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:

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

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
Urgent Medical Device Recall Notice  
R-2018-11

March 29, 2018  
<Insert Address>

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.

<table>
<thead>
<tr>
<th>No Product to Be Returned</th>
<th></th>
</tr>
</thead>
</table>

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: ______________________________________________