

**Smith & Nephew, Inc.**

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[Recipients Address]

March 3, 2020

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

Reference: R-2020-02  
Concerned Devices: NAVIO Soft Tissue Protector

Instrument Kit Number	Description	Product Number	Description
PFSR02050	NAVIO Instrument Kit	101092	NAVIO Soft Tissue Protector
PFSR02051			
PFSR02052			
PFSR02053			

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc., has initiated a voluntary recall to remove specific lots of the NAVIO Soft Tissue Protector due to a design issue. The NAVIO Tissue Protector can become stuck or bound to the bone pin intraoperatively when inserting the NAVIO bone pins.

You are receiving this notice because our records indicate you were shipped a NAVIO Instrument Kit which contains the affected NAVIO Soft Tissue Protector. This is a component of the instrument kits referenced below, the instrument is marked with product number 101092 (image below).



<b>Risks to Health</b>	The use of the affected NAVIO Soft Tissue Protector could potentially result in a surgical delay. In the most likely scenario, the surgeon would manually remove the tissue protector and bone pin without injury to the patient. In the worst case, medical intervention is needed to remove the bone pin and, although we have received no reports of the following occurrence, there is the potential that bone pin pieces could remain in the patient. Also, additional bone pin holes could potentially be required, to move the bone pins from the initial placement site.
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<p><b>Actions to be taken by the user</b></p>	<ol style="list-style-type: none"> <li>1. Please inspect your NAVIO instrument kit and locate the NAVIO Soft tissue protector (product number 101092) within the instrument kit numbers listed on the first page of this Urgent Medical Device Recall Notice, and quarantine the soft tissue protector 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>
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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-2020-02

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