

Procedure pack for PEX treatment for the Amplya™ machine

Product description

The plasma exchange (PEX) procedure pack is designed to use with the Amplya™ machine. It's a preassembled device for PEX treatment that includes tubing lines, a MICROPLAS MPS 05 plasmafilter and five 5-litre drainage bags fitted with a closing clamp. The procedure pack is composed of single-use, sterile and non-pyrogenic medical devices. The components are preconnected and fastened to a thermoformed support for easy installation on the Amplya™ machine.

Detailed below are the disposable devices that compose the procedure pack:

The preassembled device for PEX treatment includes the integrated extracorporeal circuit, a MICROPLAS plasmafilter (MPS 05) and a heater bag for use with the Amplya™ machine.

The tubing lines for extracorporeal blood circulation includes a bloodline, infusion line, and ultrafiltration line, with two cassettes for extracorporeal circulation.

The MICROPLAS MPS 05 plasmafilter is used to separate plasma from blood. It is gamma sterilized and a configuration of plasmafilter used in association with preassembled devices for Amplya™ machine, among which PEX preassembled device for PEX treatment. The MICROPLAS plasmafilter is composed by MicroPES membrane, housing and luer lock connections to the blood and plasma circuits.

The 5 litre drainage bags are included in the procedure pack for the purpose of collecting waste fluids and they belong to Class I medical devices.



Figure 1. PEX Procedure Pack for the Amplya™ machine

Applicable therapies

PEX is a treatment whereby plasma is separated and removed from the blood through a MICROPLAS 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.

