

[Recipients Address]

February 14, 2019

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Notice for Recall

Reference: R-2018-41

Concerned Devices: Modular Head Disimpactor

Product Number	Description	Batch Number		
H0103.36	MODULAR HEAD DISIMPACTOR	SC0202	VK1900	YG1892
		SI0427	VK1901	YH0301
		SI0428	WB0605	YJ0141
		SL1132	WD0889	YK1340
		UE0380	XE0894	YL1048
		VA1900	XH0693	ZB0916
		VD0182	XL0321	ZD0140
		VG0176	YA0543	
		VG1169	YA1982	
		VH0234	YC0180	
		VI0242	YF0674	

Dear Customer:

Cc: Chairman Medical Board and relevant Head of Departments

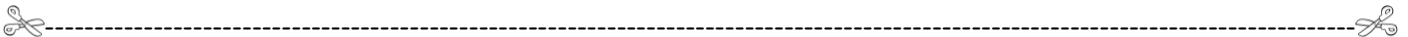
This letter is to inform you that Smith & Nephew Inc., has voluntarily initiated a recall to remove multiple lots of MODULAR HEAD DISIMPACTOR. The disimpactors used for certain head sizes will not eject the head from the stem.

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

Risks to Health	In the event the affected instrument is presented for use and the surgeon is unable to eject the head from the stem using the device, the surgeon would use an alternate instrument to remove the implant. The use of or exposure to the affected device presents a low risk adverse health consequences.
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.

	<p>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.</p> <p>5. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall is terminated to ensure effectiveness of the action.</p>
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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:

<p>Contact Details of Subsidiary / Distributor</p> <p>Smith & Nephew Pte. Ltd</p> <p>Contact No: 6270 0552</p> <p>Email: singapore.surgicalsale@smith-nephew.com</p>
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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 for Recall.

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

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

Institution: _____ Reference: R-2018-41

Name: _____ Date / Signature: _____