

[Recipients Address]

January 12, 2017

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

Reference: R-2016-56

Concerned Devices: STAINLESS STEEL 12/14 TAPER FEMORAL HEAD 22MM + 12

Product No.	Description	Batch No.
71292212	STAINLESS STEEL 12/14 TAPER FEMORAL HEAD 22MM + 12	14KT47150 & 15GT56608

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action for two lots of STAINLESS STEEL 12/14 TAPER FEMORAL HEAD 22MM + 12 due a labeling issue. The device product label was wrongly affixed with a CE Mark. The device was previously approved to bear the CE mark, but renewal of the product's registration did not occur and as such, the devices are no longer approved to bear the CE mark.

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

Risks to Health	The device was manufactured within specification and will perform as intended. Therefore, the use of or exposure to the device is not likely to cause adverse health consequences.
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.

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 hereby confirm that we are aware of this Field Safety Notice. 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	Description	Lot Number	Qty to be Returned
71292212	STAINLESS STEEL 12/14 TAPER FEMORAL HEAD 22MM + 12	14KT47150	
71292212	STAINLESS STEEL 12/14 TAPER FEMORAL HEAD 22MM + 12	15GT56608	

Institution: _____ Reference: R-2016-56

Name: _____ Date / Signature: _____