

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلْطَنَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّقَابَة الدَّوْلِيَّة
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. 100..... dated 27/05/20 Regarding NCMDR Field Safety Corrective Actions for Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology (Mfr: Medtronic)

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 للصيدلانية
والرقابة الدوائية
مسقط

Circular No. MUSCAT
100 / 2020

04-Shua-1441 H

27 -May-2020

Field Safety Corrective Actions of Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology from Medtronic

Source	(NCMDR) National Center for Medical Devices Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15143
Product	Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology
Manufacturer	Medtronic
Local Agent	Mustafa Sultan Science & Industry
The affected products	Product Number/Catalogue Number: PED-250-XX, PED-275-XX, PED-300-XX, PED-325-XX, PED-350-XX, PED-375-XX, PED-400-XX, PED-425-XX, ED-450-XX, PED-475-XX, PED-500-XX, PED2-250-XX, PED2-275-XX, PED2-300-XX, PED2-325-XX, PED2-350-XX, PED2-375-XX, PED2-400-XX, PED2-425-XX, PED2-450-XX, PED2-475-XX, PED2-500-XX All lots manufactured 22-Oct -2019 to 01-Feb-2020
Reason	Medtronic has identified the potential for device fracture at the distal section during use due to a weakened bond in a subset of devices that have been recently manufactured. Use of affected product may result in unintended separation, where the distal portion of the device delivery system remains in the patient. If this occurs, it may result in significant patient injury, including a prolonged procedure, ischemic stroke, intracranial haemorrhage, neurological deficit, and/or death. No complaints related to the issue have been confirmed within the affected population at this time. This is a peri-procedural risk. If a Pipeline Flex embolization device has already been implanted successfully, there is no increased risk to patients due to the issue. Those patients with an implanted device should continue with their normal course of treatment.
Action	Medtronic is advising customers to remove and quarantine all unused affected products in their inventory. Users should NOT use any affected product. Affected product should be returned to the Local Agent.
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

