

MEDICAL DEVICE CORRECTION NOTICE
C-2016-05

January 29, 2016

Smith & Nephew, Inc. has initiated a Field Correction for a single lot of ENDOBUTTON CL BTB STERILE 30mm due to a manufacturing error. A single lot of ENDOBUTTON devices were packaged and distributed with a metal button that is 2mm longer in length than the intended component. This letter is to notify all affected customers of the issue and provide the option to use the product as-is or return it for an exchange.

Please see product details below:

Product No	Description	Lot	Shipment Dates
7210082	ENDOBUTTON CL BTB Sterile 30mm	50499261	4/11/2014-5/28/2014

Potential Risk with Use of the Product

In the event the affected device is presented for use, the button may not be compatible with graft preparation tools and there is a slight possibility that the surgeon may have difficulty flipping the button. In the event the surgeon is unable to flip the button, minor surgical delay could be experienced as the tunnel is lengthened. Adjustments to the tunnel are often required during the standard implantation of the device and therefore, the use of or exposure to the product is not likely to cause adverse health consequences.

Actions for Hospital Representatives and Smith & Nephew Sales Personnel

1. Please inspect your inventory and complete the attached Inventory Correction Certification Form.
2. If you have the affected products and plan to use as-is, please maintain awareness of this notice.
3. If you have the affected products and would like an exchange, 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

C-2016-05

January 29, 2016

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 return and replacement.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975