Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
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....22.... dated 29/a/12 Regarding recall NCMDR of TWINFIX TI 2.8mm HS Suture Anchor with two 28" DURABRAID Suture from (Mfr: Smith & Nephew)

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

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص.ب:
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 22 / 2020

04 -0 -1441 H

29 -01-2020

Ref: 13 /2020

Recall of TWINFIX TI 2.8mm HS Suture Anchor with two 28" DURABRAID Suture from Smith & Nephew

Source of Recall	**NCMDR** National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=1502
Product	TWINFIX TI 2.8mm HS Suture Anchor with two 28" DURABRAID Suture-Orthopaedic implant
Manufacturer	Smith & Nephew Inc
Local agent	Imtnan Company
The affected products	Product No.: 72200796 Batch No.: 2010547, 2025137, 2036695, 50763859, 50773071
Reason for Recall	Smith Nephew has voluntarily initiated a recall to remove multiple lots of TWINFIX TI 2.8mm HS SUTURE ANCHOR WITH TWO 28" DURABRAID SUTURE (USP #2) due to a potential for sterile barrier breach
Action	1. Locate and quarantine affected unused devices immediately. 2. Return quarantined product to your local agent.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص . ب:
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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]

December 30, 2019

URGENT FIELD SAFETY NOTICE:
Medical Device Field Safety Notice for Recall

Reference: R-2019-22
Concerned Devices: TWINFIX° Ti 2.8mm HS Suture Anchor with two 28" DURABRAID° Suture (USP #2)

Product No.	Description	Batch No.
72200796	TWINFIX TI 2.8mm HS Suture Anchor with two 28" DURABRAID Suture (USP #2)	2010547, 2025137, 2036695, 50763859, 50773071

Dear Customer:

This letter is to inform you that Smith+Nephew, Inc. has voluntarily initiated a recall to remove multiple lots of TWINFIX TI 2.8mm HS SUTURE ANCHOR WITH TWO 28" DURABRAID SUTURE (USP #2) due to a potential for sterile barrier breach. A complaint was received that indicated the protective tube of the device came off inside the pouch enabling the pointed end of the device to puncture the package causing a breach of the sterile barrier, which could affect the sterility of the device.

This field action has been reported to the relevant competent authorities.

Risks to Health	In the most likely scenario, the failure mode would be identified prior to use. In a worst case scenario, the failure mode is not detected prior to use and the affected devices are used in a surgical procedure, potentially introducing a non-sterile device into the surgical sterile field. There have been no reported complaints for devices that have been used during a procedure.
Actions to be taken by the user	1. Locate and quarantine affected unused devices immediately. 2. Return quarantined product to your national Smith+Nephew agency/distributor. 3. Complete the return slip and fax it to your national Smith+Nephew agency/distributor. 4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 5. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall is terminated to ensure effectiveness of the action.

Smith+Nephew

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.

If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

☐ We confirm the receipt of this Field Safety Notice for Recall.

In our facility we have _____ *[Qty]* concerned devices which we will return.

_____ *[Qty]* concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2019-22

Name: _____ Date / Signature: _____