Medtronic

Technical Data Sheet

Procedure pack for Coupled Plasma Filtration and Adsorption (CPFA) treatment with the Amplya™ machine

Product description

The coupled plasma filtration and adsorption (CPFA) procedure pack is designed to be used with the Amplya™ machine. It consists of the ABL14P05 preassembled device, Mediasorb™ cartridge, and 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 of the medical device on the Amplya™ machine.

Below is the detail of the disposable devices that compose the procedure pack:

The preassembled device for CPFA treatment consists of the tubing lines (blood, infusion, and ultrafiltration) with two cassettes for extracorporeal circulation, a hemofilter (HFT 14), a MICROPLAS plasmafilter (MPS 05), and a heater bag. The components are preconnected and fastened to a thermoformed support for easy installation of the medical device on the Amplya™ machine.

The tubing lines for extracorporeal blood circulation. Two cassettes, a line for replacement fluid infusion, a line for extraction of the waste fluid (ultrafiltrate), a line for plasma clearance and its reinfusion once treated, and a pre-dilution line if needed.

Figure 1. CPFA procedure pack configuration

The hemofilter HFT 14 consists of an outer cylindrical polycarbonate body containing a bundle of microporous, high-permeability hollow fibers. The hollow-fiber bundle is secured at the end with hot melt polyurethane resin. The hemofilter has nominal filtering area of 1.4 m^2.

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

The Mediasorb™ cartridge is 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™ 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 absord 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 5-litre drainage bags are included in the procedure pack for the purpose of collecting waste fluids and they belong to Class Is of medical devices.

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.

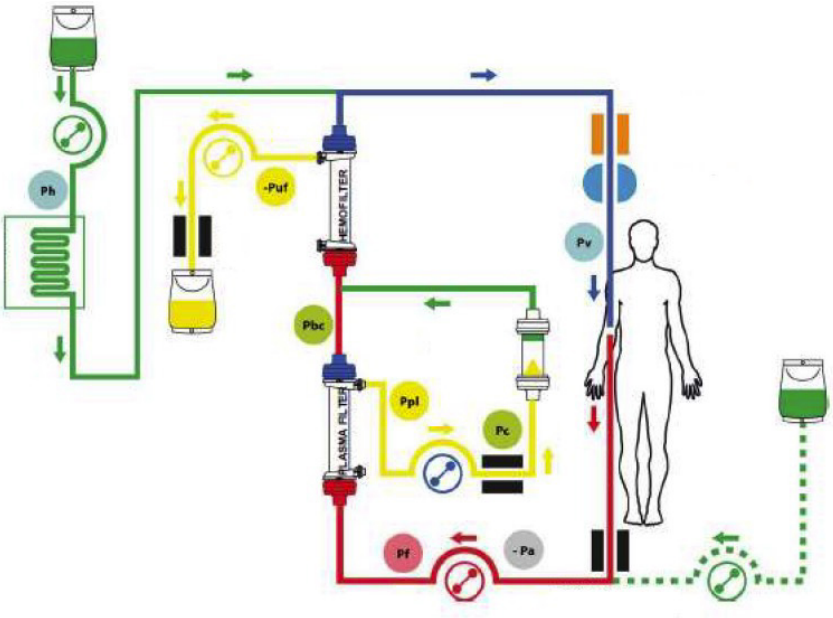

Figure 2. CPFA treatment circuit

Description of the CPFA treatment circuit:

- 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

Procedure pack for CPFA therapy.

Code available

Procedure pack REF[1]	Procedure pack name	Medical device REF	Medical device name[2]	CND[3]	GMDN[3]
IB0600000	KABL14P05 KIT CPFA X AMPLYA™ MACHINE	IB0086000	ABL14P05 – Preassembled device for CPFA for Amplya™ machine	F020199	61674
		IBP1502S	Mediasorb™ cartridge	F01080201	34422
		IB0514110	BL031 – 5-litre drainage bag	F90040101	44942

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

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

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

Sterilization method and validity

KABL14P05 Procedure pack:

The procedure pack is non-sterile and with 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, the adsorbent cartridge and the drainage bags are sterile and non-pyrogenic.

