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

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

# Urgent Medical Device Recall Notice
# R-2018-18

May 31, 2018

<Insert Address>

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a field action to remove a group of certain lots of Suture Anchor Devices, Suture Passer Devices and Coblation Wands due to a labeling error. The inner and outer product labels are incorrect.

Please see product details below:

| Product Number | Description | Batch Number |
|---|---|---|
| 22-4038 | DISP FIRSTPASS STR PASSR SELF | 1148332 & 1154410 |
| 22-4039 | DFP SUTURE PASSER STANDARD | 1124528, 1124529 & 1139236 |
| 25-1800 | 1.8MM Q-FIX ALL SUTURE ANCHOR | 1114685, 1114686, 1148254, 1154384,1167311, 1167312, 1175375, 1181666, 2002964, 2003158, 2004594 & 2006053 |
| 25-2800 | 2.8MM Q-FIX ALL SUTURE ANCHOR | 1113732, 1113733, 1114683, 1121569, 1126528, 1126961, 1146244,1146292,1162325,1166165,1174548,1174550,2001963, 2002029,2002158, 2003813, 2004263 & 2004746 |
| ACH4041-01 | TOPAZ EZ IFS | 1125756, 1129360,1129803,1133498,1146000 & 1161473 |
| ASHA4250-01 | AMBIENT SUPER TURBOVAC 90 IFS | 1124001, 1134452, 2003127, 2003307, 2003677, 2004216, 2004308 & 2004310 |
| ASHA4830-01 | AMBIENT SUPER MULTIVAC 50 IFS | 1119429, 1123981, 1137806, 1145855, 1154108, 1154708, 1166028 & 1166094 |
| OM-8175 | SMARTSTITCH PERFECTPASSER SUTURE CARTRID | 1130853 |
| OM-8176 | SMARTSTITCH PERFECTPASSER SUTURE CARTRID | 1124545 & 1181670 |
| OM-8178 | SMARTSTITCH PERFECTPASSER SUTURE CARTRID | 2006239 |

Shipment Date: March 17, 2017 through March 30, 2018

## Potential Risk with Use of the Product

In the most likely event, the user would identify the labeling error during the selection process; a replacement device would be used. In the worst case, the user does not notice the labeling errors until the device is in the surgical field, resulting in a minor surgical delay while a backup device is retrieved.

## Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

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## R-2018-18

May 31, 2018
<Insert Address>

**PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT**

**Required Actions:**

1. Please inspect your inventory and locate any unused devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
    a. If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.
2. If you have no product to return, please put an X in the appropriate location below.
3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
4. Complete the remainders of the form sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.
   **Please Note** – even if you have no product to return, this form must be completed, signed and returned.
5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

**No Product to Be Returned** ☐

| Product Part Number | Batch Number (List Specific Batch #'s to be Returned) | Quantity of Units to be Returned |
|---|---|---|
| | | |
| | | |
| | | |

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____Title: _____

Signature (required):_____ Date (required):____/____/____

Email:_____ Telephone: ( ___ ) _____-_____

S&N Account Number: _____ RA Number (S&N use only):_____
Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | 76 South Meridian Avenue| Oklahoma City, OK 73107