Biocon

CytoSorbents™

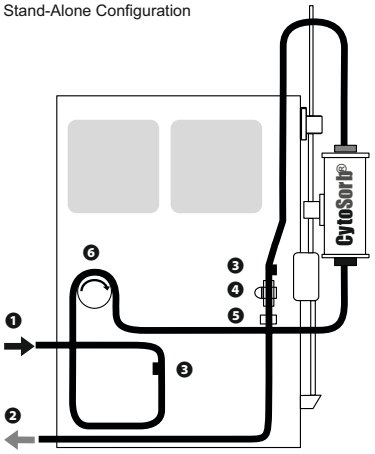
Instructions for use

CytoSorb® 300 mL Device

Symbols
CytoSorb Use Configurations
CytoSorb® 300 mL Device - Instructions For Use

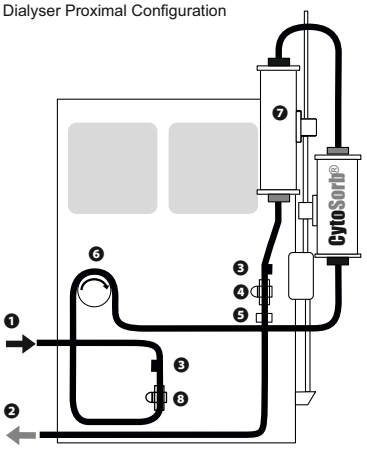
REF	Catalog Number
LOT	Batch Code
SN	Serial Number
EC REP	European Authorized Representative
	Do not reuse
STERILE R	Fluid path sterilized using Irradiation

Stand-Alone Configuration



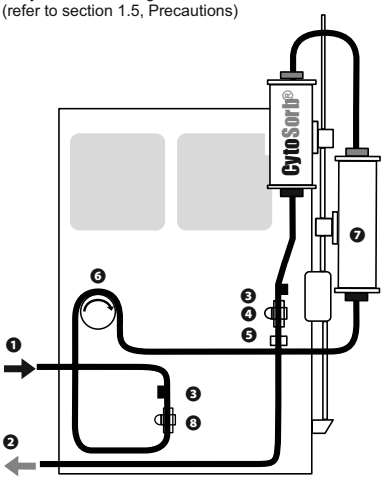
1. Arterial
2. Venous
3. Pressure Sensor
4.Venous Drip Chamber
5. Air detector
6. Blood pump

Dialyser Proximal Configuration



1. Arterial
2. Venous
3. Pressure Sensor
4.Venous Drip Chamber
5. Air detector
6. Blood pump
7. Dialyzer
8. ArterialDripChamber

Dialyser Distal Configuration
(refer to section 1.5, Precautions)



1. Arterial
2. Venous
3. Pressure Sensor
4.Venous Drip Chamber
5. Air detector
6. Blood pump
7. Dialyzer
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CE 0344

www.cytosorb.com

	Caution, consult accompanying documents
	Use by YYYY-MM-DD
	Do not use if packaging is damaged
CE 0344	European Conformity
	Manufacturer
	Consult instructions for use

1. INTRODUCTION
1.1 Intended Use
The CytoSorb Device (CytoSorb) is a non-pyrogenic, sterile, single-use device designed to remove cytokines. CytoSorb contains adsorbent polymer beads that adsorb cytokines as blood passes through the device. CytoSorb is placed in a blood pump circuit.

1.2 Indications
CytoSorb is indicated for use in conditions where excessive cytokine levels exist. Maximum Treatment Time per Device: 24 hours. Results from current studies suggest that CytoSorb may be administered for up to 7 consecutive days.
Maximum Blood Flow Rate: 700 mL/min
Minimum Blood Flow Rate: 100 mL/min
Recommended Blood Flow Rate: 150-700 mL/min
Flow rates below 150 mL/min may be required due to limitations of the catheter access, caution should be used at low flow rates as the potential for clotting may increase.

1.3 Contraindications
Patients that are Heparin Induced Thrombocytopenia (HIT) positive and citrate regional anticoagulation is unavailable as an alternative anticoagulation method.
Patients with very low platelet counts (< 20,000/µL).

1.4 Relative Contraindications
Patients in acute sickle cell crisis. Patients concurrently requiring immunosuppressive therapy, with the exception of corticosteroids, or who are profoundly immune suppressed (e.g. CD4 < 200 or neutropenia with ANC < 1,000/µL). Patients who are or may be pregnant.

