smith&nephew

[Recipients Address]

February 21, 2019

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

Reference: R-2019-01
Concerned Devices: SmartStitch PerfectPasser Connector

Product Number	Description	Batch Number				
OM-8010 SMARTSTITCH PERFECTPASSER CONNECTOR		1154857	1179855	1184077	1194208	2005153
		1154858	1179856	1184078	1194763	2005154
		1156429	1179857	1184825	2001517	2005251
		1165209	1179858	1184826	2001518	2005252
		1166194	1179859	1184827	2001519	2005494
		1168946	1181657	1184828	2002828	2006014
		1170928	1181658	1184829	2002829	2006037
		1170929	1182577	1184830	2002830	2006038
		1170930	1182578	1184831	2002831	2006039
		1170931	1182579	1185959	2002832	2006040
		1174530	1182580	1187253	2004741	
		1174531	1182581	1187254	2004933	
		1175357	1182621	1187255	2004934	
		1175401	1182622	1192014	2005147	
		1178577	1184074	1192015	2005149	
		1178578	1184075	1192016	2005150	
		1179854	1184076	1192017	2005152	

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 SMARTSTITCH PERFECTPASSER CONNECTOR due a manufacturing error resulting in incorrect upper jaw dimensions. Confirmed complaints indicated that the upper jaw could potentially disengage or detach during use.

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

Risks to Health	In the event the affected device is used during the procedure, the upper jaw could potentially detach during use, requiring additional intervention to retrieve the detached component and/or delay of procedure.

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 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

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-2019-01

Name: _____ Date / Signature: _____