

May 26, 2016

## URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall

Reference: R-2016-18

Concerned Devices: LEGION HINGE KNEE FEMORAL ASSEMBLY

| Product No.  | Description                        | Batch No.    |
|--|------------------------------------|--------------|
| 71421363; 71421364; 71421365;<br>71421373; 71421374 & 71421375 | LEGION HINGE KNEE FEMORAL ASSEMBLY | See attached |

Dear Dr.

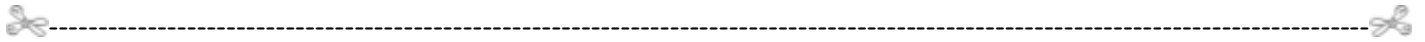
This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of several batches of LEGION HINGE KNEE FEMORAL ASSEMBLY due to a manufacturing issue. The surface inside of the femoral component, where cement is applied for adhesion, is out of specification. The expected surface roughness is 200-325 Ra. The affected devices are below allowable limits for surface roughness.

This field action has been reported to the relevant competent authorities.

|  |   |
|--|---|
| <b>Risks to Health</b>   | In the event the affected femoral implant is used during a knee procedure, adherence of the implant/ cement interface with the patient's bone structure may be impaired, as the roughness of the surface of the implant is not within specification. This could result in loosening of the implant/cement interface, potentially leading to revision surgery. Surgeons should carry on with standard knee arthroplasty follow-up protocol for patients implanted with an affected device. |
| <b>If affected devices have been implanted, Smith &amp; Nephew recommends:</b> | <ul style="list-style-type: none"> <li>• Surgeons should follow standard post-operative follow-up protocols and actions for their patients.</li> <li>• Surgeons should ensure that patients are informed about symptoms (particularly pain and knee instability) that might indicate the need for implant review or revision surgery, and the need to seek follow up care should these symptoms arise.</li> </ul>   |

|  |  |
|--|--|
| <b>Actions to be taken by the user</b> | <ol style="list-style-type: none"><li>1. Locate and quarantine affected unused devices immediately.</li><li>2. Return quarantined product to your national Smith &amp; Nephew agency/distributor.</li><li>3. Complete the return slip and fax it to your national Smith &amp; Nephew agency/distributor.</li><li>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.</li><li>5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.</li></ol> |
|--|--|

Smith & Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.



If you have any questions please feel free to contact us under the following contact details:

*Smith & Nephew Advanced Surgical Devices UK & I*  
*Fax: + 44 (0)1480 423 201, or*  
*Email: [anica.alcala@smith-nephew.com](mailto:anica.alcala@smith-nephew.com) or [greg.williams@smith-nephew.com](mailto:greg.williams@smith-nephew.com)*

**Return Slip**

**Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.**

We hereby confirm that we are aware of this Field Safety Notice concerning the LEGION HINGE KNEE FEMORAL ASSEMBLY. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

- In our facility we do not have any of the affected product in stock
- or
- We will return the following products:

