

Technical Data Sheet

MEDIASORB

Adsorbent cartridge

Product Information

The MEDIASORB adsorbent cartridge is a single-use device dedicated to extracorporeal circulation suitable for removal of a specific toxin or a wide range of toxic metabolites from a patient's blood in cases of:

- sepsis
- multiple organ dysfunction (MOD)
 - hepatic
 - pulmonary
 - cerebral
 - renal
 - cardiac

The MEDIASORB adsorbent cartridge is composed of an outer cylindrical polycarbonate body containing synthetic resin with a microporous structure in the form of white insoluble microspheres about 75 µm in diameter, which adsorb or absorb the targeted molecules in a patient's blood. The device has resin's volume of 140 mL. The internal volume not occupied by the resin is saturated by a filling liquid made of physiological solution (NaCl 0.9%).

The structure is held inside the device by filtering septums with a final porosity at the outlet of approximately 5 µm; these filters, that have different porosity, guarantee the absence of particles in the filtered fluid.

MEDIASORB cartridge is used along with MICROPLAS Plasmafilter for the purpose of Coupled Plasma Filtration Adsorption (CPFA) treatment. The plasma obtained from the plasmafilter flows through the adsorbent cartridge from the plasma inlet to the outlet and connected with the line.

The MEDIASORB adsorbent cartridge has to be installed on an equipment and has to be used in combination with a plasmafilter to perform plasma-perfusion.

The MEDIASORB adsorbent cartridge must only be used for CPFA treatment and the MEDIASORB adsorbent cartridge for Amply CPFA procedure pack must be used in combination only with AMPLYA Acute Multitherapeutic system™.



Figure 1. MEDIASORB cartridge

Applicable therapies

CPFA is a continuous treatment. CPFA is an extracorporeal blood purification treatment that combines plasma separation and adsorption of inflammatory mediators and/or toxins with hemofiltration.

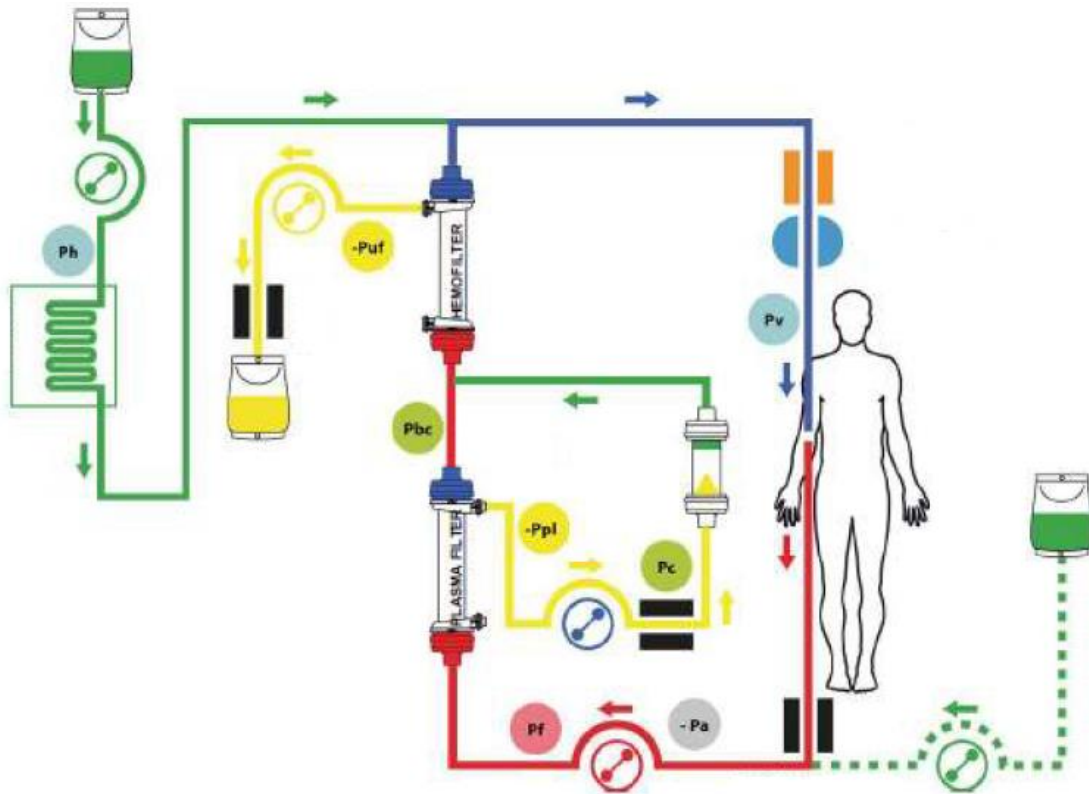


Figure 2. CPFA treatment circuit

Description of the image above:

