# Alteco® **LPS Adsorber**

Turning the course of sepsis™

Efficiency | Safety | Simplicity


Alteco Medical

*Innovation & Experience*

# Turning the course of sepsis™

## Alteco® **LPS Adsorber**


**Alteco Medical AB** is a Swedish medical device company focusing on intensive care founded in 2002. With the development and manufacturing of our modern biotechnology product - Alteco® LPS Adsorber - we offer a new logical option in the intensive care of septic patients. A unique solution for extra-corporeal removal of endotoxin in patients with gram-negative sepsis.

The **Alteco® LPS Adsorber** is a unique medical device for the safe extra-corporeal removal of endotoxin during hemoperfusion.

The biotechnology of the product is based on a synthetic tailor-made peptide that selectively binds several times the amount of endotoxin found in the circulation of a septic patient.


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# Problem
**Sepsis (Endotoxins)**

## Sepsis

**Sepsis** is a medical condition caused by a serious infection due to the presence of bacteria or fungi in the blood, eventually causing failure of one or several organs. Without prompt treatment, it can evolve into septic shock, which is a life threatening condition.

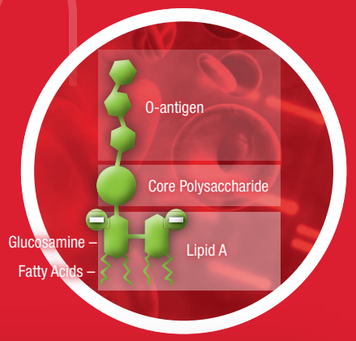
Although severe sepsis and septic shock are common in intensive care and carry high mortality rates, no specific medical treatment has been found. Current treatment for severe sepsis and septic shock consists mainly of supportive therapy.

Sepsis is a complex condition, with increasing incidence and high mortality (30-50 %)[1]. The incidence of sepsis is increasing by 8 % per year and represent 10-16% of the cost of intensive care[1,2]. The development of new treatment methods is unquestionably crucial, for both humanitarian and economical reasons. Endotoxins are a key player in sepsis and well known to induce a strong response from the immune system. This response leads to the release of inflammatory mediators and eventually sepsis or even septic shock.

## Endotoxin

**Endotoxin**, or lipopolysaccharides (LPS), is one of the major components of the cell membrane in gram-negative bacteria.

When the bacteria are lysed the endotoxin is exposed. A secondary endogenous source of endotoxin is epithelial barrier dysfunction in the gut.




Endotoxins are macromolecules, consisting of a lipid part, called Lipid A and a polysaccharide chain. The polysaccharide chain varies between different bacteria strains while the Lipid A component is constant and toxic.

When bound to Toll-like receptors (TLR4) they activate a cellular signaling mechanism, causing release of pro- and anti-inflammatory cytokines. Simultaneous disturbances in the coagulation cascade and microcirculation contribute to impaired tissue perfusion and organ failure. The final outcome is multiple organ dysfunction and in severe cases, death.

High endotoxin level is associated with worse clinical outcome[3]. The Alteco® LPS Adsorber has the capacity to significantly reduce endotoxemia when used in hemoperfusion of patients with gram-negative sepsis. The subsequent decrease of the endotoxin level is beneficial to the patients as it reduces the effects of gram-negative sepsis, such as cardiorespiratory dysfunction and the release of pro-inflammatory mediators, and thus turns the course of sepsis for the patient.

# Solution
**LPS Adsorber**

# Alteco® **LPS Adsorber**

The capturing component is a specially designed synthetic peptide developed for adsorbtion of endotoxin.

The peptide covers the surface of a porous polyethylene matrix specifically designed to provide an optimal binding surface. This structure selectively binds several times the circulating endotoxin load found in patients with severe sepsis.

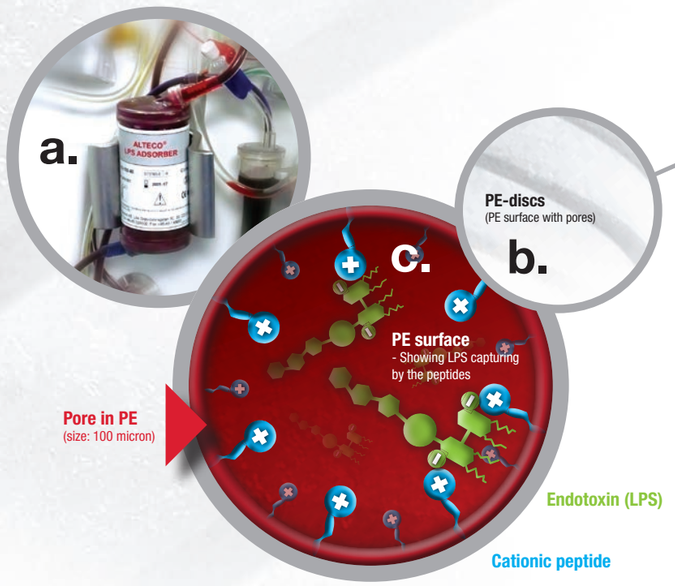
The Alteco® LPS Adsorber is a Class IIa medical device and does not contain any pharmaceutical or toxic components. Its high affinity to the Lipid A moiety of the endotoxin molecule, due to hydrophobic and ionic interactions, ensures efficient reduction of endotoxins from different bacteria species, as this component of the endotoxin molecule is constant.

