

MEDICAL DEVICE CORRECTION NOTICE
C-2016-61

February 23, 2017

Smith & Nephew, Inc. has initiated a Field Correction for the DYONICS Battery Power Hand Pieces due to an error in the Operator Manual. The Operator Manual contains incorrect dry time for Pre-vacuum Steam sterilization and Gravity Displacement Steam sterilization cycles. The Operator Manual incorrectly states the minimum dry time as "8 minutes" for all devices; however, the correct dry times should be longer and are provided below:

Device	Sterilization Cycle	Dry Time (minimum)
Dyonics Power Large Bone Battery System (Operator Manual 10601206)	Gravity Displacement Steam	20 minutes
	Prevacuum Steam	10 minutes
Dyonics Power Small Bone Battery System (Operator Manual 10601205)	Gravity Displacement Steam	60 minutes
	Prevacuum Steam	45 minutes

Please see product details below:

Product No	Description	Serial	Shipment Dates
72204114	DYONICS POWER SMALL BATTERY HANDPIECE	All Serial Numbers provided with Operator Manuals: 10601205 Rev A through C 10601206 Rev A through D	April 2015 through October 2016
72204091	DRILL/REAMER		
72204092	OSCILLATING SAW		
72204093	RECIPROCATING SAW		

Potential Risk with Use of the Product

The hospital may follow the recommended drying method set out in the IFU, but would likely inspect for wetness to ensure the device is dry prior to use – hospitals typically use a longer dry time and inspect packs and all sterile loads for wetness. In this situation, the device would be sufficiently dried, it would perform as indicated, and the procedure would be completed as intended. It is notable that these instruments have been in the field for many years with no complaints of wet packs.

Actions for Hospital Representatives (cc: Chairman Medical Board and relevant Head of Departments)

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.

Yours sincerely,



Andy Weymann, MD
Chief Medical Officer
Advance Surgical Devices Division
Smith & Nephew

Inventory Correction Certification Form

C-2016-61

February 23, 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.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:
