

## Technical specification for adsorber CytoSorb300

CytoSorb® as “Whole-blood-Adsorber” is indicated for use in conditions where levels of cytokines, DAMPS and/or PAMPS and/or bilirubin and/or myoglobin are elevated.

- 65.66.** CytoSorb® is indifferent to blood and indicated for use in treatment of endogenous intoxication in patients with liver failure. 4.; 5.

The CytoSorb adsorber is composed of highly biocompatible porous polymer beads with numerous pores on the surface. The overall surface for adsorption of one cartridge is > 40.000 m<sup>2</sup>.

- 65.66.** Single patient use treatment time per device up to 24 hours for up to 7 consecutive days. 1.

- 65.66.** The CytoSorb apyrogenic whole blood adsorber can be integrated safely and easily into 3. extracorporeal circuits such as renal replacement therapy (CRRT), extracorporeal membrane oxygenation (ECMO), cardiopulmonary bypass (CPB) and as “stand alone set up”. It is supplied complete with appropriate adapter and a set of lines (arterial and venous) suitable for any above mentioned treatment setup. 5.

Due to the needs of the extracorporeal blood purification devices, the blood flow rates for CytoSorb are between 100 and 700ml/min.

CytoSorb is ISO10993 certified and CE mark registered. It adsorbs hydrophobic substances up to 55kDa.

CytoSorb does not activate coagulation and does not remove Immunoglobulins or coagulation factors. Further no significant loss of albumin\*.

To prepare CytoSorb for use, an easy gravity priming procedure with 2 liters of saline is necessary.

The safe and easy integration is proven by more than 60.000 treatments, the beneficial use is proven in more than 460 publications (7/2019).

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Extracorporeal blood volume:	150 ml
Blood flow rates min-max:	100 - 700 ml/min
Recommended blood flow rates:	150 - 700 ml/min
Max. treatment duration	24 hours
Anticoagulation:	possible with heparin or citrate
Sterilization:	Gamma sterilization
Further details:	Latex- and PHT free product
Storage conditions:	1° to 40°C; upright storage
Maximum pressure limit	760 mmHg
Flow resistance (Hkt 23 +/- 3% @ 37 +/- 1°C)	Qb <= 700 ml/min 140 mmHg Qb <= 500 ml/min 090 mmHg Qb <= 200 ml/min 030 mmHg
GMDN Code	34422 - Haemoperfusion system adsorption column

2.

\*References:

- \* Bernardi, M. H., et al. (2016). "Effect of hemoabsorption during cardiopulmonary bypass surgery - a blinded, randomized, controlled pilot study using a novel ad- sorbent." Crit Care 20(1): 96.
- \* Gemelli, C., et al. (2018). "Removal of Bilirubin with a New Adsorbent System: In Vitro Kinetics." Blood Purif: 4-6
- \* Schaedler, D et al. (2017) "The effect fo a novel extracorporeal cytokine hemoabsorption device on IL-6 elimination in septic patients: A randomized controlled trial." PloS One 12(10):e0187015

