

[Recipients Address]

May 10, 2016

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall

Reference: R-2016-13

Concerned Devices: Double Pump RF Patient Cassette

Product No.	Description	Batch No.
72204055	Double Pump RF Patient Cassette	13I03, 14A01, 14A06, 14A09, 14A10, 14B03, 14B09, 14C06, 14C10, 14D07, 14D11, 14E06, 14E10, 14F01, 14F02, 14F03, 14F04, 14F10, 14F11, 14G07, 14H02, 14H04, 14H08, 14H09, 14J01, 14J02, 14J03

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of all batches of Double Pump RF Patient Cassettes available on the market due to a packaging issue. The sealed flange of the tray may be cracked, thus not providing a complete seal to maintain the sterile barrier.

This product is manufactured by Medical Vision and bears a Medical Vision label. It is distributed by Smith & Nephew.

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

Risks to Health	The use of the affected device could potentially result in an adverse reaction which is reversible with aftercare by the physician.
Actions to be taken by the user	<ol style="list-style-type: none">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.

Smith & Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

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

Contact Details of Subsidiary / Distributor

Return Slip

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

We hereby confirm that we are aware of this Field Safety Notice concerning the Double Pump RF Patient Cassette. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

- In our facility we do not have any of the affected product in stock
- or
- We will return the following products:

Product No.	Description	Batch No. / Quantity to be Returned							
72204055	Double Pump RF Patient Cassette	<input type="checkbox"/>	13I03	<input type="checkbox"/>	14A01	<input type="checkbox"/>	14A06	<input type="checkbox"/>	14A09
		<input type="checkbox"/>	14A10	<input type="checkbox"/>	14B03	<input type="checkbox"/>	14B09	<input type="checkbox"/>	14C06
		<input type="checkbox"/>	14C10	<input type="checkbox"/>	14D07	<input type="checkbox"/>	14D11	<input type="checkbox"/>	14E06
		<input type="checkbox"/>	14E10	<input type="checkbox"/>	14F01	<input type="checkbox"/>	14F02	<input type="checkbox"/>	14F03
		<input type="checkbox"/>	14F04	<input type="checkbox"/>	14F10	<input type="checkbox"/>	14F11	<input type="checkbox"/>	14G07
		<input type="checkbox"/>	14H02	<input type="checkbox"/>	14H04	<input type="checkbox"/>	14H08	<input type="checkbox"/>	14H09
		<input type="checkbox"/>	14J01	<input type="checkbox"/>	14J02	<input type="checkbox"/>	14J03	<input type="checkbox"/>	

Institution: _____ Reference: R-2016-13

Name: _____ Date / Signature: _____