

[Recipients Address]

September 21, 2020

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

Reference: R-2020-22

Concerned Devices: IODOFLEX Dressing

<b>Product No.</b>	<b>Description</b>	<b>Batch No.</b>
66001302	IODOFLEX Dressing 3 X 10g	CDB201

Dear Customer:

This letter is to inform you that Smith+Nephew has initiated a Field Action to voluntarily remove a single lot of IODOFLEX Dressing due to a manufacturing error. The inadequate welding of dressing seals could potentially result in a sterile barrier breach.

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

<b>Risks to Health</b>	In the most likely scenario, the breached package does not lead to product contamination and the use of the product has no impact on the procedure or patient. In the worst case the package breach resulted in a non-sterile product, the product use could potentially result in a biological response such as local infection and/or systemic 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 email or 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:

Please return slip to and contact the customer service to arrange product returns:

Email: [AWM.CS.UKI@smith-nephew.com](mailto:AWM.CS.UKI@smith-nephew.com)

Telephone: 0 800 157573 Option 1

Fax:+ 44 (0) 1480 423201

## 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-2020-22

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

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