Smith & Nephew Inc
1450 Brooks Road
Memphis, TN 38116

T 901-396-2121

www.smith-nephew.com

We are smith&nephew

Urgent – Product Recall 1st Notification – Urgent
R-2015-09

June 10, 2015

Smith & Nephew, Inc. has initiated a voluntary recall for a group of PROCISE EZ View◊ with Integrated Cable and EVAC◊ 70 XTRA with Integrated Cable Wands due to a manufacturing inspection issue. A number of the devices have been released without meeting the dielectric specifications.

PLEASE NOTE: Smith & Nephew Inc. purchased ArthroCare Corporation on May 29, 2014. For the purpose of this communication, the product being recalled was manufactured, packaged, labeled, and branded by ArthroCare Corporation at the time of shipment. The manufacturer of the product being recalled is ArthroCare Corporation.

Please see product details below:

Product No	Description	Lot No.	Shipment Dates
EIC8875-01	PROCISE EZ VIEW	1093290	March 9, 2015-March 18, 2015
EICA5872-01	EVAC 70 XTRA	1091254	March 9, 2015-March 18, 2015

Potential Risk with Use of the Product
In the event an affected wand is presented for surgery, the wand may develop a dielectric breakdown creating a small gap leading to arcing. This created arcing could lead to diminished ablation and coagulation performance, and in rare instances a surgeon or patient burn. Also, the decreased hemostasis resulting in injury or impairment could require additional medical intervention.

Actions for Hospital Representatives:

1. Please inspect your inventory and locate any unused devices from the above listed product and batch number, and quarantine them immediately.
2. Complete the last two columns in the Inventory Return Certification Form on the following page, indicating the quantities that need to be returned, and include the product lot number along with your phone and fax number in the spaces provided. If you do not have product to return, please place an "x" in the column "No product to return".
3. Please contact Smith & Nephew's Field Action Department via email at [redacted] or [redacted] to obtain a return authorization (RA) number.
4. Return any affected product to the address listed on the Inventory Return Certification Form. Please indicate the RA number on your return shipment.

Actions for Smith & Nephew Sales Personnel

1. Carry out a physical count of all affected product in your territory and record this data on the Inventory Return Certification Form on the following page.
2. If you do not have product to return, please place an "x" in the column "No Product to Return", and then fill in the Acknowledgement of Responsibility at the bottom of the form.
3. Fax or email a copy of the completed Inventory Return Certification Form to: [redacted]
4. Return any affected product to the address listed on the Inventory Return Certification Form. Please indicate the RA number on your return shipment.

Smith & Nephew Inc
1450 Brooks Road
Memphis, TN 38116

T 901-396-2121

www.smith-nephew.com

We are smith&nephew

Inventory Return Certification Form

June 10, 2015

R-2015-09

Product No	Description	Batch No	Individual Units to be Returned	No Product to Return
EIC8875-01	PROCISE EZ VIEW	1093290		
EICA5872-01	EVAC 70 XTRA	1091254		

For Hospital Representatives or Sales Offices with Consumed Products

Name (Print) _____ Signature _____ Date _____

Facility Name _____

Facility Address _____

Contact Phone _____ Fax _____

Smith & Nephew RA Number _____

Smith & Nephew Account No. _____

For Smith & Nephew Affiliates/Distributors

Name (Print) _____ Signature _____ Date _____

Name of Organization _____

Contact Phone # _____ Fax _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | 76 South Meridian Avenue| Oklahoma City, |OK 73107