[Recipients Address]

July 10, 2018

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Notice for Recall

Reference: WR-2018-27
Concerned Devices: Jelonet Dressing

Product No.	Description	Batch No. / UDI No.
7415	JELONET 15CM X 2M CTN 12 (JOAR)	201724

Dear Customer:

This letter is to inform you that Smith & Nephew Medical., have voluntarily initiated a recall to remove a single lot of JELONET 15CM X 2M CTN 12 (JOAR) dressing due to a packaging seal error. The affected products contained an insufficient or creased seals.

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

Risks to Health	The JELONET dressing is a low adherent, sterile paraffin Tulle Gras dressing made from open weave gauze. The dressings are used as a primary wound contact layer with paraffin to reduce the adherence of the product to the surface of a granulating wound. In the event of a broken or open seal, the paraffin would leak making the compromised seal visually obvious to the user. The dressing would be replaced, and the procedure would be completed as intended. If the failure went unnoticed, the loss of the sterile seal could potentially lead to bacterial or particulate contamination to the wound.
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 Notice for Recall 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.

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 for Recall.

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

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

Institution: _____ Reference: WR-2018-27

Name: _____ Date / Signature: _____