

**Smith & Nephew, Inc.**

Global Field Actions  
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[Recipients Address]

27<sup>th</sup> October 2021

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

Reference: *R-2021-09*  
 Concerned Devices: *EVOS Locking Screw*

<b>Product No.</b>	<b>Description</b>	<b>Batch No.</b>
72413575	EVOS 3.5MM x 75MM LCK SCR S-T	21FM24289
72413570	EVOS 3.5MM X 70MM LCK SCR S-T	21GM04743

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc., has initiated a field action to voluntarily remove a single lot of EVOS 3.5MM X 75MM Locking Screw S-T and a single lot of EVOS 3.5MM X 70MM Locking Screw S-T due to a packaging error. The affected products contain screws of a length different from what is presented on the product label. The screws in the package labeled as 75mm are 70mm in length, and screws in the package labeled 70mm are 75mm in length.

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

<b>Risks to Health</b>	In the most likely scenario, the length discrepancy is identified prior to the procedure and a back-up device is used with no associated patient harm. In the worst case, the 75mm screw (incorrectly labeled as a 70mm screw) is not detected prior to surgery, is used in the procedure, and the decision is made to not remove the screw. This scenario could result in soft tissue injury and could require subsequent removal of the screw after initial implantation.
<b>Actions to be taken by the user</b>	<ol style="list-style-type: none"> <li>1. Locate and quarantine affected unused devices immediately.</li> <li>2. Return quarantined product to your national Smith+Nephew agency/distributor.</li> <li>3. Complete the return slip and fax it to your national Smith+Nephew agency/distributor.</li> <li>4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.</li> <li>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.</li> </ol>

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:

Please return slip to <a href="mailto:greg.williams@smith-nephew.com">greg.williams@smith-nephew.com</a>
Fax: + 44 (0) 1480 423201

## Return Slip

<b>Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.</b>	
<input type="checkbox"/>	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: <i>R-2021-09</i>
Name: _____	Date / Signature: _____
Country: _____	