Safety Communication رسالة سلامة

Inadequacy information in IFU may lead to indirect harm

Device/ Product Description:	Disposable Hemoperfusion Cartridge (HA)
Affected product:	ALL the Disposable Hemoperfusion Cartridge (HA) Since the Launch.
Manufacturer:	Jafron Biomedical Co.,Ltd
Problem:	Indirect Harm from inadequacy information in IFU. 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.
Recommendation /Actions:	• It should not be used by inexperienced clinical personnel. • 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 For more information, please click here.

	If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center	
Authorized Representative Details	AR name:	Medical Elements Co
	Assigned Contact Person:	Wassem Sameer Alssorani
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