

**--- URGENT ---**  
**FIELD ACTION NOTIFICATION**

**REGENETEN Tendon Anchors (8)**

Please see product detail below / in the attached list

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

**FSCA no.: R-2024-06**  
**12-AUG-2024**

**DESCRIPTION OF THE PROBLEM**

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.

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 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.

**REPORTING TO NATIONAL COMPETENT AUTHORITIES**

In the US this field action is considered a US Class II Recall. As the EU market is affected, FSCA reporting within the EU region is required. Field Action Reporting to local governments in RoW is the responsibility of the local subsidiary/distributor(s).

If any subsidiary/distributor has further distributed the mentioned devices to other countries, please indicate asap to the Field Action Coordinator (FAC), including the information whether you will notify the consignee and the respective competent authority yourself or if you require support of the FAC.

**ACTIONS TO BE TAKEN BY THE DISTRIBUTOR**

- Identify and quarantine the products in your warehouse.
- Identify and inform all users, which have received affected products with the attached Field Safety Notice for Recall.

- Collect return slips of the Field Safety Notice for Recall (to confirm awareness of all affected users) and forward them to the specified contact below. If acknowledgement is not provided by any of the affected users provide evidence of three attempts to notify these users.
- Complete the acknowledgment section on page 3 and return it to the specified contact below.
- Return collected products as instructed below.

Please maintain awareness on this notice and resulting action until the Field Action is terminated to ensure effectiveness of the action. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.

## DISTRIBUTION

Country		Product No.	Batch No. / UDI No.	Distribution Qty.
AE	United Arab Emirates/Dubai (UAE)	72205201	51192154	10
AU	Australia	72205201	51192146	18
		72205201	51192151	9
		72205201	51192152	34
		72205201	51204485	15
		72205201	51204491	67
BE	Belgium	72205201	51192153	3
		72205201	51192154	6
		72205201	51204480	24
		72205201	51223243	16
CA	Canada	72205201	51223249	13
		72205201	51192136	10
		72205201	51192144	21
		72205201	51192146	10
		72205201	51192154	40
		72205201	51204488	64
		72205201	51204489	63
CH	Switzerland	72205201	51223242	103
		72205201	51192144	2
		72205201	51192153	4
		72205201	51204480	6
		72205201	51204481	2
		72205201	51223241	5
CL	Chile	72205201	51223243	2
		2504-1	51185291	1
CN	China	72205201	51192143	140
		72205201	51192144	20
		72205201	51192145	25
DE	Germany	72205201	51192153	2
		72205201	51192154	6
		72205201	51204480	1

		72205201	51204481	1
		72205201	51204484	1
		72205201	51223193	1
		72205201	51223241	17
ES	Spain	72205201	51192144	5
		72205201	51192148	62
		72205201	51192153	15
		72205201	51204484	45
		72205201	51204488	43
FR	France	72205201	51192153	40
		72205201	51192154	39
		72205201	51204480	44
		72205201	51204481	46
		72205201	51223243	33
		72205201	51223249	50
GB	Great Britain	72205201	51192153	10
		72205201	51192154	15
		72205201	51204480	33
		72205201	51204481	35
		72205201	51223193	21
		72205201	51223241	15
		72205201	51223243	13
		72205201	51224282	3
GR	Greece	72205201	51192153	2
		72205201	51223243	3
		72205201	51224282	2
HK	Hong Kong	2504-1	51180060	34
IN	India	72205201	51192152	38
		72205201	51204485	3
		72205201	51204489	21
		72205201	51204491	24
IT	Italy	72205201	51192148	24
		72205201	51192153	22
		72205201	51192154	7
		72205201	51204480	16
		72205201	51204481	21
		72205201	51223241	5
		72205201	51223243	2
JP	Japan	72205201	51192136	130
		72205201	51192144	80
		72205201	51192145	88
		72205201	51192146	83
		72205201	51192148	43
		72205201	51192150	140
		72205201	51192151	131
		72205201	51192152	68

