

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِيَّاطِنَا جَمَانَا
وَزَارَةُ الصِّحَّةِ
وَالرِّقَابَةِ الدَّوْلِيَّةِ
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. 94..... dated 25/05/20 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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سلطنة عمان
وزارة الصحة
المديرية العامة للصحة
والدواء والرقابة
مسقط

Circular No. 94 / 2020

26 -Ramadhan-1441 H

20 -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	1. Locate and remove the affected product lots from your facility. The product code and lot number can be found on the individual product packaging. 2. 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

