Class 2 Recall
Sarns’ SoftFlow Aortic Cannula without Suture Flange

Date Posted: November 08, 2013
Recall Status: Terminated on July 18, 2014
Recall Number: Z-0193-2014
Recall Event ID: 666242
Premarket Notification 510(K) Numbers: K905224, K934127
Product Classification: Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass - Product Code DWF
Product: Sarns’ Soft-Flow® Aortic Cannula without Suture Flange, angled tip, wire-reinforced with latex port, aortic cannula, 8.0 mm (24 Fr) OD with 3/8" connector, 14” (36 cm) long. Indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.

Code Information: Catalog Number 5762 Lot Numbers 0677300
Recalling Firm/Manufacturer: Terumo Cardiovascular Systems Corporation
6200 Jackson Rd
Ann Arbor, Michigan 48103-9586

Manufacturer Reason for Recall: During an in-process inspection, Terumo Cardiovascular Systems (Terumo CVS) identified the presence of loose fiber particulate that exceeded finished product specifications on certain product lots of Sarns’ Soft-Flow® Aortic Cannulae and Sarns’ Venous Return Cannulae.

FDA Determined Cause: TRAINING: Employee Error

Action: On 10/23/13, Terumo Cardiovascular Systems sent an URGENT MEDICAL DEVICE RECALL LETTER to their consignees. The letter identified the reason for the device removal, identified the affected product and associated potential hazards, and provided recall instructions to their customers regarding affected product return. Questions regarding this recall are directed to CVS Customer Service M-F, 8am-8pm at 1-800-521-2618.

Quantity in Commerce: 90 units
Distribution: Worldwide Distribution-USA including DC and the states of MO, TX, OK, LA, MA, CA, WI, and MI and the country of Canada.

Total Product Life Cycle: TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database: 510(K)s with Product Code = DWF and Original Applicant = 3M HEALTH CARE. SARN5

Links on this page:

Class 2 Recall
Sarns® Soft-Flow Aortic Cannula without Suture Flange

Date Posted: November 08, 2013
Recall Status: Terminated on July 18, 2014
Recall Number: Z-0194-2014
Recall Event ID: 66624
Premarket Notification 510(K) Numbers: K905224, K934127
Product Classification: Catheter; Cannula And Tubing; Vascular; Cardiopulmonary Bypass
Product: Sarns® Soft-Flow® Aortic Cannula without Suture Flange, straight tip, wire-reinforced with luer port, aortic cannula, 7.0 mm (21 Fr) OD with 3/8" connector, 14" (36 cm) long. Indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.

Code Information: Catalog Number 5798 Lot Numbers 0677301
Recalling Firm/Manufacturer: Terumo Cardiovascular Systems Corporation 6200 Jackson Rd Ann Arbor, Michigan 48103-9586
Manufacturer Reason for Recall: During an in-process inspection, Terumo Cardiovascular Systems (Terumo CVS) identified the presence of loose fiber particulate that exceeded finished product specifications on certain product lots of Sarns® Soft-Flow® Aortic Cannulae and Sarns® Venous Return Cannula.

FDA Determined Cause: TRAINING: Employee Error
Action: On 10/20/13, Terumo Cardiovascular Systems sent an URGENT MEDICAL DEVICE RECALL LETTER to their customers. The letter identified the reason for the device removal, identified the affected product and associated potential hazards, and provided recall instructions to their customers regarding affected product return. Questions regarding this recall are directed to CVS Customer Service M-F, 8am-6pm at 1-800-521-2018.

Quantity in Commerce: 70 units
Distribution: Worldwide Distribution-USA including DC and the states of MO, TX, OK, LA, MA, CA, WI, and MI and the country of Canada.

Total Product Life Cycle: TPLC Device Report

1. For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 83.57.56
2. Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database: 510(K)s with Product Code = DWF and Original Applicant = SARNES

Links on this page:

**Class 2 Recall Sarns® SoftFlow Aortic Cannula without Suture Flange**

**Date Posted**
November 08, 2013

**Recall Status**
Terminated on July 18, 2014

**Recall Number**
Z-0195-2014

**Recall Event ID**
666242

**Premarket Notification 510(K) Numbers**
K905224, K934127

**Product Classification**
Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass - Product Code DWF

**Product**
Sarns® Soft-Flow®, Aortic Cannula without Suture Flange, straight tip, wire-reinforced with luer port, aortic cannula, 8.0 mm (34 Fr) OD with 3/8" connector, 14" (36 cm) long. Indicated for use in perfusion of the ascending aorta during cardiopulmonary bypass surgery.

**Code Information**
Catalog Number 5841 Lot Numbers 0677302

**Recalling Firm/Manufacturer**
Terumo Cardiovascular Systems Corporation
8200 Jackson Rd
Ann Arbor, Michigan 48103-9586

**Manufacturer Reason for Recall**
During an in-process inspection, Terumo Cardiovascular Systems (Terumo CVS) identified the presence of loose fiber particulate that exceeded finished product specifications on certain product lots of Sarns® Soft-Flow®, Aortic Cannulae and Sarns® Venous Return Cannulae.

**FDA Determined Cause**
TRAINING, Employee Error

**Action**
On 10/23/13, Terumo Cardiovascular Systems sent an URGENT MEDICAL DEVICE RECALL LETTER to their consignees. The letter identified the reason for the device removal, identified the affected product and associated potential hazards, and provided recall instructions to their customers regarding affected product return. Questions regarding this recall are directed to CVS Customer Service M-F, 8am-6pm at 1-800-521-2318.

**Quantity in Commerce**
30 units

**Distribution**
Worldwide Distribution—USA including DC and the states of MO, TX, OK, LA, MA, CA, WI, and MI and the country of Canada.

**Total Product Life Cycle**
TPC Device Report

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1. For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 870.35
2. Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

**510(K) Database**
510(k)s with Product Code = DWF, and Original Applicant = 3M HEALTH CARE, SARN

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Links on this page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=122799

8/4/2014