June 10, 2015

URGENT FIELD SAFETY NOTICE

Concerned Devices: PROCISE EZ View® with Integrated Cable
Reference: R-2015-09
FSCA action: Product recall

Product No.	Description	Batch No. / UDI No.
EIC8875-01	PROCISE EZ VIEW	1093290

Dear Sir/Madam,

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action for a group of PROCISE EZ View® with Integrated Cable. 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. The products being recalled were manufactured, packaged, labeled, and branded by ArthroCare Corporation at the time of shipment. The manufacturer of the product being recalled is ArthroCare Corporation.

This field action has been reported to the relevant competent authorities.

Risks to Health	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 to be taken by the user	1. Locate and quarantine affected unused devices immediately. 2. Return quarantined product to your national Smith & Nephew agency/distributor. 3. Complete the return slip and fax it to your national Smith & Nephew agency/distributor. 4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.

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Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to surgeons and patients who use those products.

If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor:

1. FAX: 01480 423 201

2. Email: anica.alcala@smith-nephew.com **or** greg.williams@smith-nephew.com **or** uk.serviceoperations@smith-nephew.com

Yours faithfully

Greg Williams – Quality & Regulatory Manager
Smith & Nephew Advanced Surgical Devices

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

☐ We confirm the receipt of this Field Safety Notice.

In our facility we have _____ *[Qty]* concerned devices which we will return.

_____ *[Qty]* concerned devices have been used in our facility.

Institution: _____ Reference: R-2015-09

Name: _____ Date / Signature: _____

Telephone Number: _____