



رقم المحفوظات: ٣٨٢٥
رقم الصادر: ١٣/٧٥٥٤
بيروت، في: ٥ - كانون الثاني ٢٠١٣

جانب نقب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي Soft Flow Aortic Cannulae

الجهاز المعنى بالمتابعة:

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

بناء على التقرير الصادر عن وكالة الـ fda،

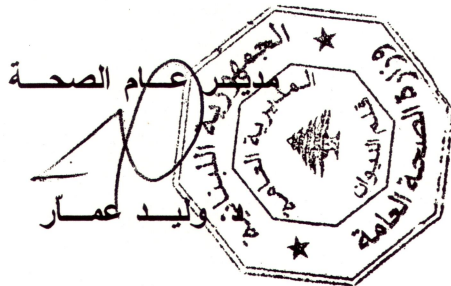
الذي يفيد بوجود خلل في عمل الصنف المذكور أعلاه، قد يؤدي الى مضاعفات على المريض،
نرجو منكم تعميم هذه النشرة على جميع المستشفيات.

مرفق ربطاً:

- التوصية الصادرة عن وكالة الـ fda.

يلف:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





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الموضوع: إشعار بمتابعة جهاز طبي

Soft Flow Aortic Cannulae

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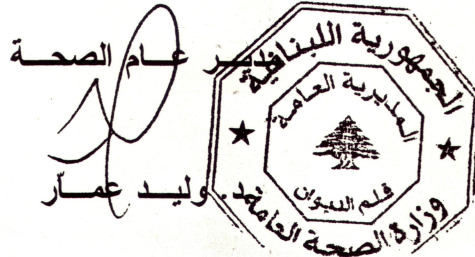
الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمل هذا الصنف مما يؤدي الى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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510(k)⁷ | Registration & Listing⁸ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ | CFR Title 21¹⁴ | Radiation-Emitting Products¹⁵ | X-Ray Assembler¹⁶ | Medsun Reports¹⁷ | CLIA¹⁸ | TPLC¹⁹

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Class 2 Recall
Sarns Soft Flow Aortic Cannulae



Date Posted	December 03, 2012
Recall Number	Z-0462-2013
Product	24 Fr 8mm Soft Flow Ang W/L 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 of use.
Code Information	catalog number: 5774 and lot number: 0595116.
Recalling Firm/Manufacturer	Terumo Cardiovascular Systems Corporation 6200 Jackson Road Ann Arbor, Michigan 48103-9586
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 Sarns" 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 specif
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 , ND , NE , NH , NY , 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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Product Name	Recall Class	Date Posted	Recalling Firm
Z-0456-2013 - <u>24 Fr 8mm Sft Flow Str Wire W/L 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 hou... ⁷</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation
Z-0459-2013 - <u>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</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation
Z-0460-2013 - <u>18 Fr 6mm Sft Flow Ang Wire W/L 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 hou... ⁹</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation
Z-0462-2013 - <u>24 Fr 8mm Soft Flow Ang W/L 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</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation
Z-0458-2013 - <u>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</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation
Z-0461-2013 - <u>24 Fr 8mm Soft Flow Ang Wire W/L 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 ho... ¹²</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation
Z-0457-2013 - <u>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 hou... ¹³</u>	2	Dec-03-2012	Terumo Cardiovascular Systems Corporation

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