1.5 Precautions
CytoSorb should only be administered by personnel who have been properly trained in administration of extracorporeal therapies. Complications associated with extracorporeal therapies include: dyspnea, hypoxia/hypotension, and death due to air embolism. The extracorporeal circuit should be monitored continuously during treatment for blood leaks.
In the event of a blood leak during treatment, the health care provider should respond according to the facility's established protocols.
Discretion should be used when treating a patient weighing less than 100 lb. (45 kg).
CytoSorb will affect trans membrane pressure (TMP). Attention should be paid if CytoSorb is placed distal to the dialyzer membrane. In such cases use only CRRT equipment where an integral weight scale is available that will self-correct for ultrafiltration volume for changes in TMP. To minimize chances of clotting in this setting, pre-dilution is recommended.

1.6 CytoSorb may be capable of removing drugs (i.e. antibiotics, pressor agents, etc.) similar to dialysis. The physician is advised to measure concomitant drug concentrations, where a test exists, after CytoSorb treatment and adjust drug dosing accordingly. In addition, when nutritional supplementation is indicated, the physician is encouraged to administer gastric or other internal tube feeding rather than total parenteral intravenous nutrition and lipids. Lipid or fat emulsions may negatively affect CytoSorb. If lipids (e.g. lipid containing parenteral nutrition) are clinically indicated, then the physician is advised to administer these after CytoSorb treatment is completed or discontinue administration two (2) hours prior to the next CytoSorb treatment.

1.7 Air entering the extracorporeal circuit during treatment can result in serious injury or death.
Check the integrity of all bloodlines and connections prior to the initiation of blood perfusion and periodically during the treatment. The venous return line or drip chamber should be continuously monitored with an air detector.

1.8 CytoSorb should only be used as directed by a physician.

1.9 Side Effects
In rare cases, hypersensitivity reactions may occur during extracorporeal treatment. A history of allergies (polystyrene/divinylbenzene, polycarbonate, polypropylene, silicone and polyester) is an indication requiring careful monitoring for hypersensitivity reactions. In the event of a hypersensitivity reaction, treatment must be discontinued and aggressive, first line therapy for anaphylactoid reaction must be initiated. The decision to return the blood to the patient encountering a hypersensitivity reaction must be made by a physician. The patient should also be monitored for other clinical events associated with extracorporeal treatment, including but not limited to hypotension, change in body temperature, feeling of coldness, muscle cramping, headache, nausea, vomiting, fever, or pruritus.

1.10 Limitations
CytoSorb is a single-use device and should not be reused. CytoSorb must be stored/used within the temperature range of 1 – 40ºC.

2. PREPARATION FOR TREATMENT
2.1. CytoSorb is intended for use with standard, commercially available bloodlines compatible with the pump system used. Female blood line DIN connectors are required to connect with CytoSorb blood ports. CytoSorb may be used with extracorporeal blood pumps, e.g. intermittent hemodialysis, continuous renal replacement therapy (CRRT), cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) equipment where hemofilters/dialyzers are used.
CAUTION: Pressure monitoring of the bloodline between the blood pump and CytoSorb is recommended. If the pump system is not equipped with a pressure sensing device for this line, use of an accessory pressure monitoring device is recommended. In the case of CPB or ECMO, CytoSorb placement should be in a shunt off of the main flow as is the current practice with hemoconcentrators, and flow monitoring (≤700 mL/min.) is recommended, e.g. ultrasonic flow probe.

2.2. The fluid pathway in an intact device inside the protective pouch is sterile. Inspect the protective pouch for any sign of damage to CytoSorb. Carefully remove CytoSorb from the pouch and examine for defects.
CAUTION: DO NOT USE CytoSorb if it appears to be damaged. DO NOT USE CytoSorb if beads appear to be free-floating within the endcaps.

2.3. When renal replacement therapy (dialysis, hemofiltration) is required, CytoSorb may be placed upstream (proximal) or downstream (distal, with equipment with integral weight scale) of the hemofiltration/dialysis device. An accessory bloodline between CytoSorb and the hemofiltration/dialysis device is required. Priming will require 2 liters of normal saline, and anticoagulation requirements may need to be increased for the dual devices.

2.4. Locate the blood inlet (arterial) end of the device. With the inlet end of CytoSorb facing downward, firmly secure the device in a vertical position to the pump system's device holding pole (or alternate device holding system) using a standard hemofilter/dialyzer clamp. Leave the port plugs in place.

