

[Recipients Address]

Device Field Safety Notice for Recall

Reference: R-2018-25

Concerned Devices: Legion HK Tibial Base Size 5 Left

Product No.	Description	Batch No. / UDI No.
71421305	LEGION HK TIBIAL BASE SZ 5 LEFT	15DAF0010K

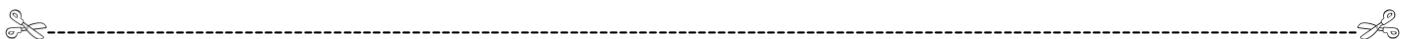
Dear Customer:

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a recall to remove a single lot of the LEGION HK TIBIAL BASES due to a manufacturing error. The guided motion screw was incorrectly inserted on the underside of the tibial base. In a correctly assembled tibial base, the guided motion screw is inserted from the top side.

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

Risks to Health	The use of the affected device could potentially result in a surgical delay. If the user fails to notice the assembly error prior to implantation, the device will not sit flush on the prepared bone surface. Consequently, the surgical staff would be required to remove the incorrectly assembled tibial base, clean the bone surface and implant a correctly assembled tibial base, hence requiring more time to perform the surgery.
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 Notice for Recall is terminated to ensure effectiveness of the action.

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

Return Slip

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

☐ We confirm the receipt of this Field Safety Notice for Recall.

In our facility we have _____ [Qty] concerned devices which we will return.

_____ [Qty] concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2018-25

Name: _____ Date / Signature: _____