Alteco® **LPS Adsorber**

Model LPS-33-100-46

INSTRUCTIONS FOR USE

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Alteco Medical

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1. DESCRIPTION

The Alteco® LPS Adsorber is a device for extracorporeal treatment. The device consists of a housing filled with porous plates of polyethylene. A tailormade synthetic peptide with a high affinity for endotoxin (LPS - Lipopolysaccharide) is bound to the surface of the porous plates. During treatment, the peptide captures LPS from the patient's bloodstream.

2. INDICATIONS

The Alteco® LPS Adsorber is intended for the treatment of endotoxemia and/or sepsis or septic shock caused by suspected or verified gram negative bacteria.

3. CONTRAINDICATIONS

No known contraindications.

4. PRECAUTIONS

There is no experience of using the Alteco® LPS Adsorber in patients with a body weight below 30 kg. If treatment with Alteco® LPS Adsorber should be considered beneficial for the patient, special consideration should be taken to the effects of extracorporeal circulation in relation to the patient's weight and blood volume.

The Alteco® LPS Adsorber may only be used by qualified health care professionals acting under the supervision of physicians. Rinsing of the adsorber is important since it contains glycerin as a stabilizer.

Treatment with the Alteco® LPS Adsorber requires anticoagulation to avoid clotting of the adsorber.

The dose of anticoagulant may need to be adjusted for patients with coagulation disorders or active bleeding.

Strict haemodynamic monitoring of the patient is mandatory during treatment.

Strict aseptic procedures must be maintained to avoid contamination of the patient's blood.

The product may adsorb substances administered for therapeutic purposes. Consequently, the attending physician must carefully monitor drug levels.

No hypersensitivity reactions when using the Alteco® LPS Adsorber have been reported. However, the occurrence of such hypersensitivity reactions cannot be excluded. Should hypersensitivity reactions be suspected, the treatment should be terminated immediately.

5. PACKING AND STORAGE

The product is provided sterile and packed individually in a sterile pouch. Sterility is maintained if the pouch remains unopened and undamaged. The product should be stored in its original box.

6. ADDITIONAL REQUIRED EQUIPMENT

- Rinsing and Priming tubing lines or set.
- Machine for extracorporeal treatment with an air-trap and monitoring equipment for blood flow and pressures.

7. PROCEDURES FOR PREPARING AND USING THE ADSORBER

7.1 RINSING PROCEDURE

Inspect the Alteco® LPS Adsorber for shipping damages. Only use the Alteco® LPS Adsorber if its sterile packaging is intact.

Remove the Alteco® LPS Adsorber from its packaging and insert it vertically into a holder.

Connect a rinsing line including a waste bag to the lower port of the Alteco® LPS Adsorber.

Connect a priming line to the other port of the Alteco® LPS Adsorber and connect it to a bag of 500 ml I.V. saline (0.9%) solution. Let the saline pass through the adsorber by gravity.

7.2 PRIMING PROCEDURE

Turn the adsorber upside down.

Remove the empty saline bag and connect a new bag of 500 ml I.V. saline (0.9%) solution with 2500 International Units of heparin added.

Prime the adsorber and remove any residual air from the bloodpath of the adsorber by letting the 500 ml I.V. saline (0.9%) solution with heparin added pass through the adsorber by gravity.

After the priming procedure, turn the Alteco® LPS Adsorber again. The purpose is to maximize the flow distribution within the adsorber.

Disconnect the adsorber from the lines and insert it into the treatment circuit.

7.3 TREATMENT

Connect to appropriate venous access - selected by responsible physician.

Start the blood pump gently (50 ml/min) and gradually increase the blood flow to 150 ± 50 ml/min.

To avoid the risk of blood clotting in the system, the blood pump should never be stopped during the adsorber treatment.

The recommended extracorporeal adsorber treatment time is between 2-6 hours.

When the treatment is finished, dispose the adsorber in regular waste for blood disposal.

Normally one treatment is enough. If needed, depending on the patient´s condition and hemodynamic response, another treatment can be performed, upon judgement from the responsible physician.

8. SPECIFICATIONS

Reorder information	
Product name:	Alteco® LPS Adsorber
Product reference number:	LPS-33-100-46
Dimensions and weight	
Length:	135 mm
Outer diameter:	52 mm
Net weight in grams:	~130 g
Materials	
Housing:	Acrylic polymer
End caps:	Acrylic polymer
Matrix (porous plates):	Polyethylene
Active component:	Synthetic Peptide
Latex Free:	Yes
Technical data	
Priming volume:	100 ml
Blood flow, recommended:	150 ± 50 ml/min
Treatment time:	2-6 hours
Sterilization:	e-beam radiation
Expiration time:	3 years
Connector type:	Standard dialysis connectors (ISO 8637)

9. EXPLANATION OF SYMBOLS

Symbol	Explanation
	Intended for single use only
	Consult instructions for use
	Expiration date
	Sterilized by radiation
	Reference number Reorder number
	Lot number
	Do not resterilize
	Manufacturer
	Do not use if package is damaged
	Russian mark of conformity for mandatory certification

10. CONTACT INFORMATION

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