

[Recipients Address]

February 18, 2019

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

Reference: R-2018-42

Concerned Devices: SMF Stem With Stiktite

Product No.	Description	Batch No. / UDI No.
71352510	SMF STEM WITH STIKTITE STANDARD OFFSET SIZE -1	11AM15163U, 11AM15184T, 11CM01097U, 15MM06466, 16EM13018, 16EM13035 & 18CM08027
71352511	SMF STEM WITH STIKTITE HIGH OFFSET SIZE -1	11CM01091T, 11EM12764T, 11EM12764U, 13MM16036B, 14GM13037D, 15MM09360A, 15MM10833A, 18CM24036 & 18EM15257

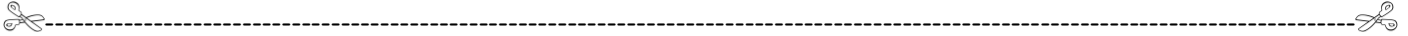
Dear Customer:

This letter is to inform you that Smith & Nephew Inc., has voluntarily initiated a recall to remove multiple lots of SMF STEMS WITH STIKTITE due to a labeling error. Complaints were received indicating that the outer label incorrectly identified the product as size “1” instead of “-1”. The product contained within the package is size “-1”, however there is the potential that the unclear label appears as size “1”.

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

Risks to Health	In the event the incorrectly labeled device is presented for use, the surgeon would evaluate the device and recognize the size discrepancy (size “-1” rather than size “1”). In most circumstances the procedure can be completed using a back-up device. However, in the event of lack of availability of a back-up device, the surgeon could select a larger size device to complete the procedure. The use of a larger size implant carries the risk of potential leg lengthening or fracture of the femur in an attempt to accommodate the larger size stem.
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.	
<input type="checkbox"/>	We confirm the receipt of this Field Safety Notice for Recall.
In our facility we have _____ <i>[Qty]</i> concerned devices which we will return.	
_____ <i>[Qty]</i> concerned devices have been discarded in our facility.	
Institution: _____	Reference: R-2018-42
Name: _____	Date / Signature: _____