

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-2018-01

February 1, 2018

<Insert Address>

This letter is to inform you that Smith & Nephew Inc., have initiated a field action to voluntarily remove a single lot of LEGION HK DISTAL WEDGE SIZE 5 due to a packaging error. The screws packaged with the devices within the affected lot were 5MM, instead of 10MM, and are too short to be used with the device.

Please see product details below:

Product Number	Description	Batch Number
71422159	LEGION HK DISTAL FEMORAL WEDGE SZ5 5MM	14AAP6352A

Shipment Date: July 22, 2015 through November 7, 2017

Potential Risk with Use of the Product

In the event that this product batch is presented in surgery, a backup wedge and screw from another lot should be used as a replacement. In the event the incorrect device is presented for use and a backup device is not available, additional bone cuts to upsize the wedge maybe warranted. This could lead to extended surgery time and require additional bone sacrifice. Additional bone resection in some instances could result in weakening of the bone with possible periprosthetic fracture under stress.

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

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Product Part Number	Batch Number (List Specific Batch #'s to be Returned)	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