

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

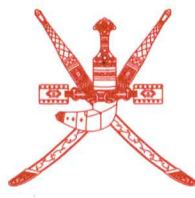
After Compliments,

Please find attached our Circular No 188 dated 16/10/2022 Regarding Recall of In-Ka®
ureteral balloon dilatation catheter kit from (mfr: Coloplast).

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





Circular No. 188 / 2022

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16 -10-2022

ببمودة بثقة
Moving Forward
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رؤية عمان
2040
Oman Vision

Recall of In-Ka® ureteral balloon dilatation catheter kit from Coloplast.

Source	Coloplast through their authorized distributor Etihad Medical Services LLC.
Product	In-Ka® ureteral balloon dilatation catheter kit.
Description	Ureteral dilatation catheter.
Manufacturer	Coloplast.
Local agent	Etihad Medical Services LLC.
The affected products	REF: BD4144, BD4145 and BD4146 (UDI-DI): 570893262832602R2 Lot numbers: refer to "Appendix 1" in the attached FSN.
Reason	The expiration date labelled on the IN-KA® Ureteral balloon dilatation catheter kit is not correct. The shelf life of one component within the kit (syringe) is shorter than the expiration date of the kit.
Action	1. Customers are kindly advised to return any unused products from the affected lots. 2. 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

