

[Recipients Address]

January 7, 2019

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

Reference: R-2018-35

Concerned Devices: SL PLUS MIA DBL OFFSET ADAPT

Product No.	Description	Batch No. / UDI No.
75004613	SL PLUS MIA DBL OFFSET ADAPT. RT 60/25MM	C63165
		C63306
		C63495

Dear Customer:

Cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew, has voluntarily initiated a recall to remove multiple lots of SL PLUS MIA Double Offset Adapter, RT 60/25MM due to a manufacturing error. The pin that holds the spring mechanism is not properly mounted. The pin could potentially disassemble. Please see product details below:

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

Risks to Health	We have not received any reports of pin disassembly during the use of the device. However, there is a remote possibility that if the pin disassembles during a procedure, the surgeon would switch to another system. The use of an alternative system could potentially result in a surgical delay.
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 Notice for Recall 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 Smith & Nephew Pte. Ltd. Contact No: 6270 0552 Email: singapore.surgicalsale@smith-nephew.com
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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 for Recall.</p> <p>In our facility we have _____ <i>[Qty]</i> concerned devices which we will return. _____ <i>[Qty]</i> concerned devices have been discarded in our facility.</p> <p>Institution: _____ Reference: R-2018-35</p> <p>Name: _____ Date / Signature: _____</p>
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