

**Smith & Nephew, Inc.**

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[Recipients Address]

May 24, 2021

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

Reference: *R-2021-04*  
 Concerned Devices: *JELONET 5X5CM CTN 50*

| <b>Product No.</b> | <b>Description</b>   | <b>Batch No.</b>                                      |
|--------------------|----------------------|---|
| 7403               | JELONET 5X5CM CTN 50 | 202018, 202019<br>202020, 202021<br>202022 and 202036 |

Dear Customer:

This letter is to inform you that Smith & Nephew Medical Ltd. has initiated a field action to voluntarily remove multiple lots of the JELONET 5x5CM. There is a potential for a sterile barrier breach and paraffin leakage due to manufacturing error.

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

|  |  |
|--|--|
| <b>Risks to Health</b>                 | In the most likely event, the pouch is presented for use without an opened seal and the dressing is applied to the patient and performs as intended. However, in the event a pouch with an open seal is not detected and the dressing is applied to the patient, it may potentially result in an infection.  |
| <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+Nephew agency/distributor.</li> <li>3. Complete the return slip and fax it to your national Smith+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 Notice for Recall 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 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: R-2021-04

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

Country: \_\_\_\_\_