

November 30, 2016

**URGENT MEDICAL DEVICE RECALL - FIELD NOTIFICATION
ATRIUM OCEAN, OASIS, EXPRESS and EXPRESS MINI CHEST DRAINS
Packaging Configuration Clarification
All Lot Numbers With Expiration Date Prior To October 2019**

Manufacturing Dates: October 2011 to October 2016

**PLEASE FORWARD THIS INFORMATION TO ALL USERS AND STAFF WHO MAY USE
ATRIUM CHEST DRAIN PRODUCTS.**

Dear Risk Management Staff,

This letter is intended to provide clarification about the current packaging configuration of the Atrium Ocean, Oasis, Express and Express Mini chest drainage products. Atrium chest drainage products are packaged with a double sequential sterile wrap and placed into an outer dust cover. The dust cover is folded over and secured with the package label.

This packaging system is the same configuration used on Atrium chest drainage products for the past 30 years. This Field Notification is to provide clarification as to which part of the packaged drain is sterile.

The label on the outer package denotes the product as being sterile. The chest drain inside the packaging is sterile; the outer dust cover is not sterile. The two sterilization wraps are what provide the sterile barrier for the product.

Please inform responsible personnel of the following steps for introduction of the Atrium Chest Drains into the sterile field.

To introduce the chest drain into the sterile field:

- 1. Remove the wrapped chest drain from the dust cover.**
- 2. Open the 2 sterilization wraps using sterile technique.**
- 3. Only enter the chest drain into the sterile field.**

This Field Notification applies to all Atrium chest drain products listed in Table 1 (ref. **Attachment 1**) with an expiration date prior to October 2019.

NEW WARNING LABEL:

Atrium Chest Drains manufactured after October 18, 2016 will contain a new warning label that identifies the pouch as not being a sterile barrier and warns the user that only the chest drain can be entered into the sterile field.

Atrium Chest Drains having lot number 244887 and higher will contain the new warning label.

A copy of the new warning label is provided as **Attachment 2**.

ACTIONS FOR USERS:

- Please ensure that all Atrium chest drain users are aware of the new warning label.
- Please make copies of new warning label (ref. **Attachment 2**) and post the warning label near all Atrium chest drain product inventory with expiration date prior to October 2019.
- Please sign the attached Field Notification Reply Form acknowledging receipt of this Field Notification and return the Field Notification Reply Form to the following email address: packaging.atrium@getinge.com or you may fax it to 1-603-386-6430.

If you have any questions, please contact your local Atrium/Maquet/Getinge chest drainage representative.

This field action is being conducted in accordance with the supervision of the U.S. Food & Drug Administration.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** Download form 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

Thank you for your continued support of Atrium chest drainage products.

Sincerely,

Karen LeFevere
Director Regulatory Affairs and Quality Compliance Field Actions
USA Shared Service
Getinge Group
45 Barbour Pond Drive
Wayne, New Jersey 07470

ATTACHMENT 1

Table 1: Atrium Product Codes (Model) Subject To This Field Notification


Model	Chest Drain Product Description
2002	Ocean Drains
2002-000	Ocean single drain, with in-line connectors and suction control stopcock
2002-040	Ocean single drain, in-line connector and suction control stopcock, Pedi connector in bag on back of the drain
2002-050	Ocean single drain with in-line connector and suction control stopcock, Pre-connected 2550 ATS Bag
2002-100	Ocean single drain with in-line connector, no suction control stopcock
2002-300	Ocean single drain with suction control stopcock, no in-line connector
2002-400	Ocean single drain, no in-line connector or suction control stopcock, Water ampoule
2020	Ocean Drains
2020-000	Ocean dual chamber, in-line connectors and suction control stopcock (2 Patient Tubes)
2020-100	Ocean dual chamber with in-line connectors and no suction control stopcock (2 Patient Tubes)
2020-300	Ocean dual chamber with suction control stopcock, no in-line connector (2 Patient Tubes)
2012	Ocean Drains
2012-320	Ocean Infant/Pediatric drain, with in-line connector and suction control stopcock, ¼ in. Tubing, Sims and Pedi connector in bag on back of drain
2050	Ocean Drains
2050-000	Ocean Blood Recovery drain with in-line connector and suction control stopcock
2050-300	Ocean Blood Recovery drain with suction control stopcock, no in-line connector
2052-000	Ocean Double Blood Recovery drain with in-line connector and suction control stopcock - 2 patient lines connected by one "Y" connector
2052-300	Ocean Double Blood Recovery drain with suction control stopcock, no in-line connector - 2 patient lines connected by one "Y" connector
3600	Oasis Drains
3600-100	Oasis single drain with in-line connector
3600-150	Oasis single drain with in-line connector and Pre-connected 2550 ATS Bag

