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-2018-11

March 29, 2018

<Insert Address>

This letter is to inform you that Smith & Nephew Inc., have initiated a field action to voluntarily remove several lots of LEGION CR HIGH FLEX XLPE due to a manufacturing packaging error. The inner and outer packaging was inadvertently sealed together.

Please see product details below:

Product Number	Description	Batch Number
71453101	LEGION CR HIGH FLEX XLPE SZ 1-2 9MM	08BM09288; 12EM05884 & 12EM07720
71453121	LEGION CR HIGH FLEX XLPE SZ 5-6 9MM	11DM11664 & 15BM09445
71453122	LEGION CR HIGH FLEX XLPE SZ 5-6 11MM	09FM04561; 14AM05774 & 15GM11501
71453185	LEGION CR HIGH FLEX XLPE SZ 5-6 10MM	16EM12620

Shipment Date: October 24, 2016 through July 26, 2017

Potential Risk with Use of the Product

In the event, the user opens the outer pouch the inner pouch will be opened as well. The packaging error could potentially result in the use of a contaminated device if a replacement device is not available.

Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

smith&nephew

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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 (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