



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 39 dated 21/2/2023 Regarding NCMDR Recall of Original Perfusor® Line 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



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

Twitter: dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 39 / 2023

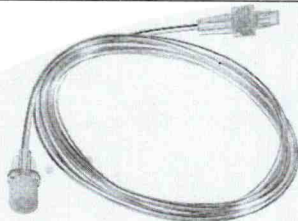
نتقدم بـ
Moving Forward
with Confidence

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2040
Vision Oman

30-07-1444 H

21 -02-2023

Recall of Original Perfusor® Line from B Braun Medical Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18418
Product	Original Perfusor® Line.
Description	Single-use.
Manufacturer	B Braun Medical Inc.
The affected products	Check the list of affected products in the attachment.
Reason	The risk for holes and leakages in the listed article batch combinations of Original Perfusor® Line. The deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.
Action	1. Identify, quarantine, and return affected articles. Do not use affected devices anymore. 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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



Appendix 1 – List of affected article-batch combinations

Article Number	Article Name	Batch
8250146	PERFUSOR LINE, PE, LL, 300 CM	22A27E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22B02E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B09E8SC6
8723010	PERFUSOR LINE, OPAQUE , PE, LL,150CM	22B09E9SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B11E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22B12E8SC6
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22B14E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B15E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B18E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B20E8SC6
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22B21E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B22E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22B23E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B24E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B25E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22C03E8SC3
8723026	PERFUSOR LINE,PE,MAGENTA TUBE,LL,200cm	22C03E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22C04E8SC3
8723018	PERFUSOR LINE, UV-PROT. PE, LL, 200CM	22C04E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22C05E8SC3
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C05E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22C06E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22C06E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL,150CM	22C07E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22C09E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C11E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22C12E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C17E8SC6
8929055E	PERFUS. PE 1x2 MAGENTA LL 2,00M NST BULK	22C19E0SC3
8723018	PERFUSOR LINE, UV-PROT. PE, LL, 200CM	22C19E8SC6
8723017-20	PERFUSOR LINE,UV-PROTECT,PE,LL,150CM-CIS	22C21E8SC6
8723024	PERFUSOR LINE, PE, GREEN TUBE, LL, 200CM	22C24E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C25E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C27E8SC6
8723018	PERFUSOR LINE, UV-PROT. PE, LL, 200CM	22C29E8SC6
8723021	PERFUSOR LINE, PE, BLUE TUBE, LL, 200CM	22C30E8SC6
8723017-20	PERFUSOR LINE,UV-PROTECT,PE,LL,150CM-CIS	22C30E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22C31E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22D01E8SC3

Article Number	Article Name	Batch
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D01E8SC6
8255067	PERFUSOR LINE, PE, LL, 100 CM	22D02E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D03E8SC6
8723025	PERFUSOR LINE, PE, MAGENTA TUBE, LL, 150cm	22D04E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D06E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL, 150CM	22D08E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D09E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D10E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D12E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D13E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D14E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D16E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D18E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22D19E8SC3
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22D19E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D21E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22D25E8SC3
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL, 150CM	22D26E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22D27E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22D27E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22D28E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22D30E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL, 150CM	22E02E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E04E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E06E8SC6
8272565	PERFUSOR LINE, PE, LL, 250 CM	22E09E8SC3
8255067	PERFUSOR LINE, PE, LL, 100 CM	22E09E8SC6
8723017	PERFUSOR LINE, UV-PROTECT, PE, LL, 150CM	22E10E8SC6
8250146	PERFUSOR LINE, PE, LL, 300 CM	22E11E8SC3
8723060	PERFUSOR LINE, PE, LL, 200 CM	22E12E8SC6
8723026	PERFUSOR LINE, PE, MAGENTA TUBE, LL, 200cm	22E16E8SC6
8722935-20	PERFUSOR LINE, PE, LL, 150 CM-CIS	22E18E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E20E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22E22E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E24E8SC6
8723017-20	PERFUSOR LINE, UV-PROTECT, PE, LL, 150CM-CIS	22E26E8SC6
8722935	PERFUSOR LINE, PE, LL, 150 CM	22E28E8SC6
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8722935	PERFUSOR LINE, PE, LL, 150 CM	22F06E8SC6

Article Number	Article Name	Batch
8722935	PERFUSOR LINE, PE, LL, 150 CM	22F12E8SC6