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



سلطنة عُـمان وزارة الـصحـة الـمديـريـة النعامـة للـصيـدلـة والـرقـابـة الـدوائيـة مـسـقـط

Circular No.

19/2022 in back with Confidence

27 -06-1443 H

30-01-2022

Field Safety Corrective Action of Perfusor Space from B Braun Medical Inc.

	Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15994
	Product	Perfusor Space.
	Description	Syringe Infusion Pump.
	Manufacturer	B Braun Medical Inc.
×	The affected products	Article number: 8713030 Serial Number: 97027044L1, 97023811I1, 97021016G1 Manufactured between Jul-2021 and Dec-2021.
	Reason	Certain steps in the final inspection of the affected devices may have not been conducted.
	Action	 Identify and quarantine the affected devices. Contact the local agent for completion of the missed out final inspection procedures.
K	Product image	080000
	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

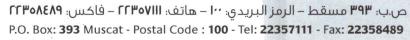
Dr. Mohammed Hamdan Al Rubaie

Director General









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



سلطنة عُـمان وزارة الـصحـة الـمديـريـة العامـة للـصيـدلـة والـرقـابـة الـدوائـيـة مـساقـط

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. 1.9.1.20.27 dated .35.1.27. Regarding NCMDR Field Safety Corrective Action of Perfusor Space from (mfr: B Braun Medical Inc).

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







Kingdom of Saudi Arabia Saudi Food & Drug Authority

Medical Devices Sector

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ICMDR

National Center for Medical Devices Reporting

المركز الوطني ليلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 012 01 22 000

Date submitted:

1/13/2022

Back

Manufacturer:

B Braun Medical Inc.

Device Type:

Perfusor Space

Description:

Syringe Infusion Pump

Medical Device Identifier:

Article number: 8713030

Serial Number: 97027044L1, 97023811I1, 97021016G1

Manufactured between Jul-2021 and Dec-2021.

Reason of Field Safety Corrective

Action:

Certain steps in the final inspection of the affected devices may have not

been conducted.

Remedy Action:

Identify and quarantine the affected devices.

Medical supplies & Services Co.Ltd Mediserv

Your responsible B.Braun service organization will contact you

immediately for completion of the missed out final inspection procedures

Athorized

Representative/Importer/Distributor:

Report Source:

NCMDR

Source Ref. Number:

C2C43AF8182D0

SFDA Comments:

SFDA urges all hospitals that have devices subjected to FSCA, to contact

the company.

Attachments:

B Braun Medical Inc.pdf

View History

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