Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحة مركز سلامة الدواء 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 58 dated 04 11 2024 Regarding Field Safety Corrective Action of Minicap Extended Life PD Transfer Set with Twist Clamp from (mfr: Baxter Healthcare).

Copy to:

- · Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information





Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحــة مـركـز سلامـة الــدواء

Circular No. 158/2024

02 -0**5**1446 H 04 -11 -2024

Field Safety Corrective Action of Minicap Extended Life PD Transfer Set with Twist Clamp from Baxter Healthcare.

Source	Baxter Healthcare through their local distributor Mustafa Sultan Science & Industry Co.LLC.
Product	Minicap Extended Life PD Transfer Set with Twist Clamp.
Manufacturer	Baxter Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	(Code): R5C4482 (Description): MINICAP EXTEND LIFE PD TRANS (Lot Number): Lot H23K15033 and higher (Code): R5C4482E (Description): MINICAP EXTEND LIFE PD TRANSF (Lot Number): H23J18054, H24G10063
Reason	Separation of the female connector from the main body of the transfer set. These separations may occur while connecting or disconnecting from PD therapy products.
Action	 If your transfer set is still intact and has not experienced separation issues, please continue to safely use the transfer set while following aseptic technique. If you experience a separation of the transfer set, please close the transfer set twist clamp and do not cut the patient line. Contact your doctor and/or nurse immediately to arrange for a transfer set replacement and further guidance. Contact the local agent for remedial action.
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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al-Rubaie **Director General**





ص.ب: ۳۹۳ مسقط - الرمز البريدي الماريخي الماريخي الماريخي الماريخي الماريخي الماريخي الماريخي الماريخي الماريخي P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

@DSCPHO Email: dscpho@moh.gov.om