Class 2 Device Recall Medline Anterior Cervical Distraction Pin

Date Initiated by Firm
December 14, 2016

Create Date
May 17, 2017

Recall Status
Open, Classified

Recall Number
Z-2105-2017

Recall Event ID
762963

Product Classification
Orthopedic manual surgical instrument - Product Code LXH

Product
10 mm Distraction Pin, Aggressive Qty: 1 per pack; STERILE; Manufactured for: Medline Industries, Inc., Mundelein, IL 60060 USA. Distraction Pin is designed for Anterior Cervical Fusion Procedures. Use with vertebral body distraction instruments. It is intended as a temporary fixation screw utilized during cervical spine procedures.

Code Information
Item# MDS9091010; Lots #133115, 136754

Recalling Firm/Manufacturer
MEDLINE INDUSTRIES INC
3 Lakes Dr
Northfield IL 60093-2753

For Additional Information Contact
Kassandra Cotner
847-643-3245

Manufacturer Reason for Recall
Product's non-conformity involves the integrity of the seal in the sterile packaging. It is possible that the seal on the sterile packaging has been compromised resulting in a loss of sterility of the medical device contained within.

FDA Determined Cause
Process control

Action
Medline Industries sent an Immediate Action Required letter dated December 14, 2016, to all affected customers with response forms via US mail, notifying them of the recall. Customers were instructed to quarantine affected product and return it to the firm. The product will be repackaged and sterilized. Customers with questions were instructed to call 866-359-1704. For questions regarding this recall call 847-643-3245.

Quantity in Commerce
49 individual packs

Distribution
Nationwide Distribution

Total Product Life Cycle
TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=152773

5/26/2017
## Class 2 Device Recall Medline Anterior Cervical Distraction Pin

<table>
<thead>
<tr>
<th>Date Initiated by Firm</th>
<th>December 14, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create Date</td>
<td>May 17, 2017</td>
</tr>
<tr>
<td>Recall Status¹</td>
<td>Open², Classified</td>
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<tr>
<td>Recall Number</td>
<td>Z-2103-2017</td>
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<tr>
<td>Recall Event ID</td>
<td>76298²³</td>
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<tr>
<td>Product Classification</td>
<td>Orthopedic manual surgical instrument²⁴ - Product Code LXH²⁵</td>
</tr>
<tr>
<td>Product</td>
<td>16 mm Distraction Pin, Titanium, Qty: 1 per pack, STERILE; Manufactured for: Medline Industries, Inc., Mundelein, IL 60060 USA Distraction Pin is designed for Anterior Cervical Fusion Procedures. Use with vertebral body distraction instruments. It is intended as a temporary fixation screw utilized during cervical spine procedures.</td>
</tr>
<tr>
<td>Code Information</td>
<td>Item# MDS0991616T, Lot #132638</td>
</tr>
<tr>
<td>Recalling Firm/Manufacturer</td>
<td>MEDLINE INDUSTRIES INC</td>
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<td></td>
<td>3 Lakes Dr</td>
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<td>Northfield IL 60093-2753</td>
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<tr>
<td>For Additional Information Contact</td>
<td>Kassandra Cotner</td>
</tr>
<tr>
<td></td>
<td>847-643-3245</td>
</tr>
<tr>
<td>Manufacturer Reason for Recall</td>
<td>Product’s non-conformity involves the integrity of the seal in the sterile packaging. It is possible that the seal on the sterile packaging has been compromised resulting in a loss of sterility of the medical device contained within.</td>
</tr>
<tr>
<td>FDA Determined Cause²</td>
<td>Process control</td>
</tr>
<tr>
<td>Action</td>
<td>Medline Industries sent an Immediate Action Required letter dated December 14, 2016, to all affected customers with response forms via US mail, notifying them of the recall. Customers were instructed to quarantine affected product and return it to the firm. The product will be relabeled and sterilized. Customers with questions were instructed to call 866-359-1704. For questions regarding this recall call 847-643-3245.</td>
</tr>
<tr>
<td>Quantity in Commerce</td>
<td>198 individual packs</td>
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<tr>
<td>Distribution</td>
<td>Nationwide Distribution</td>
</tr>
<tr>
<td>Total Product Life Cycle</td>
<td>TPLC Device Report²⁶</td>
</tr>
</tbody>
</table>

