Smith & Nephew Inc
1450 Brooks Road
Memphis, TN 38116

www.smith-nephew.com

We are smith&nephew

*[Recipients Address]*

July 13, 2015

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

Reference: R-2015-10
Concerned Devices: SURESHOT Humeral 3.2 MM AO Drills

| Product No. | Description | Batch No. | | |
|---|---|---|---|---|
| 71691155 | SURESHOT Humeral 3.2 MM AO Drills | 14LNG0019 | 14LNG0021C | 14MNG0019B |
| | | 14LNG0021 | 14LNG0021D | 14MNG0019C |
| | | 14LNG0021A | 14MNG0019 | 14MNG0019D |
| | | 14LNG0021B | 14MNG0019A | |

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary Field Safety Corrective Action of several batches of SURESHOT Humeral 3.2 MM AO Drills due to a manufacturing error. The affected drills may not adequately puncture the bone.
This field action has been reported to the relevant competent authorities.

| | |
|---|---|
| **Risks to Health** | In the event the affected drill is presented for use; the drill could break or overheat and potentially lead to a surgical delay. |
| **Actions to be taken by the user** | 1. Locate and quarantine affected devices immediately.<br>2. Return quarantined product to your national Smith & Nephew agency/distributor.<br>3. Complete the return slip and fax it to your national Smith & Nephew agency/distributor.<br>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.<br>5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action. |

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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.

In our facility we have _____ *[Qty]* concerned devices which we will return.

_____ *[Qty]* concerned devices have been used in our facility.

Institution: _____ Reference: R-2015-10

Name: _____ Date / Signature: _____