Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

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

MEDICAL DEVICE CORRECTION NOTICE
C-2016-60

February 02, 2017

Smith & Nephew, Inc. has initiated a Field Correction for several lots of OSTEORAPTOR SUTURE ANCHOR WITH ULTRABRAID SUTURES devices due to a labeling error. The outer box label incorrectly states the suture color as blue; the provided suture is white. The inner label is correct.

This letter is to notify all affected customers of the issue.

Please see product details below:

Product Number	Description	Lot	Shipment Dates
72201991	OSTEORAPTOR 2.3 Suture Anchor W/ONE ULTRABRAID (#2) Suture	50600657, 50560521, 50487785, 50494254, 50506297, 50476988, 50530461, 50597650, 50598959, 50537141, 50564182, 50595170, 50555978, 50511342, 50570333, 50542668, 50571777, 50487786, 50497603, 50488284, 50497277, 50486698, 50575504, 50571782, 50588643, 50554079, 50500339, 50496037, 50507463, 50595167, 50526004, 50595166, 50474895, 50598741, 50532061, 50571772, 50604177, 50498825, 50598958, 50592970	September 2013 through October
72202165	OSTEORAPTOR 2.9 Suture Anchor W/ONE ULTRABRAID (#2) Suture	50496068, 50558049, 50594103, 50479835, 50550566, 50479833, 50483677, 50579175, 50482234, 50519599, 50510232, 50485395, 50477593, 50514234, 50482885, 50497416	

Potential Risk with Use of the Product

In the event the affected device is presented for use, the user may notice the difference in the label and the suture color. However, the device is not necessarily selected based on color and although a physician may prefer a non-white suture, the color does not impact the performance characteristics of the device.

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.

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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. I acknowledge the correction notification.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975