INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Drenajes Torácicos ATRIUM
NO. IDENTIFICACIÓN RISARH	I1612-584
REFERENCIAS DEL DISPOSITIVO MEDICO	2002-000, 2002-040, 2002-100, 2002-300, 2002-400, 2020-000, 2020-100, 2020-300, 2012-320, 2050-000, 2050-300, 2052-000, 3600-100, 3600-150, 3612-100, 3612-400, 3620-100, 3650-100, 3652-100, 4020-100N, 16400.
REGISTRO SANITARIO	2008DM-0001833
INDICACIONES Y USO ESTABLECIDOS	Los drenajes torácicos ATRIUM son sistemas desechables no invasivos de recipientes de varias cámaras con válvulas, puerto y reguladores de succión, cámara de recolección de fluidos o aire, indicadores de vacío y de fuga y conectores para succión diseñados para: evacuar fluidos o aire de la cavidad torácica o del mediastino mediante succión y recolectarlos en el recipiente o cámara de desecho. Ayudar a restablecer la expansión de los pulmones y restablecer la dinámica respiratoria, mediante el drenaje logrado. Facilitar la evaluación temprana de pacientes postquirúrgicos que requieren drenaje de pecho, mediante el drenaje logrado.
NOMBRE DEL FABRICANTE	Atrium Medical Corporation
DESCRIPCION DEL PROBLEMA	El fabricante afirma que se están revisando las etiquetas de advertencia para el etiquetado de los drenajes de tórax, con el fin de inspeccionar la configuración actual del envase aclarando que parte del mismo es estéril, el producto afectado se envasa con un envoltorio estéril doble secuencial, se coloca una cubierta protectora externa de polvo, y luego se dobla y asegura con la etiqueta del envase, el drenaje es estéril dentro del envase pero la cubierta externa de polvo no lo es, conllevando a que se presenten posibles eventos adversos serios sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	16 de Diciembre de 2016

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[Normal Priority] - A27675 02 : Cardinal Health—Maquet Atrium Chest Drains: Manufacturer Updates Warning Label to Clarify Packaging Configuration

Medical Device Ongoing Action

Published: Tuesday, December 13, 2016
Last Updated: Thursday, December 15, 2016

UMDNS Terms:

- Drainage Systems, Pleural [10817]
- Drains, Thoracic [11308]

Product Identifier: Maquet Atrium Chest Drains *[Consumable]*
Cardinal Health Catalog Nos.: 2002-000, 2002-040, 2002-050A, 2002-100, 2002-300, 2002-400, 2020-000, 2020-100, 2020-300, 2012-320, 2050-000, 2050-300, 2052-000, 3600-100, 3600-150, 3612-100, 3612-400, 3620-100, 3650-100, 3652-100, 4000-IOON, 4000-IOOP, 4020-100N, 4050-IOON, 4050-IOOP, 16400
Expiration Dates before OCT 2019
Units manufactured between October 2011 and October 2016

Geographic Regions: Worldwide

Distributor(s):

- Cardinal Health 1500 Waukegan Road, Waukegan, IL 60085, United States

Manufacturer(s): Atrium Medical Corp 5 Wentworth Drive, Hudson, NH 03051, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Critical Care, Infection Control, OR/Surgery, Pulmonology/Respiratory Therapy, Materials Management

Summary:
This Alert provides information on a Cardinal Health notification regarding the above chest drains, which were subject to a correction by Maquet. For information on the action initiated by Maquet, see Alert Accession No. A27675 .

Problem:
[December 12, 2016]
In a December 8, 2016 letter submitted by an ECRI Institute member hospital, Cardinal Health issued a notification regarding the above chest drains, which were subject to a correction by Maquet. The distributor has not confirmed the information provided in the source material.
[December 8, 2016]
In a November 29, 2016, Urgent Medical Device Recall Field Notification letter submitted by ECRI Institute member hospitals, Maquet states that it is revising the warning labels for the packaging of the above chest drains for the current packaging configuration to clarify which part of the packaged drain is sterile. The affected product is packaged with a double sequential sterile wrap, placed into an outer dust cover, and then folded over and secured with the package label. The chest drain inside the packaging is sterile, the outer dust cover is not. The 2 sterilization wraps are what provide the sterile barrier for the product.

Action Needed:
Verify that you have received the December 8, 2016, letter and copy of the November 29, 2016, Maquet Urgent Medical Device Recall Field Notification letter, Field Notification Reply Form, and new warning labels from Cardinal Health. The following actions are those listed in Alert Accession No. A27675 . To introduce affected drains into the sterile field, do the following:

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

Complete the Field Notification Reply Form, and return it to Maquet using the instructions on the form. Make copies of new warning labels, and post the warning label near affected product. Notify all relevant personnel at your facility of the information in the letters, and forward a copy of the letters to any facility to which you have further distributed affected product. Affected product manufactured after October 18, 2016, with lot numbers 244887 and above will contain the new warning label clarifying that the pouch is not a sterile barrier and only the chest drain should enter the sterile field. U.S. customers should report adverse reactions or quality problems experienced with the use of affected product to FDA's MedWatch Adverse Event Reporting program by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here), at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the MedWatch website .

For Further Information:
Cardinal Health:
Todd King, product quality and regulatory compliance senior specialist
Tel.: (800) 292-9332
Website: Click here
Atrium customer service department
Tel.: (800) 528-7486 8 a.m. to 5 p.m. Eastern time, Monday through Friday
Website: Click here

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide .

Source(s):

- 2016 Dec 12. Member Hospital. December 8, 2016 Cardinal Health letter submitted by ECRI Institute member hospital Download