



Circular No. 19/2022


27 -06-1443 H

30 -01-2022

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ
Moving Forward
with Confidence



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, 9702381111, 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	1. Identify and quarantine the affected devices. 2. Contact the local agent for completion of the missed out final inspection procedures.
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

Dr. Mohammed Hamdan Al Rubaie

Director General





To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)
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. 19/2022 dated 30/01/22 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


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NCMDR Recall

Reference Number: mdprc 012 01 22 000

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Date submitted: 1/13/2022

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. Your responsible B.Braun service organization will contact you immediately for completion of the missed out final inspection procedures
Athorized Representative/Importer/Distributor:	Medical supplies & Services Co.Ltd Mediserv
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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