachment. 2. Please ensure that all Atrium Ocean, Oasis, or Express Single Collection Chest Drain users at your facility are aware of the content. 3. The updated IFU containing the new Precaution will be communicated to all customers upon release, including reminder of the attachment on Page 4 may be removed upon the facility's receipt of product with the updated IFU. 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

GETINGE

20 September 2023

URGENT FIELD SAFETY NOTICE – MEDICAL DEVICE Correction
FSCA: 011175548-08/18/2023-001-C
Atrium Ocean, Oasis, and Express Chest Drains

Product REF Number	Product Name	UDI
2002-000	DRAIN, OCEAN SINGLE W/AC,S	20650862100017
2002-040	DRAIN, OCEAN SINGLE,PEDI CONNECTOR	20650862100345
2002-100	DRAIN, OCEAN SINGLE W/AC	20650862100093
2002-300	DRAIN, OCEAN SINGLE W/S	20650862100109
2002-400	DRAIN, OCEAN SINGLE	20650862100215
2012-320	DRAIN, OCEAN PEDI W/S	20650862101021
2050-000	DRAIN, OCEAN BRU W/AC,S	20650862103018
3600-100	DRAIN, OASIS SINGLE W/AC	20650862110016
3612-100	DRAIN, OASIS PEDI A/C	20650862111013
3650-100	DRAIN, OASIS BRU W/AC	20650862113017
4000-100N	DRAIN, EXPRESS, SINGLE	20650862115134
4050-100N	DRAIN, EXPRESS, BRU	20650862115141
Distributed Affected Lot Number:	All lots within labeled product expiry	
Manufacturing Dates:	Any product manufactured on and after July 21, 2020	
Distribution Dates:	Any product shipped on and after August 6, 2020	

Dear Customer,

Atrium/Getinge is initiating a voluntary Medical Device Correction for the Atrium Ocean, Oasis, and Express chest drains. The Instructions for Use (IFU) for the Atrium Ocean, Oasis, and Express chest drains do not provide sufficient precaution instruction for proper set up of catheter(s) and patient line connections with single collection chamber chest drains. **No Devices Need to Be Returned.**

Identification of the issue:

Five (5) complaints were received from a single hospital site related to five (5) patients treated with two thoracic catheters connected by a Y-connector to a single collection drain (Part Number 3600-100). Each of the patients experienced a pulling sensation and pain at their catheter insertion sites. In the complaint investigation, it was noted that the catheters were cut too short to enable sufficient distance between the patient and the chest drain when using a Y-connector. This tension caused pain at the patient's catheter insertion site, and as a result, the patients required a higher than typical dosage of pain medication.

During a historical complaint review, one (1) additional complaint was identified as potentially related to the use of two thoracic catheters connected to a single collection chest drain. The complainant reported a patient with two chest tubes experienced an air leak identified through

continuous bubbling in the air leak chamber. It is unknown if the patient was using two separate chest drains or if the two chest tubes were connected to a single collection chest drain.

Risk to Health:
Pain from thoracic catheters/chest tubes is a common complaint for patients that require use of chest drainage systems. Additionally, it is not uncommon for these patients to occasionally require treatment with pain medication. The amount of pain experienced by a patient who is being treated with a thoracic catheter certainly varies. However, the amount of pain experienced may potentially be greater if there is increased pressure/tension/stress placed on the thoracic catheters due to inadequate set up of catheter(s) and patient line connections, such as the use of a Y-connector attaching two catheters together to allow connection of the catheters to a single collection chamber chest drainage system, specifically if the Y-connector is placed in close proximity to where the thoracic catheters exit the patient's thoracic cavity.

Additionally, it is important that proper set up of the catheter(s) and patient line connections avoid any excess tubing, as well as ensures there are tight connections made between the catheters, connector (such as a Y-connector), and chest drainage tubing. If there are not proper connections, there is a risk of the device becoming open to the air and/or loosing suction. This situation could lead to more serious patient harm, such as a delay of intrathoracic drainage (delay of intended therapy) and/or resulting dyspnea, pneumothorax, and hemodynamic instability.

