

[Recipients Address]

September 19, 2016

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

Reference: R-2016-35

Concerned Devices: 5.2mm Suction Punch

Product No.	Description	Batch No.
2685	5.2mm Suction Punch	50568539, 50560357, 50559396, 50555648 & 50549486

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of five batches of 5.2mm SUCTION PUNCH due to a manufacturing issue. The weld penetration was found to be under specification potentially causing the distal tip to bend or break.

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

Risks to Health	In the event the device yields at the distal tip and break off in the joint space, the failure could potentially result in a slight 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 Corrective Action 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 hereby confirm that we are aware of this Field Safety Notice concerning the 5.2mm Suction Punch. 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 No.	Description	Batch No.	Quantity to be Returned
2685	5.2mm Suction Punch	50549486	
		50555648	
		50559396	
		50560357	
		50568539	

Institution: _____ Reference: R-2016-35

Name: _____ Date / Signature: _____