

[Recipients Address]

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; 71421373; 71421374 & 71421375	LEGION HINGE KNEE FEMORAL ASSEMBLY	See attached

Dear Dr.

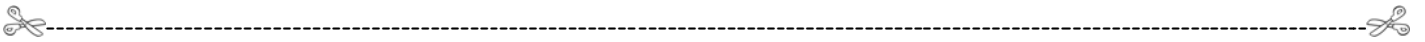
This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of several batches of LEGION HINGE KNEE FEMORAL ASSEMBLY due to a manufacturing issue. The surface inside of the femoral component, where cement is applied for adhesion, is out of specification. 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.

Risks to Health	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.
If affected devices have been implanted, Smith & Nephew recommends:	<ul style="list-style-type: none"> • Surgeons should follow standard post-operative follow-up protocols and actions for their patients. • 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.

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

Contact Details of Subsidiary / Distributor
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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		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	15KM09183	15KM09184	
71421375		15LM08835	15LM08837	15LM08839	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		