October 30, 2014

Facility Name
ATTN: Risk Management Dept.

RE: URGENT: MEDICAL DEVICE RECALL
ArthroCare Ambient HipVac 50 Wand (Catalog No. ASHA4730-01)

Dear Sir/Madam:

PLEASE NOTE: Smith & Nephew Inc. purchased ArthroCare Corporation on May 29, 2014. For the purpose of this communication, the name ArthroCare is still being used as all products herein were packaged, labeled and branded ArthroCare at the time of shipment.

The purpose of this letter is to advise you that ArthroCare Corporation (ArthroCare) is voluntarily recalling all affected lots of the Ambient HipVac 50 Wand with Integrated Finger Switches (HipVac Wand), **Catalog No. ASHA4730-01**. The HipVac Wand is a bipolar, high frequency electrosurgical device indicated for the resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic and orthopedic procedures.

Our records indicate that your facility has received an affected HipVac Wand.

Reason for the Voluntary Recall:
Based on internal investigation, ArthroCare has confirmed that the tray that houses the HipVac Wand may have damage that could result in a breach of the sterile barrier.

Risks to Health:
A breach of the sterile barrier of the HipVac Wand packaging could result in infection in the patient on which the device is used.

Actions to be Taken
1. Immediately discontinue all use and take steps to quarantine the affected device(s).
2. Complete and return the attached acknowledgement form using the instructions provided.
3. If you still possess a device from the affected lots, please contact the ArthroCare Customer Service Representative for your market at the number listed below to obtain a Return Material Authorization (RMA) Number, further instructions for return and information on a replacement.

Market(s)	Contact Phone Number
Australia, Denmark, Finland, Hong Kong, Israel, Italy, Malaysia, Norway, Poland, Spain, South Africa, Sweden, Turkey	00-1-512-895-1400
Austria, Switzerland	+41 32 686 88 99
Belgium	+32 (0)2 702 29 11
Netherlands	+31 020 654 39 99
France	+33 3 84 768138
Germany	+49 2191 93342 0
Ireland, United Kingdom	+44 1480 423210

Product and Distribution Information:

Product Name	Catalog No.	Affected Lot Number
Ambient HipVac 50 Wand with Integrated Finger Switches	ASHA4730-01	1021255, 1021620, 1022188, 1022482, 1022636, 1023089, 1024067, 1025482, 1025480, 1025481, 1025764, 1025765, 1026875, 1027163, 1027702, 1028327, 1029265, 1030025, 1031353, 1031759, 1031760, 1032765, 1032766, 1033773, 1033974, 1034227, 1034451, 1035036, 1035295, 1038550, 1039318, 1039903, 1042371, 1042370, 1043421, 1044678, 1045361, 1046599, 1047067, 1050441, 1053407, 1053408, 1052669, 1054471, 1056213, 1057010, 1055117, 1058810, 1058291, 1059396, 1061007, 1061008, 1064276, 1064641, 1065989, 1070710, 1070711, 1071321, 1071322, 1071360, 1071361, 1073431, 1073432, 1074079, 1074140, 1076027, 1077459, 1078013, 1078911

Your prompt attention to this notification is greatly appreciated.

Sincerely,

Mitchell A. Dhority
Vice President, Regulatory Affairs

ACKNOWLEDGEMENT FORM – RESPONSE REQUIRED

URGENT PRODUCT RECALL NOTIFICATION
ArthroCare Ambient HipVac 50 Wand (Catalog ASHA4730-01)

PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

I acknowledge that I have received, read and understood the Urgent Product Recall Notification Letter from ArthroCare regarding the above product/lot.

Check One:

- ☐ I have checked my stock and I/my facility no longer possesses any HipVac devices.
- ☐ I have checked my stock and my facility still possesses a HipVac device(s). Steps will be/have been taken to quarantine the device(s) from further use. I will contact the Returns Department at the number provided in the Urgent Recall Letter to coordinate return and replacement.

Lot Number(s) for Return	Quantities to be Returned

For Hospital Representatives

Name (Print) _____ Signature _____ Date _____

Facility Name _____

Facility Address _____

Contact Phone _____ Fax _____

Account No. _____

For Sales Representatives

Name (Print) _____ Signature _____ Date _____

Contact Phone _____ Fax _____

For Affiliates/Distributors

Name (Print) _____ Signature _____ Date _____

Name of Organization _____

Contact Phone _____ Fax _____

Please return this completed form via email to productrecovery@smith-nephew.com or fax 00-1-978-749-1185