Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
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 217 dated 22/12/2025.

Copy to:

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

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Circular No. 217 / 2025

02-07-1447 H

22-12-2025

Attached below is the weekly report of Safety Alerts for Medical Devices. To identify the affected products and required action, please open the link.

No. of Safety Alerts 24

Medical Device	Manufacturer	Link
Active Implantable Devices		
Vanta Implantable Neurostimulator (INS)	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
Anaesthetic and respiratory devices		
SLE1500 & INTERFLOW GAS BLENDER	Inspiration Healthcare Limited	https://apps.tga.gov.au/Prod/DRAC/a
Diagnostic and therapeutic radiation devices		
Head Fixation Device	IMIRIS imaging Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
Philips Azurion R2.1.10 and R2.2.10 Systems	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
Philips Azurion R3.1 Systems	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
Electro mechanical medical devices		
AGILIA SP TIVA	Fresenius Kabi	https://apps.tga.gov.au/PROD/DRAC/
AMSCO	STERIS Corporation..	https://www.accessdata.fda.gov/scrip
Cardiosave Hybrid IABP Cardiosave Rescue	Datascope Corp	https://www.accessdata.fda.gov/scrip

Medical Device	Manufacturer	Link
Cardiosave Hybrid IABP Cardiosave Rescue	Datascope Corp	https://www.accessdata.fda.gov/scrip
Hemodialysis System, Surdial DX	Nipro Corporation.	https://www.accessdata.fda.gov/scrip
Ivenix Infusion System (IIS)	Fresenius Kabi	https://www.accessdata.fda.gov/scrip
MV3 Bariatric Bed Arise 1000EX Mattress	Stryker Communications……	https://www.accessdata.fda.gov/scrip
In vitro diagnostic devices		
TS-10	Sysmex Corporation	https://ade.sfda.gov.sa/Fsca/PublishD
Medical software		
Leksell GammaPlan	Elekta Inc	https://ade.sfda.gov.sa/Fsca/PublishD
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
Non-active implantable devices		
Trial Phantom Buttress	Enovis Corporation	https://www.bfarm.de/SharedDocs/K
Ophthalmic and optical devices		
Photodynamic Therapy Device	Xuzhou Kernel Medical Equipment Co., Ltd.	https://www.bfarm.de/SharedDocs/K
Reusable devices		
HFD100 Torque Screw Assembly	Deerfield Imaging	https://www.bfarm.de/SharedDocs/K

Medical Device	Manufacturer	Link
Single-use devices		
Bard InLay Optima Ureteral Stent Kit	C.R. BARD…	https://www.accessdata.fda.gov/scrip
basixCOMPAK Inflation Device	Merit Medical Systems Inc....	https://apps.tga.gov.au/Prod/DRAC/a
ChemoPlus gowns	Cardinal Health 200, LLC..	https://www.accessdata.fda.gov/scrip
DEXLOCK Achilles Repair Implant Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
Quick Strip CURAD Fur Friends	Medline Industries Inc	https://www.accessdata.fda.gov/scrip ts/cdrh/cfdocs/cfRES/res.cfm?id=217
SCISSORS, OR, SHARP/BLUNT, 5.5", STERILE&ce related information	Medline Industries Inc	https://www.accessdata.fda.gov/scrip

The local agent shall coordinate with the Drug Safety Center to ensure that appropriate actions are taken in response to the listed alerts. In the event of a safety notice or a defect related to any medical device, the local agent must implement the necessary corrective measures in accordance with Ministerial Decision No. 113/2020, Articles (88) and (89).

Device users are advised to contact the respective local agent to follow up on the implementation of corrective actions needed.

Ph. Ibrahim Nasser Al Rashdi
Director General

DSC
مركز سلامة الدواء
Drug Safety Center

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