1450 Brooks Road
Memphis, TN 38116
USA

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

Urgent Medical Device Recall Notice
WR-2019-09

May 13, 2019

<Insert Address>

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

This letter is to inform you that Smith & Nephew Medical Ltd. has voluntarily initiated a recall to remove four lots of RENASYS Foam Kits with soft ports due to a manufacturing error. A quality control failure occurred during the sterilization process for these four lots, thus the sterility of these lots cannot be guaranteed.

Please see affected product details below:

Product Number	Description	Batch Number
66800795	RENASYS FOAM MEDIUM W/SOFT PORT	2018080683 & 2018090334
66800794	RENASYS FOAM SMALL W/SOFT PORT	2018091570 & 2018100021

Shipment Date: February 4, 2019 through February 27, 2019

Potential Risk of Use of the Product

In the event a non-sterile foam kit is used, the use could potentially result in an increased risk of infection including a local infection, skin graft failure or systemic infection.

Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

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PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any 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 item, batches and quantities 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 ☐

Account #/ District Office Name	Sales Area #/Name	Product Part Number	Batch Number	Quantity of Units to be Returned	RA Number (for internal use only)

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: (___) _____-_____

Return affected product to: Smith & Nephew | Attn: Global Field Actions 2225 Cedars Road | Lawrenceville, GA 30043