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

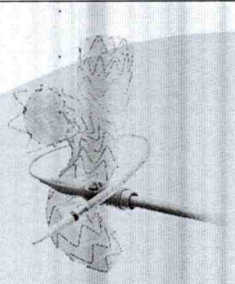
سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 9 / 2022

21-06-1443 H

24-01-2022

Recall of Endurant II/IIs Stent Graft System from Medtronic SA.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15996
Product	Endurant II/IIs Stent Graft System.
Description	Stent/Grafts, Vascular, Aortic.
Manufacturer	Medtronic SA.
Local agent	Al Zahrawi Medical Supplies LLC.
The affected products	Model: STENT GRAFT ETBF2516C166EE ENDUR II BIF, Serial Number: V30674276 Model: STENT GRAFT ETBF2816C145EE ENDUR II BIF, Serial Number: V30560300
Reason	Devices built with specific batches of taper tip assemblies have the potential for the taper tip to detach from the delivery system.
Action	1. Immediately identify and quarantine all unused affected devices. 2. Return all unused affected devices to Medtronic. 3. 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 the E-mail: Med-device@moh.gov.om

A-S

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

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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. 9/2022 **dated** 24/11/2022 **Regarding NCMDR Recall of Endurant II/IIs Stent Graft System from (mfr: Medtronic SA).**

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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
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Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 014 01 22 000 Back
Date submitted: 1/13/2022

Manufacturer:	Medtronic SA
Device Type:	Endurant II/IIs Stent Graft System
Description:	Stent/Grafts, Vascular, Aortic
Medical Device Identifier:	Model: STENT GRAFT ETBF2516C166EE ENDUR II BIF, Serial Number: V30674276 Model: STENT GRAFT ETBF2816C145EE ENDUR II BIF, Serial Number: V30560300
Reason of Field Safety Corrective Action:	Devices built with specific batches of taper tip assemblies have the potential for the taper tip to detach from the delivery system.
Remedy Action:	- Immediately identify and quarantine all unused affected devices - Return all unused affected devices to Medtronic. Your local Medtronic Field Representative can assist you as necessary in initiating the return and replacement of this product.
Athorized Representative/Importer/Distributor:	Medtronic Saudi Arabia
Report Source:	NCMDR
Source Ref. Number:	BBD85C4CBD2F8
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Medtronic SA.pdf

View History