جانيب نق. المستشفى الخاصة في لبنان

الموضوع: إشعار بمتاحة جهاز طبي

الجهاز المعني بالمتاحة:
- Soft Flow Aortic Cannulae
- Trade Mark: Terumo Cardiovascular Systems Corporation
- Local Representative:

بناء على التقرير الصادر عن وكالة الـ fda الذي يفيد بوجود خلل في عمل الصنف المذكور أعلاه، قد يؤدي إلى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات.

مرفق بطا:
- التوصية الصادرة عن وكالة الـ fda
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

الجمهورية اللبنانية
وزارة الصحة العامة
مدير العام

رقم المحفوظات: 0
رقم الصادر: 13/1000
بيروت، في: 5 - كانون الثاني 2012

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb
الموضوع: إشعار بمتاحة جهاز طبي
Soft Flow Aortic Cannulae

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FDA

بناءً على التقرير الصادر عن وكالة ال
الذي يحذر فيه من استخدام الصنف المذكور أعلاه بسبب وجود خلل في عمل هذا الصنف مما يؤدي
 إلى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:

FDA

التقرير الصادر عن وكالة ال

بلاغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

ر. ج. ع.
Medical & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

FDA Home Medical Devices Databases

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Class 2 Recall
Sams Soft Flow Aortic Cannulae

Date Posted December 03, 2012
Recall Number Z-0462-2013
Product 24 Fr 8mm Soft Flow Ang WIL The Sams' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours of use.
Code Information catalog number: 5774 and IM number: 0595116.
Recalling Firm/Manufacturer Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103-9566
Consumer Instructions Contact the recalling firm for information
Reason for Recall Based on a review retrospective review of quality data, the presence of plastic flash was identified at the tip of certain lots of Sams' Soft-Flow Aortic Cannula. The plastic flash has the potential to detach and contribute to an adverse patient effect. While this potential failure has not been reported from the field as an observed defect, it was determined that the product does not meet spec!
Action TERUMO sent an URGENT MEDICAL DEVICE RECALL letter dated September 20, 2012, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to remove this cannulae from circulation and return them for credit. Customers with questions should call 1-800-521-2818. For questions regarding this recall call 734-741-6173.
Quantity In Commerce 5760 total units
Distribution Worldwide Distribution - USA including AL, CA, CO, DC, DE, FL, GA, IL, IN, KS, KY, LA, MA, MI, MO, MS, MT, NC, NE, ND, OH, PA, TN, TX, VA, and WI. Internationally to Australia, United Arab Emirates (UAE), Singapore, USA, Malaysia, Belgium, Japan, and Canada.

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4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /cfMN/pmn.cfm
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9. /cFMAUDE/TextSearch.cfm
10. /cRES/res.cfm
11. /cfPMA/pma.cfm
12. /cfPCD/classification.cfm
13. /cfStandards/search.cfm
14. /cfCFR/CFRSearch.cfm
15. /cfPCD_RH/classification.cfm
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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=114084

12/12/2012
Medical & Radiation Emitting Device Recalls

1 to 7 of 7 Results
Related recalls
New Search

Product Name  Recall Class  Date Posted  Recalling Firm
Z-0456-2013 - 24 Fr 8mm Sft Flow Str Wire W/I The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hour. 7
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation
Z-0459-2013 - 18 Fr 6mm Sft Flow Angled Wire The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hour. 8
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation
Z-0460-2013 - 18 Fr 8mm Sft Flow Ang Wire W/I The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hour. 9
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation
Z-0462-2013 - 24 Fr 8mm Soft Flow Ang Wire W/I The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours o. 10
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation
Z-0458-2013 - 24 Fr 8mm Sft Flow Straight The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours o. 11
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation
Z-0461-2013 - 24 Fr 8mm Soft Flow Ang Wire W/I The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hour. 12
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation
Z-0457-2013 - 24 Fr 8mm Sft Flow Straight Wir The Sarns' Aortic Cannula is indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hour. 13
2  Dec-03-2012  Terumo Cardiovascular Systems Corporation

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4. http://www.fda.gov/MedicalDevices/default.htm

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