



Health Technology Review	
Technology Ref.:	HTA21053
Technology Name:	HA330/HA380
Approvals by International Bodies:	CE certificate
Company name:	Horizon International Medical Supplies
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Short Description of the Technology:	<p>Disposable Hemoperfusion cartridge for removal of inflammatory mediators (Cytokines) to be used for the treatment of severe and critical cases in the early and middle stages of cytokine storm. The cartridges contain highly biocompatible sorbents and neutro-macroporous resin made of styrene-divinylbenzene copolymer. Their adsorbing beads' pore size ranged from 500D to 60kD, giving them the ability to absorb various medium-sized factors, including most inflammatory cytokines (IL-1, IL-6, IL-8, and TNF-a).</p> <p>The Hemoperfusion cartridge can be used on CRRT machines in combination with CVVH, CVVHFD, or it can be used alone as Hemoperfusion therapy on Hemoperfusion machines.</p>
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>Ha330/HA380 hemoperfusion therapy can be used alone or in combination with other extracorporeal blood circulations, which provides a new solution to reduce inflammatory mediators and cytokines for critical-ill patients in ICU or those undergoing cardiac surgery. It's also a method of blood filtering to remove toxins and inflammatory factors. Cytokine storms and high levels of inflammatory factors play a role in the pathogenesis of coronavirus disease 2019 (COVID-19). H330 & HA380 are similar product with different capacity (surface)</p>	
Advantages	Disadvantages
CE Marked Product	Lack of local cost effectiveness study ; Limited evidence on the economic impact of using cytokine absorbers was identified.
Clinical Effectiveness: Available studies proven the effectiveness in Reducing the cytokine storm & treating patients in ICU with Sepsis & Covid19.	Large prospective trials in carefully selected patient populations and well-defined conditions are needed to definitely evaluate the efficacy of sorbent devices.
HA330/380 (Jafron) is approved by NICE as a cytokine adsorption device for treating respiratory failure in people with COVID-19; Treating Hemoperfusion could improve respiratory distress and reduced the CRP in	Risks of the technology are similar to the risks of the current practice; Complications of hemoperfusion.

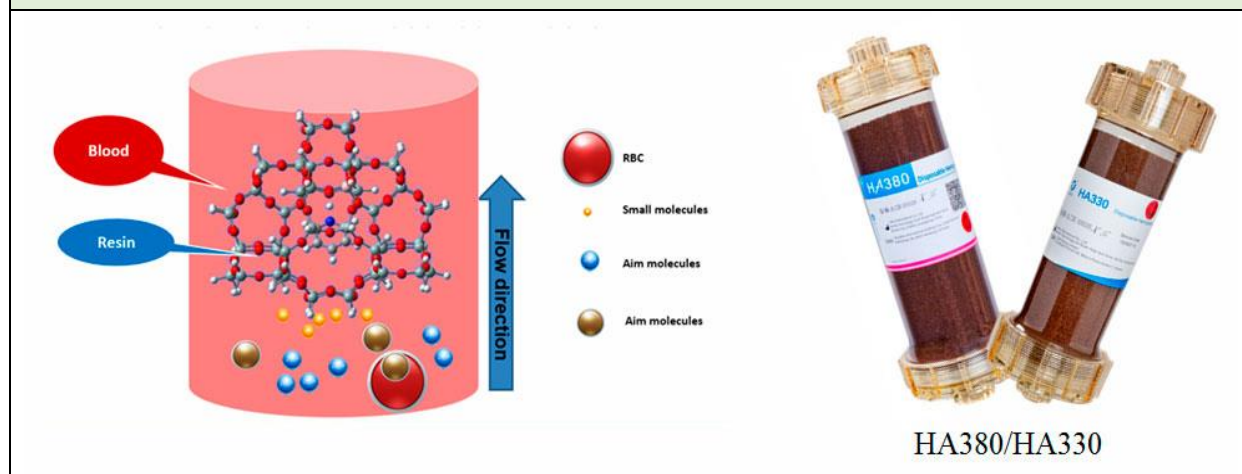
patients with severe COVID-19. (It is recommended that further studies are performed in this regard)	
Health Benefits; Improve hemodynamic and respiratory parameters, lower intensive care unit (ICU) length of stay, reduced ICU mortality, and no safety concerns. (Further studies required)	Restrictions; The technology is not effectively in patients with low cytokine plasma concentrations.
Easy to use- disposable – no filter needed	limited peer reviewed clinical trials
Safety: Available studies shows that there is no serious unexpected device related adverse events, no clinically relevant albumin or platelet loss, and no clotting problems associated with its use	

We recommend an **approval of using this technology** with the following conditions:

1. Utilizing the Cartridge as per the manufacturer & treatments guidelines & standards.
2. Expert physician feedback is required
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and Patient
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image:





HA330/HA380 Use Criteria

Question	Answer	Comments
Which case?	According to clinical experience, hemoperfusion therapy can be applied in the listed conditions; - Pancreatitis - Sepsis - Trauma - Cardiac Surgery - severe Infection -Severe Burn	
Which doctors?	Specialist – Consultant	
Which hospital?	Specialized Hospitals	
Inclusion criteria	Hemoperfusion therapy can be used alone or in conjunction with CRRT/HD/HDF/SLED	
Exclusion criteria	patients with allergies to HA 330 (characterized by hypotension and/or tachycardia), age <18 or >85 years, and acute respiratory distress syndrome (ARDS) or history of septic shock for >12 h after diagnosis. Patients not treated with RRT	