

--- URGENT ---
FIELD ACTION NOTIFICATION

BIOSURE HA 6×20 mm / BIOSURE REGENESORB (RG) 5×20 mm Interference Screws
 Please see product detail below

Product No.	Description	Batch No.	Unique Device Identifier(s)
72201768	BIOSURE HA 6×20 mm interference screw	51315219	03596010611642
72204389	BIOSURE REGENESORB (RG) 5×20 mm interference screw	51306803	00885554036572

FSCA no.: R-2025-07
24-November-2025

DESCRIPTION OF THE PROBLEM

This letter is to inform you that Smith & Nephew, Inc., has initiated a field action to voluntarily remove one lot of BIOSURE HA 6×20 mm interference screws and one lot of BIOSURE REGENESORB (RG) 5×20 mm interference screws due to a labeling error. Complaints were received indicating a partial mix of packages containing BIOSURE REGENESORB (RG) 5×20 mm interference screws instead of BIOSURE HA 6×20 mm interference screws as described on the product label.

In the most likely scenario, the labeling mismatch is identified during surgery set up, or the screw size difference or presence/absence of fenestrations is identified by the surgeon prior to screw insertion. A backup device is used, and the surgery is completed without a significant delay. There is no hazardous situation and no harm.

In the worst case scenario, the discrepancy is not identified, and the incorrect screw is used and inserted. If the screw breaks, there is a remote possibility of a surgical delay greater than 30 minutes to remove the broken screw and use a backup device to complete the surgery.

REPORTING TO NATIONAL COMPETENT AUTHORITIES

In the US this field action is considered a US Class II Recall. 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 who 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 the last page 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.	Distribution Qty.
Australia	72204389	51306803	5
Switzerland	72204389	51306803	2
Czech Republic	72201768	51315219	1
Germany	72201768	51315219	10
Finland	72204389	51306803	1
France	72201768	51315219	17
	72204389	51306803	2
Martinique (France)	72201768	51315219	1
Indonesia	72201768	51315219	10
Italy	72201768	51315219	4
Mexico	72201768	51315219	4
Malaysia	72204389	51306803	2
Netherlands	72204389	51306803	2
Norway	72201768	51315219	3
Poland	72201768	51315219	1
Singapore	72204389	51306803	20

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 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 to allow for the tracking of returns.
- To complete the Acknowledgement 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 | Attn: Quality Hold and Field Action Returns Department | 76 South Meridian Avenue, Dock A | Oklahoma City, OK 73107

CONTACT PERSON

For questions, please contact:
Cori Hughes, Senior Quality Specialist
P: +1 901-399-1392
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
72201768	51315219		<input type="checkbox"/>
72204389	51306803		<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/RA Number: _____

■ 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-2025-07

Name/Title (please print): _____

City: _____ Country: _____

Date: _____ Signature: _____