

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطِنَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّقَابَة وَالدُّوَاءِ
مَسْقَط

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. 1014..... dated 27/05/20..... Regarding HEMASHIELD GOLD and HEMASHIELD PLATINUM Double Velour Vascular Grafts FSCA of (Mfr:- Intervascular)

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

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Circular No. 104 / 2020

04-Shawwal 1441 H

27 -May-2020

Field Safety Corrective Actions (FSCA): of HEMASHIELD GOLD and HEMASHIELD PLATINUM Double Velour Vascular Grafts from:- Intervascular

Source	NCMDR - National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15143
Product	HEMASHIELD GOLD and HEMASHIELD PLATINUM Double Velour Vascular Grafts
Manufacturer	Intervascular
The affected products	(PRODUCT REF.X , Y) SERIAL NO.111 and 222) (LOT NO. 99,99)
Reason	Potential bleeding at the seam line of the branches of Hemashield
Action	Isolate, and discontinue use of any affected product. Contact the local agent to provide your facility with replacement product or credit.
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 department of Medical Device Control Contact E-mail Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

