Class 2 Recall
Sarns" SoftFlow Aortic Cannula without Suture Flange

See Related Information[21]

Date Classified	November 08, 2013
Recall Number	Z-0193-2014
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.
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.

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Class 2 Recall
Sarns" SoftFlow Aortic Cannula without Suture Flange

See Related Information[21]

Date Classified	November 08, 2013
Recall Number	Z-0194-2014
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.
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.

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13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
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20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20Sarns%22%20%20Soft%2DFlow%C2%AE%20Aortic%20Cannula%20without%20Suture%20Flange%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=66624&item2_text=medical%20device%20recalls%20&item2_url=www.fda.gov/medicaldevices/safety/recallscorrectionsremovals/listofrecalls/default.htm&item3_text=fda%20enforcement%20report%20index&item3_url=www.fda.gov/safety/recalls/enforcementreports/default.htm

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Class 2 Recall
Sarns" SoftFlow Aortic Cannula without Suture Flange

See Related Information[21]

Date Classified	November 08, 2013
Recall Number	Z-0195-2014
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.
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.

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Class 2 Recall
Sarns" Venous Return Cannulae

See Related Information[21]

Date Classified	November 08, 2013
Recall Number	Z-0196-2014
Product	Sarns" Venous Return Cannulae, 20 Fr with 1/4" flare, 14.5" (37 cm) long. Indicated for venous drainage during cardiopulmonary bypass surgery for dial cannulation of the superior and inferior vena cava.
Code Information	Catalog Number 9473 Lot Numbers 0689812
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.
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	40 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.

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21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20Sarns%22%20%20Venous%20Return%20Cannulae%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=66624&item2_text=medical%20device%20recalls%20&item2_url=www.fda.gov/medicaldevices/safety/recallscorrectionsremovals/listofrecalls/default.htm&item3_text=fda%20enforcement%20report%20index&item3_url=www.fda.gov/safety/recalls/enforcementreports/default.htm

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