| Product No. | Batch No. / Quantity to be Returned |           |                          |           |                          |           |                          |           |                          |           |                          |           |
|-------------|-------------------------------------|-----------|--------------------------|-----------|--------------------------|-----------|--------------------------|-----------|--------------------------|-----------|--------------------------|-----------|
| 71421363    | <input type="checkbox"/>            | 15LM08798 |                          |           |                          |           |                          |           |                          |           |                          |           |
| 71421364    | <input type="checkbox"/>            | 15KM20807 | <input type="checkbox"/> | 15KM20808 | <input type="checkbox"/> | 15KM20811 | <input type="checkbox"/> | 15KM20812 | <input type="checkbox"/> | 15LM08258 | <input type="checkbox"/> | 15LM12482 |
|             | <input type="checkbox"/>            | 15MM03005 |                          | 15MM03007 |                          |           |                          |           |                          |           |                          |           |
| 71421365    | <input type="checkbox"/>            | 15JM04561 | <input type="checkbox"/> | 15JM04570 | <input type="checkbox"/> | 15JM04589 | <input type="checkbox"/> | 15KM08936 | <input type="checkbox"/> | 15KM08937 | <input type="checkbox"/> | 15KM08940 |
|             | <input type="checkbox"/>            | 15KM08942 | <input type="checkbox"/> | 15KM08948 | <input type="checkbox"/> | 15KM08949 | <input type="checkbox"/> | 15KM09010 | <input type="checkbox"/> | 15KM09011 | <input type="checkbox"/> | 15KM09013 |
|             | <input type="checkbox"/>            | 15KM09014 | <input type="checkbox"/> | 15KM09015 | <input type="checkbox"/> | 15KM09016 | <input type="checkbox"/> | 15LM09119 | <input type="checkbox"/> | 15LM09122 | <input type="checkbox"/> | 15LM09123 |
|             | <input type="checkbox"/>            | 15LM09124 | <input type="checkbox"/> | 15LM12483 | <input type="checkbox"/> | 15LM12484 | <input type="checkbox"/> | 15LM12486 | <input type="checkbox"/> | 15LM12488 | <input type="checkbox"/> | 15LM15652 |
|             | <input type="checkbox"/>            | 15MM09829 | <input type="checkbox"/> | 15MM09833 | <input type="checkbox"/> | 16AM12222 | <input type="checkbox"/> | 16AM12224 | <input type="checkbox"/> | 16AM12235 | <input type="checkbox"/> | 16AM12237 |
|             | <input type="checkbox"/>            | 16AM12240 | <input type="checkbox"/> | 16AM12243 | <input type="checkbox"/> | 16AM12255 | <input type="checkbox"/> | 16AM12268 | <input type="checkbox"/> | 16AM12269 |                          |           |
| 71421373    | <input type="checkbox"/>            | 15LM08792 | <input type="checkbox"/> | 15LM15638 | <input type="checkbox"/> | 15LM15639 | <input type="checkbox"/> | 15MM03011 | <input type="checkbox"/> | 15MM03012 | <input type="checkbox"/> | 15MM03014 |
|             | <input type="checkbox"/>            | 15MM09814 |                          |           |                          |           |                          |           |                          |           |                          |           |
| 71421374    | <input type="checkbox"/>            | 15KM09161 | <input type="checkbox"/> | 15KM09163 | <input type="checkbox"/> | 15KM09175 | <input type="checkbox"/> | 15KM17714 | <input type="checkbox"/> | 15KM17800 | <input type="checkbox"/> | 15KM17806 |
|             | <input type="checkbox"/>            | 15KM17809 | <input type="checkbox"/> | 15KM17817 | <input type="checkbox"/> | 15LM01258 | <input type="checkbox"/> | 15LM01259 | <input type="checkbox"/> | 15LM01260 | <input type="checkbox"/> | 15LM01261 |
|             | <input type="checkbox"/>            | 15LM08803 | <input type="checkbox"/> | 15LM08816 | <input type="checkbox"/> | 15LM08820 | <input type="checkbox"/> | 15LM08821 | <input type="checkbox"/> | 15KM09183 | <input type="checkbox"/> | 15KM09184 |
| 71421375    | <input type="checkbox"/>            | 15LM08835 | <input type="checkbox"/> | 15LM08837 | <input type="checkbox"/> | 15LM08839 | <input type="checkbox"/> | 15LM08840 |                          |           |                          |           |

Institution: \_\_\_\_\_ Reference: R-2016-18

Name: \_\_\_\_\_ Date / Signature: \_\_\_\_\_

**Affected Product and Batch Numbers**

|          |           |           |           |           |           |           |           |           |
|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| 71421363 | 15LM08798 |           |           |           |           |           |           |           |
| 71421364 | 15KM20807 | 15KM20808 | 15KM20811 | 15KM20812 | 15LM08258 | 15LM12482 | 15MM03005 | 15MM03007 |
| 71421365 | 15JM04561 | 15JM04570 | 15JM04589 | 15KM08936 | 15KM08937 | 15KM08940 | 15KM08942 | 15KM08948 |
|          | 15KM08949 | 15KM09010 | 15KM09011 | 15KM09013 | 15KM09014 | 15KM09015 | 15KM09016 | 15LM09119 |
|          | 15LM09122 | 15LM09123 | 15LM09124 | 15LM12483 | 15LM12484 | 15LM12486 | 15LM12488 | 15LM15652 |
|          | 15MM09829 | 15MM09833 | 16AM12222 | 16AM12224 | 16AM12235 | 16AM12237 | 16AM12240 | 16AM12243 |
|          | 16AM12255 | 16AM12268 | 16AM12269 |           |           |           |           |           |
| 71421373 | 15LM08792 | 15LM15638 | 15LM15639 | 15MM03011 | 15MM03012 | 15MM03014 | 15MM09814 |           |
| 71421374 | 15KM09161 | 15KM09163 | 15KM09175 | 15KM17714 | 15KM17800 | 15KM17806 | 15KM17809 | 15KM17817 |
|          | 15LM01258 | 15LM01259 | 15LM01260 | 15LM01261 | 15LM08803 | 15LM08816 | 15LM08820 | 15LM08821 |
| 71421375 | 15KM09183 | 15KM09184 | 15LM08835 | 15LM08837 | 15LM08839 | 15LM08840 |           |           |