Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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.....59..... dated 05/03/20 Regarding NCMDR recall Recall of Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology from 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**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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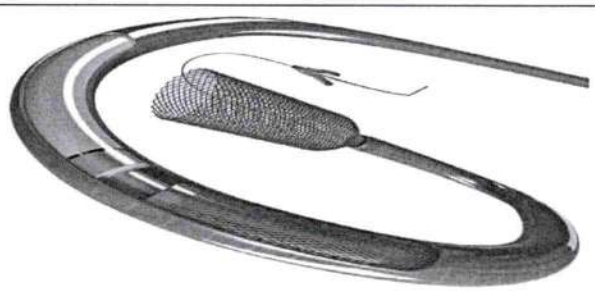
Circular No. 59 / 2020

14 -07-1441 H

09 -03-2020

Ref:44/2020

Recall of Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology from Medtronic

Source of Recall	NCMDR National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15090
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 for Recall	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	1. Kindly check your stock, contact your 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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

dg-padc@moh.gov.om : ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني
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