



Circular No. 20/2022

27 -06-1443 H

30 -01-2022

تقدم بـ  
Moving Forward  
with Confidence



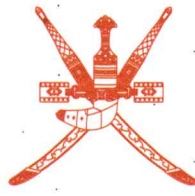
Recall of Stryker CLAW II ORTHOLOC and Stryker DARCO Screw from Wright Medical Technology, Inc

Source	NCMDR-National Center for Medical Device Reporting <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=2&amp;rid=15977">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=2&amp;rid=15977</a>
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie

Director General





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





Kingdom of Saudi Arabia  
Saudi Food & Drug Authority

## Medical Devices Sector

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# NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

## U.S FDA Recall

**Reference Number:** mdprc 026 12 21 000

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**Date submitted:** 12/29/2021

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

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