Smith & Nephew Inc
1450 Brooks Road
Memphis, TN 38116

T 901-396-2121

www.smith-nephew.com

We are smith&nephew

MEDICAL DEVICE CORRECTION NOTICE
C-2016-07

January 29, 2016

Smith & Nephew, Inc. has initiated a Field Correction for several lots of TWINFIX 5.0 AB Suture Anchor w/Two 38" Ultrabraid Suture Needles and Threaded Dilator due to a labeling error. The pouch label and patient label for the affected lots contain the incorrect description of the suture, indicating "Durabraid" as opposed to "Ultrabraid". The box label is correct and the product contains an Ultrabraid suture. 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
7210711	TWINFIX 5.0 AB Suture Anchor w/Two 38" Ultrabraid Suture Needles and Threaded Dilator	50520619, 50521940, 50542098 & 50544512	November 28, 2014-November 9, 2015

Potential Risk with Use of the Product

In the event the affected devices are presented for use, both the Ultrabraid and Durabraid are indicated for orthopedic repair and both products exceed the minimum requirements for USP <881>. 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 to obtain a return authorization (RA) number.

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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 return and replacement.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO: