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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

20

Circular No. 20/ 2022

27 -06-1443 H

30 -01-2022

Recall of Stryker CLAW II ORTHOLOC and Stryker DARCO Screw from Wright Medical Technology, In

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=15977
Product	Stryker CLAW II ORTHOLOC and Stryker DARCO Screw.
Description	Bone fixation, Plate, and screws.
Manufacturer	Wright Medical Technology, Inc.
Local agent	Global Leading Excellence.
The affected products	Stryker CLAW II ORTHOLOC 3DSi Plate, Hole Qty: 4, 30mm, REF 40240430, Lot #1642103. Stryker DARCO Screw, Locking, Ti6A14V, REF DC2825016, 2.7mm x 16mm, Lot #1643355.
Reason	The incorrect product is contained in the packaging.
Action	1. Identify, quarantine, and return affected products. The company will provide a replacement. 2. 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

NHR

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
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سلطنة عُمان
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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. 20/2022 **dated** 30/01/22 **Regarding NCMDR Recall of Stryker CLAW II ORTHOLOC and Stryker DARCO Screw from (mfr: Wright Medical Technology, Inc).**

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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
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Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

U.S FDA Recall

Reference Number: mdprc 026 12 21 000 Back
Date submitted: 12/29/2021

Manufacturer:	Wright Medical Technology, Inc.
Device Type:	Stryker CLAW II ORTHOLOC and Stryker DARCO Screw
Description:	Bone fixation, Plate, and screws
Medical Device Identifier:	Stryker CLAW II ORTHOLOC 3DSi Plate, Hole Qty: 4, 30mm, REF 40240430, Lot #1642103 Stryker DARCO Screw, Locking, Ti6A14V, REF DC2825016, 2.7mm x 16mm, Lot #1643355
Reason of Field Safety Corrective Action:	The incorrect product is contained in the packaging.
Remedy Action:	Identify, quarantine, and return affected products. The company will provide a replacement.
Athorized Representative/Importer/Distributor:	Cure Development International Ltd
Report Source:	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=190461
Source Ref. Number:	Z-0392-2022, Z-0393-2022
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	No Attachments

View History