- The blood pump and the blood flow on the access in red.
- The blood flow on the return side in blue.
- The infusion pump, the bags and the infusion flow in green on the left.
- The pre-dilution pump, the bags and the pre-dilution flow in green on the right.
- The ultrafiltration or ultrafiltration pump, the bags and ultrafiltration (plasma water) flow in yellow on the left.
- In the center, the plasma flow into the MEDIASORB adsorbent cartridge in yellow, the plasma flow out of the MEDIASORB in green, and the plasma pump in blue.
- The hemofilter, the plasma filter and the MEDIASORB adsorbent cartridge.
- The heater, the sensors and the venous electroclamp.
- The pressures measured directly or indirectly access (-Pa), return (Pv), plasma filter inlet (Pf), hemofilter inlet or plasma filter outlet or MEDIASORB outlet (Pbc), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf), MEDIASORB inlet (Pc), plasma pump inlet (-Ppl).

Intended Use

The MEDIASORB adsorbent cartridge is a medical device dedicated to the removal of toxic metabolites in the treatment of:

- sepsis
- MOD (e.g. hepatic, pulmonary, cerebral, renal and cardiac dysfunction).

Codes Available

| Code | Name | Description | CND | GMDN |
|----------------------|-----------|---|-----------|-------|
| IBP1502 IBP1502S* | MEDIASORB | Cartridge for plasma perfusion during CPFA treatment. | F01080201 | 34422 |

*included only in CPFA procedure pack – not available standalone

Sterilization method and validity

Sterile and non-pyrogenic.

Sterilizing agent: steam air mix cycle sterilized.

Shelf life: 2 years.

Do not resterilise.

Technical characteristics

The technical characteristics of the MEDIASORB adsorbent cartridge are reported below:

| Components | Materials |
|------------------------|--|
| Adsorbent materials | Polymeric resin (Polystyrene-divinylbenzene) |
| Internal filters 25 µm | Polypropylene |
| Internal filters 5 µm | Nylon |
| Filling solution | Saline solution (Sodium chloride 0.9%) |
| Housing | Polycarbonate |
| Header | Polycarbonate |
| Protective caps | Thermoplastic elastomer ¹ |
| O-ring | Silicon |
| Supporting ring | Polycarbonate |
| Spacer | Polycarbonate |
| External ring | High density polyethylene |

¹ not in contact with blood and fluids

Technical characteristics (continued)

| Model | Internal retention filters (µm) | Outlet retention filters ² (µm) | Surface area ³ (m ² /g) | Particle size ⁴ (µm) | Total length ⁵ (m) | External diameter ⁵ (mm) | Weight (g) | Average pore diameter (Å) | Maximum operating pressure (mmHg) |
|-----------|---------------------------------|--|---|---------------------------------|-------------------------------|-------------------------------------|------------|---------------------------|-----------------------------------|
| MEDIASORB | 25 | 25 + 5 | 700 | 50-100 | 145 | 43 | 240 | 300 | 500 |

²The outlet internal retention septum is made up of two different filter: one with porosity of 25 µm and the other with 5 µm of porosity

³ Minimum surface area

⁴ 80% in range

⁵ Outer body characteristics

Functional specifications

The efficiency of the adsorbent cartridges was evaluated by means of in vitro adsorption tests with substances having medium-high molecular weight (Myoglobin PM = 17.8 kDa).

Myoglobin removal ≥ 90% (4hours)

Packaging

| Model | Code | Primary packaging | |
|-----------|----------------------|--|---------------------|
| | | Material | Weight |
| MEDIASORB | IBP1502 IBP1502S* | Individual Pouch Material: Polyamide/Polypropylene film | 10.1 g |
| | | Individual bubble wrap Material: polythene (150x250 mm) | 70 g/m ² |

*included only in CPFA procedure pack – not available standalone

| Model | Code | Secondary packaging | | |
|-----------|---------|---|--------------------------|----------------------|
| | | Dimension(mm) | Weight ⁶ (kg) | Pcs/Box ⁷ |
| MEDIASORB | IBP1502 | Single box 4 mm Dimensions: 90 x 74 x 180 mm | 0.3 | 1 |
| | | Multiple box 1 mm Dimensions: 600 x 395 x 162 mm | 8.0 | 24 |

⁶ Box weight filled with products

⁷ There are twenty-four individual boxes with in one adsorbent cartridge, included in a multiple box.

Storage and disposal conditions

Storage conditions: store at temperatures between +1 and +30 Celsius degrees and do not expose to direct sunlight.

Disposal: remove from the place of dialysis immediately after use. Disposal must be carried out in accordance with the regulations in force.

Biocompatibility

Biocompatibility tests of MEDIASORB adsorbent cartridge have been performed according to ISO 10993-1 and related applicable standard series.

MEDIASORB adsorbent cartridge is a non-active, non-invasive class IIb medical device CE0123 manufactured by Bellco S.r.l

Important: Please refer to the package inserts for complete instructions, contraindications, warnings and precautions in your respective geography.

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