### Class 2 Recall
 Merit Custom Syringe Kit

<table>
<thead>
<tr>
<th>Date Posted</th>
<th>April 03, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Status</td>
<td>Open</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-1320-2014</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>6784222</td>
</tr>
<tr>
<td>Premarket Notification Number</td>
<td>K875196</td>
</tr>
</tbody>
</table>

**Product Classification:** Syringe, Piston[^24] - Product Code FMF[^25]

**Product:** Merit Custom Syringe Kit, Convenience Kit, I.R. Embolization Pack, K02-01010A, Sterile EO.

**Code Information:** Lot Number H574228

**Recalling Firm/Manufacturer:** Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095

**For Additional Information Contact:**
Paul Kennedy
801-208-4301

**Manufacturer Reason for Recall:** The products are labeled as sterile but were not sterilized.

**FDA Determined Cause[^2]:** COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Release of Mat./Comp. prior to Test Results

**Action:** Merit Medical sent an Urgent Product Recall Notice dated March 14, 2014 to all customers and sales representatives via email. The letter identified the affected product, problem and actions to be taken. Customers were provided a Product Retrieval Form, product identification information, instruction to immediately quarantine any devices and discontinue use, ensure all personnel to whom devices were distributed are made aware of this field action, and instructions to contact their Merit representative to arrange product return and replacement. For questions call 1-801-316-4822.

**Quantity in Commerce:** 15

**Distribution:** Worldwide Distribution - USA Nationwide in the state of WI and countries of Thailand and Hong Kong.

**Total Product Life Cycle:** TPLC Device Report[^26]

[^2]: For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.56[^27]

[^24]: Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[^5]: 510(K) Database: 510(K)s with Product Code = FMF and Original Applicant = MERIT MEDICAL SYSTEMS, INC.

[^1]: Links on this page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=126485

4/14/2014
Class 2 Recall
Pressure Monitoring Tubing

Date Posted: April 03, 2014
Recall Status: Open
Recall Number: Z-1319-2014
Recall Event ID: 67842
Premarket Notification 510(K) Number: K883710
Product Classification: Display, Cathode-Ray Tube, Medical - Product Code DXJ
Product: Pressure Monitoring Tubing, PM6006. Pressure Monitoring Tubing (PM series) is used between the manifold and transducer as a conduit to transmit the fluid pressure of the patient to the pressure transducer.
Code Information: Lot Number H591335
Recalling Firm/Manufacturer: Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
For Additional Information Contact: Paul Kennedy
801-208-4301
Manufacturer Reason for Recall: The products are labeled as sterile but were not sterilized.
FDA Determined Cause: COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Release of Mat./Comp. prior to Test Results
Action: Merit Medical sent an Urgent Product Recall Notice dated March 14, 2014 to all customers and sales representatives via email. The letter identified the affected product, problem, and actions to be taken. Customers were provided a Product Retrieval Form, product identification information, instruction to immediately quarantine any devices and discontinue use, ensure all personnel to whom devices were distributed are made aware of this field action, and instructions to contact their Merit representative to arrange product return and replacement. For questions call 1-801-316-4822.
Quantity in Commerce: 80
Distribution: Worldwide Distribution - USA Nationwide in the state of WI and countries of Thailand and Hong Kong.
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)is with Product Code = DXJ and Original Applicant = MERIT MEDICAL SYSTEMS, INC.

Links on this page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/res.cfm?id=126484

4/14/2014