

Smith & Nephew, Inc.

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[Recipients Address]

August 03, 2020

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

Reference: R-2020-16
Concerned Devices: Single RIKKI Retractor

Catalog Number	Description	Lot Numbers
71934609	Single RIKKI Retractor	18DM14901, 18FM21215, 18DM07309, 18GM20885, 19EM21519, 18JM05681 & 19EM21520

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove multiple lots of Single RIKKI Retractor due to a supplier manufacturing error. The affected products do not meet the applicable hardness specification as the products were insufficiently heat treated.

Risks to Health	In the event the affected product is presented for use, the retractor could potentially bend during the procedure. In the worst case, the surgeon would use a different device with no significant surgical delay.
Actions to be taken by the user	<ol style="list-style-type: none"> 1. Locate and quarantine affected 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

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-2020-16

Name: _____ Date / Signature: _____