

***Urgent – Product Recall 1st Notification – Urgent
R-2015-19***

November 11, 2015

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary recall of two batches of REFLECTION® SPHER HEAD SCREWS due to a packaging error. The affected screws are misbranded; the devices were packaged and distributed with an incorrect IFU.

Please see product details below:

Product No	Description	Batch No	Shipment Dates
71332530	REFLECTION SPHERICAL	14EM02599	October 2, 2014 thru March 18, 2015
71332535	HEAD SCREW	14DM22389	

Potential Risk with Use of the Product

There is no additional risk associated with the use of the device. The screws were manufactured per the specification, the ChartStik®, outer and inner labels were also correct.

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] 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] email 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

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Product No	Description	Batch No	Individual Units to be Returned	No Product to Return
71332530	REFLECTION	14EM02599		
71332535	SPHERICAL HEAD SCREW	14DM22389		

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]
[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 _____