2.5. Install the arterial and venous bloodlines on the blood pump.
Note: Refer to the manufacturer's instructions for use that were included with the blood tubing set or blood pump.
Priming by gravity: Aseptically connect to a 0.9% sterile isotonic saline bag with a clamped standard priming line (spike or luer to female DIN-lock line) and standardized adapters if required.
Prime lines completely. Connect the saline primed blood supply line (and adapter if required) of pump circuit to CytoSorb blood inlet port. Now remove CytoSorb outlet port plug and connect venous priming line (and adapter if required) with CytoSorb outlet port and a waste bag. Open clamps on lines, flush CytoSorb and priming lines using a minimum of 2 liters sterile isotonic saline in total for both priming of the lines and CytoSorb flush. Disconnect and discard the waste bag when complete. Clamp inlet and outlet lines.
Note: Gently thump the outlet side of CytoSorb with the palm of your hand during priming to remove air.

Priming by pump (e.g. standalone configuration): Prime the blood supply line of pump circuit and adapter, if required, using 0.9% sterile isotonic saline. Remove CytoSorb inlet port plug and connect the saline primed blood supply line to the CytoSorb inlet port. Now remove CytoSorb outlet port plug and connect venous priming line (and adapter if required) with CytoSorb outlet port and a waste bag. Open clamps on lines, turn on pump and prime (flush) device at a flow of ~150 mL/min., using a minimum of 2 liters sterile isotonic saline total for both priming of the lines and CytoSorb flush. Disconnect and discard the waste bag when complete and connect blood return line of pump circuit to CytoSorb outlet port and clamp inlet and outlet lines.

Note: Gently thump the outlet side of CytoSorb with the palm of your hand during priming toremove air.

CAUTION: Avoid the entry of air into CytoSorb. Rinse always to waste bag.

3. INITIATION OF TREATMENT
3.1. Anticoagulation
Heparin: Patient shall be anticoagulated to an ACT of 160 – 210 seconds or an aPTT of 60 – 80 seconds prior to the start of treatment for CRRT or hemoperfusion. Clinicians shall monitor and maintain these levels throughout the treatment. Patients undergoing ECMO or CPB should be anticoagulated according to standard clinical practice for those procedures.
Citrate: When using regional anticoagulation, a hemofilter/dialyzer shall be used to remove calcium citrate complexes.

3.2. Initiate treatment as prescribed by a physician and directed by the Instructions For Use included with CytoSorb. Refer to the blood pump Instructions for Use regarding pump set-up and operation.

4. During Treatment
4.1. Monitor the pressure in the extracorporeal circuit, including the line between the blood pump and CytoSorb, if available. Investigate any indication of abnormal pressure.

4.2. Visually inspect CytoSorb for any signs of clotting or blood leaks from the circuit or within the dialyzer. Report all clotting or blood leaks to the responsible medical professional.

4.3. Periodically monitor the extracorporeal circuit for evidence of obstruction, security of fittings, and air within the circuit.

5. Termination of Treatment
5.1. When the treatment is completed, terminate the treatment as directed by the Instructions For Use included with bloodlines and blood pump circuit.

5.2. Discard the bloodlines and CytoSorb in an appropriate biohazard waste receptacle.
CAUTION: Reuse of CytoSorb may result in secondary infection, device clotting and/or a biohazardous situation.

6. Performance Characteristics
Flow Resistance (HCT 32 ± 3% @ 37 ± 1° C)
Qb ≤ 700 mL/min: 140 mmHg
Qb ≤ 500 mL/min: 90 mmHg
Qb ≤ 200 mL/min: 30 mmHg
Blood Priming Volume: 150 mL
Maximum Blood Flow Rate: 700 mL/min
Minimum Blood Flow Rate: 100 mL/min
Recommended Blood Flow Rate: 150-700 mL/min
Maximum Pressure Limit: 760 mmHg
Storage Fluid: Isotonic Saline
Priming Fluid: Isotonic Saline
Sterilization: Gamma Irradiation

7. Blood Contact Materials
Adsorbent Material: Crosslinked Divinylbenzene/ polyvinylpyrrolidone
Housing: Polycarbonate
O-ring Seals: Silicone
Screen: Polyester/Polypropylene

8. Accessories
When treating with CytoSorb and a dialyzer/hemofilter simultaneously, a Female-Female DIN blood line connector is required.

9. European Authorized Representative
MedPass International Limited, Company #3628305
Windsor House, Bretforton, Evesham, Worcestershire
WR11 7JJ, United Kingdom
Ph: +44 (0) 1 452 619 22, Email: MedPass.AR@MedPass.org

10. Certifications

CE 0344

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