Date: 11 March 2024

URGENT FIELD SAFETY NOTICE (REMOVAL)
TFNA Femoral Nails (7 lots), VA-LCP Clavicle Plate (1 lot), OPAL Intervertebral Cage (1 lot)

Subject Product:

Part Number	Part Description	Lot(s)	UDI/DI
04.037.944S	TFNA Femoral Nail Ø 9mm, right, 130°, L 235mm	3744P37 H861026	10886982098047
04.037.144S	TFNA Femoral Nail Ø 11mm, right, 130°, L 235mm	4489P98	10886982096562
04.037.112S	TFNA Femoral Nail Ø 11mm, left, 125° L 170mm	447P160	07611819650268
04.037.945S	TFNA Femoral Nail Ø 9mm, left, 130° L 235mm	H861035 H861036 H861037	07611819651876
02.112.621S	VA-LCP Clavicle Plate 2.7, shaft, CS1, right	1201P12	10886982279118
08.803.231S	Opal, Intervertebral Cage, 10x32mm, h 11mm, Revolvable	427P153	07611819318489

Dear Valued Customer,

Synthes GmbH is initiating a field safety notice (removal) for seven lots of TFNA Femoral Nails, one lot of VA-LCP Clavicle Plates, and one lot of OPAL Intervertebral Cages listed in the table above. The TFNA system is intended for temporary fixation and stabilization of proximal femur fractures. The VA-LCP Clavicle Plate is intended for fixation of clavicle bone fragments. The OPAL Intervertebral Cage is intended for degenerative spine disease.

Our records show that you, or your facility, received one or more units of the product lots listed above. Please carefully review this notice for the steps that you should take to respond to this field safety notice (removal).

Reason for the Field Safety Notice (Removal):
The subject products are being removed from the field because lots 3744P37, H861026, 447P160, H861035 H861036, and H861037 were not sterilized, and sterility cannot be confirmed on lots 4489P98, 1201P12, and 427P153.

Potential Patient Impact:
While manufacturing conditions of the subject devices are maintained to reduce contamination, their use may result in infection. Health care providers who have implanted the subject products should continue to follow those patients pursuant to their standard of care for those procedures.

To date, we have not received any complaints related to infection for the subject products.

Please Take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject products and quarantine them immediately. DO NOT USE THE SUBJECT PRODUCTS.

2. Contact your DePuy Synthes Sales Consultant or contact the customer support services at (enter country contact) mailto: to coordinate the return/credits of the subject products.

3. Review, complete, sign, and return the attached Business Response Form (page 3 of this letter) to (enter

country contact) within three (3) business days of receipt of this notification. Please include in the email subject: FA 2348044.

4. Please complete the attached Business Response Form even if you do not have the subject products on hand.

5. Forward this notice to anyone in your facility that needs to be informed (e.g., those who manage, transport, store, stock, or use the subject products).

6. If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.

7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This field safety notice (removal) has been reported to the relevant health authorities. If you have any questions, please contact your local DePuy Synthes Sales Consultant. For Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir.

Sincerely,

Shannon Rook

Digitally signed by Shannon Rook
DN: c=US, o=JNJ, ou=Subscribers, cn=Shannon Rook, 0.9.2342.19200300.100.1.1=1030460
Reason: I am the author of this document.
Date: 2024.03.11 10:48:10 -04'00'
Adobe Acrobat version: 2020.013.20064

Shannon Rook
Staff Quality Systems Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

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Business Response Form

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☐ The subject product has been located. A copy of this notice is being retained and I have read and understood the notification. RETURNED Quantity:_____

☐ None of the subject product is available for return. A copy of this notice is being retained and I have read and understood the notification.

Please complete this Business Response Form (BRF) Form within 3 days after the receipt of this notification. Please return this form via email to at (enter country contact). Please include in the email subject: FA 2348044.

Your Name/Title:	Facility/Business Name:
Signed*:	Date:
Address:	
Account Number:	
Returned Authorization Number	
J&J Sales Rep (as applicable):	
Email Address:	Telephone Number:
Comments (if any):	
**Your signature provides confirmation that you have received and understood this notification.*	