		72205201	51204485	122
		72205201	51204486	140
		72205201	51204487	139
		72205201	51204488	40
		72205201	51204489	59
LT	Lithuania	72205201	51224282	2
MT	Malta	72205201	51192154	2
MY	Malaysia	2504-1	51180060	5
NZ	New Zealand	2504-1	51180060	3
PL	Poland	72205201	51192154	1
		72205201	51204480	1
PR	Puerto Rico	2504-1	51180061	13
		2504-1	51184280	3
		2504-1	51185286	17
		2504-1	51185290	16
		2504-1	51185295	27
		2504-1	51189250	3
		2504-1	51189256	15
PT	Portugal	72205201	51192153	8
		72205201	51192154	9
		72205201	51204480	16
		72205201	51204481	1
		72205201	51223249	23
RO	Romania	72205201	51192154	1
		72205201	51204481	1
SG	Singapore	72205201	51192144	7
		72205201	51192145	27
		72205201	51192146	28
		72205201	51204491	46
		2504-1	51180060	8
SI	Slovenia	72205201	51192144	2
		72205201	51192154	5
ZA	South Africa	2504-1	51189249	15

## RETURN INSTRUCTIONS

All Field Action Returns from PR1 Countries:

- Units are to be returned via NB2C Return STO Process to the shipping location below.
- List Return STO Number and shipment tracking number on the Acknowledgement Section Form below.

All Field Action returns from NON PR1 Countries:

- Will continue to be returned using the RA (ZRE) return process.
- Please contact Smith & Nephew's Global Field Actions Department via e-mail at [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com) to obtain a return authorization (RA) number.

Customer Returns direct to Arvato NL (Plant 2630):

- Local Customer Service teams, as RAs are issued, please provide the customer FSNs and RAs to Smith & Nephew's Global Field Actions Department via e-mail at [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com) to allow for the tracking of returns.
- To complete the Acknowledgment Section below, provide a complete list of customer accounts and RAs for all units returned to Arvato NL under recall.

Please write the **RA/STO number on the outside of your shipping container and on the documents attached** for efficient and accurate processing of the returned products.

**Products returned under these procedures should not be mixed with other stock and must be returned within 30 days from the date of the completed FAN.**

Shipping address:

- Smith+Nephew Oklahoma | Attn: Quality Hold and Field Action Returns Department | 76 South Meridian Avenue, Oklahoma City, OK 73107

## CONTACT PERSON

For questions, please contact:

Cori Hughes / Quality Assurance Specialist

P: +1 (901) 399-1392

[fieldactions@smith-nephew.com](mailto:fieldactions@smith-nephew.com)

## ACKNOWLEDGMENT SECTION

Please complete and return this feedback information to the Field Action Team to prevent repetitive enquiries.

Product No.	Batch No. / UDI No.	Quantity to be Returned	No Product to Return
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

- [Qty] customers in my territory have provided written acknowledgement of receipt of the FSN.
- [Qty] customers have not provided written feedback after three notification attempts.
- Return STO Number: \_\_\_\_\_ (for PR1 Countries only)
- Shipment Tracking Number: \_\_\_\_\_ Carrier: \_\_\_\_\_
- Comments: \_\_\_\_\_

----- For those advised above to perform national competent authority (NCA) reporting: -----

- NCA reporting has been performed as instructed above:  
**Initial Report:** YES  NO       **Final Report:** YES  NO
- NCA reference number: \_\_\_\_\_

Rationale if NO: \_\_\_\_\_

- Copies of the respective reporting documents have been provided to the Field Action Team:      YES       NO

Rationale if NO: \_\_\_\_\_

Country / Region: \_\_\_\_\_ Reference: R-2024-06

Name/Title (please print): \_\_\_\_\_

City: \_\_\_\_\_ Country: \_\_\_\_\_

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