Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 7 / 2022

21 -06-1443 H
24 -01-2022

Field Safety Corrective Action of Disposable Hemoperfusion Cartridge (HA) from Jafron Biomedical Co.,Lt

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15989
Product	Disposable Hemoperfusion Cartridge (HA).
Description	Injections / Infusions / Transfusions / Dialysis - therapeutic apheresis.
Manufacturer	Jafron Biomedical Co.,Ltd.
The affected products	ALL the Disposable Hemoperfusion Cartridge (HA) Since the Launch.
Reason	Indirect Harm from inadequacy information in IFU.
Action	1. Details of the revision IFU are viewed in the table in the attached FSCA. 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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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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. 7/2022 **dated** 24/11/2022 **Regarding NCMDR Field Safety Corrective Action of Disposable Hemoperfusion Cartridge (HA) from (mfr: Jafron Biomedical Co.,Lt).**

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**

PADC
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JaFron

Urgent Field Safety Notice

Disposable Hemoperfusion Cartridge (HA)
FSCA-2021-001
Indirect Harm from inadequacy information in IFU

Date: Sept. 15, 2021
Attention:

Details on affected devices:
ALL the Disposable Hemoperfusion Cartridge (HA) Since the Launch.

Description of the problem:
1) Problem: [Intended Use] in the product operation manual of HA is described as removing the endogenous and exogenous materials such as residual drugs, toxins and metallic substances. This description is too broad.
2) Impact: It may mislead the untrained or inexperienced clinical users for therapeutic schedule and patient selection.

Advise on action to be taken by the user:
1) It should not be used by inexperienced clinical personnel.
2) If you have any doubt about the intended use before use, please contact the medical support personnel of the local distributor or manufacturer in time.

Action to be taken by the manufacturer:
Revision of the instructions has been started, it's expected to clarify the intended use and add clear indications. Relevant details of the revision are viewed in the following table. The new manual will be used after obtaining the approval of the notified body.

Before the change	After the change
[Intended Use] Disposable Hemoperfusion Cartridge ..... remove the endogenous and exogenous materials such as residual drugs, toxins and metabolic substances in patients by means of adsorption by the synthetic resin and extracorporeal blood circulation.	**[Intended Use]** Disposable Hemoperfusion Cartridge ..... remove endogenous and exogenous molecules such as inflammatory mediators and cytokines, bilirubin, metabolic toxins, protein-bound toxins, residual drugs. **[Indications]** According to clinical practices and studies, disposable hemoperfusion cartridge is indicated to remove the following substances: 1) Inflammatory mediators and cytokines such as IL-1, IL-6, IL-8, IL-10, TNF-α. 2) Overdosed drugs and poisons such as

	organophosphorus, paraquat, carbamazepine. 3) Accumulated β2-MG, PTH, leptin and protein-bound toxins in end stage renal disease hemodialysis related complications. 4) Excessive triglyceride and cholesterol in hyperlipidemic severe acute pancreatitis. 5) Other substances: bilirubin, myoglobin.

p.s.: In order to optimize the customer experience, other textual changes will be implemented simultaneously. For details, please refer to the approved documents after the changes.

Transmission of this Field Safety Notice:
This notice needs to be passed on all the physicians and nurses requiring hemoperfusion with HA in your organization.

Contact reference person:
Name: Michelle Zhu
Organization: Jafron Biomedical Co., Ltd
Address: No. 98, Technology Sixth Road, High-tech Zone, Zhuhai City, Guangdong, China
Phone: 0086-137-63325404
E-mail: zhumengxiao@jafron.com

[redacted]

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
قطاع الأجهزة الطبية

NCMDR
National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

BfArM Recall

Reference Number: mdprc 008 01 22 000
Date submitted: 1/6/2022

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Manufacturer:	Jafron Biomedical Co.,Ltd
Device Type:	Disposable Hemoperfusion Cartridge (HA)
Description:	Injections / Infusions / Transfusions / Dialysis - therapeutic apheresis
Medical Device Identifier:	ALL the Disposable Hemoperfusion Cartridge (HA) Since the Launch.
Reason of Field Safety Corrective Action:	Indirect Harm from inadequacy information in IFU
Remedy Action:	Details of the revision IFU are viewed in the table in the attached FSN
Athorized Representative/Importer/Distributor:	Medical Elements
Report Source:	BfArM
Source Ref. Number:	20030/21
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	Jafron Biomedical Co.,Ltd.pdf

View History