

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com



MEDICAL DEVICE CORRECTION NOTICE
C-2016-31

July 05, 2016

Smith & Nephew, Inc. has initiated a Field Correction of six lots of DYONICS SMALL SAGITTAL BLADES due to a labeling error. Based on an internal evaluation, Smith & Nephew has identified two products with incorrect information on both the pouch and box labels. The product labeling incorrectly identifies the saw blades as having 36 TPI (teeth per inch) for PN 72204261 and 34 TPI for PN 72204275. Both products actually have 22 TPI. 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 replacement

Please see product details below:

Product No	Description	Lot	Shipment Dates
72204261	DYONICS SMALL SAGITTAL BLADE 9.5x 25.4x1.0, 36TPI (BOX of 6)	1213250322	November 2014-April 2016
72204275	DYONICS SMALL SAGITTAL BLADE 9.5x 25.4x1.0, 34TPI (BOX of 6)	1213249644, 1014257483, 1014254984, 0815276574, 0815275924	

Potential Risk with Use of the Product

The use of or exposure to the referenced device is not likely to cause adverse health consequences. In the event the user does not notice the label error, the provided components meet specification; therefore the procedure can be completed as intended.

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.

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Inventory Correction Certification Form

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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 return and replacement.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975