Class 2 Device Recall Medline Anterior Cervical Distraction Pin

See Related Information 22

Date Initiated by Firm	December 14, 2016
Create Date	May 17, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2105-2017
Recall Event ID	76298[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
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 [2]	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[26]

[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[27].

[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

See Related Information [22]

Date Initiated by Firm	December 14, 2016
Create Date	May 17, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2103-2017
Recall Event ID	76298[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	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.
Code Information	Item# MDS9091616T; Lot #132638
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 [2]	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	*198 individual packs*
Distribution	Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[26]

[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[27].
[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

See Related Information 22

Date Initiated by Firm	December 14, 2016
Create Date	May 17, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2107-2017
Recall Event ID	76298[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
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 [2]	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[26]

[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[27].

[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

See Related Information 22

Date Initiated by Firm	December 14, 2016
Create Date	May 17, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2104-2017
Recall Event ID	76298[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
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 |, 18 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 847-643-3245
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 [2]	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	2,112 individual packs
Distribution	Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[26]

[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[27].
[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.