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-2018-08

April 13, 2018

<Insert Address>

This letter is to inform you that Smith & Nephew Inc., have initiated a field action to voluntarily remove several lots of PERI-LOC VLP 3.5MM POSTEROLATERAL DISTAL FIBULA LOCKING PLATE due to a packaging error. The plates were incorrectly packaged and labeled as a 7-hole plate. The package contained a 6-hole plate.

Please see product details below:

Product Number	Description	Batch Number
72820807	PERI-LOC VLP 3.5MM POSTEROLATERAL DISTAL FIBULA LOCKING PLATE 7H LEFT	17FM19639
72800806	PERI-LOC VLP 3.5MM POSTEROLATERAL DISTAL FIBULA LOCKING PLATE 6H LEFT	17FM19620, 17FM19618, 17FM19638 & 17FM19619

Shipment Date: July 22, 2017 through August 17, 2017

Potential Risk with Use of the Product

The affected non-sterile plates will be used to replenish device trays. The packaging error is noticed prior to entering the surgical field. Therefore, the use of or exposure to the device poses a low risk of adverse health consequences.

Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

smith&nephew

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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 | Building G, 1450 Brooks Rd. East |Memphis, TN 38116