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 106 dated 27/10/2026.

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Department, DSC**
- **Director of Pharmacovigilance Department, DSC**
- **Director of Medicine Registration Department, DSC**
- **Director of Regulatory Compliance Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

Circular No. 106 / 2026

16-05-1448 H

27-10-2026

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 28

Medical Device	Manufacturer	Link
Active Implantable Devices		
Abre™ Venous Self-Expanding Stent System	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
Impella CP with SmartAssist®	ABIOMED Inc	https://www.bfarm.de/SharedDocs/K
Anaesthetic and respiratory devices		
SPIROMETRY SETS AND ANAESTHETIC BREATHING SYSTEMS CONTAINING SPIROMETRY SETS	Intersurgical Limited	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2026/47839-
Assistive products for persons with disability		
Likorall Overhead Lifts	Baxter Healthcare	https://www.accessdata.fda.gov/scrip
Biologically-derived devices		
Grafton" Orthoblend, Grafton" Paste	Medtronic Sofamor Danek USA	https://www.accessdata.fda.gov/scrip
Dental devices		
Orthodontic Metal Devices	American Orthodontics	https://www.bfarm.de/SharedDocs/K
Diagnostic and therapeutic radiation devices		
Philips MR systems	Philips Healthcare	https://apps.tga.gov.au/Prod/DRAC/a

Medical Device	Manufacturer	Link
Electro mechanical medical devices		
Cell for SCHILLER FRED easy defibrillator	Schiller AG	https://www.bfarm.de/SharedDocs/K
NeuroStar Advanced Therapy System	Neuronetics, Inc.	https://www.accessdata.fda.gov/scrip
Power F2 Powered Fastening System	Ferno-Washington Inc.	https://www.accessdata.fda.gov/scrip
Healthcare facility products and adaptations		
IOMAX Cortical Module	Cadwell Industries, Inc.	https://www.accessdata.fda.gov/scrip
In vitro diagnostic devices		
Atellica CH HDL Cholesterol (HDLC) & Atellica CH Total Protein_2 (TP_2)	Siemens Healthcare Diagnostics GmbH	https://apps.tga.gov.au/Prod/DRAC/a
HemosIL AcuStar HIT-IgG (PF4-H)	Werfen..	https://www.accessdata.fda.gov/scrip
Troponin T Control	Randox Laboratories Ltd.	https://apps.tga.gov.au/Prod/DRAC/a
Laboratory equipment		
BD Phoenix™ CPO Detect 6-well panel	Becton Dickinson & Co. (BD)	https://www.accessdata.fda.gov/scrip
Medical software		
RayStation 4.7 to v2026	RaySearch Laboratories AB (publ)	https://www.bfarm.de/SharedDocs/K
Non-active implantable devices		
Abre Venous Self-Expanding Stent System	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a
CoLag SCREW, FT, Dia. 6.7X62.5 mm	In2Bones, SAS.	https://www.accessdata.fda.gov/scrip
iFuse TORQ Implant System	SI-BONE, Inc.	https://www.accessdata.fda.gov/scrip
NaviFlex LW Pusher	oston Scientific Neuromodulation Corporatio	https://www.accessdata.fda.gov/scrip

Medical Device	Manufacturer	Link
Reusable devices		
FORWARD Gunshot Wound Kit	INTEGRATED MEDCRAFT LLC	https://www.accessdata.fda.gov/scrip
Single-use devices		
Curaplex Capnography	Sarnova HC, Llc	https://www.accessdata.fda.gov/scrip
GORE VIABIL Short Wire Biliary Endoprosthesis	W.L. Gore & Associates Inc	https://www.accessdata.fda.gov/scrip
PERMAHAND" Silk Suture	Ethicon Inc.	https://www.accessdata.fda.gov/scrip
Steriflush Syringes NaCl 0.9%	Sterisets Medical Products.	https://www.bfarm.de/SharedDocs/K
Surfacer® Inside-Out® Access Catheter System	Merit Medical Systems Inc....	https://www.bfarm.de/SharedDocs/K
TraumaFix Professional Pelvic Splint	Reliance Medical	https://apps.tga.gov.au/Prod/DRAC/a
Trilogy Delivery Catheter	JenaValve Technology GmbH	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

سلطنة عمان - وزارة الصحة
مركز سلامة الدواء
DRUG SAFETY CENTER
SULTANATE OF OMAN - MINISTRY OF HEALTH