Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810
USA

1-978-749-1000
1-800-343-8386
www.smith-nephew.com

MEDICAL DEVICE CORRECTION NOTICE
C-2016-43

December 21, 2016

Smith & Nephew, Inc. has initiated a Field Correction for all serial numbers of the HD1200 AUTOCLAVABLE CAMERA HEAD AND HD1200 AUTOCLAVABLE CAMERA CONTROL UNITS due to an Operator Manual error. The distributed Operator Manual includes incorrect Electromagnetic emission classifications. The radiated emission (CISPR 11) should be Class A instead of Class B; harmonic emission (IEC 61000-3-2) should be, not applicable opposed to Class B. The voltage fluctuations/flicker emissions (IEC 61000-3-3) should have also been classified as not applicable. See table below for the correct information:

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Smith & Nephew HD1200 Autoclavable Camera System is intended for use in the electromagnetic environment specified below. The customer or user of the HD1200 Autoclavable Camera System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
HF emissions CISPR 11	Group 1	The HD1200 Autoclavable Camera System uses HF energy only for its internal functions. Therefore its HF emissions are very low and are not likely to cause interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class A	The HD1200 Autoclavable Camera System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Please see product details below:

Product No.	Description	Serial Numbers	Shipment Dates
72203360	HD1200 AUTOCLAVABLE CAMERA HEAD	All Serial Numbers	July 2011 through September 2016
72203361	HD1200 AUTOCLAVABLE CAMERA CONTROL UNIT		

Potential Risk with Use of the Product

The use of or exposure to the referenced devices are not likely to cause adverse health consequences. The IFU error has no clinical or functional effects on the use of the device.

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.

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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 devices from the affected serial numbers.

☐ I have checked my inventory and my facility still possesses a device(s) from the affected serial numbers. I acknowledge and will maintain awareness of the correction notification.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975