

MEDICAL DEVICE CORRECTION NOTICE
C-2016-45

December 07, 2016

Smith & Nephew, Inc. has initiated a Field Correction for several lots of SPLIT ELECTRODE GROUND PAD due to an expiration date labeling error. A discrepancy was found between the expiration date printed on the outer packaging human readable barcode data and the expiration date provided on the inner product identification label. The inner product identification label provides the correct expiration date of May 2017.

This letter is to notify all affected customers of the issue and provide the option to use the product as is prior to May 2017, the expiration date provided on the inner label or return it for a credit.

Please see product details below:

Product No	Description	Lot	Shipment Dates
7209687	SPLIT ELECTRODE GROUND PAD	50570649; 50569785; 50569784 & 50569783	October 2015-August 2016

Potential Risk with Use of the Product

The use of or exposure to the referenced devices are not likely to cause adverse health consequences. The affected devices are currently within the expiry period and will perform as intended.

Actions for Hospital Representatives

1. Please inspect your inventory and complete the attached Inventory Correction Certification Form.
2. If you have the affected products, please maintain awareness of this notice.
3. If you have the affected products and would like a credit, please contact the S&N Returns team at 800-343-5717, option 3 or endoreturn@smith-nephew.com to obtain a return authorization (RA) number.

Inventory Correction Certification Form

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PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Acknowledgement of Correction Notification

By signing below, I acknowledge that I have received the notification and I have taken the appropriate actions.

Printed Name: _____ Title _____

Telephone: (____) _____ - _____ Date: ____/____/____

Facility Name:

Account Number:

Signature _____

Check One:

- ☐ I have checked my inventory and my facility no longer possesses any device from the affected lots.
- ☐ I have checked my inventory and my facility still possesses a device(s) from the affected lots. Although I acknowledge the correction notification, the device(s) will not be returned.
- ☐ I have checked my inventory and my facility still possesses a device(s) from the affected lots. I will contact the S&N Returns team at the number provided in the letter to coordinate a credit.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975