

<Recipients Address>

URGENT FIELD SAFETY NOTICE: Product Recall

Date Issued: 22-Aug-2022

Reference: R-2022-07

Legal Manufacturer: Smith & Nephew, Inc.

Concerned Devices: TIBIAL SPACER BLOCK STANDARD

Product No.	Description	Batch No.
74012645	TIBIAL SPACER BLOCK STANDARD	19HM00711
74012645	TIBIAL SPACER BLOCK STANDARD	19MM14023

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc., has initiated a field action to voluntarily remove two lots of the Journey II Tibial Spacer Block Standard due to a manufacturing error which resulted in the incorrect orientation of the "L" (Left) and "R" (Right) laser etch. The "M" (Medial) laser etching is correct.

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

Patient Impact

Smith + Nephew recommends that physicians maintain their routine patient follow-up protocol.

Risks to Health	In the event the affected devices are presented for use, most likely the incorrect laser etch orientation is identified and a back-up device is used to complete the surgery. Contrarily, in the worst case the incorrect laser etch orientation is not identified and the block is used in the wrong orientation during the procedure. Initial adjustments to the posterior cut could be made based on the incorrect flexion gap assessment. As a result, additional bone cuts could be necessitated at subsequent surgical steps. Balancing the joint and potential refinement of the cuts is part of the standard surgical technique at multiple steps after the initial assessment. Therefore, there is no anticipated impact to the patient or the surgical outcome.
Actions to be taken by the user	1. Ensure that the contents of this Field Safety Notice are read and understood by those within your organisation who may use Tibial Spacer Block Standard.

	<ol style="list-style-type: none">2. Locate and quarantine affected devices immediately. If you have further distributed the product to other organisations, please inform them at once of this Field Action and provide to them a copy of this letter.3. Please complete the Customer Response form and email or fax it to your national Smith+Nephew agency/distributor.4. Return quarantined product to your national Smith+Nephew agency/distributor.5. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.
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If you or any of the healthcare providers you serve have any questions regarding this information, please contact your national Smith+Nephew agency/distributor.

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.

Thank you for your attention and cooperation.

Customer Response Form

Please read in conjunction with the Field Safety Notice and return the completed and signed Customer Response Form by <date>.

Reference: R-2022-07
 Concerned Devices: Tibial Spacer Block Standard

1. Return Acknowledgement details	
Email	<Local market to add>
Customer Helpline	<Local market to add>
Fax	<Local market to add>

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

2. Customer Details			
Healthcare Organisation / Facility Name*	<Fillable form field>		
Name of all Facilities/Hospitals covered by this response*	<Fillable form field>		
Facility / Hospital Address*	<Fillable form field>		
Telephone Number	<Fillable form field>	Email address	<Fillable form field>
Name of your supplier / wholesaler (if not Smith+Nephew)	<Fillable form field>		
Healthcare Organisation / Facility Stamp (if available)	<Fillable form field>		

3. Customer action undertaken on behalf of Healthcare Organisation / Facility Please complete/tick as appropriate.	
<input type="checkbox"/> Yes	I confirm receipt of the Field Safety Notice and that I read and understood its content. *
<input type="checkbox"/> Yes <input type="checkbox"/> No	Has your Healthcare Organisation / Facility distributed the product to other organisations? If you have answered yes, tick all that apply: *
	<input type="checkbox"/> I have identified customers that received or may have received this device.
	<input type="checkbox"/> I have informed the identified customers of this FSN.
<input type="checkbox"/> I have received confirmation of reply from all identified customers.	
<input type="checkbox"/> Yes	I performed all actions requested by the FSN. *
Tick Appropriate Response: *	<input type="checkbox"/> Yes Neither I nor any of my customers has any affected devices in inventory.
	<input type="checkbox"/> Yes In our Organisation / Facility we have concerned devices that: - have been placed in quarantine and - returned as indicated in Section 4 below. Complete Section 4 with material, batch/serial, and quantity information related to devices to be returned.

4. Devices to be Returned		
Material Number	Batch or Serial Number	Quantity Quarantined and to be returned

Print Name*	<Fillable form field>		
Signature*	<Fillable form field>	Date*	<Fillable form field>

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

