Smith & Nephew Inc
150 Minuteman Road
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We are smith&nephew

[Recipients Address]

November 02, 2015

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

Reference: R-2015-16
Concerned Devices: Cavity SPINEWAND Device, 8-gauge

Product No.	Description	Batch No.
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1024313; 1024482; 1027160; 1034306; 1041879 and 1059328

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of a group of Cavity SPINEWAND Device, 8-gauge due to a potential breach in the sterile barrier. Cracks were observed in the packaging trays during the manufacturing process.

This field action does not include the Cavity SPINEWAND Device, 11-gauge (product No KP-CAV-7700-01).

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

PLEASE NOTE: Smith & Nephew Inc. purchased ArthroCare Corporation on May 29, 2014. For the purpose of this communication, the products being recalled were manufactured, packaged, labeled, and branded by ArthroCare Corporation at the time of shipment. The manufacturer of the products being recalled is ArthroCare Corporation.

Risks to Health	Due to a breach of the sterile barrier, use of the affected wand could potentially lead to an infection. The Cavity SPINEWAND Device is designed to be used within the vertebral body, and therefore complications can be paravertebral soft tissue infection and also osteomyelitis of the treated vertebral body.
Actions to be taken by the user	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.

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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 hereby confirm that we are aware of this Field Safety Notice concerning the Cavity SPINEWAND Devices. 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
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1024313	
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1024482	
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1027160	
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1034306	
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1041879	
KP-CAV-7705-01	Cavity SPINEWAND Device, 8-gauge	1059328	

Institution: _____ Reference: R-2015-16

Name: _____ Date / Signature: _____