Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 47 **dated** 31/3/2024 **Regarding NCMDR Recall of TFNA Femoral Nail from (mfr: Synthes GmbH).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 47 **/ 2024**

20 -09-1445 H

31 -03-2024

Recall of TFNA Femoral Nail from Synthes GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20968
Product	TFNA Femoral Nail.
Description	Non-active implantable devices.
Manufacturer	Synthes GmbH.
Local agent	Bahawa Healthcare Center.
The affected products	Part Number: 04.037.945S Part Description: TFNA Femoral Nail Ø 9mm, left, 130° L 235mm Lot: H861035 UDI: 07611819651876
Reason	The affected lot was not sterilized.
Action	1. Please examine your inventory immediately to determine if you have the subject products and quarantine them immediately. Do not use the subject products. 2. Please follow the steps in the attachment to handle these products. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Date: 13 March 2024

URGENT FIELD SAFETY NOTICE (REMOVAL)
TFNA Femoral Nails (1 lot)

Subject Product:

Part Number	Part Description	Lot(s)	UDI/DI
04.037.945S	TFNA Femoral Nail Ø 9mm, left, 130° L 235mm	H861035	07611819651876

Dear Valued Customer,

Synthes GmbH is initiating a field safety notice (removal) for seven lots of TFNA Femoral Nails. The TFNA system is intended for temporary fixation and stabilization of proximal femur fractures.

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 lot H861035 was not sterilized.

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. Review, complete, sign, and return the attached Business Response Form (page 3 of this letter) to (HAlzamel@ITS.JNJ.com) within three (3) business days of receipt of this notification. Please include in the email subject: FA 2348044.

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

4. 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).

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

6. 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.

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Sincerely,

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

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

URGENT FIELD SAFETY NOTICE (REMOVAL)
TFNA Femoral Nails (1 lot)

Business Response Form

Subject Product:

Part Number	Part Description	Lot(s)	UDI/DI
04.037.945S	TFNA Femoral Nail Ø 9mm, left, 130° L 235mm	H861035	07611819651876

☐ 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 (HAlzamel@ITS.JNJ.com). 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.*	