

[Recipients Address]

July 06, 2016

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

Reference: R-2016-30

Concerned Devices: REFLECTION SPHERICAL HEAD SCREW 25MM

Product No.	Description	Batch No.
71332525	REFLECTION SPHERICAL HEAD SCREW 25MM	16AM14274

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action for a single batch of 25mm REFLECTION Spherical Head Screws due to a packaging error. The labels correctly state that the product should be a 25mm screw, but the batch produced had longer, 35mm screws in the box. The catalog item number and description on the label are aligned, but the wrong product is inside the box.

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

<b>Risks to Health</b>	In the event the user does not notice the error and attempts to use the screw, the screw might be difficult to properly secure. This would result in the need to re-drill to accommodate the full length of the longer screw. In the rare event the screw is positioned in a non-safe area of the acetabulum; the 10mm length difference may present an additional risk for potential damage to the vascular and nerve structure depending on where the screw is positioned in the acetabulum.
<b>Actions to be taken by the user</b>	<ol style="list-style-type: none"><li>1. Locate and quarantine affected unused devices immediately.</li><li>2. Return quarantined product to your national Smith &amp; Nephew agency/distributor.</li><li>3. Complete the return slip and fax it to your national Smith &amp; Nephew agency/distributor.</li><li>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.</li><li>5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.</li></ol>

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 REFLECTION Spherical Head Screw. 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
71332525	REFLECTION Spherical Head Screw 25mm	16AM14274	

Institution: \_\_\_\_\_ Reference: R-2016-30

Name: \_\_\_\_\_ Date / Signature: \_\_\_\_\_