Model	Chest Drain Product Description
3612	Oasis Drains
3612-100	Oasis Infant/Pediatric drain with in-line connector, ¼ in. tubing, Sims and Pedi connector in bag on back of drain
3612-400	Oasis Infant/Pediatric drain with no in-line connector, ¼ in. tubing, Sims and Pedi connector in bag on back of drain
3620	Oasis Drains
3620-100	Oasis dual chamber drain with in-line connectors (2 Patient Tubes)
3650 & 3652	Oasis Drains
3650-100	Oasis Blood Recovery drain with in-line connector
3652-100	Oasis Double Blood Recovery drain with in-line connectors - 2 patient lines connected by one "Y" connector
4000 Series	Express Drains
4000-100N	Express single collection drain with in-line connector
4000-100P	Express PreFilled Chest Drain
4020-100N	Express dual chamber drain with in-line connectors (2 Patient Tubes)
4050-100N	Express Blood Recovery drain with in-line connector
4050-100P	Express PreFilled Chest Drain
16400	Express Mini
16400	Express Mini 500 dry seal drain

ATTACHMENT 2

URGENT: ATRIUM OCEAN, OASIS, EXPRESS AND EXPRESS MINI CHEST DRAINS NEW WARNING LABEL

PLEASE POST THIS WARNING LABEL NEAR ALL PRODUCT INVENTORY
WITH EXPIRATION DATE PRIOR TO OCTOBER 2019

**POUCH IS NOT A STERILE BARRIER.
ONLY THE CHEST DRAIN CAN BE ENTERED
INTO THE STERILE FIELD.**

fr- La pochette n'est pas une barrière stérile. Seul le système de drainage thoracique peut être admis dans le champ stérile.

de- Der Beutel stellt keine sterile Barriere dar. Nur die Thoraxdrainage darf in das sterile Feld gelegt werden.

es- La bolsa no es una barrera estéril. Sólo el drenaje torácico se puede introducir en el campo estéril.

it- La busta non è una barriera sterile. Solo il drenaggio toracico può essere introdotto nel campo sterile.

pt- A bolsa não constitui uma barreira estéril. Apenas o dreno torácico pode ser introduzido no campo estéril.

nl- Het pouch is geen steriele barrière. Enkel de borstdrain mag in het steriele veld geplaatst worden.

da- Posen er ikke en steril barriere. Kun brystkasseudløbet kan indføres i det sterile område.

sv- Påsen är inte sterilt förseglad. Endast bröstdränaget får föras in i det sterila området.

fi- Pussi ei ole steriili este. Vain pleuradreeni voidaan viedään steriiliin kenttään.

no- Lommen er ikke en steril barriere. Bare brystdrenet kan legges i det sterile feltet.

el- Η σακούλα δεν αποτελεί στείρο φράγμα. Μόνο η αποστράγγιση θώρακα μπορεί να εισαχθεί στο στείρο πεδίο.

pl- Torba nie stanowi bariery sterylnej. Jedynie drenaż klatki piersiowej może być wprowadzany do jałowego pola.

ja- パウチは滅菌バリアではありません。
滅菌フィールドには胸腔ドレーンのみ挿入することができます。

zh- 邮袋不是无菌屏障。仅胸腔引流器可被带入无菌区。

ar- العبوة البلاستيكية ليست معقمة. لا يدخل المجال المعقم سوى أنبوب التصريف الصدري.

cs- Vak není sterilní bariéra. Do sterilního pole může být umístěn pouze hrudní drén.

hu- A tasak nem steril védőcsomagolás. Kizárólag a mellkasi drén kerülhet a steril területre.

ko- 주머니는 무균 장벽이 아닙니다. 무균 영역에는 흉부 배출관만 들어갈 수 있습니다.

ru- Пакет не оснащен системой защиты стерильности. В стерильное поле можно вносить только грудной дренаж.

tr- Poşet steril tutma özelliğine sahip değildir. Steril Alana sadece göğüs tüpü girebilir.

LS000095 1

To introduce the chest drain into the sterile field:

1. Remove the wrapped chest drain from the dust cover.
2. Open the 2 sterilization wraps using sterile technique.
3. Only enter the chest drain into the sterile field.

30 November 2016

**URGENT MEDICAL DEVICE RECALL – FIELD NOTIFICATION
REPLY FORM
ATRIUM OCEAN, OASIS, EXPRESS and EXPRESS MINI CHEST DRAINS
PACKAGING CONFIGURATION CLARIFICATION
EMAIL TO: packaging.atrium@getinge.com or
FAX BACK TO: **Insert Fax Number****

**HOSPITAL: [INSERT CUSTOMER NAME]
[INSERT CUSTOMER ADDRESS]**

I acknowledge that I have reviewed and understand the Urgent Medical Device Recall – Field Notification for Atrium Ocean, Oasis, Express and Express Mini Chest Drains.

I confirm that all appropriate staff that use and/or maintain Atrium Ocean, Oasis, Express and Express Mini Chest Drains at this facility have been notified accordingly and are aware of the new warning label that identifies the pouch as not being a sterile barrier and warns the user that only the chest drain can be entered into the sterile field.

Please complete the reply form by entering the required information below, including signature and date.

Print Name: _____

Signature: _____ Date: _____

Title: _____

Telephone: _____

Hospital Name: _____

Address: _____

City and State: _____

EMAIL TO: packaging.atrium@getinge.com or FAX BACK TO: **Insert fax number**