

[Recipients Address]

November 14, 2016

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

Reference: R-2016-49

Concerned Devices: LATERAL SHOULDER CONNECTION BAR

Product No.	Description	Batch No.
7210576	LATERAL SHOULDER CONNECTION BAR	6066

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of a single batch of LATERAL SHOULDER CONNECTION BAR devices due to a manufacturing error. The part number 7210571, SHOULDER CONNECTION BAR, incorrectly was placed in the package instead of part number 7210576, LATERAL SHOULDER CONNECTION BAR.

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

Risks to Health	The affected device cannot be adequately assembled and therefore cannot be used.
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 concerning the LATERAL SHOULDER CONNECTION BAR. 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	Number Returned
7210576	LATERAL SHOULDER CONNECTION BAR	6066	

Institution: _____ Reference: R-2016-49

Name: _____ Date / Signature: _____