

[Recipients Address]

February 03, 2016

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

Reference: R-2015-28

Concerned Devices: BIOSURE® Ratcheted Driver

Product No.	Description	Batch No.
72201888	BIOSURE Ratcheted Driver	50536704

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of one lot of the BIOSURE Ratcheted Driver due to a labeling error. The devices were packaged and laser marked "Not For Human Use". The devices were manufactured in accordance with the specification; therefore, the device is expected to perform as indicated.

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

Risks to Health	In the event the laser mark error is noticed upon the completion of the procedure, it could potentially cause the user undue alarm.
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 BIOSURE Ratcheted Driver. 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
72201888	BIOSURE Ratcheted Driver	50536704	

Institution: _____ Reference: R-2015-28

Name: _____ Date / Signature: _____