ABL14P05 Preassembled device:

Sterilizing agent: gamma radiation.

Shelf life: 12 months.

Mediasorb™ cartridge:

Sterilizing agent: moist heat with saturated steam.

Shelf life: 2 years.

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 CPFA treatments with the Amplya™ machine are reported below.

HFT 14 - Hemofilter	
Components	**Materials**
Membrane	Polyethersulfone
Housing	Polycarbonate
Header	Polycarbonate
Caps	Polycarbonate
Potting	Polyurethane
O-ring	Silicone rubber

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.

Mediasorb™ Cartridge	
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[5]
O-ring	Silicon
Supporting ring	Polycarbonate
Spacer	Polycarbonate
External ring	High density polyethylene
Saline solution	Sodium chloride 0.9%

[5] not in contact with blood and fluids

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
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

Heater bag	
Components	**Materials**
Film	Polyvinyl chloride
Tube	Polyvinyl chloride

BL031 5-litre drainage bag	
Components	**Materials**
Bag[6]	Soft Polyvinyl chloride

[6] The component of bag is indirect contact with blood

Technical characteristics HFT14 - Hemofilter								
Model	**Surface area (m^2)**	**Fiber wall thickness (µm)**	**Fiber internal diameter (µm)**	**Filling volume blood compartment (mL)**	**Blood compartment pressure drop[7] (mmHg)**	**Weight (g)**	**Total length[8] (mm)**	**External diameter[8] (mm)**
HFT 14	1.4	30	200	85	< 45	191	305	55

[7] Bovine blood: Hct 32±3%, proteins 60±5 g/L, Q_B = 200 mL/min

[8] Outer body characteristics

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[9] (mm)**	**External diameter[9] (mm)**
MPS05	0.45	2000	100	300	0.5	50	125	305	55

[9] Outer body characteristics

Technical characteristics Mediasorb™ cartridge									
Model	**Internal retention filters (µm)**	**Outlet retention filters[10] (µm)**	**Surface area[11] (m^2/g)**	**Particle size[12] (µm)**	**Total length[13] (mm)**	**External diameter[13] (mm)**	**Weight (g)**	**Average pore diameter (A)**	**Maximum operating pressure (mmHg)**
MEDIASORB™ CARTRIDGE	25	25 + 5	600	50-100	145	43	240	300	500

[10] 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

[11] Minimum surface area

[12] 80% in range

[13] Outer body characteristics

Performance and Functional Specifications

The measurements in the charts below are taken in accordance with EN ISO 8637. The values indicated are to be considered approximate and may vary due to measurement methods, inherent variations of the membrane, manufacturing, and storage conditions. During the treatment, performance on the individual patient may vary due to variable clinical parameters of the patient.

The reported performances below refer to each hemofilter present in preassembled device for CPFA treatment.

UF Coefficient[14]	
Model	**Ultrafiltration (mL/h*mmHg)**
HFT 14	41

[14] Q_b = 300 ml/min; bovine blood (Hct 32±3%; proteins 60±5 g/L)

The efficiency of Mediasorb™ cartridge was evaluated by means of in vitro adsorption tests with substances having medium-high molecular weight (Myoglobin PM = 17.8 KDa).

Myoglobin removal ≥ 90% (4 hours)

Packaging

Model	Primary packaging	
	Pouch material	**Pouch weight (g)**
ABL14P05	Low density polyethylene and Tyvek	132.44
MEDIASORB™ CARTRIDGE	Polyamide/Polypropylene film	10.1
BL031	Pouch with one side in transparent polyethylene and one side in medical paper.	21.5

Model	Secondary packaging – Box		
	Single Box (mm)	**Weight[15] (kg)**	**Pcs/Box**
KABL14P05	Carton box Dimensions : 690 x 580 x 140	3.9	1

[15] Max box weight filled with products

Storage and disposal conditions

Storage conditions: store at temperatures between +1 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 CPFA treatments with the Amplya™ machine have been performed according to EN ISO 10993-1 and related applicable standard series.

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