



Date: June 8, 2026

**Jafron Biomedical Co., Ltd.**

No. 98, Technology Sixth Road, High-tech Zone

Zhuhai, 519085, Guangdong, P.R. China

Email: zhaoshourui@jafron.com

www.jafron.com

FSN Ref: FSN-2026-001

FSCA Ref: FSCA-2026-001

**URGENT Field Safety Notice**  
**Update to Instructions for Use — Clarification of Performance Specifications**  
**Disposable Hemoperfusion Cartridge (HA Series)**

**For Attention of:** Healthcare professionals, Hospital Pharmacies, Risk Management Department, Distributors

<b>Contact details of local representative</b>	
<b>Company:</b>	Casus Switzerland GmbH
<b>Address:</b>	Hinterbergstrasse 49, 6312 Steinhausen, Switzerland
<b>Email:</b>	rep@casusconsulting.com
<b>Phone:</b>	+353 61 524 947

<b>Device name (family):</b>	Disposable Hemoperfusion Cartridge (HA Series)
<b>Models affected:</b>	HA60, HA80, HA100, HA130, HA150, HA180, HA230, HA280, HA330, HA330-II, HA380, HA430, HA480
<b>Lot number affected:</b>	All
<b>Certificates:</b>	MDD 0197/HD 60138860 0001; MDR HZ 2119660-1



Dear Healthcare Professional,

Jafron Biomedical Co., Ltd. is writing to inform you of updates to the Instructions for Use (IFU) for the HA Series Disposable Hemoperfusion Cartridges. The HA Series is intended for use in extracorporeal hemoperfusion circuits for the removal of endogenous and exogenous toxins from the blood by adsorption.

### What is the issue?

As part of our ongoing market surveillance and regulatory review process, Jafron identified an opportunity to improve the clarity and precision of certain performance statements in the Instructions for Use (IFU). The previous IFU described the device's adsorption capabilities using generalized substance categories. The revised IFU now lists only the specific substances and indications for which Jafron holds well-supported device-specific clinical evidence, providing healthcare professionals with more precise information for clinical decision-making reflecting state-of-the-art literature and clinical evidence.

**No change has been made to the device itself** — its design, materials, manufacturing process, and sterilization method remain unchanged.

### What are the corrections?

Jafron is providing you with a revised IFU that makes the following clarifications:

What has changed	Details
<b>Substance list and Removed claims</b>	<p>The revised IFU now removes or narrows claims, and explicitly lists only substances for which Jafron holds product-specific evidence, organized into five indication categories:</p> <ol style="list-style-type: none"><li>1) <i>Inflammatory mediators and including IL-1, IL-6, IL-8, IL-10, TNF-<math>\alpha</math>;</i></li><li>2) <i>Overdosed drugs and poisons: organophosphorus, paraquat, carbamazepine;</i></li><li>3) <i>Accumulated <math>\beta</math>2-MG, PTH, leptin, and protein-bound toxins (Hippuric Acid, p-Cresyl Sulfate, Indoxyl Sulfate) in end stage renal disease hemodialysis related complications.</i></li><li>4) <i>Excessive triglyceride and cholesterol in hyperlipidemic severe acute pancreatitis.</i></li><li>5) <i>Other substances: bilirubin, myoglobin.</i></li></ol> <p>A clarifying statement has been added:</p> <p><i>Disposable Hemoperfusion Cartridge is indicated to use in conditions where elevated levels of above substances exist. Although clinical literature has reported the clearance of other substances by this device, there is currently insufficient clinical evidence to confirm its safety and efficacy for those indications. It is recommended to use this device strictly according to the approved indications and target substances specified in the instructions for use.</i></p>
<b>Serious incident reporting</b>	Reporting statement repositioned to a dedicated, bolded section for better visibility.
<b>Warning item 1 revised</b>	<i>The cartridge must be used with extracorporeal blood circuit tubing sets whose connectors comply with EN ISO 8637-2:2024.</i>

What has changed	Details
<b>Treatment mode recommendations</b>	<p>A structured recommendation table has been added to the IFU, providing treatment mode-specific guidance on blood flow rates, treatment durations, and corresponding indications for four clinical modes:</p> <p><i>HP, HP+HD/HDF, HP+CRRT, and HP+CPB.</i></p> <p>This new table complements the existing maximum operating parameters (10 hours, 100–700 mL/min) with mode-specific recommended ranges to support evidence-based clinical decision-making.</p>

### Risk to Health

Jafron has conducted a risk assessment and concluded:

- **No adverse event, serious incident, or patient harm has been reported** in any country that is attributable to the IFU performance statements being corrected.
- Post-market surveillance data (2022–2025) covering over 16 million devices sold worldwide (42,271 in the EU/EEA) confirms zero serious incidents and an extremely low adverse event incidence of 0.0032%.
- The device’s physical adsorption mechanism is unchanged and continues to function as designed.
- In clinical practice, healthcare professionals apply hemoperfusion within established institutional protocols and under clinical supervision, which provides an additional layer of risk mitigation.

