

Preassembled device for plasma exchange (PEX) treatment with Amplya™ system

Product description

The preassembled device for plasma exchange (PEX) treatment is a sterile, single-use, non-pyrogenic with integrated extracorporeal circuit, a plasmafilter and a heater bag for use with the Amplya™ system.

Plasma exchange (PEX) is a treatment whereby plasma is separated and removed from the blood through a plasmafilter and the removed plasma is replaced with a replacement fluid. The treatment is only performed in post-infusion.

These preassembled devices are composed by the tubing lines (blood, infusion, and ultrafiltration) with two cassettes for extracorporeal circulation, a plasmafilter, and a heater bag. All the components are preconnected and fastened to a thermoformed support for easy installation of the medical device on the machine.

The plasmafilter MPS 05 is a filter used in association with the preassembled devices for plasma exchange (PEX) treatment. The MICROPLAS plasmafilter is composed by MicroPES membrane and by luer lock connections to the blood and plasma circuits. The MICROPLAS is a plasmafilter to separate plasma from blood.



Figure 1. Preassembled PEX photo device

Applicable therapies

Plasma exchange (PEX) is a treatment whereby plasma is separated and removed from the blood through a plasmafilter and the removed plasma is replaced with a replacement fluid. The replacement fluids are colloidal type pharmaceutical solution (e.g. albumin solution) or frozen fresh plasma (from a donor).

The single-use circuit includes a line for plasma infusion at the plasmafilter outlet (post-infusion) and a line for plasma extraction from the patient's blood. The treatment is only performed in post-infusion.

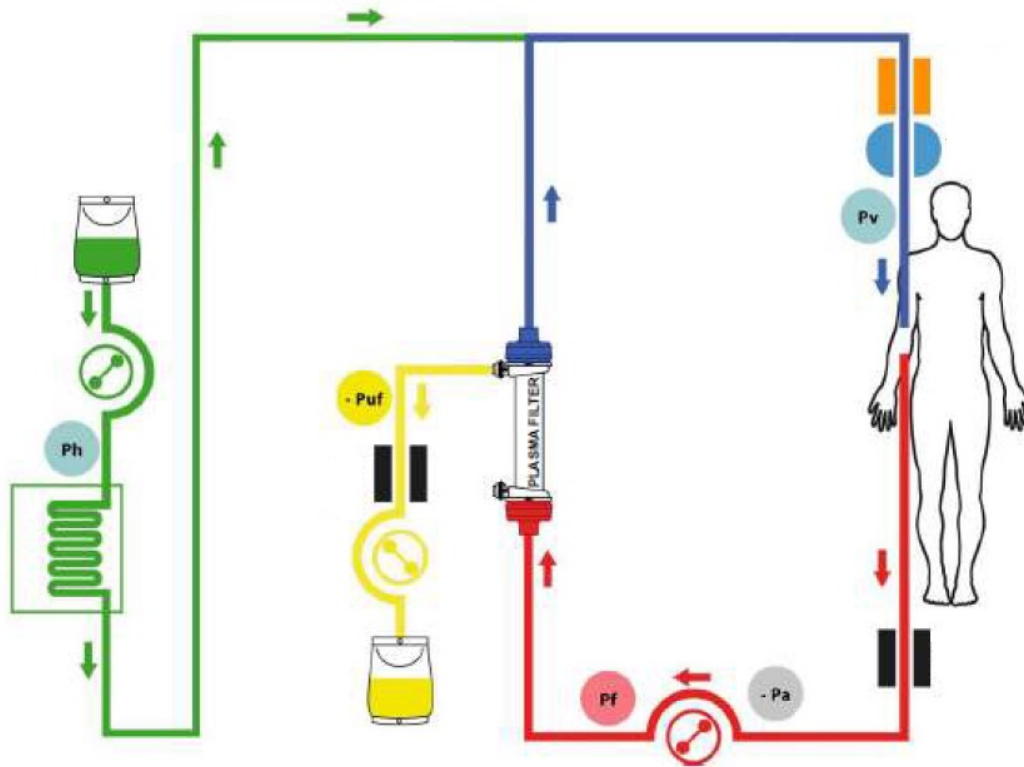


Figure 2. Plasma Exchange Treatment circuit

Description of the image above:

The blood pump and the blood flow on the access side in red.

