Class 2 Device Recall Sarns" SoftFlow Aortic Cannula without Suture Flange

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See Related Information[21]

Class 2 Recall
Sarns" SoftFlow Aortic Cannula without Suture Flange

Date Posted	November 08, 2013
Recall Status[1]	Terminated on July 18, 2014
Recall Number	Z-0193-2014
Recall Event ID	66624[22]
Premarket Notification 510(K) Numbers	K905224[23] K934127[24]
Product Classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass[25] - **Product Code** DWF[26]
Product	Sarns" Soft-Flow® Aortic Cannula without Suture Flange, angled tip, wire-reinforced with luer 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 [2]	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 1-800-521-2818.
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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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, SARNS[29]

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Class 2 Recall Sarns" SoftFlow Aortic Cannula without Suture Flange

Date Posted	November 08, 2013
Recall Status[1]	Terminated on July 18, 2014
Recall Number	Z-0194-2014
Recall Event ID	66624[22]
Premarket Notification 510(K) Numbers	K905224[23] K934127[24]
Product Classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass[25] - **Product Code** DWF[26]
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 Cannulae.
FDA Determined Cause [2]	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 1-800-521-2818.
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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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, SARNS[29]

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Class 2 Device Recall Sarns" SoftFlow Aortic Cannula without Suture Flange

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Class 2 Recall
Sarns" SoftFlow Aortic Cannula without Suture Flange

Date Posted	November 08, 2013
Recall Status[1]	Terminated on July 18, 2014
Recall Number	Z-0195-2014
Recall Event ID	66624[22]
Premarket Notification 510(K) Numbers	K905224[23] K934127[24]
Product Classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass[25] - **Product Code** DWF[26]
Product	Sarns" Soft-Flow® Aortic Cannula without Suture Flange, straight tip, wire-reinforced with luer 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 5841 Lot Numbers 0677302
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 [2]	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 1-800-521-2818.
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	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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, SARNS[29]

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