

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com



Urgent Medical Device Recall Notice
R-2017-29

November 15, 2017

<Insert Address>

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove a single lot of JETX BAR FREEDOM CLAMP 10.5 TO 5 MM due to a manufacturing error. The peening process was omitted during assembly causing the device to disassemble during use.

Please see product details below:

| Product Number | Description | Batch Number |
|----------------|--------------------------------------|--------------|
| 71064001 | JETX BAR FREEDOM CLAMP 10.5MM TO 5MM | 16BM21021 |

Shipment Date: April 24, 2017 through July 11, 2017

Potential Risk with Use of the Product

In the event the affected devices are presented for use, the clamp could potentially become disassembled during use. External fixation strategy would need to be revised and an alternative strategy used with available devices. The surgeon would be able to complete the procedure using a replacement device.

Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

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PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any unused devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
 - a. If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.
 2. If you have no product to return, please put an X in the appropriate location below.
 3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
 4. Complete the remainders of the form sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.
- Please Note** – even if you have no product to return, this form must be completed, signed and returned.
5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

No Product to Be Returned

| Product Part Number | Batch Number <small>(List Specific Batch #'s to be Returned)</small> | Quantity of Units to be Returned |
|---------------------|---|----------------------------------|
| | | |
| | | |
| | | |

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____ Title: _____

Signature (required): _____ Date (required): ____/____/____

Email: _____ Telephone: (____) _____ - _____

S&N Account Number: _____ RA Number (S&N use only): _____

Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Building G, 1450 Brooks Rd. East | Memphis, TN 38116