The blood flow on the return side in blue.

The infusion pump and the plasma bag in green on the left.

The ultrafiltration or ultrafiltration pump, the collection bag and the flow of plasma removed from the blood in yellow in the center.

The plasmafilter, the heater, the sensors and the venous electroclamp.

The pressures measured directly or indirectly: access (-Pa), return (Pv), plasmafilter inlet (Pf), infusion pump outlet (Ph), ultrafiltration pump inlet (-Puf).

Intended use

The device has been designed for extracorporeal blood circulation in:

- Therapeutic plasma therapy treatments.

Code available

CFN	Models	Plasmafilter	Description	CND	GMDN
IB0081200	ABLP05	MPS 05	Preassembled device for PEX for Amplya™ system	F020199	46998

Sterilization method and validity

Sterile and non-pyrogenic.

Sterilizing agent: gamma radiation.

Shelf life: 12 months.

Do not resterilize.

Technical characteristics

The technical characteristics of the preassembled devices for PEX treatments with Amplya™ system are reported below.

Tubing lines	
Components	Materials
Cassette body	Rigid Polyvinyl chloride
Cassette Membrane	Ethylene-propylene diene monomer
Venous filter	High density polyethylene
Tubing lines	Soft Polyvinyl chloride
T connector	Rigid Polyvinyl chloride
Y connector	Rigid Polyvinyl chloride
Seal and caps	High density polyethylene
Luer lock and dialyzer connection	Rigid Polyvinyl chloride - Acrylonitrile butadiene styrene
Blood catcher	Polyvinyl chloride
Transducer protector	Rigid and Soft Polyvinyl chloride
Laminate Membrane	Expanded Polytetrafluoroethylene
Check valve	Acrylonitrile butadiene styrene or Silicone rubber
Cuvette	Polyethylene terephthalate glycol copolyester for the body - Polyvinyl chloride for the connection
Bowl	Rigid Polyvinyl chloride

MPS05 - Plasmafilter	
Components	Materials
Membrane	Polyethersulfone
Housing	Polycarbonate
Header	Polycarbonate
Luer cap	High density polyethylene
Protective caps	Polypropylene
Potting A ¹	Polyol
Potting B ¹	Isocyanate
O-ring	Termoplastic Elastomer TPE
Luer joint for gluing	Polycarbonate
Sterilization cap	Polypropylene
Side Caps	Polyethylene

¹Potting A and Potting B are the materials that mixed together make up potting component.

Heater bag	
Components	Materials
Film	Polyvinyl chloride
Tube	Polyvinyl chloride

Technical characteristics MPS05 - Plasmafilter									
Model	Surface area (m ²)	Number of fibers	Fiber wall thickness (µm)	Fiber internal diameter (µm)	Maximum pore size (µm)	Filling volume blood compartment (ml)	Plasma compartment priming volume (ml)	Total length ² (mm)	External diameter ² (mm)
MPS05	0.45	2000	100	300	0.5	50	125	305	55

² Outer body characteristics

Technical characteristics preassembled device	
Model	Priming volume hematic circuit (plasmafilter excluded) (ml)
ABLP05	109

Packaging

Model	Primary packaging	
	Pouch material	Pouch weight (g)
ABLP05	Low density polyethylene and Tyvek	132,90

Storage and disposal conditions

Storage conditions: store at temperatures between +0 and +30 degrees Celsius.

Disposal: dispose the device after treatment in accordance with applicable government and health center regulations.

Biocompatibility

Biocompatibility tests of the preassembled devices for PEX treatments with Amplya™ system have been performed according to ISO 10993-1 and related applicable standard series.