Medtronic

Technical Data Sheet

ABLE - Preassembled device for extracorporeal hemoperfusion with Amplya™ system

Product description

The preassembled device for extracorporeal hemoperfusion is a sterile, single-use, non-pyrogenic extracorporeal circuit for use with the Amplya™ system.

The device is composed of blood lines for extracorporeal circulation (consisting of tubes, pressure transducer, expansion chambers, infusion tubing and drip chambers, one cassette) and a priming collection bag. The device is preconnected and fastened to a thermoformed support for easy installation on the Amplya™ system.

Hemoperfusion (HP) is an extracorporeal technique used on patients affected by conditions where the immediate removal of toxic substances by adsorption is required.

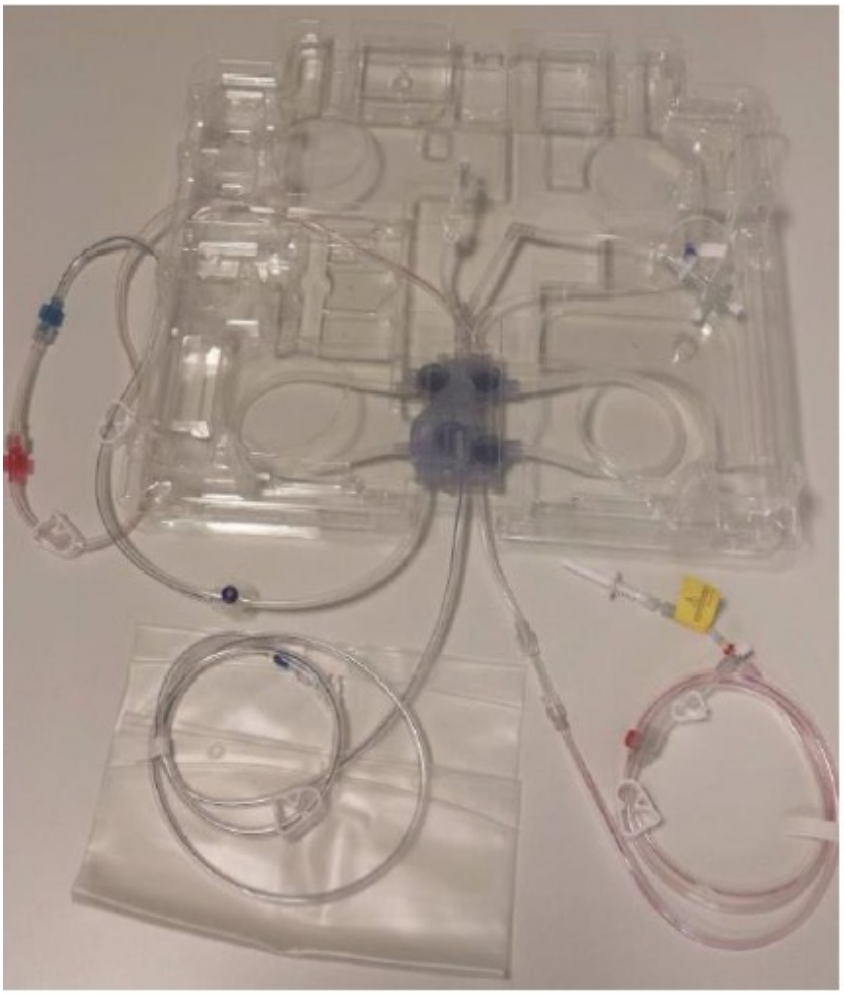

Figure 1. Preassembled hemoperfusion photo device

Applicable therapies

Hemoperfusion is a therapeutic treatment aimed at blood clearence by means of adsorption of toxic substances during extracorporeal circulation when the patient's blood is passed through an adsorbent column.

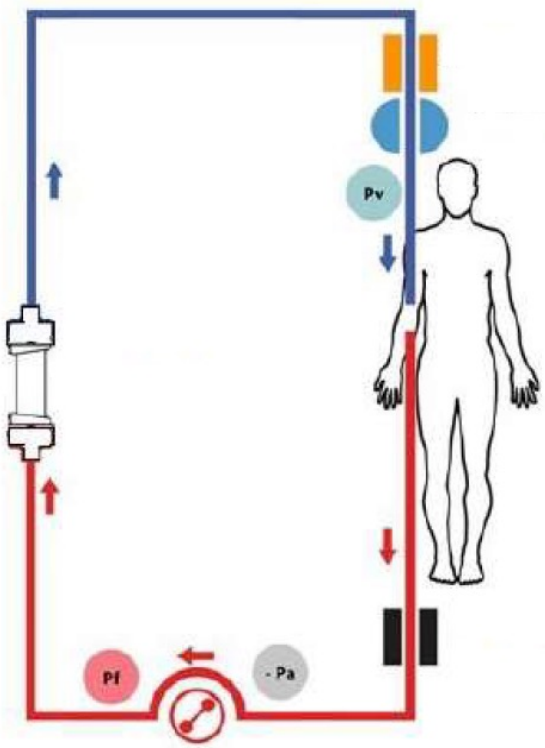

Figure 2: Hemoperfusion treatment circuit

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 pressures measured directly or indirectly: access (-Pa), return (Pv) and adsorbent column inlet (Pf).

Intended use

Preassembled devices for blood circulation management to be used in combination with an adsorbent filter (column containing adsorbent particles) during extracorporeal hemoperfusion procedures.

Code available

CFN	Name	Description	CND	GMDN
IB0580790	ABLE	Preassembled device for hemoperfusion (HP) for Amplya™ system	F9099	61674

Sterilization method and validity

Sterile and non-pyrogenic.
Sterilizing agent: gamma radiation.
Shelf life: 30 months.
Do not resterilize.

Technical characteristics

The technical characteristics of the preassembled device for extracorporeal hemoperfusion with Amplya™ system are reported below.

Max preassembled device utilization time (hours)	60
Max recommended flow (ml/min)	30
Max allowed flow (ml/min)	450
Max pressure drop on the circuit (mmHg)[1]	800

[1] Reference to the blood lines of the extracorporeal circuit

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
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

5 Lt Priming Collection Bag	
Components	**Materials**
Medical Film	Polyvinyl chloride
Tube	Polyvinyl chloride
Female luer lock	Polyvinyl chloride
Non-hermetic male Luer Lock cap	Polypropylene
Clamp	Polypropylene

Packaging

Model	Primary packaging	
	Pouch material	Pouch weight (g)
ABLE	Low density polyethylene and Tyvek	133,60

Model	Secondary packaging – Box		
	Single Box	Weight[2] (kg)	Pcs[3]
ABLE	White colored micro-triple Kraft cardboard, double wave EB Dimensions: 690 x 590 x 140 mm	2,3	1

[2] Single box weight

[3] Number of preassembled devices in a single box

Storage and disposal conditions

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

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

Biocompatibility

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

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