

MEDICAL DEVICE CORRECTION NOTICE
C-2016-54

January 12, 2017

Smith & Nephew, Inc. has initiated a Field Correction for four lots of the RCI SCREW, 7mm x 35mm with 8mm Head devices due to a carton labeling error. The carton label incorrectly identifies the screw as a "Reverse Thread" screw. The screw presented in the package is a standard thread screw, which is correctly identified on the inner pouch label.

This letter is to notify all affected customers of the issue and provide the option to use the product as is or return it for a credit.

Please see product details below:

Product No	Description	Lot	Shipment Dates
7209409	7 x 35 mm RCI Screw with 8 mm head	50604301, 50617125, 50508969 & 50576152	July 2014 through August 2016

Potential Risk with Use of the Product

In the event the screw is presented for use, the user would notice that the device is not a reverse thread screw. The user would replace the screw or use the provided screw to complete the procedure utilizing a clockwise rotation.

Actions for Hospital Representatives

1. Please inspect your inventory and complete the attached Inventory Correction Certification Form.
2. If you have the affected products, please maintain awareness of this notice.
3. If you have the affected products and would like a credit, please contact the S&N Returns team at 800-343-5717, option 3 or endoreturn@smith-nephew.com to obtain a return authorization (RA) number.

Inventory Correction Certification Form

C-2016-54

January XX, 2017

PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Acknowledgement of Correction Notification

By signing below, I acknowledge that I have received the notification and I have taken the appropriate actions.

Printed Name: _____ Title _____

Telephone: (___) _____ - _____ Date: ___/___/___

Facility Name:

Account Number:

Signature _____

Check One:

- I have checked my inventory and my facility no longer possesses any device from the affected lots.
- I have checked my inventory and my facility still possesses a device(s) from the affected lots. Although I acknowledge the correction notification, the device(s) will not be returned.
- I have checked my inventory and my facility still possesses a device(s) from the affected lots. I will contact the S&N Returns team at the number provided in the letter to coordinate a credit.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975