

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: <ol style="list-style-type: none">1) Inflammatory mediators and cytokines such as IL-1, IL-6, IL-8, IL-10, TNF-α.2) Overdosed drugs and poisons such as

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

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The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Jianhua Cai

Sept. 15, 2021