

***Urgent – Product Recall 1st Notification – Urgent
R-2015-04***

April 30, 2015

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary recall of all batches of ULTRA FAST-FIX Knot Pusher Suture Cutters manufactured from April 2010 to April 2014 (which have corresponding expiration dates of April 2015 to April 2019) due a packaging defect. A Smith & Nephew internal investigation found the packaging material and design to be insufficient to prevent the ULTRA FAST-FIX Knot Pusher Suture Cutter's sharp edges from potentially puncturing the pouch and rendering the device unsterile.

Please see product details below:

Product No	Description	Batch No	Shipment Dates
72201537	ULTRA FAST-FIX Knot Pusher/Suture Cutter, Straight	All batches manufactured from April 2010 to April 2014 which have corresponding expiration dates of April 2015 to April 2019	March 2010-April 2014

Potential Risk with Use of the Product

Smith & Nephew conducted a Health Hazard Evaluation which found the most likely scenario to be that damage to the sterile barrier packaging (pouch) will be visible to the user prior to use and the device discarded. However, the worst case scenario is that defects in the packaging are not detected and an unsterile device is used during an arthroscopic repair. This could potentially lead to a post-operative infection.

To date there have been no complaints or adverse effects associated with this issue.

Actions for Hospital Representatives:

1. Please inspect your inventory and locate any unused devices from the above listed product and batch numbers, and quarantine them immediately.
2. Complete the last two columns in the Inventory Return Certification Form on the following page, indicating the quantities that need to be returned, and include your phone and fax number in the spaces provided. If you do not have product to return, please place an "x" in the column "No product to return".
3. Please contact Smith & Nephew's Field Action Department via email at [REDACTED] or [REDACTED] to obtain a return authorization (RA) number.
4. Return any affected product to the address listed on the Inventory Return Certification Form. Please indicate the RA number on your return shipment.

Actions for Smith & Nephew Inventory Specialists

1. Carry out a physical count of all affected product in your territory and record this data on the Inventory Return Certification Form on the following page.
2. If you do not have product to return, please place an "x" in the column "No Product to Return", and then fill in the Acknowledgement of Responsibility at the bottom of the form.
3. Fax or email a copy of the completed Inventory Return Certification Form to: [REDACTED]
4. Return any affected product to the address listed on the Inventory Return Certification Form. Please indicate the RA number on your return shipment.

Inventory Return Certification Form

April 30, 2015

R-2015-04

Product No	Description	Batch No	Individual Units to be Returned	No Product to Return
72201537	ULTRA FAST-FIX Knot Pusher/Suture Cutter, Straight	All batches manufactured from April 2010 to April 2014 which have corresponding expiration dates of April 2015 to April 2019		

Actions for Smith & Nephew Affiliates/Distributors

1. Send this letter to your customers and ask them to return the recalled product.
2. Please inspect your inventory and locate any unused devices from the above listed product and batch numbers.
3. Complete the last two columns in the Inventory Return Certification Form above, indicating the quantities that need to be returned, and include your phone and fax number in the spaces provided. If you do not have product to return, please place an "x" in the column "No Product to Return".
4. Fax or email a copy of the completed Inventory Return Certification Form to: [REDACTED]
5. You will receive an additional communication from Smith & Nephew in order to coordinate the replacement of your devices.

For Hospital Representatives or Sales Offices with Consumed Products

Name (Print) _____ Signature _____ Date _____
Facility Name _____
Facility Address _____
Contact Phone _____ Fax _____
Smith & Nephew RA Number _____
Smith & Nephew Account No. _____

For Smith & Nephew Affiliates/Distributors

Name (Print) _____ Signature _____ Date _____
Name of Organization _____
Contact Phone # _____ Fax _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Global Distribution Center | 3303 East Holmes Road | Memphis, TN 38141-8101

We apologize for any inconvenience this may cause.