

CytoSorb®

Expanding the dimension
of blood purification



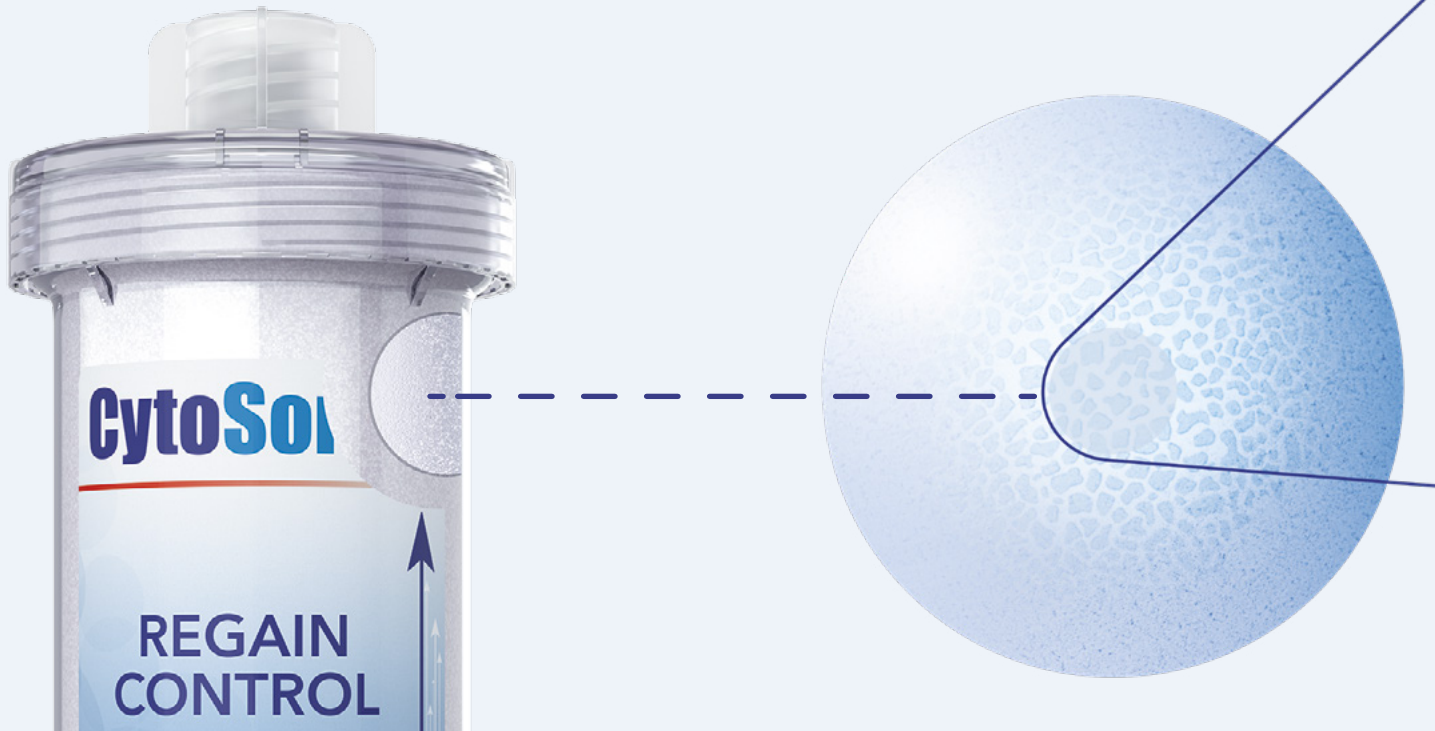
Restoring balance with hemoadsorption through removal of:

- Cytokines in intensive care and cardiac surgery^(1,2)
- Bilirubin in liver dysfunction⁽³⁾
- Myoglobin in rhabdomyolysis⁽⁴⁾
- Antithrombotics during cardiopulmonary bypass⁽⁵⁾

Protect your patients with CytoSorb®

CytoSorb® Therapy extracorporeal blood purification helps to restore balance:

