1. Introduction

1.1. Intended Use

The CytoSorb Device (CytoSorb) is a non-precipitating, 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 or may be pregnant.

Patients in acute sickle cell crisis.

Patients with very low platelet concentrations, where a test exists, after CytoSorb treatment and adjust drug concentrations, where a test exists, after CytoSorb treatment.

1.4. Limitations

This device is intended for use on persons 18 years and older.

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.

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.

2.2. The fluid pathway in an intact device inside the protective pich is sterile. Inspect the protective puch for any signs of damage to the CytoSorb device. Carefully remove CytoSorb from the puch and examine for defects.

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.

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 that the outlet 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 aPTT 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.
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**

    ![EC REP](image)

    **EXPLANATION OF SYMBOLS**

    - LOT = Batch Code
    - SN = 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

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Page 2 of 2