



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 230 dated 26/10/2023 Regarding NCMDR Field Safety Notice of stay*safe Disinfection Cap from (mfr: Fresenius Medical Care).

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





نقدم بثقة
Moving Forward
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رؤية عمان
2040
Oman Vision

Circular No. 230/2023

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26 -10-2023

Field Safety Notice of stay•safe Disinfection Cap from Fresenius Medical Care.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19737
Product	stay•safe Disinfection Cap.
Description	Disinfection Cap.
Manufacturer	Fresenius Medical Care.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Article no. 2845091, F00005376, F00005996.
Reason	A potent antiseptic present in the stay•safe Disinfection Cap used to close the PD catheter extension could lead to iodine-induced hypothyroidism and associated clinical sequelae. Povidone-iodine could also lead to hypersensitivity.
Action	1. It is recommended close monitoring of thyroid function in patients with small peritoneal fill volumes, typically infants and children, when using iodine containing products and avoid using of the product in case of known povidone-iodine allergy. 2. The updating of the labeling is in the process to include these medical warnings and contraindications. 3. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