The optimal effect of the product is achieved if the endotoxemia can be reverted in an early stage. When endotoxemia is suspected, treatment should be initiated as early as possible for patients with vasopressor dependent sepsis.

Usage of the Alteco® LPS Adsorber has no reported side effects, contraindications or known drug interactions. It offers an efficient means of treatment for patients suffering from endotoxemia and sepsis, and has been used successfully in ICUs around the world for treatment of more than 1500 patients.

The clinical reports and published data on the efficacy of the Alteco® LPS Adsorber to remove endotoxin from the blood as well as to improve the cardiorespiratory function in patients suffering from severe gram-negative sepsis and septic shock are unequivocal[4].

For more information, please refer to the Instruction for Use




a. The Alteco® LPS Adsorber in an extracorporeal circuit for treatment of patients with gram-negative sepsis.

b. PE-discs

c. The cationic peptides are covalently immobilized onto the PE-discs. During treatment the cationic part of the peptide captures the negatively charged endotoxin molecules.


The Alteco® LPS Adsorber approximate actual size.

# Alteco® **LPS Adsorber**

## Treatment Data

| | |
|---|---|
| Rinsing: | 500 ml 0.9 % NaCl |
| Priming: | 0.9 % NaCl solution with heparin |
| Priming volume: | 20 ml |
| Adsorption capacity: | > 7500 Endotoxin Units |
| Blood flow, hemoperfusion: | 150 ± 50 ml/min |
| ACT (Activated Clotting Time): | > 180 s |
| Pressure drop at 100 ml/min: | ~ 23 mm Hg |
| Pressure drop at 200 ml/min: | ~ 50 mm Hg |
| Recommended treatment time: | 2 hours |

## Product Specification

| | |
|---|---|
| Housing: | Acrylic polymer |
| End caps: | Acrylic polymer |
| Matrix (porous plates): | Polyethylene |
| Active component: | Peptide (100 % synthetic) |
| Sterilisation: | Radiation (e-beam) |
| Expiration time: | 3 years |
| Inlet/outlet connectors: | Standard dialysis |
| Storage temperature: | + 5 °C to + 30 °C |

## Regulatory Information

| | |
|---|---|
| Product registration: | ~ 30 countries around the world |
| Notified body: | Lloyd´s Registered QA |
| Classification: | Medical Device, Class IIa |
| ISO certificate: | ISO 13485 |

## Dimensions and Weight

| | |
|---|---|
| Length: | 135 mm |
| Outer diameter: | 52 mm |
| Net weight: | ~ 150 g |

## Order Information

| | |
|---|---|
| Product name: | Alteco® LPS Adsorber |
| Product reference number: | LPS-33-100-46 |
| Developer and manufacturer: | Alteco Medical AB |
| | Höstbruksvägen 8 |
| | 226 60 Lund |
| | Sweden |
| | sales@altecomedical.com |
| | **www.altecomedical.com** |

**Alteco®** is a registered trademark of Alteco Medical AB. The Alteco® LPS Adsorber is based on technology for which patents have been granted in the EU, China (PRC), Russia, USA, etc. The product is bar-coded according to GTIN-13. Not for sale in the US.

For Single Use

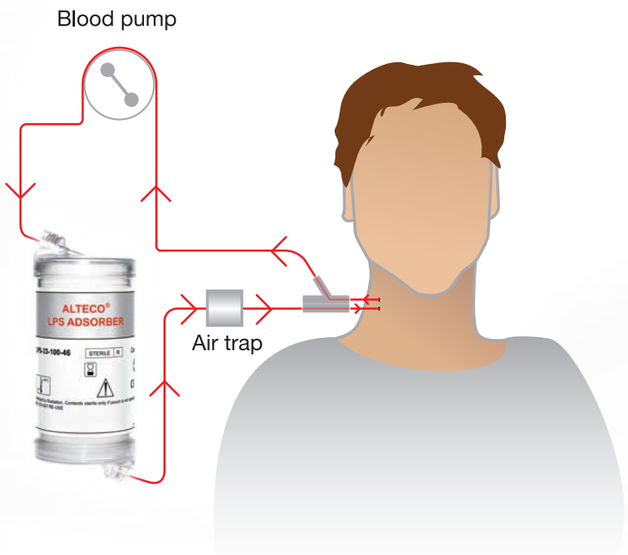
CE 0088

## Proven technology made in Sweden.

The Alteco® LPS Adsorber (CE 0088) is a medical device based on modern biotechnology, developed and produced in highly advanced facilities in Lund, Sweden.

Order the Alteco® LPS Adsorber by contacting
**sales@altecomedical.com**
to find your local distributor.


## Easy to set up - Easy to use

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3. Opal SM et al., 1999. Relationship between plasma levels of lipopolysaccharide (LPS) and LPS-binding protein in patients with severe sepsis and septic shock. J Infect Dis, 180/5:1584-1589
4. Ala-Kokko, T.I., et al., 2011. A New Endotoxin Adsorber in Septic Shock: Observational Case Series. Blood Purif, 35/4:303-309

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