Smith & Nephew Inc
130 Forbes Boulevard
Mansfield MA 02048
www.smith-nephew.com

Fax: 508-261-3620
Direct: 508-261-3731

We are smith&nephew

Urgent – Addendum to Product Recall 1st Notification – Urgent

August 17, 2012

On August 6, 2012, Smith & Nephew Endoscopy initiated a voluntary recall of 63 metal and PEEK suture anchors from the BIORAPTOR®, FOOTPRINT, HEALICOIL® and TWINFIX® product lines due to a packaging issue. Specifically, pin holes were found in a small number of pouches, which constitutes a breach of the sterile barrier. A copy of the notification that was issued on August 6 is included for your reference.

We have amended that voluntary recall to include 11 additional part numbers. Three of those part numbers are for suture anchors. Another three part numbers represent different package configurations (i.e. multi-packs) and contain the same products that were voluntarily recalled on August 6. The remaining five part numbers were custom-made packs and do not apply to you.

Please refer to the table on page 3 for a list of affected product numbers.

Potential Risk with Use of the Product

In the most likely scenario, a patient would have no adverse reaction to a device with a pin hole in the package; however, it is possible that, during a surgical procedure, a fixation device is prepared for the procedure, but the physician or prep nurse will overlook a pin hole in the pouch before placing the device into the sterile field. The non-sterile device will then be used during a routine surgical procedure, and may result in an adverse reaction (surgical site infection) that is reversible with aftercare by the physician. In rare instances, there exists the remote possibility that the patient may experience a systemic infection (sepsis) resulting in organ failure and death.

Actions for Hospital Representatives

1. Please inspect your inventory, locate any unused devices identified in the table on page 3 and quarantine them immediately.
2. Complete the columns in the table on page 3, indicating the product and lot numbers, and quantities that need to be returned. If you do not have product to return, please place an "x" in the column "No Product to Return".
3. Provide your contact information in the space provided on the following page and forward it to Hoangthi Le whose contact information is provided at the end of this letter.
4. Please contact Smith & Nephew's Returns Group at 800-343-5717, option 3, or by email at endo.andreturns@smith-nephew.com. They will provide you with a Return Authorization (RA) and your replacement product will ship upon availability. To expedite this process, please include a copy of the contact information that you provide on the following page.

Actions for Sales Representatives

1. Please inspect your inventory, locate any unused devices identified in the attached list of affected product and quarantine them immediately.
2. Complete the columns in the table on page 3, indicating the product and lot numbers, and quantities that need to be returned. If you do not have product to return, please place an "x" in the column "No Product to Return".
3. Provide your contact information in the space provided on the following page and forward it to Hoangthi Le whose contact information is provided at the end of this letter.
4. Please contact Smith & Nephew's Demo Service Department for a Return Authorization (RA), include a copy of the contact information that you provide on the following page. You may contact them by phone at 800-343-5717, option 5, option 1 or by email (preferred method) to Endoscopy.DemoSvc@smith-nephew.com.

Smith & Nephew Inc
130 Forbes Boulevard
Mansfield MA 02048
www.smith-nephew.com

Fax: 508-261-3620
Direct: 508-261-3731

We are smith&nephew

Actions for Smith & Nephew Affiliates/Distributors

1. Send this letter to your customers and ask them to return the recalled product. You may translate the letter into your local language as applicable.
2. Please inspect your inventory, locate any unused devices identified in the attached list of affected product and quarantine them immediately.
3. Complete the columns in the table on page 3, indicating the product and lot numbers, and quantities that need to be returned. If you do not have product to return, please place an "x" in the column "No Product to Return".
4. Provide your contact information in the space provided below and forward it to Hoangthi Le whose contact information is provided at the end of this letter.
5. Please contact Smith & Nephew's Returns Group at 800-343-5717, option 3, or by email at endo.andreturns@smith-nephew.com. They will provide you with a Return Authorization (RA) and issue a credit once your product is received.

For Hospital Representatives

Name (Print) _____ Signature _____ Date _____

Facility Name _____

Facility Address _____

Contact Phone # _____ Fax _____

Smith & Nephew Account # _____

For Smith & Nephew Sales Representatives

Name (Print) _____ Signature _____ Date _____

Contact Phone # _____ Fax _____

For Smith & Nephew Affiliates/Distributors

Name (Print) _____ Signature _____ Date _____

Name of Organization _____

Contact Phone # _____ Fax _____

Please return this form to Hoangthi Le by email at Hoangthi.Le@smith-nephew.com or by fax at +1-508-261-3620. If you have questions, you may also contact Hoangthi Le directly by phone at +1-508-261-3731.

We apologize for any inconvenience this may cause.

Respectfully,

Albert A. Pytka
Director, Quality

Smith & Nephew Inc
130 Forbes Boulevard
Mansfield MA 02048
www.smith-nephew.com

Fax: 508-261-3620
Direct: 508-261-3731

We are smith&nephew

Addendum – Additional Affected Product Numbers

Product Number	Description (suture anchors omitted from August 6 recall)	Lot Number	Quantity to Return	No Product to Return
72203258	BIORAPTOR® 2.3 mm CURVED PK Suture Anchor BL, 42 HIP			
72203259	BIORAPTOR 2.3 mm CURVED PK Suture Anchor WHT, 42 HIP			
72200795	MINITAC® 2.0 mm Ti with 2 DURABRAID® sutures			
Product Number	**Description (suture anchors included in August 6 recall)**	**Lot Number**	**Quantity to Return**	**No Product to Return**
72200759 Multi-pack of 5	Part Nr 72200755, 5.0 mm TWINFIX® Ti Suture Anchor with two #2 preloaded ULTRABRAID® sutures, sterile			
72200760 Multi-pack of 5	Part Nr 72200752, 3.5 mm TWINFIX Ti Suture Anchor with two #2 preloaded ULTRABRAID			
72200749 Multi-pack of 5	Part Nr 72200750, 2.8 mm TWINFIX Ti Suture Anchor with one #2 preloaded ULTRABRAID suture, sterile			