

[Recipients Address]

Device Field Safety Corrective Action / Recall

Reference: WR-2017-06

Concerned Devices: Cuticerin Dressings

Product No.	Description	Batch No. / UDI No.
66045560, 66045562, 66045502, 66045561 & 66045563	CUTICERIN Surgical Dressing	1522, 1530, 1537, 1551, 1643, 1502, 1539, 1552, 1607, 1639, 1519, 1537, 1546, 1502, 1506, 1520, 1534, 1604, 1509, 1528 & 1547

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. have initiated a field action to voluntarily remove several lots of CUTICERIN Surgical Dressing due to a labeling error. The sterilization method registered with The Federal Service for Surveillance in Healthcare (Roszdravnadzor), was incorrectly specified as Ethylene Oxide (EtO) instead of Gamma.

The affected dressings are labeled and distributed with the correct method of sterilization which is Gamma.

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

Risks to Health	The affected dressings were manufactured within specification and will perform as indicated. Therefore the use of or exposure to the dressings are not likely to cause adverse health consequences.
Actions to be taken by the user	<ol style="list-style-type: none"> 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 Corrective Action 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.

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.

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

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

Institution: _____ Reference: WR-2017-06

Name: _____ Date / Signature: _____