1450 Brooks Road
Memphis, TN 38116
USA

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

Urgent Medical Device Recall Notice
R-2018-34

December 11, 2018

<Insert Address>

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a recall to remove a single lot of LEGION PRESSFIT STEM 10MM X 120MM and a single lot LEGION PRESSFIT STEM 16MM X 160MM due to a labeling error. The affected devices, manufactured in Malaysia, were incorrectly labeled as being made in the US.

Please see product details below:

Product Number	Description	Batch Number
71424023	LGN PRESSFIT STEM 10MM X 120MM	18ASM1333A
71424049	LGN PRESSFIT STEM 16MM X 160MM	18ASM0247B

Shipment Date: June 8, 2018 through July 6, 2018

Potential Risk of Use of the Product

In the event the affected device is presented for use, the product will perform as intended. The affected devices were manufactured within the required specifications. Therefore, the use of or exposure to the affected device presents a negligible risk of adverse health consequences.

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 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 item, batches and quantities 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 ☐

Account #/ District Office Name	Product Part Number	Batch Number	Quantity of Units to be Returned	RA Number (for internal use only)

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: (___) _____-_____

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