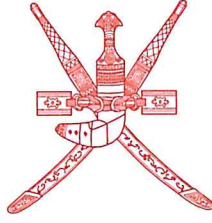


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَا عُومَانِ
وَزَارَةُ الصِّحَّةِ
الطَّبِيبِيَّةِ الْعَامَّةِ لِلصِّدْقِ
وَالرَّقَابَةِ الدَّوَلِيَّةِ
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...157... dated 3.5.15/28 Regarding FDA Recall of ClosureFast Micro Introducer Sheath Set from (mfr: Argon Medical Device).

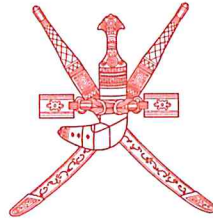
Copy to:

- 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 للأدوية
والرقابة الدوائية
مسقط

Circular No. 157/2020

10 -01-1442 H

30 -08-2020

Recall of ClosureFast Micro Introducer Sheath Set from Argon Medical Devices, Inc.

Source	Food and Drug Administration- FDA https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=182544
Product	ClosureFast Micro Introducer Sheath Set
Description	Dilator, vessel, for percutaneous catheterization
Manufacturer	Argon Medical Device, Inc.
Local agent	Muscat Pharmacy and Stores LLC.
The affected products	LOT 11295042
Reason	Sterile introducer sheath set manufactured under one lot with different expiration dates.
Action	Contact the local agent for remedial action.
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 through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