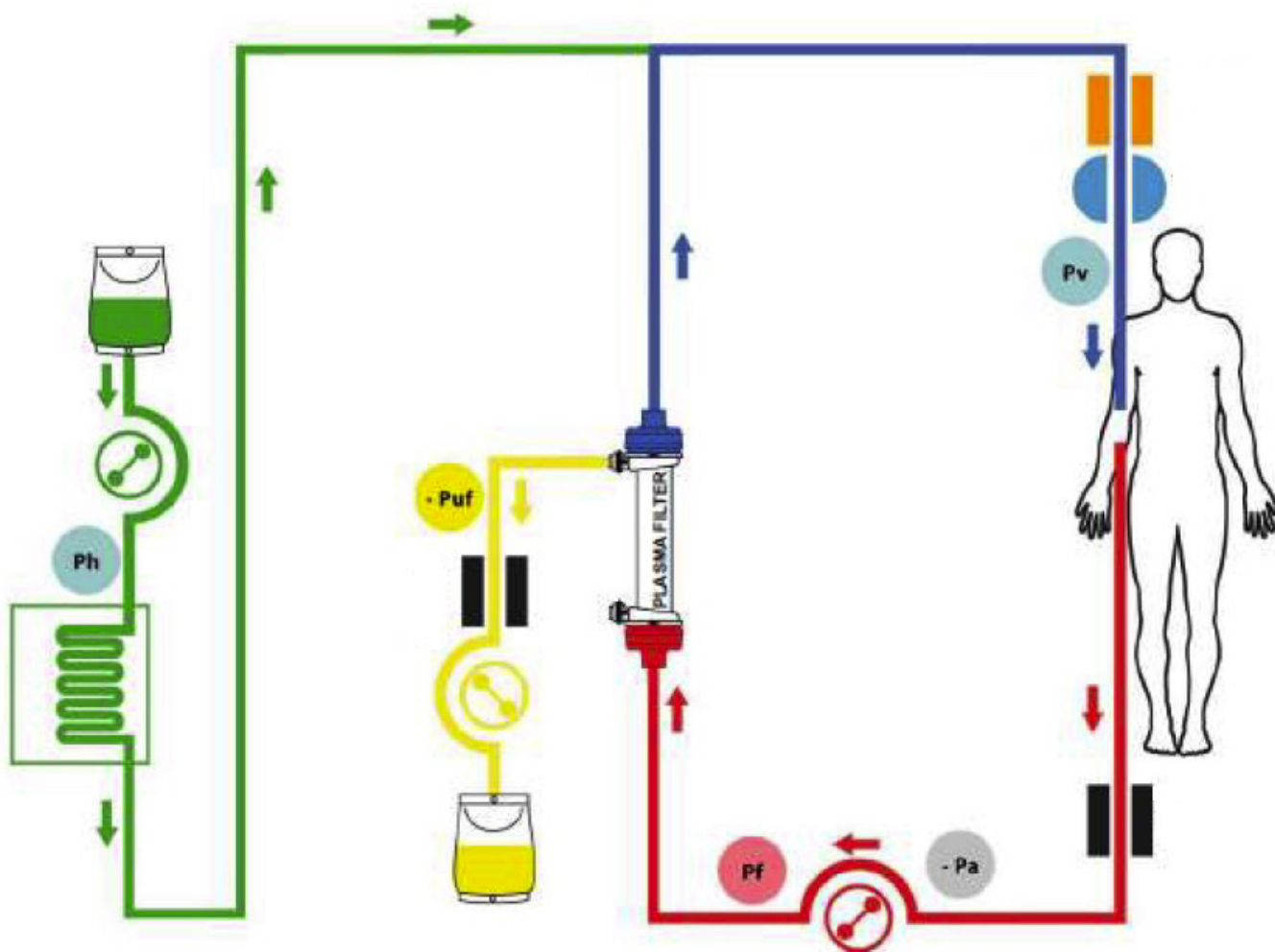


Figure 2. Plasma Exchange Treatment circuit

Description of the PEX treatment circuit:

The blood pump and the blood flow on the access side 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

Procedure pack for PEX therapy.

Code available

Procedure pack REF ¹	Procedure pack name	Medical device REF	Medical device name ²	CND ³	GMDN ³
IB0590040	KABLP05 KIT PEX X AMPLYA™ MACHINE	IB0081200	ABLP05 - Preassembled device for PEX for Amplya™ machine	F020199	46998
		IB0514110	BL031 - 5-litre drainage bag	F90040101	44942

¹The procedure pack assembler is Bellco S.r.l and it is not marked CE.

²The medical devices manufacturer is Bellco S.r.l and they are marked CE.

³The CND and GMDN indicated in the table above refer to the preassembled device and 5 litre drainage bag.

Sterilization method and validity

KABLP05 Procedure pack:

The procedure pack is non-sterile, it has a shelf life of 12 months.

The shelf life of the procedure pack is determined by the component with the shortest shelf life.

In particular, the preassembled device and the drainage bags are sterile and non-pyrogenic.

ABLP05 Preassembled device:

Sterilizing agent: gamma radiation

Shelf life: 12 months.

BL031 5- Litre drainage bag:

Sterilizing agent: ethylene oxide

Shelf life: 5 years.

Technical characteristics

The technical characteristics of the devices contained in the procedure pack for PEX treatments with the Amplya™ machine are reported below.

Tubing lines	
Components	Materials
Cassette body	Rigid Polyvinyl chloride
Casette 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 ⁴	Polyol
Potting B ⁴	Isocyanate
O-ring	Termoplastic Elastomer TPE
Luer joint for gluing	Polycarbonate
Sterilization cap	Polypropylene
Side Caps	Polyethylene

⁴ Potting A and Potting B are the materials that mixed together make up potting component.

Heater bag	
Components	Materials
Film	Polyvinyl chloride
Tube	Polyvinyl chloride

BL031 5-litre drainage bag	
Components	Materials
Bag ⁵	Soft Polyvinyl chloride

⁵ The component of bag is indirect contact with blood

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 ⁶ (mm)	External diameter ⁶ (mm)
MPS05	0.45	2000	100	300	0.5	50	125	305	55

⁶ Outer body characteristics

Packaging

Model	Primary packaging	
	Pouch material	Pouch weight (g)
ABLP05	Low density polyethylene and Tyvek™.	132.90
BL031 - 5LITRE DRAINAGE BAG	Pouch with one side in transparent polyethylene and one side in medical paper.	21.5

Model	Secondary packaging - Box		
	Single Box	Weight ⁷ (kg)	Pcs/Box
KABLP05	Carton box Dimensions: 690 x 580 x 140 mm	3.2	1

⁷ Max box weight filled with products

Storage and disposal conditions

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

Disposal: At the end of the therapy, dispose of the procedure pack and the individual medical devices in compliance with the national laws and the applicable internal procedures of the centre.

Biocompatibility

Biocompatibility tests of the devices contained in the procedure pack for PEX treatments with Amplya™ machine have been performed according to EN ISO 10993-1 and related applicable standard series.

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