



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

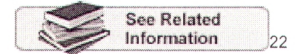
## Class 2 Device Recall Medline Anterior Cervical Distraction Pin

[6 510\(k\)|DeNovo<sup>8</sup>](#) | [Registration & Listing<sup>9</sup>](#) | [Adverse Events<sup>10</sup>](#) | [Recalls<sup>11</sup>](#) | [PMA<sup>12</sup>](#) | [HDE<sup>13</sup>](#) | [Classification<sup>14</sup>](#) | [Standards<sup>15</sup>](#)  
[CDRH SuperSearch](#) | [CFR Title 21<sup>16</sup>](#) | [Radiation-Emitting Products<sup>17</sup>](#) | [X-Ray Assembler<sup>18</sup>](#) | [Medsun Reports<sup>19</sup>](#) | [CLIA<sup>20</sup>](#) | [TPLC<sup>21</sup>](#)

[New Search](#)

[Back to Search Results](#)

### Class 2 Device Recall Medline Anterior Cervical Distraction Pin



<b>Date Initiated by Firm</b>	December 14, 2016
<b>Create Date</b>	May 17, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2105-2017
<b>Recall Event ID</b>	<a href="#">76298</a> <sup>23</sup>
<b>Product Classification</b>	<a href="#">Orthopedic manual surgical instrument</a> <sup>24</sup> - <b>Product Code</b> <a href="#">LXH</a> <sup>25</sup>
<b>Product</b>	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.
<b>Code Information</b>	Item# MDS9091010; Lots #133115, 136754
<b>Recalling Firm/Manufacturer</b>	MEDLINE INDUSTRIES INC 3 Lakes Dr Northfield IL 60093-2753
<b>For Additional Information Contact</b>	Kassandra Cotner 847-643-3245
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause<sup>2</sup></b>	Process control
<b>Action</b>	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.
<b>Quantity in Commerce</b>	49 individual packs
<b>Distribution</b>	Nationwide Distribution
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>26</sup>

<sup>1</sup> 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](#)<sup>27</sup>.

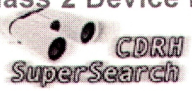
<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall Medline Anterior Cervical Distraction Pin**

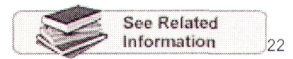


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Medline Anterior Cervical Distraction Pin**



<b>Date Initiated by Firm</b>	December 14, 2016
<b>Create Date</b>	May 17, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2103-2017
<b>Recall Event ID</b>	<u>76298</u> <sup>23</sup>
<b>Product Classification</b>	<u>Orthopedic manual surgical instrument</u> <sup>24</sup> - <b>Product Code</b> <u>LXH</u> <sup>25</sup>
<b>Product</b>	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.
<b>Code Information</b>	Item# MDS9091616T; Lot #132638
<b>Recalling Firm/Manufacturer</b>	MEDLINE INDUSTRIES INC 3 Lakes Dr Northfield IL 60093-2753
<b>For Additional Information Contact</b>	Kassandra Cotner 847-643-3245
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause<sup>2</sup></b>	Process control
<b>Action</b>	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.
<b>Quantity in Commerce</b>	198 individual packs
<b>Distribution</b>	Nationwide Distribution
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>26</sup>

<sup>1</sup> 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](#)<sup>27</sup>.

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

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





[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

## Class 2 Device Recall Medline Anterior Cervical Distraction Pin

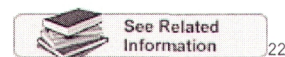


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

### Class 2 Device Recall Medline Anterior Cervical Distraction Pin



<b>Date Initiated by Firm</b>	December 14, 2016
<b>Create Date</b>	May 17, 2017
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2107-2017
<b>Recall Event ID</b>	<a href="#">76298</a> <sup>23</sup>
<b>Product Classification</b>	<a href="#">Orthopedic manual surgical instrument</a> <sup>24</sup> - <b>Product Code</b> <a href="#">LXH</a> <sup>25</sup>
<b>Product</b>	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.
<b>Code Information</b>	Item# MDS9091212B; Lots #136780
<b>Recalling Firm/Manufacturer</b>	MEDLINE INDUSTRIES INC 3 Lakes Dr Northfield IL 60093-2753
<b>For Additional Information Contact</b>	Kassandra Cotner 847-643-3245
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause</b> <sup>2</sup>	Process control
<b>Action</b>	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.
<b>Quantity in Commerce</b>	300 individual packs
<b>Distribution</b>	Nationwide Distribution
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>26</sup>

<sup>1</sup> 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](#)<sup>27</sup>.

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

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



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall Medline Anterior Cervical Distraction Pin**

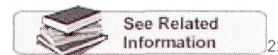


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Medline Anterior Cervical Distraction Pin**



<b>Date Initiated by Firm</b>	December 14, 2016
<b>Create Date</b>	May 17, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2104-2017
<b>Recall Event ID</b>	<a href="#">76298</a> <sup>23</sup>
<b>Product Classification</b>	<a href="#">Orthopedic manual surgical instrument</a> <sup>24</sup> - <b>Product Code</b> <a href="#">LXH</a> <sup>25</sup>
<b>Product</b>	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.
<b>Code Information</b>	16 mm Pin: Item# MDS9091212; Lots #136469, 136754  , 18 mm Pin: Item# MDS9091818; Lot #136470
<b>Recalling Firm/Manufacturer</b>	MEDLINE INDUSTRIES INC 3 Lakes Dr Northfield IL 60093-2753
<b>For Additional Information Contact</b>	Kassandra Cotner 847-643-3245
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause<sup>2</sup></b>	Process control
<b>Action</b>	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.
<b>Quantity in Commerce</b>	2,112 individual packs
<b>Distribution</b>	Nationwide Distribution
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>26</sup>

<sup>1</sup> 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](#)<sup>27</sup>.

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

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