

[Recipients Address]

August 1, 2018

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Notice for Recall

Reference: R-2018-28

Concerned Devices: Genesis II Femoral Size 6

Product No.	Description	Batch No. / UDI No.
71420026	GENESIS II NON POROUS C/R FEMORAL SIZE 6 RIGHT	16CMB0061A & 16CMB0066A

Dear Customer:

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a recall to remove two lots of GENESIS II NON POROUS C/R FEMORAL SIZE 6 RIGHT due to a manufacturing packaging error. The affected devices were packaged and labeled as GENESIS II C/R Femoral size 6 Right; the package actually contained a GENESIS II C/R Femoral size 4 Left.

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

Risks to Health	The procedure requires a size 6 right femoral, but after the user opens the package a size 4 left femoral is presented for use. The user recognizes the error and elects to use a backup device or an alternate size. The use of a backup device or an alternate size could potentially result in additional bone cuts or surgical delay.
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-2018-28

Name: _____ Date / Signature: _____