

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-2017-35

January 15, 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 RK/HK HEMI SZ 3-4 LTMD/RTLA 5MM wedges due to a manufacturing error. A set screw was incorrectly packaged and distributed with the wedges which should have been accompanied by a wedge screw.

Please see product details below:

Product Number	Description	Batch Number
71423432	LEGION RK/HK HEMI SZ 3-4 LTMD/RTLA 5MM	13KSL0038C

Shipment Date: December 6, 2016 through September 15, 2017

Potential Risk with Use of the Product

In the event the device is presented for use and if a backup is not available the surgeon would have the option to make additional bone cuts to upsize the wedge. This could potentially lead to extended surgery time and require additional bone sacrifice.

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