**This is a precautionary labeling correction, not a safety alert.** No patient safety issue has been identified.

### Action to be taken by you

Jafron requests you to take the following actions:

1. **Carefully read** the content of this Field Safety Notice and the enclosed revised IFU.
2. **Ensure all personnel**, including clinical staff involved in hemoperfusion procedures, are aware of the updated performance specifications.
3. **Continue normal clinical use.** You may continue to use the HA Series Disposable Hemoperfusion Cartridges. No device return, quarantine, or disposal is required. The device remains safe and effective for its validated clinical applications.
4. **If you have any doubt** about whether a specific clinical application is within the device’s validated performance, please contact the medical support personnel of your local distributor or the manufacturer.
5. **Indicate on the Reply Form** that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Jafron representative (Casus Switzerland GmbH) by [July 8, 2026 — 30 days from distribution].
6. **If you have distributed** these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice.



### Action being taken by the manufacturer

- Jafron is issuing a revised IFU with clarified and precisely defined performance specifications.
- The revised IFU and this notice are being distributed to all known customers in Switzerland through the Swiss Authorized Representative (Casus Switzerland GmbH).
- Distribution and receipt acknowledgment are being tracked.

### Important — Continued use

**This notice does NOT require you to stop using the device.**

The HA Series Disposable Hemoperfusion Cartridge continues to be safe and effective for its intended clinical applications. No change has been made to the device itself. No device recall or return is necessary.

### Additional information

This FSCA is being conducted as part of a comprehensive quality improvement program. Jafron has implemented systemic changes to its Quality Management System that ensures all future labeling claims are directly traceable to product-specific evidence.

The Competent Authority (Swissmedic) has been informed of this communication to customers.

Jafron requests that you report any complaints or adverse events to Casus Switzerland GmbH ([rep@casusconsulting.com](mailto:rep@casusconsulting.com)) or directly to Jafron ([zhaoshourui@jafron.com](mailto:zhaoshourui@jafron.com)). Adverse events experienced with the use of this product should also be reported to Swissmedic.

Jafron regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact us at the details below for any additional information or support.

Sincerely,

A black rectangular box redacting the signature of Shourui Zhao.

**Shourui Zhao**

Person Responsible for Regulatory Compliance

Jafron Biomedical Co., Ltd.

Email: [zhaoshourui@jafron.com](mailto:zhaoshourui@jafron.com)



### **Transmission of this Field Safety Notice**

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

**Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority (Swissmedic), as this provides important feedback.**

# CUSTOMER REPLY FORM

## Field Safety Notice Acknowledgment

### 1. Field Safety Notice Information

FSN Reference Number	FSN-2026-001
FSCA Reference Number	FSCA-2026-001
FSN Date	June 8, 2026
Device Name	HA Series Disposable Hemoperfusion Cartridge
ReferenceNumbers/Models	HA60, HA80, HA100, HA130, HA150, HA180, HA230, HA280, HA330, HA330-II, HA380, HA430, HA480
Manufacturer	Jafron Biomedical Co., Ltd.

### 2. Customer Details

Healthcare Organization Name	
Organization Address	
Department/Unit	
Contact Person Name	
Title/Function	
Telephone Number	
Email Address	

### 3. Customer Acknowledgment

Please confirm the following by marking the appropriate boxes:

- I confirm receipt of the Field Safety Notice (FSN-2026-001) and that I have read and understood its content.
- I confirm that the information and required actions have been communicated to all relevant clinical and technical personnel within our organization.
- I confirm that we have NOT transferred any affected devices to another organization.



I confirm that we HAVE transferred affected devices to another organization, and we have forwarded this FSN to that organization. (Please provide details below.)

If devices were transferred, please provide the organization name and contact:

---

---

#### 4. Additional Comments or Queries

- I have no additional comments or queries.
- I have a query — please contact me. (Brief description below.)

---

---

#### 5. Signature

Print Name	
Signature	
Date	

#### 6. Return Instructions

Please return this completed form to:

Attention:	Casus Switzerland GmbH
Address:	Hinterbergstrasse 49, 6312 Steinhausen, Switzerland
Email:	rep@casusconsulting.com
Deadline:	Please return within 30 days of receipt of this notice.

**It is important that your organization acknowledges receipt of this Field Safety Notice. Your reply is the evidence needed to monitor the progress and effectiveness of the corrective action.**

If you have any questions regarding this Field Safety Notice, please contact your local Jafron representative or Casus Switzerland GmbH at the contact details provided above.