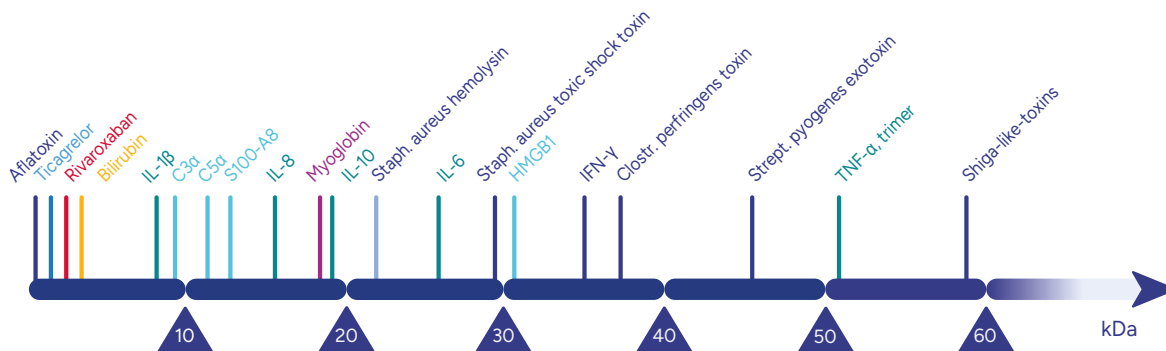
- in conditions with excessive levels of cytokines, bilirubin or myoglobin
- intraoperatively during cardio-pulmonary bypass (CPB) surgery for the removal of P2Y₁₂-inhibitor ticagrelor and/or Factor Xa-inhibitor rivaroxaban.



How CytoSorb® works

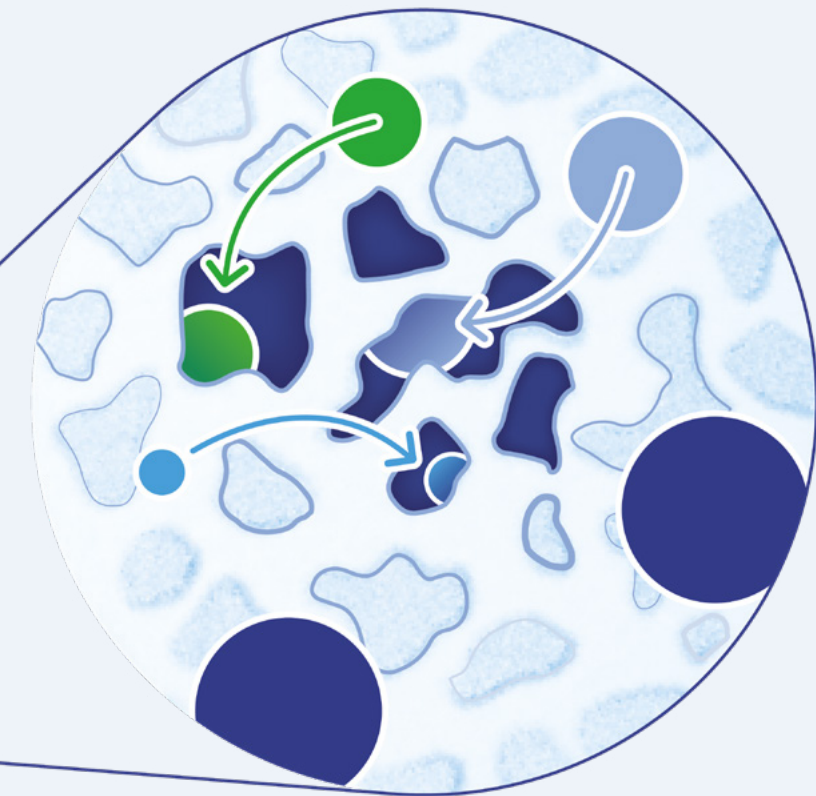
CytoSorb® is a technology complementary to dialysis. It removes a broad range of water-insoluble substances (hydrophobic) of small and middle sizes up to approx. 60kD.

