

**URGENT FIELD SAFETY NOTICE:  
Medical Device Advisory Notice**

Reference: C-2019-11  
Concerned Devices: PROFIX<sup>◊</sup> 750 Grams Mallet Cleaning and Sterilization Guide

<b>Product No.</b>	<b>Description</b>	<b>Shipment Date</b>
71512452	PROFIX 750 GRAMS Mallet	February 6, 2017 through April 5, 2019

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a Field Safety Corrective Action to voluntarily provide updates to the PROFIX 750 Grams Mallet Cleaning and Sterilization Guide, in alignment with the updates previously completed by the supplier, Signal Medical Corporation. Signal received customer complaints regarding a potential failure mode associated with the use of the mallet, wherein the poly tip of the mallet may become loose and/or come off during use. If the potential failure mode occurs, particles generated in the poly thread potentially could enter the surgical field or a delay in surgery could occur if the tip disengages during the use of the mallet. Additionally, this notice is to remind users that the poly tip must be removed for cleaning and sterilization. Failure to remove the tip could prevent proper sterilization and introduce an infection risk.

The failure mode can occur when the poly tip is removed during sterilization and is not fully screwed to the base of the mallet body upon re-assembly before use during surgery. The poly tip is secured by a threaded fitting to the base of the mallet body. When the poly tip is fully screwed down, the poly tip's relieved portion will rest on the mallet body and absorb the force of the blow during use. Failure to fully screw the poly tip to the mallet body will cause the force of the blow to be absorbed by the poly thread, potentially causing the thread to strip, resulting in particulate formation. Repeated failures to secure the tip to the mallet body will cause the thread to fail, preventing the tip from securely attaching to the mallet and potentially cause failure during use. A failure may be detected by observing the threads in the poly tip; they should not be stripped in any way.

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

<p><b>Risks to Health</b></p>	<p>In the event the device is presented for use, in the most likely case the poly tip is fully secured prior to impaction. The device functions as intended, and the procedure is completed successfully. Contrarily, in the worst case if the poly tip is not fully secured prior to impaction and thread damage occurs, particles from the damaged threads could potentially fall into the wound and remain undetected.</p>
<p><b>Actions to be taken by the user</b></p>	<ol style="list-style-type: none"> <li>1. 1. Please check your inventory and complete the attached return slip.</li> <li>2. 2. If you have the PROFIX 750 Gram Mallet, please maintain awareness of this notice.</li> <li>3. 3. When preparing for cleaning, disassemble the poly tip from the mallet and inspect disassembled components for damage or wear.</li> <li>4. 4. After cleaning, inspect disassembled components and ensure the components can be re-assembled securely.</li> <li>5. 5. Ensure the PROFIX 750 Gram Mallet is sterilized in the disassembled state.</li> <li>6. 6. After sterilization, ensure the poly tip is re-assembled to the mallet securely.</li> <li>7. 7. Please make sure this information is passed on to all those who need to be aware of it within your organization.</li> <li>8. 8. Please maintain awareness on this notice and resulting action until the Field Action 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  
sandeep.garcha@smith-nephew.com  
or  
greg.williams@smith-nephew.com  
fax: + 44 (0) 1480 423201

### Return Slip

**Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.**

- I have checked my inventory and my facility no longer possesses any device from the affected lots.
- I have checked my inventory and my facility still possesses a device(s) from the affected lots and I acknowledge the Field Safety Notice.

Institution: \_\_\_\_\_

Reference: C-2019-11

Name: \_\_\_\_\_

Date / Signature: \_\_\_\_\_