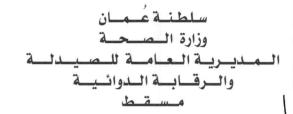
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





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

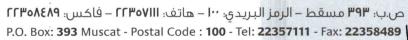
Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15989	
Product	Disposable Hemoperfusion Cartridge (HA).	
Description	Injections / Infusions / Transfusions / Dialysis - therapeutic apheresis.	
Manufacturer	Jafron Biomedical Co.,Ltd.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

Dr. Mohammed Hamdan Al Rubaie

Director General

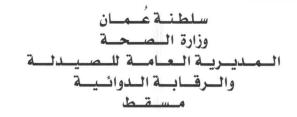






Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat





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. 120.22. dated 2.411.2022 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







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]	[Intended Use]
Disposable Hemoperfusion Cartridge	Disposable Hemoperfusion Cartridge
remove the endogenous and exogenous	remove endogenous and exogenous
materials such as residual drugs, toxins and	molecules such as inflammatory mediators and
metabolic substances in patients by means of	cytokines, bilirubin, metabolic toxins,
adsorption by the synthetic resin and	protein-bound toxins, residual drugs.
extracorporeal blood circulation.	[Indications]
	According to clinical practices and studies,
1	disposable hemoperfusion cartridge is
	indicated to remove the following substances:
	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.
- 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



Medical Devices Sector

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National Center for Medical Devices Reporting

المركز الوطنى لبلاغات الأجهزة والمنتجات الطبية

Back

BfArM Recall

Reference Number: mdprc 008 01 22 000

Date submitted:

Manufacturer:

1/6/2022

Jafron Biomedical Co.,Ltd

Device Type: Disposable Hemoperfusion Cartridge (HA)

Description: Injections / Transfusions / Dialysis - therapeutic apheresis

Medical Device Identifier: ALL the Disposable Hemoperfusion Cartridge (HA) Since the Launch.

Reason of Field Safety Corrective Indirect Harm from inadequacy information in IFU

Action:

Remedy Action:

Details of the revision IFU are viewed in the table in the attached FSN

Athorized Medical Elements

Representative/Importer/Distributor:

Report Source:

Source Ref. Number:

20030/21

BfArM

SFDA Comments: SFDA ur

SFDA urges all hospitals that have devices subjected to this FSCA to

contact the company.

Attachments: Jafron Biomedical Co.,Ltd.pdf

View History

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