Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com

# Urgent Medical Device Recall Notice
# WR-2019-07

April 08, 2019

<Insert Address>

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove several lots of ALGISITE M Surgical Dressing due to a registration inconsistency. The labeling details registered with The Federal Service for Surveillance in Healthcare (Roszdravnadzor) were inconsistent. The agency indicated that the shelf life, sterilization method and IFU information in the registration dossier were inconsistent with the actual product data. Therefore the affected products are not covered in the certification.

Please see product details below:

| Product Number | Description | Batch Number |
|---|---|---|
| 66000519 | Algisite M 5x5 | S15470, S15723 |
| 66000520 | Algisite M 10x10 | S13300, S15795, S15833, S16010, S16129, S16288, S16358 |
| 66000521 | Algisite M 15x20 | S13218, S13983, S14066, S15722 |
| 66000522 | Algisite M 2x30 | R13299 |

## Potential Risk with Use of the Product

The affected devices were manufactured in accordance with the correct manufacturing specification. Therefore, in the event the devices are presented for use, the devices will perform as intended and no additional risk to the patient will be introduced due to the inconsistent information in the submitted dossier.

## Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

smith&nephew

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<Insert Address>

**PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT**

**Required Actions:**

1. Please inspect your inventory and locate any unused devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
    a. If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.
2. If you have no product to return, please put an X in the appropriate location below.
3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
4. Complete the remainder of the form, sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.
   **Please Note** – even if you have no product to return, this form must be completed, signed and returned.
5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

**No Product to Be Returned** ☐

| Product Part Number | Batch Number (List Specific Batch #'s to be Returned) | Quantity of Units to be Returned |
|---|---|---|
| | | |
| | | |
| | | |

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____Title: _____

Signature (required):_____ Date (required):____/____/____

Email:_____ Telephone: ( ___ ) _____-_____

S&N Account Number: _____ RA Number (S&N use only):_____

Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Itella LLC, 143391, Russia, Moscow, Marushkinskoe, Krekshino village, Tupikovyi proezd, building 2