

[Recipients Address]

January 18, 2016

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

Reference: R-2016-02

Concerned Devices: LEGION® Screw-On Hemi Stepped Tibial Wedges

| Product No. | Description | Batch No. |
|-------------|---|-----------|
| 71421147 | LEGION Screw-On Hemi Stepped Tibial Wedge, 5mm Sz 5-6 Lt-Lat/Rt-Mdl | 14KM16422 |

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 LEGION Screw-On Hemi Stepped Tibial Wedges due a packaging issue. The device packaging included the tibial wedge alongside a 5mm screw component instead of a HEMI/Full step wedge screw component intended for use with the tibial wedge.

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

| | |
|--|--|
| Risks to Health | The affected device is presented for use and the surgeon notices intraoperatively that the screw is too long. In the event that a replacement screw is not available; the surgeon would cement the wedge to the femoral component potentially leading to loosening over time. |
| 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 LEGION Tibial Wedge. 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 |
|-------------|--|-----------|-------------------------|
| 71421147 | LEGION Screw-On Hemi Stepped Tibial Wedge, 5mm Sz 5-6 Lt-Lat/Rt-Mdl | 14KM16422 | |

Institution: _____ Reference: R-2016-02

Name: _____ Date / Signature: _____