The large adsorptive surface of the adsorber (45,000 sqm) contains a highly developed unique mesoporous pore structure, which allows removal of middle-sized as well as small (< 10 kDa) proteins.⁽⁶⁾



CytoSorb® specifically removes

- Cytokines
- Bilirubin
- Myoglobin
- Ticagrelor
- Rivaroxaban



Adsorption criteria

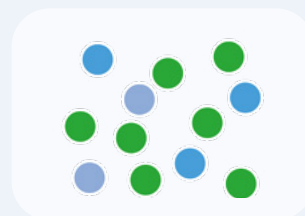
Hydrophobic attraction to surface



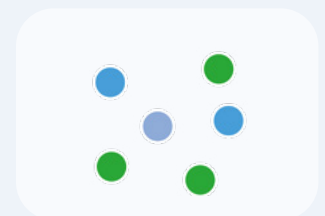
Size selection <60kDa



Concentration dependent



Before



After

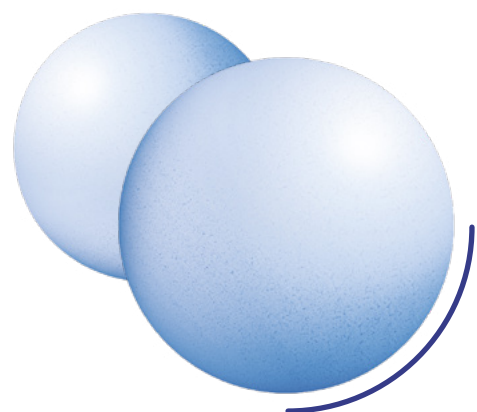
Beads matter

- CytoSorb[®], tightly packed with porous polymer beads, facilitates substance removal through targeted adsorption to restore balance.
- It selectively captures molecules with hydrophobic structures while maintaining biocompatibility to prevent coagulation or complement system activation.
- This concentration dependent mechanism ensures efficient removal at high concentrations while preserving physiological mediators at lower concentrations to maintain normal bodily functions.

Proven safety

CytoSorb[®] has shown in clinical studies:

- concentration dependent removal⁽⁷⁾
- minimal removal of important substances such as albumin⁽⁸⁾
- no activation of the coagulation and complement systems^(9,10)



CytoSorb® Technical Data / Application

CE Certified / notified body / QM-System	YES / 0344 – DEKRA/ISO 13485						
Intended use	The CytoSorb Device (CytoSorb®) is a non-pyrogenic, sterile, single-use device containing adsorbent polymer beads designed to remove cytokines, and/or bilirubin, and/or myoglobin and/or P2Y ₁₂ inhibitor ticagrelor and/or rivaroxaban as blood passes through the device. CytoSorb® is placed in a blood pump circuit.						
Extracorporeal blood volume	150 ml						
Adsorbent / surface	Proprietary and patented cross-linked divinylbenzene polymer, exclusively developed and produced by CytoSorbents in the USA / 45,000m ² .						
Adsorption spectrum / biocompatibility	Adsorption midsize hydrophobic molecules up to a size of approximately 60kDa / Biocompatibility tested as required in ISO10993						
Mode of operation covered by IFU	Any extracorporeal blood circuit (hemoperfusion (HP)), intermittent hemodialysis (HD), continuous renal replacement therapy (CRRT), cardiopulmonary bypass (CPB), extracorporeal membrane oxygenation/ extracorporeal life support (ECMO/ECLS).						
Blood flow rates min-max	100 - 700 ml/min						
Pressure drop ΔP (Hct 32% \pm 3% at 37°C \pm 1°C)	<table><tr><td>Qb \leq 700 ml/min</td><td>140 mmHg</td></tr><tr><td>Qb \leq 500 ml/min</td><td>90 mmHg</td></tr><tr><td>Qb \leq 200 ml/min</td><td>30 mmHg</td></tr></table> <p style="text-align: right;"><i>Qb = blood flow</i></p>	Qb \leq 700 ml/min	140 mmHg	Qb \leq 500 ml/min	90 mmHg	Qb \leq 200 ml/min	30 mmHg
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Priming fluid, procedure and duration	<p>Flushing with 2 liters of sterile isotonic saline (NaCl 0,9%). Priming takes approximately 5 minutes. CytoSorb® contains pre-loaded physiological saline with a pH level of 6.8 pre-flush. Heparin priming is NOT required to coat the bead surface prior to use.</p> <p>Use on heparin induced thrombocytopenia (HIT) patients if anticoagulated with citrate.</p>						
Max. pressure limit	760 mmHg						
Max. treatment time per device	Change CytoSorb® after 24 hours maximum. Change CytoSorb® every 12 hours for the first 24 hours if indicated by ongoing hemodynamic instability.						
Anticoagulation	Heparin or citrate						
Sterilization / shelf life / storage conditions	Gamma sterilization / 3 years / 1°C to 40°C						
Further details	Latex- and PHT free product						
GMDN-Code	34422 - Hemoperfusion system adsorption column						