OrthoPediatrics Corp.

Date 10/25/2022

URGENT FIELD SAFETY NOTICE

Orthex Large Bone Shoulder Bolt, AS-17

(1) Attention to Customer:

Customer Name
Street Address
City, State, Zip Code

Dear Customer/Distributor,

(2) Purpose of this letter

The purpose of this letter is to advise you that OrthoPediatrics is recalling four lots (922000760-E, 922023360-E, 922023370-E) of AS-17 Orthex Large Bone Shoulder Bolts. These Bolts are components of the Orthex System which is an external fixation system used to perform large bone deformity correction surgery.

(3) Reason for the Recall:

OrthoPediatrics was informed in 4 complaints that Bolts from the effected lots broke off at the head or on the threaded portion. It was determined that changes made as part of a new revision (rev E) of this component may have resulted in the breakages, so all lots of the new revision are being included in this recall. This breakage may cause strut dissociation from the frame. No patient injury, delay in surgery or other adverse event resulted.

(4) Risk to Health:

4a) Bolt breakage may cause loss of strut continuity with frame which may cause loss of deformity correction and/or disruption of bone regeneration.

4b) **How to recognize that the device may fail:** The Bolt is part of an external fixator that is routinely checked by the patient / surgeon. When the Bolt breaks it falls from the frame and the strut may become visibly loose. In addition, the lot E Bolts are easily recognizable by containing an internal hex within the head of the Bolt.

(5) Actions to be taken by the Customer/User:

The affected product must be returned to OrthoPediatrics. Replacement product will be provided. Please contact customer service to arrange return of the affected product. Distributors should retrieve affected product that may be with customers.

Customers who have patients in frames should be made aware of the possibility of Bolt breakage and continue monitoring their patients. Please complete and return the attached response acknowledgement form confirming your understanding of these instructions.

(6) Product and Distribution Information:

Product and Distribution Information Table				
Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number	Manufacturing/ Distribution Dates	Expiration Date (MM/DD/YYYY) *if applicable*
Orthex Large Bone Shoulder Bolt	AS-17	922000760-E	Feb 2022 / Apr – Jul 2022	N/A
Orthex Large Bone Shoulder Bolt	AS-17	922023360-E	Jun 2022 / Jul – Aug 2022	N/A
Orthex Large Bone Shoulder Bolt	AS-17	922023370-E	Jun 2022 / Jun - Jul 2022	N/A

(7) Type of Action by the Company:

OrthoPediatrics is making the previous Bolt version available and conducting a root cause analysis of the lot E Bolts to determine corrective action(s). Any corrective action(s) will be verified as effective in addressing the root cause prior to making any further Bolts available that are designed as the Bolts were in lot E.

(8) OTHER INFORMATION:

Any questions regarding this recall can be directed to Joel Batts, Senior VP of Clinical and Regulatory Affairs, at OrthoPediatrics at jbatts@orthopediatrics.com or 574-367-5396

Authorized by:
Name: (Print)

_____

Signature:

_____

Title:

_____

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:
Customer Name
Street Address
Town, State, Zip Code

Orthex Large Bone Shoulder Bolt, AS-17

I have read and understand the recall instructions provided in the October 25, 2022 letter accompanying this acknowledgement and receipt form. Yes _ No_

I have or will notify my customers that were shipped or may have been shipped this product so that product in their possession can be returned. Yes _ No_

Any adverse events associated with recalled product of which you are aware? Yes _ No _
If yes, please explain:
_____
_____
_____
_____

Affected Product Information: Include information that is applicable for affected product.

Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Quantity in inventory	Quantity returned

Return Response Box:

Please provide any additional information, if applicable.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE SEND COMPLETED RESPONSE FORM TO: RECALLS@ORTHOPEDIATRICS.COM
OR MAIL TO:
Recall Team - OrthoPediatrics, Inc.
2850 Frontier Drive
Warsaw, IN 46582
(574) 268-6379