Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT





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. 9.4....... dated 20/05.120 Regarding Recall of GEM Microvascular Coupler Devices (Mfr: Synovis Micro Companies Alliance, Inc)

Copy to:

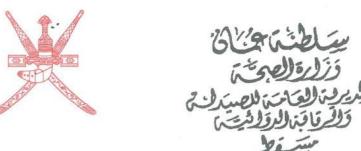
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central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

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Circular No. 94 / 2020

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2 -May-2020

Recall of GEM Microvascular Coupler Devices from Synovis Micro Companies Alliance, Inc.

Source	NCMDR (National Center for Medical Devices Reporting) https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15126
Product	GEM Microvascular Coupler Devices.
Manufacturer	Synovis Micro Companies Alliance, Inc.
The affected products	- 2.5 mm 6 Pack GEM2753 Microvascular Coupler Devices, 5111-00250-060, Lot No. SP19J11- 1402242, SP19J11-1402246. Expiration Date 2024 Aug 28 2.5 mm 1 Pack GEM2753 Microvascular Coupler Devices, 5111-00250-010, SP19J11-1402265, 2024 Aug 28 2.0 mm 6 Pack GEM2752 Microvascular Coupler Devices, 5111-00200-060, 10844735002642, SP19J08-1401476, SP19J09-1401614, 2024 Sep 3 2.0 mm 1 Pack GEM2752 Microvascular Coupler Devices, 5111-00200-010, 00844735002638, SP19J09-1401617, SP19J08-1401480, 2024 Sep 3.
Reason	Coupler Size Labeling on Outer Tray May Not Match Coupler Size Labeling on Inner Tray.
Action	 Locate and remove the affected product lots from your facility. The product code and lot number can be found on the individual product packaging. Contact the local agent to arrange for return and replacement of the product.
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