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrec/cfrec.cfm?id=152726).  
² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.  
³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.
Class 2 Device Recall Medline Anterior Cervical Distraction Pin

Date Initiated by Firm: December 14, 2016

Create Date: May 17, 2017

Recall Status: Open, Classified

Recall Number: Z-2107-2017

Recall Event ID: 76206

Product Classification: Orthopedic manual surgical instrument

Product: 12 mm Distraction Pin, Blunt Qty: 1 per pack; STERILE; Manufactured for: Medline Industries, Inc., Mundelein, IL 60060 USA

Distraction Pin is designed for Anterior Cervical Fusion Procedures. Use with vertebral body distraction instruments. It is intended as a temporary fixation screw utilized during cervical spine procedures.

Code Information: Item# MDS9091212B; Lots #136780

Recalling Firm/Manufacturer: MEDLINE INDUSTRIES INC

3 Lakes Dr

Northfield IL 60093-2753

For Additional Information Contact: Kassandra Cotner

847-643-3245

Manufacturer Reason for Recall: Product's non-conformity involves the integrity of the seal in the sterile packaging. It is possible that the seal on the sterile packaging has been compromised resulting in a loss of sterility of the medical device contained within.

FDA Determined Cause: Process control

Action: Medline Industries sent an Immediate Action Required letter dated December 14, 2016, to all affected customers with response forms via US mail, notifying them of the recall. Customers were instructed to quarantine affected product and return it to the firm. The product will be repackaged and sterilized. Customers with questions were instructed to call 866-359-1704. For questions regarding this recall call 847-643-3245.

Quantity in Commerce: 300 individual packs

Distribution: Nationwide Distribution

Total Product Life Cycle: TPLC Device Report

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2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.
Class 2 Device Recall Medline Anterior Cervical Distraction Pin

Date Initiated by Firm: December 14, 2016
Create Date: May 17, 2017
Recall Status: Open, Classified
Recall Number: Z-2104-2017
Recall Event ID: 762968
Product Classification: Orthopedic manual surgical instrument - Product Code LXH

Product: 16 mm [or 18 mm] Distraction Pin, Qty: 1 per pack; STERILE; Manufactured for: Medline Industries, Inc., Mundelein, IL 60060 USA
Distraction Pin is designed for Anterior Cervical Fusion Procedures. Use with vertebral body distraction instruments. It is intended as a temporary fixation screw utilized during cervical spine procedures.

Code Information: 16 mm Pin: Item# MDS9091212; Lots #136469, 136754, 16 mm Pin: Item# MDS9091818; Lot #136470
Recalling Firm/Manufacturer: MEDLINE INDUSTRIES INC
3 Lakes Dr
Northfield IL 60093-2753

For Additional Information Contact:
Kassandra Cotner
847-843-3245

Manufacturer Reason for Recall: Product's non-conformity involves the integrity of the seal in the sterile packaging. It is possible that the seal on the sterile packaging has been compromised resulting in a loss of sterility of the medical device contained within.

FDA Determined Cause: Process control
Action: Medline Industries sent an Immediate Action Required letter dated December 14, 2016, to all affected customers with response forms via US mail, notifying them of the recall. Customers were instructed to quarantine affected product and return it to the firm. The product will be repackaged and sterilized. Customers with questions were instructed to call 866-359-1704. For questions regarding this recall call 847-843-3245.

Quantity in Commerce: 2,112 individual packs
Distribution: Nationwide Distribution
Total Product Life Cycle: TPLC Device Report

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2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=152772