Updated Instructions – New Precaution
The facility can continue to use Atrium Ocean, Oasis, or Express Single Collection Chest Drains with the IFU currently provided along with consideration of the following:

- **NEW Precaution for the Ocean, Oasis, and Express Single Collection drain models:**
    - Ensure proper setup of catheter(s) and patient line connections to avoid potential kinking and/or tension at the thoracic catheter insertion site. For single collection chest drainage systems, it is recommended to use one chest drain per thoracic catheter.

Actions to be taken by the Customer:
Our records indicate that you have received the Atrium Ocean, Oasis, or Express Single Collection Chest Drain that is affected by this voluntary Medical Device Correction.

- Your facility can continue use of the device. **No devices need to be returned.**
- Please ensure that all Atrium Ocean, Oasis, or Express Single Collection Chest Drain users at your facility are aware of this Safety Notice and post a copy of the Notice on Page 4 in all inventory locations within your facility where the devices are stored.
    - Notification of the release of the updated IFU containing the new Precaution will be communicated to all customers upon release, including reminder the Notice on Page 4 may be removed upon the facility's receipt of product with the updated IFU.

- Please forward this information to all current and potential Atrium Ocean, Oasis, or Express Single Collection 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.
- Whether or not your facilty has affected product(s) listed in this notice, please complete and sign the attached MEDICAL DEVICE- CORRECTION RESPONSE FORM (Page 5) to acknowledge that you have received this notification.
- Return the completed form to Getinge by e-mailing a scanned copy to **mubashir.javed@getinge.com**

Type of Action by Getinge:
Atrium /Getinge has identified the cause of the issue and has initiated updates to the Atrium Oasis and Express Chest Drain Instructions for Use (IFU). The Atrium Ocean Chest Drain IFU will not be updated as the product has been discontinued.

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

GETINGE

URGENT: MEDICAL DEVICE – CORRECTION

Atrium Ocean, Oasis, and Express Single Collection Chest Drains

Product Codes: 2002-000, 2002-040, 2002-100, 2002-300, 2002-400, 2012-320, 2050-000, 3600-100, 3612-100, 3650-100, 4000-100N, 4050-100N

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 Atrium Ocean, Oasis, and Express Single Collection chest drains. The Instructions for Use (IFU) for Atrium Ocean, Oasis, and Express chest drains do not provide sufficient precaution to ensure proper set up of catheter(s) and patient line connections with single collection chamber chest drains.

READ PRIOR TO USE OF DEVICE

NEW Precaution for Atrium Ocean, Oasis, and Express Single Collection Chest Drains:

Ensure proper setup of catheter(s) and patient line connections to avoid potential kinking and/or tension at the thoracic catheter insertion site. For single collection chest drainage systems, it is recommended to use one chest drain per thoracic catheter.

GETINGE

20 September 2023

URGENT: Field Safety Notice – MEDICAL DEVICE Correction

RESPONSE FORM

FSCA: 011175548-08/18/2023-001-C

Atrium Ocean, Oasis, and Express Single Collection Drain Models

DISTRIBUTION DATES: Any product shipped on and after 06-AUG-2020

I acknowledge that I have read and understand this Medical Device Correction Notice for the Atrium Ocean, Oasis, and Express Single Collection Chest Drain Models.

I ensure that all users of the Getinge Atrium Ocean, Oasis, and Express Single Collection Chest Drain Models at this facility have been notified accordingly.

No Devices Need to Be Returned.

Facility Representative Information:

Signature:	**Date:**
Name (Printed):	**Title/Department:**
Email:	**Phone:**
Hospital Name:	
Address, City, and State	

Return the completed form by EMAIL to mubashir.javed@getinge.com