

Mediasorb Cartridge

Product description

The Mediasorb 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 and/or multiple organ failure (e.g. hepatic, pulmonary, cerebral, renal and cardiac dysfunction).

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 cartridge is used within a system comprising of a:

- Mediasorb cartridge
- Preassembled device for CPFA consisting of plasmafilter for plasma separation, dialyzer with high flux fiber, and bloodlines for CPFA treatment
- Amplya™ system or Lynda™ machine.



Figure 1:
Mediasorb cartridge

Applicable therapies

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

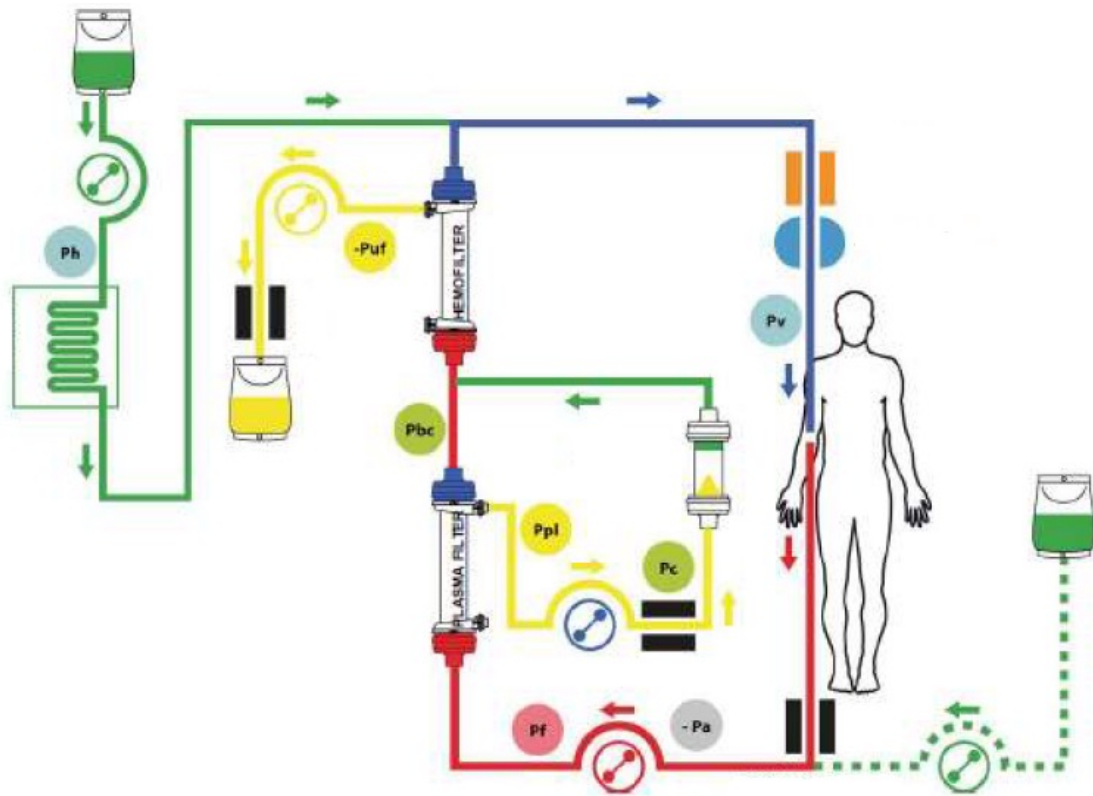


Figure 2. CPFA treatment circuit

Description of the Figure 2:

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 cartridge in yellow, the plasma flow out of the Mediasorb cartridge in green, and the plasma pump in blue.

The hemofilter, the plasma filter, and the Mediasorb 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 cartridge outlet (Pbc), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf), Mediasorb cartridge inlet (Pc), plasma pump inlet (Ppl).

Intended use

The Mediasorb cartridge is a medical device dedicated to the removal of toxic metabolites in the treatment of sepsis and multiple organ failure (e.g. hepatic, pulmonary, cerebral, renal and cardiac dysfunction).

Code available

Code	Name	Description	CND	GMDN
IBP1502	Mediasorb Cartridge	Cartridge for plasma regeneration during CPFA treatment.	F01080201	34422

Sterilization method and validity

Sterile and pyrogen free.

Sterilizing agent: Wet Heat

Shelf life wet heat sterilization: 2 years.

Do not resterilize.

Technical characteristics

The technical characteristics of the Mediasorb cartridge are reported below.

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

¹Not in contact with blood and fluids

Technical characteristics									
Model	Internal retention filters (µm)	Outlet retention filters ² (µm)	Surface area ³ (m ² /g)	Particle size ⁴ (µm)	Total length ⁵ (mm)	External diameter ⁵ (mm)	Weight (g)	Average pore diameter (A)	Maximum operating pressure (mmHg)
Mediasorb Cartridge	25	25 + 5	600	50-100	145	43	240	300	500

² The 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 \geq 90% (4hours)

Packaging

Model	Primary packaging - Pouch	
	Material	Pouch weight (g)
Mediasorb Cartridge	Polyamide/Polypropylene film	10,1

Model	Secondary packaging - Box			
	Box	Weight ⁶ [kg]	Individual bubble wrap	Pcs/Box ⁷
Mediasorb Cartridge	Individual box 4 mm Dimensions: 9.0 x 7.4 x 18.0 cm	0.3	Bubble bag - 70 g/m ² polythene 15x25 cm	24
	Generic box 1 mm Dimensions: 60.0 x 39.5 x 16.2 cm	8.0		

⁶ Box weight filled with products

⁷ A box contains twenty-four individual boxes, each containing an adsorbent cartridge

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 cartridge have been performed according to ISO 10993-1 and related applicable standard series.