smith&nephew

[Recipients Address]

March 27, 2019

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

Reference: R-2019-03

Concerned Devices: VLP MINI-MOD 2.0MM STRAIGHT PLATE 6 HOLE

Product No.	Description	Batch No. / UDI No.
74442022	VLP MINI-MOD 2.0MM STRAIGHT PLATE 6 HOLE	15EM11918A,15HM07435, 15EM19074 & 15EM17479

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has voluntarily initiated a recall to remove multiple lot numbers of VLP MINI-MOD 2.0MM STRAIGHT PLATE 6 Hole. Complaints were received indicating that the VLP MINI-MOD 2.0MM STOUT PL TEMPLATE eight (8) Hole was incorrectly packaged and labeled as a VLP MINI-MOD 2.0MM STRAIGHT PL six (6) Hole.

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

Risks to Health	In the event the user does not initially recognize the affected product is a template, rather than the intended implantable device, and attempts to implant the affected product, the user will be unsuccessful due to the difference in hole size. However, this would cause the user to realize the affected product is incorrect and an alternate device would be used.
Actions to be taken by the user	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-2019-03

Name: _____ Date / Signature: _____