

***Urgent – Product Recall 1<sup>st</sup> Notification – Urgent  
R-2016-47***

October 21, 2016

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary recall for a three lots of ORTHOMATCH QUICK CONNECT HANDLES due a manufacturing issue. A complaint was received indicating that the handle would not fit into the femoral sizer and stemless tibial baseplate trials.

Please see product details below:

Product	Description	Lot Number	Shipment Date
71442131	ORTHOMATCH QUICK CONNECT HANDLE	15LNC0004; 16ENC0002A & 16ENC0002	August 2016-September 2016

**Potential Risk with Use of the Product**

The quick connect handle is presented for use and will not connect with mating components. An alternative surgical technique will be used and the procedure is completed as intended.

**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. If you do not have product to return, please place an "x" in the column "No Product to Return". Include your contact information in the spaces provided at the bottom of the form.
3. Please contact Smith & Nephew's Field Actions Department via email at [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com) or fax +1-901-566-7975 to return the completed Inventory Return Certification Form and obtain a return authorization (RA) number if you have product to return.
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 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, cease distribution and use of those products, and quarantine them immediately.
3. Complete the last two columns in the Inventory Return Certification Form above, indicating the 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". Include your contact information in the spaces provided at the bottom of the form.
4. Please contact Smith & Nephew's Field Actions Department via email at [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com) or fax +1-901-566-7975 to return the completed Inventory Return Certification Form and obtain a return authorization (RA) number if you have product to return.
5. Return any affected product to the address listed below. Please indicate the RA number on your return shipment.

## Inventory Return Certification Form

October 21, 2016

**R-2016-47**

Product	Description	Lot Numbers	Number Returned	No Product to Return
71442131	ORTHOMATCH QUICK CONNECT HANDLE	15LNC0004; 16ENC0002A & 16ENC0002		

### Actions for Smith & Nephew US Sales Personnel

1. Please inspect your inventory and locate any unused devices from the above listed product and batch numbers, and quarantine them immediately.
2. 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. If you do not have product to return, please place an "x" in the column "No Product to Return". Include your contact information in the spaces provided at the bottom of the form.
3. Please contact Smith & Nephew's Field Actions Department via email at [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com) or fax +1-901-566-7975 to return the completed Inventory Return Certification Form and obtain a return authorization (RA) number if you have product to return

### For Hospital Representatives or Sales Offices with Consumed Products

Name (Print) \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_  
Facility Name \_\_\_\_\_  
Facility Address \_\_\_\_\_  
Contact Phone # \_\_\_\_\_ Fax \_\_\_\_\_  
Contact Email \_\_\_\_\_  
Smith & Nephew RA Number \_\_\_\_\_  
Smith & Nephew Account No. \_\_\_\_\_

### For Smith & Nephew Affiliates/Distributors

Name (Print) \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_  
Name of Organization \_\_\_\_\_  
Contact Phone # \_\_\_\_\_ Fax \_\_\_\_\_  
Contact Email \_\_\_\_\_