Smith & Nephew, Inc.
Global Field Actions
1450 Brooks Road
Memphis, TN 38116
Tennessee, USA

T: + 1 901 396 2121
T: 1 800 821 5700 (USA toll free)
www.smith-nephew.com

Smith+Nephew

<Recipients Address>

URGENT FIELD SAFETY NOTICE:
Product Recall

Date Issued: 12-AUG-2024

Reference: R-2024-06

Legal Manufacturer: Smith & Nephew, Inc.

Concerned Devices: REGENETEN Tendon Anchors (8)

Product No.	Description	Batch No.	Unique Device Identifier(s)
2504-1	TENDON ANCHORS (8)	See Appendix 1	00854501006067
72205201	TENDON ANCHORS (8)	See Appendix 1	00885556733486

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a Field Action to voluntarily remove multiple lots of the REGENETEN Tendon Anchors (8). There is a potential for a sterile barrier breach due to a packaging issue. Specifically, an issue identified in the product packaging process may result in an improper or incomplete seal of the outer foil pouch surrounding the inner Tyvek pouch, which contains the sterile product. As a result of the breached foil pouch, the sterile field may be contaminated by the outside of the inner pouch.

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 most likely scenario, the outer foil pouch is breached and is not detected prior to use. As a result of the breached foil pouch, the sterile field is contaminated by the outside of the inner pouch. The procedure is completed as anticipated without knowledge of the contamination. The patient is potentially exposed to that contamination, but no infection develops. There is no harm. In the worst case scenario, the outer foil pouch is breached and is not detected prior to use. As a result of the breached foil pouch, the sterile

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	field is contaminated by the outside of the inner pouch. The procedure is completed as anticipated without knowledge of the contamination. The patient is exposed to that contamination which may potentially result in an infection. To date, Smith & Nephew has received no complaints for the worst case.
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 REGENETEN Tendon Anchors (8). 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.

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.

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Appendix 1: Concerned Product Codes and Descriptions

Product Number	Batch Number
72205201	51192136
72205201	51192143
72205201	51192144
72205201	51192145
72205201	51192146
72205201	51192148
72205201	51192150
72205201	51192151
72205201	51192152
72205201	51192153
72205201	51192154
72205201	51204480
72205201	51204481
72205201	51204484
72205201	51204485
72205201	51204486
72205201	51204487
72205201	51204488
72205201	51204489
72205201	51204491
72205201	51223193
72205201	51223241
72205201	51223242
72205201	51223243
72205201	51223249
72205201	51224282

Product Number	Batch Number
2504-1	51180055
2504-1	51180056
2504-1	51180057
2504-1	51180058
2504-1	51180059
2504-1	51180060
2504-1	51180061
2504-1	51180062
2504-1	51180063
2504-1	51180064
2504-1	51180065
2504-1	51184280
2504-1	51184281
2504-1	51184282
2504-1	51184283
2504-1	51184284
2504-1	51184285
2504-1	51184286
2504-1	51184287
2504-1	51184288
2504-1	51184289
2504-1	51184290
2504-1	51185286
2504-1	51185287
2504-1	51185288
2504-1	51185289

Product Number	Batch Number
2504-1	51185290
2504-1	51185291
2504-1	51185292
2504-1	51185293
2504-1	51185294
2504-1	51185295
2504-1	51185296
2504-1	51189247
2504-1	51189249
2504-1	51189250
2504-1	51189251
2504-1	51189252
2504-1	51189254
2504-1	51189255
2504-1	51189256
2504-1	51189257
2504-1	51189258
2504-1	51189259
2504-1	51193811
2504-1	51193816
2504-1	51193818
2504-1	51193820

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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-2024-06
Concerned Devices: REGENETEN Tendon Anchors (8)

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>		

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3. Customer action undertaken on behalf of Healthcare Organisation / Facility Please complete/tick as appropriate.		
☐ Yes	I confirm receipt of the Field Safety Notice and that I read and understood its content.*	
☐ Yes ☐ No	Has your Healthcare Organisation / Facility distributed the product to other organisations? If you have answered yes, tick all that apply: *	
	☐ I have identified customers that received or may have received this device.	
	☐ I have informed the identified customers of this FSN.	
	☐ I have received confirmation of reply from all identified customers.	
☐ Yes	I performed all actions requested by the FSN. *	
Tick Appropriate Response:*	☐ Yes	Neither I nor any of my customers has any affected devices in inventory.
	☐ 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.