CytoSorb™ 300 mL Device – Instructions For Use

English

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.

Results from current studies suggest that CytoSorb may be used 6 hours per day, for up to 7 consecutive days.

Acceptable Blood Flow Rate: 200-400 mL/min
Optimum Blood Flow Rate: 250-400 mL /min

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.

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.

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. Lipovena), fat emulsions or TPN-containing lipids are required or 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 analphylactoid 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 pruitis.

1.10. Limitations

This device is intended for use on persons 18 – 80 years old.
Note: Discretion should be used when treating a patient weighing less than 100 lb. (45 kg). Blood flow rate should be adjusted to reduce the risk of an adverse effect.

This device is not to be used for more than one treatment.

CytoSorb is a single-use device.

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 Luer connectors are required to connect with CytoSorb blood ports. The roller blood pump should be capable of delivering up to 400 mL/min blood flow rate.

CAUTION: Pressure monitoring of the bloodline between the blood pump and the CytoSorb device 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.

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

2.4. 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.

2.5. Aseptically spike 0.9% Sterile Normal Saline with a clamped IV administration set. Attach the IV administration set to the patient end of the arterial bloodlines.

2.6. Open the clamp on the IV set. Prime the arterial bloodline using a blood pump speed of approximately 150 mL/min. Refer to the pump's manual.
Note: If air bubbles are observed within the outlet of the device, gently thump the outlet side of the device with the palm of your hand during priming to remove them.

2.7. Stop the blood pump. Clamping the line, remove the inlet port plug of CytoSorb and connect the primed arterial bloodline to the inlet port. DO NOT remove the outlet port plug at this time.

CAUTION: Avoid the entry of air into CytoSorb.

2.8. Turn CytoSorb so the inlet end is facing downward. Remove CytoSorb outlet port plug and attach the venous line.

2.9. Turn on the blood pump and prime the venous line at approximately 150 mL/min.

2.10. Turn the blood pump off.

CAUTION: Verify that the circuit connections to CytoSorb are as shown in the illustration (on reverse). DO NOT kink any of the blood lines.

2.11. Complete priming the extracorporeal circuit at a blood pump speed of approximately 150 mL/min with a **minimum of 2 L** of normal saline.

2.12. When renal replacement therapy (dialysis, hemofiltration) is required, CytoSorb shall be placed upstream (proximal) of the dialysis device. An accessory bloodline between CytoSorb and the dialysis device is required. Priming will require 2L of normal saline, and anticoagulation requirements may need to be increased for the dual devices.

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. Clinicians shall monitor and maintain these levels throughout the treatment.

Citrate: When using regional anticoagulation, a dialyzer or hemofilter shall be used downstream of CytoSorb to remove calcium citrate complexes.

3.2. If being used with a dialysis device, initiate treatment as directed by the Instructions For Use included with the hemodialyzer.

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 the 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.

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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.

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

Blood Priming Volume:	120 mL
Flow Resistance (Qb < 500 mL/min):	300 mmHg
Maximum Blood Flow Rate:	400 mL/min
Maximum Pressure Limit:	500 mm Hg
Storage Fluid:	Isotonic Saline
Priming Fluid:	Physiologic 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 Luer Lock Connector is required to connect CytoSorb to the dialyzer/hemofilter.

9. European Authorized Representative

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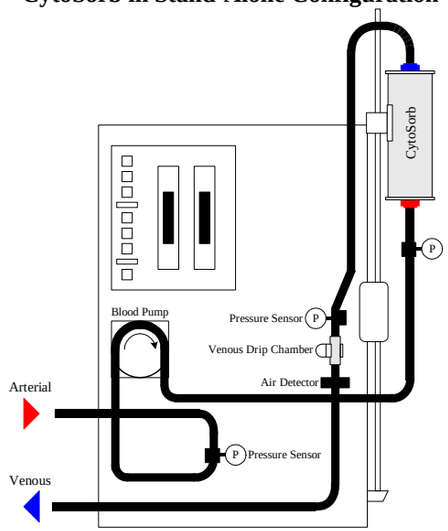
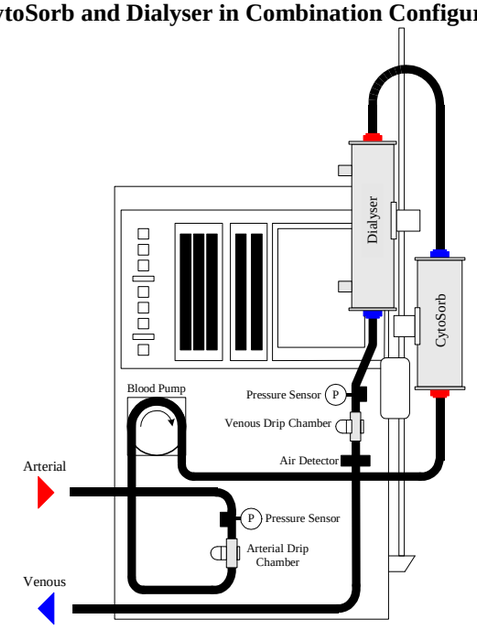
10. Certifications

CE 0344

CytoSorb in Stand-Alone Configuration



CytoSorb and Dialyser in Combination Configuration



EXPLANATION OF SYMBOLS

= Batch Code

= Serial Number

= Fluid Path Sterilized using Irradiation


= Do Not Reuse


= Caution, Consult Accompanying Documents


= Use By YYYY-MM-DD


= Do Not Use if Packaging is Damaged


= European Conformity


= Manufacturer

= European Authorized Representative