

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
والدواء العامة للصحة
والرعاية الدوائية
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... 15..... dated 17/1/2012. Regarding Field Safety
Corrective Action of Artiset HD DNL HC from (Baxter Healthcare).

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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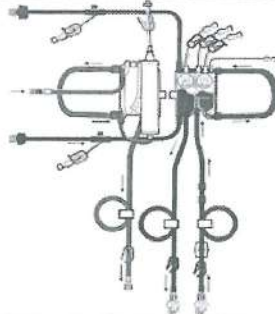
سلطنة عمان
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Circular No. ١٥ / 2021

٥٣ -06 -1442 H

١٧ -01-2021

Field Safety Corrective Action of Artiset HD DNL HC from Baxter Healthcare.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15502
Product	Artiset HD DNL HC.
Description	Hemodialysis Tubing Sets.
Manufacturer	Baxter Healthcare.
Local Agent	Mustafa Sultan Science & Industry Co.L.L.C.
The affected products	Product Code: 955075 Product Description: Artiset HD DNL HC Lot Number: All lots within expiry. - Affected Lots: PLN036F - Expiry Date: 01 Jun 2021.
Reason	A kinked access lines observed during treatment using cartridge sets for hemodialysis treatments.
Action	1. Customers can continue to safely use the affected cartridge sets listed above by inspecting sets prior to use as advised in the relevant IFU. If a kink is identified during inspection, the cartridge set must not be used. If a kink is identified during treatment, therapy must be interrupted, and the set must be replaced to restart therapy. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

