

MEDICAL DEVICE CORRECTION NOTICE
C-2016-03

January 13, 2016

Smith & Nephew, Inc. distributes the DYONICS RF Broadnose 90 Wand (Product No. 72202142) which is labeled on the outer box, inner tray and patient record labels. The name of the product is intended to be consistent across all labels.

Smith & Nephew distributed one lot (Lot 1053121) in which the inner tray is mislabeled. The inner tray for this lot incorrectly reflects the name DYONICS RF WHIRLWIND and the Product No. 72202139. The correct name (DYONICS RF BROADNOSE) and Product No. 72202142 is reflected on the outer box and patient record labels and is consistent with the product contained in the box.

Please see product details below:

| Product No | Description | Lot | Shipment Dates |
|------------|-----------------------------|---------|-------------------|
| 72202142 | DYONICS RF BROADNOSE 90 DEG | 1053121 | 6/3/2014-8/6/2014 |

Potential Risk with Use of the Product

The product contained in the package is the DYONICS RF BROADNOSE 90 DEG Wand as indicated by the labeling on the outer box and patient record labels. In the event the affected devices are presented for use; there is no associated risk, the device will perform as indicated, and all other product names and size indicators are correct. Therefore the use of, or exposure to the product is not likely to cause adverse health consequences.

Actions for Hospital Representatives and Smith & Nephew Sales Personnel

1. Please inspect your inventory and locate any unused devices from the above listed product and batch number. Disregard the incorrect inner tray catalog number (72202139).
2. If you have the affected products please complete the attached Inventory Correction Certification Form as an Acknowledgment of the correction.
3. If you do not have the affected product please completed the Inventory Correction Certification Form and place a "X" in the box marked "No affected Products."
4. Fax or email a copy of the completed Correction Certification Form to: _____ or email to: _____

Inventory Correction Certification Form

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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 _____

No affected Products