Class 2 Recall Green Mamba Suture Passer

Date Posted: October 09, 2014
Recall Status: Open
Recall Number: Z-0057-2015
Recall Event ID: 6936023
Product Classification: Passer22 - Product Code HWQ25
Product: Green Mamba Suture Passer. The Biomet Sports Medicine Mamba instruments are utilized to aid in passing sutures through soft tissue. The Mamba Needle is designed for use with the Mamba Suture Passer. The needles are sterile, disposable, and for single-patient use only.
Code Information: Catalog Number: 110010850 Lot Number: 231120, 253210
Recalling Firm/Manufacturer: Biomet, Inc.
56 E Bell Dr
Warsaw, Indiana 46581
For Additional Information Contact: Audrey Daenzer
574-372-1570
Manufacturer Reason for Recall: An investigation identified that high level friction may exist between the needle and Mamba suture passer instrument, causing the needle to break during use.
Action: On 9/26/2014, "URGENT MEDICAL DEVICE RECALL NOTICE" notifications were sent via courier to the affected distributors with instructions for returning the affected product. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, contact information, and instructions for responding to the formal recall notification.
Quantity in Commerce: 12 units
Distribution: Nationwide Distribution-including the states of FL, NY, TX, VA, NV, MI, CA, IN, SD, GA, KY, NC, and AR.
Total Product Life Cycle: TPLC Device Report26

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5527

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
### Class 2 Device Recall Black Mamba Suture Passer

<table>
<thead>
<tr>
<th>Date Posted</th>
<th>October 09, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall Status</td>
<td>Open</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-0066-2015</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>6536923</td>
</tr>
<tr>
<td>Product Classification</td>
<td>Passer24 - Product Code HWQ25</td>
</tr>
<tr>
<td>Product</td>
<td>Black Mamba Suture Passer. The Biomet Sports Medicine Mamba instruments are utilized to aid in passing suture through soft tissue. The Mamba Needle is designed for use with the Mamba Suture Passer. The needles are sterile, disposable, and for single-patient use only.</td>
</tr>
<tr>
<td>Code Information</td>
<td>Catalog Number: 110010849 Lot Number: 169620, 253190</td>
</tr>
<tr>
<td>Recalling Firm/Manufacturer</td>
<td>Biomet, Inc. 56 E Bell Dr Warsaw, Indiana 46581</td>
</tr>
<tr>
<td>For Additional Information Contact</td>
<td>Audrey Daenzer 574-372-1570</td>
</tr>
<tr>
<td>Manufacturer Reason for Recall</td>
<td>An investigation identified that high level friction may exist between the needle and Mamba suture passer instrument, causing the needle to break during use.</td>
</tr>
<tr>
<td>Action</td>
<td>On 9/26/2014, &quot;URGENT MEDICAL DEVICE RECALL NOTICE&quot; notifications were sent via courier to the affected distributors with instructions for returning the affected product. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, contact information, and instructions for responding to the formal recall notification.</td>
</tr>
<tr>
<td>Quantity in Commerce</td>
<td>15 units</td>
</tr>
<tr>
<td>Distribution</td>
<td>Nationwide Distribution-including the states of FL, NY, TX, VA, NV, MI, CA, IN, SD, GA, KY, NC, and AR.</td>
</tr>
<tr>
<td>Total Product Life Cycle</td>
<td>TPLC Device Report26</td>
</tr>
</tbody>
</table>

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5527

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
Class 2 Recall Mamba Disposable Nitinol Needle

Date Posted: October 09, 2014
Recall Status: Open
Recall Number: Z-0058-2015
Recall Event ID: 6936623
Product Classification: Crimper, Pin - Product Code HXQ
Product: Mamba Disposable Nitinol Needle. The Biomet Sports Medicine Mamba instruments are utilized to aid in passing suture through soft tissue. The Mamba Needle is designed for use with the Mamba Suture Passer. The needles are sterile, disposable, and for single-patient use only.
Code Information: Catalog Number: 110010851 Lot Numbers: 139800, 139810, 139820
Recalling Firm/Manufacturer: Biomet, Inc.
56 E Bell Dr
Warsaw, Indiana 46581
For Additional Information Contact: Audrey Daenzer
574-372-1570
Manufacturer Reason for Recall: An investigation identified that high level friction may exist between the needle and Mamba suture passer instrument, causing the needle to break during use.
Action: On 9/26/2014, "URGENT MEDICAL DEVICE RECALL NOTICE" notifications were sent via courier to the affected distributors with instructions for returning the affected product. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, contact information, and instructions for responding to the formal recall notification.
Quantity in Commerce: 154 units
Distribution: Nationwide Distribution-including the states of FL, NY, TX, VA, NV, MI, CA, IN, SD, GA, KY, NC, and AR.
Total Product Life Cycle: TPLC Device Report

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55.