

Circular No. 11 / 2022

21 -06-1443 H

24 -01-2022

بالتقدم
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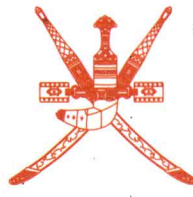
Field Safety Notice of MiniCap Extended Life PD Transfer Sets from Baxter Healthcare.

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15995
Product	MiniCap Extended Life PD Transfer Sets- Peritoneal dialysis system tubing set.
Manufacturer	Baxter Healthcare.
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Product Code: R5C4482 Lot # : All lots within expiry
Reason	The following products may cause damage (for example, leaking or cracking), if they come into direct contact with the transfer set: - Cleaning products such as hand sanitizer, or those containing, but not limited to, hydrogen peroxide, bleach, alcohol or antiseptic agents - Solvents intended to remove adhesive residue, such as those containing acetone, toluene, xylene, or cyclohexanone.
Action	1. If you are using one of the above-mentioned cleaning products or solvents, please discontinue use of this product or solvent immediately. Please ensure all home patients are aware of proper cleaning practices. Clinicians who are not using any of the above-mentioned cleaning products or solvents may continue to use Baxter transfer sets. 2. If you have patients who have used the cleaning products or solvents listed above and have identified damage to their transfer set, please replace their transfer set and contact Baxter. 3. Baxter will be updating the Instructions for Use (IFU) for all Luer transfer sets to instruct patients not to allow cleaning products or solvents to come into contact with the transfer set. 4. 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





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. 11/2022, dated 24/1/2022, Regarding NCMDR Field Safety Notice of MiniCap Extended Life PD Transfer Sets from (mfr: 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





Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

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National Center for Medical Devices Reporting


المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 013 01 22 000

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Date submitted: 1/13/2022

Manufacturer:	Baxter Healthcare
Device Type:	MiniCap Extended Life PD Transfer Sets
Description:	Peritoneal dialysis system tubing set
Medical Device Identifier:	Product Code: R5C4482 Lot # : All lots within expiry
Reason of Field Safety Corrective Action:	The following products may cause damage (for example, leaking or cracking), if they come into direct contact with the transfer set: - Cleaning products such as hand sanitizer, or those containing, but not limited to, hydrogen peroxide, bleach, alcohol or antiseptic agents - Solvents intended to remove adhesive residue, such as those containing acetone, toluene, xylene, or cyclohexanone
Remedy Action:	<ol style="list-style-type: none"> 1. If you are using one of the above-mentioned cleaning products or solvents, please discontinue use of this product or solvent immediately. Please ensure all home patients are aware of proper cleaning practices. Clinicians who are not using any of the above-mentioned cleaning products or solvents may continue to use Baxter transfer sets. 2. If you have patients who have used the cleaning products or solvents listed above and have identified damage to their transfer set, please replace their transfer set and contact Baxter. 3. Baxter will be updating the Instructions for Use (IFU) for all Luer transfer sets to instruct patients not to allow cleaning products or solvents to come into contact with the transfer set.
Athorized Representative/Importer/Distributor:	Baxter AG
Report Source:	NCMDR
Source Ref. Number:	BBD85C4CBD2F8
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	 Baxter Healthcare.pdf

[View History](#)

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