

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلانية
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. 134 dated 14/7/2020 Regarding NCMDR Field Safety Notice of Dialyser xevonta Lo 18, xevonta Hi 18, xevonta Hi 20 (Mfr: B Braun Medical).

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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Circular No. 134/2020

22 -11-1441 H

14 -07-2020

Field Safety Notice of Dialyser xevonta Lo 18, xevonta Hi 18, xevonta Hi 20 from B Braun Medical.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15195
Product	Dialyser xevonta Lo 18, xevonta Hi 18, xevonta Hi 20- Dialysis, haemodialysis, dialyser.
Manufacturer	B Braun Medical.
The affected products	1. XEVONTA DIALYSER LO 18, GAMMA:- Article Codes: 7204550 2. XEVONTA DIALYSER LO 18 AP, GAMMA:- Article Codes: 72045500 3. XEVONTA DIALYSER HI 18, GAMMA.- Article Codes: 7204657 4. XEVONTA DIALYSER HI 18 AP, GAMMA.- Article Codes: 72046570
Reason	B Braun became aware of occasional leakages at one of the blood caps of the above mentioned dialysers. The leakages occurred during preparation phase of the dialysis machine and some during therapy. The blood loss was marginal and without any health consequences for the patients. The leakage is located between housing and blood cap of the dialyser due to a deviation in the production process. The root cause of the deviation is clearly defined and potentially affected dialysers could be identified unequivocally.
Action	1. Check whether you have above mentioned products in stock, and quarantine them. 2. 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 contact E-mail Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL





Medical Devices Sector

قطاع الأجهزة الطبية

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NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 013 05 20 000

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Date submitted: 5/10/2020

Manufacturer:	B Braun Medical
Device Type:	Dialyser xevonta Lo 18, xevonta Hi 18, xevonta Hi 20
Description:	Dialysis, haemodialysis, dialyser
Medical Device Identifier:	<p>1) XEVONTA DIALYSER LO 18, GAMMA: - Article Codes: 7204550</p> <p>2) XEVONTA DIALYSER LO 18 AP, GAMMA: - Article Codes: 72045500</p> <p>3) XEVONTA DIALYSER HI 18, GAMMA. - Article Codes: 7204657</p> <p>4) XEVONTA DIALYSER HI 18 AP, GAMMA. - Article Codes: 72046570</p>
Reason of Field Safety Corrective Action:	<p>B Braun became aware of occasional leakages at one of the blood caps of the above mentioned dialysers. The leakages occurred during preparation phase of the dialysis machine and some during therapy. The blood loss was marginal and without any health consequences for the patients.</p> <p>The leakage is located between housing and blood cap of the dialyser due to a deviation in the production process. The root cause of the deviation is clearly defined and potentially affected dialysers could be identified unequivocally.</p>
Remedy Action:	Check whether you have above mentioned products in stock, and quarantine them. The isolated products will be exchanged.
Athorized Representative/Importer/Distributor:	Medical supplies & Services Co.Ltd Mediserv
Report Source:	NCMDR
Source Ref. Number:	BBFC1E75F8342
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.
Attachments:	B Braun Medical Inc.pdf

[View History](#)

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