October 24, 2017

<Insert Address>

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove a single lot of INTERTAN 10S 10MM X 18CM 130D due to a manufacturing error. The screw was inserted upside down.

Please see product details below:

<table>
<thead>
<tr>
<th>Product Number</th>
<th>Description</th>
<th>Batch Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>71675384</td>
<td>INTERTAN 10S 10MM X 18CM 130D</td>
<td>16LM07111</td>
</tr>
</tbody>
</table>

Shipment Date: March 1, 2017 through September 28, 2017

**Potential Risk with Use of the Product**

In the event the affected devices are presented for use and the guide bolt advances into the nail but the set screw does not function as intended, the surgeon would notice the failure and a backup device would be used.

**Required Actions:**

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form
**Urgent Medical Device Recall Notice**

**R-2017-26**

October 24, 2017

<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**  □

<table>
<thead>
<tr>
<th>Product Part Number</th>
<th>Batch Number (List Specific Batch #’s to be Returned)</th>
<th>Quantity of Units to be Returned</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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: ______________________________________________________