Medical & Radiation Emitting Device Recalls

New Search

Class 2 Recall
Sams' Soft-Flow Aortic Cannula without Suture Flange

Date Classified
November 08, 2013

Recall Number
Z-0193-2014

Product
Sams' 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 cardiosurgical bypass surgery.

Code Information
Catalog Number 5762 Lot Numbers 0677300

Recalling Firm/Manufacturer
Terumo Cardiovascular Systems Corporation
6200 Jackeon 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 Sams' Soft-Flow® Aortic Cannulas and Sams' Venous Return Cannulas.

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.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMADE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
12. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfTPLC.inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssembler/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfCIA/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=122796
12/10/2013
Medical & Radiation Emitting Device Recalls

Sams' Soft-Flow® Aortic Cannula without Suture Flange

Date Classified: November 08, 2013
Recall Number: Z-0194-2014
Product: Sams' 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 5796 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 Sams' Soft-Flow® Aortic Cannulae and Sams' 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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4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cdfdocs/cfPMN/pmnm.cfm
8. /scripts/cdrh/cdfdocs/cfRl/ri.cfm
9. /scripts/cdrh/cdfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cdfdocs/cfRES/tesc.cfm
11. /scripts/cdrh/cdfdocs/cfPMA/pma.cfm
12. /scripts/cdrh/cdfdocs/cfCPCD/classification.cfm
13. /scripts/cdrh/cdfdocs/cfSTAND/stand.cfm
14. /scripts/cdrh/cdfdocs/cfTPLC/inspect.cfm
15. /scripts/cdrh/cdfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cdfdocs/cfPCEP/pcep.cfm
17. /scripts/cdrh/cdfdocs/cfAssemble/assemble.cfm
18. /scripts/cdrh/cdfdocs/Medsur/searchReportText.cfm
19. /scripts/cdrh/cdfdocs/cfClo#'Search.cfm
20. /scripts/cdrh/cdfdocs/cfTPLC/tplc.cfm

Page Last Updated: 12/09/2013
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Class 2 Recall
Sarms® Soft-Flow Aortic Cannula without Suture Flange

Date Classified: November 08, 2013
Recall Number: Z-0195-2014
Product:
Sarms® 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 Sarms® Soft-Flow® Aortic Cannulae and Sarms® 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-5pm 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.

Links on this page:
domain
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmnm.cfm
8. /scripts/cdrh/cfdocs/cfRL/r1.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMA/pme.cfm
12. /scripts/cdrh/cfdocs/cfPICO/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPICO_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsum/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClinia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tipc.cfm
3Eitem1_url=http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm
start_search=1&event_id=65624&item2_text=medci%20device%20recall%20cannula%20without%20suture%20flange%3C%3E&
item2_url=http://www.fda.gov/medicaldevices/safety/recalls/scroll/122799/12/09/2013
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**Medical & Radiation Emitting Device Recalls**

**Class 2 Recall**  
Sams® Venous Return Cannulae

<table>
<thead>
<tr>
<th>Date Classified</th>
<th>November 08, 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Number</td>
<td>Z-0196-2014</td>
</tr>
<tr>
<td>Product</td>
<td>Sams® Venous Return Cannulae, 20 Fr with 1/4&quot; flare, 14.5&quot; (37 cm) long. Indicated for venous drainage during cardio pulmonary bypass surgery for dial cannulation of the superior and inferior vena cava.</td>
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<tr>
<td>Code Information</td>
<td>Catalog Number 9473 Lot Numbers 0698912</td>
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<td>Recalling Firm/Manufacturer</td>
<td>Terumo Cardiovascular Systems Corporation</td>
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<td>Manufacurer</td>
<td>6200 Jackson Rd</td>
</tr>
<tr>
<td>Ann Arbor, Michigan 48103-9586</td>
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<td>Manufacturer Reason for Recall</td>
<td>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 Sams® Soft-Flow® Aortic Cannulae and Sams® Venous Return Cannulae.</td>
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<tr>
<td>Action</td>
<td>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 1-800-521-2018.</td>
</tr>
<tr>
<td>Quantity in Commerce</td>
<td>40 units</td>
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<tr>
<td>Distribution</td>
<td>Worldwide Distribution USA including DC and the states of MO, TX, OK, LA, MA, CA, WI, and MI and the county of Canada.</td>
</tr>
</tbody>
</table>

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4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfdad/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfRl/ri.cfm
9. /scripts/cdrh/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfPMAP/pma.cfm
12. /scripts/cdrh/cfcdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfTPPLC/inspect.cfm
15. /scripts/cdrh/cfCFR/cfrSearch.cfm
16. /scripts/cdrh/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsur/searchReportText.cfm
19. /scripts/cdrh/cfCIA/Search.cfm
20. /scripts/cdrh/cfTP/tpc.cfm
21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?page_title=medical%20device%20recalls&item1_text=3%3Chi%3Crelated%20recalls%20for%20Sams%22&20%20Venous%20Return%20Cannulae%3C%3C%3C%3Chi%3Citem2_text=medical%20device%20recalls%20for%20Sams%22&20%20Venous%20Return%20Cannulae&item2_url=www.fda.gov/medicaldevices/safety/recalls correcltionsremovals/listofrecalls/default.htm&item3_text=fda%20enforcement%20report%20index&item3_url=www.fda.gov/safety/recalls/enforcementreports/default.htm

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