

[Recipients Address]

Device Field Safety Corrective Action / Recall

Reference: WR-2017-03

Concerned Devices: Versajet II Hydrosurgery System Console CE

Product No.	Description	Batch No. / UDI No.
66800039	VERSAJET [®] II Hydrosurgery System Console	KWHJ160001; KWHH160027 & KWHH160028

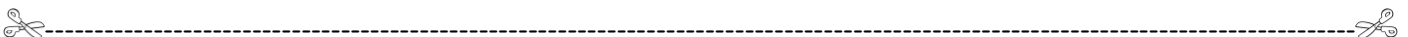
Dear Dr.

This letter is to inform you of a voluntary Field Safety Corrective Action (FSCA) due to a product labeling error. The limited number of consoles for the VERSAJET[®] II Hydrosurgery System (the VERSAJET System), manufactured by Smith & Nephew Inc. USA and Smith & Nephew Medical, United Kingdom was distributed without the CE Mark. This FSCA requires device modification/exchange in order to ensure compliance with the Medical Device Directive 33/42/ECC. Affected devices do not present any safety risks to patients.

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

Risks to Health	As noted above, this issue does not present any safety concerns for patients or end-users of the consoles.
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

<p>Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.</p> <p><input type="checkbox"/> We confirm the receipt of this Field Safety Notice.</p> <p>In our facility we have _____ [Qty] concerned devices which we will return.</p> <p>_____ [Qty] concerned devices have been discarded in our facility.</p> <p>Institution: _____ Reference: WR-2017-03</p> <p>Name: _____ Date / Signature: _____</p>
