Medtronic

Technical Data Sheet

MICROPLAS Plasmafilters

Product description

The MICROPLAS Plasmafilter product family is composed of single-use devices intended to be used with standard blood and plasma circuits and dedicated machines. It is intended for separating the plasma from the corpuscular part of the blood. A filter is designed to separate and contain a component of the blood. The device is equipped with Luer-lock connections to blood and plasma circuits.

MICROPLAS Plasmafilters come in three models (MPS 03, MPS 05, MPS 07) differentiated by the surface areas and quantity of hollow fibers. The device consists of a cylindrical polycarbonate body containing a bundle of microporous, highly permeable polyethersulfone (MicroPES) hollow fibers secured to the ends by means of hot-melt polyurethane resin.

Figure 1. MICROPLAS Plasmafilter

The different connection points as shown in **Figure 1**

- **a.** Blood inlet: connection with arterial blood line
- **b.** Blood outlet: connection with venous blood line
- **c.** Plasma outlet: luer fitting for connection to the plasma collection line
- **d.** Outlet connector: luer fitting

Applicable therapy

Correct connection of plasma separation:

Description of correct connection of the blood drawing line (arterial) to the inlet at the bottom of the filter and the blood return line (venous) to the connector at the top of the filter. Install the tubing and filters in aseptic conditions. It is recommended to heparinize the extracorporeal circuit during rinsing and priming. In order to rinse the tubing system, connect the bag of sodium chloride solution to the arterial line and a collection bag to the venous line. When the system has undergone the correct rinsing and priming procedure, the treatment session can be started.

The correct set up of the circuit for a typical plasma separation, as shown in **Figure 2**.

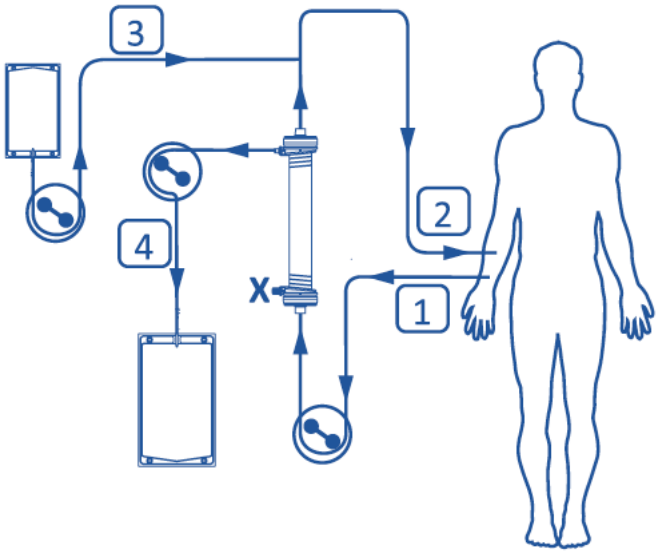


Figure 2 – legend:

1. Drawing line
2. Return line
3. Infusion line (plasma or derivatives)
4. Drainage line

Figure 2. A typical plasma separation circuit diagram

Plasmapheresis Treatment:

During the plasmapheresis treatment, the blood is aspirated from the patient and pumped into the extracorporeal circuit. The blood is sent to the lower part of the MICROPLAS Plasmafilter (blood side) and enters the membrane. It flows into the hollow fibers where, due to the particular characteristics of the membrane (porosity, fiber diameter), part of the plasma is separated from the whole blood and flows to the outside of the hollow fibers. The plasma is collected outside the fiber, accumulates at the bottom of the plasma filter where it is collected and stored in a collection bag or purified to be reinfused to the patient. The treated blood is then reinfused to the patient.

Coupled Plasma Filtration and Adsorption (CPFA) Treatment:

Besides plasmapheresis treatment, MICROPLAS Plasmafilter in combination with Mediasorb™ cartridge constitute the heart of CPFA treatment.

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

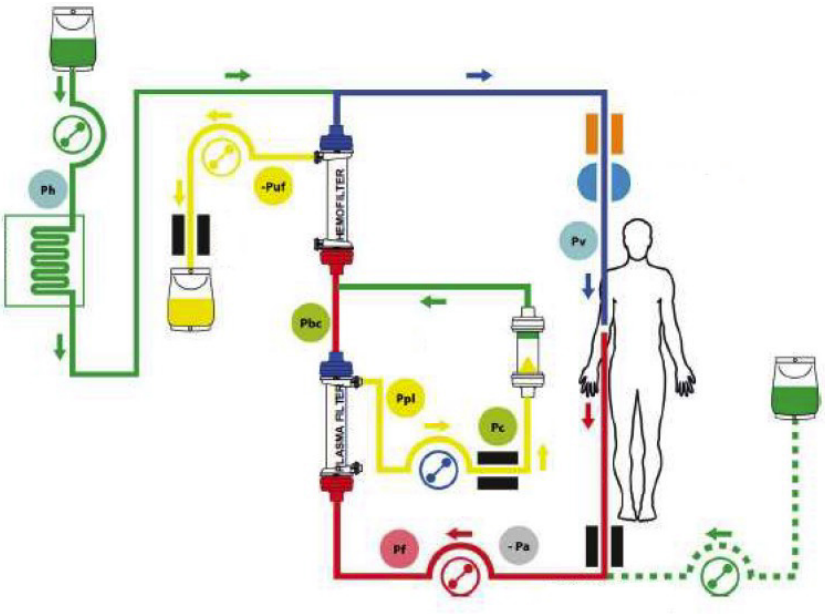


Figure 3. CPFA treatment circuit

Description of the image:

- 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

MICROPLAS is a filter to separate plasma from blood.

Codes available

CFN	Models	Description	CND	GMDN
IBP4102	MICROPLAS MPS05	0.5 m^2 plasmafilter sterilized ethylene oxide.	B02010199	36194
IBP4103	MICROPLAS MPS07	0.7 m^2 plasmafilter sterilized by ethylene oxide	B02010199	36194
IBP4104	MICROPLAS MPS03	0.3 m^2 plasmafilter sterilized by ethylene oxide	B02010199	36194

Sterilization method and validity

Sterile and non-pyrogenic

Sterilizing agent: Ethylene Oxide

Shelf life ethylene oxide sterilization: 5 years

Do not resterilize

Technical characteristics

The technical characteristics of the MICROPLAS Plasmafilter are reported below.

MICROPLAS Plasmafilter	
Components	**Materials**
Housing[1]	Polycarbonate
Luer Lock[1]	Polycarbonate
Fiber[1]	Polyethersulfone
Headers[1]	Polycarbonate
O-ring[1]	Thermoplastic Elastomer
Potting Compound[1]	Polyol[3]
	Isocyanate[3]
Protective Caps[2]	High density Polyethylene
Blood Port Caps[2]	Polypropylene

[1] In contact with blood and fluids

[2] Not in contact with blood and fluids

[3] The component "potting" is obtained from the mixture and polymerization of two components: component A (Polyol) and component B (Isocyanate). The resulting material is known as polyurethane.

Model	Surface area (m^2)	Number of hollow fibers	Wall thickness (µm)	Inside diameter (µm)	Maximum pore width (µm)	Total length[4] (mm)	External diameter[4] (mm)	Filling volume blood compartment (mL)
MICROPLAS MPS03	0.30	1300	100	300	0.5	305	55	30
MICROPLAS MPS05	0.45	2000	100	300	0.5	305	55	50
MICROPLAS MPS07	0.68	3000	100	300	0.5	305	55	70

[4] Outer body characteristics

Performance

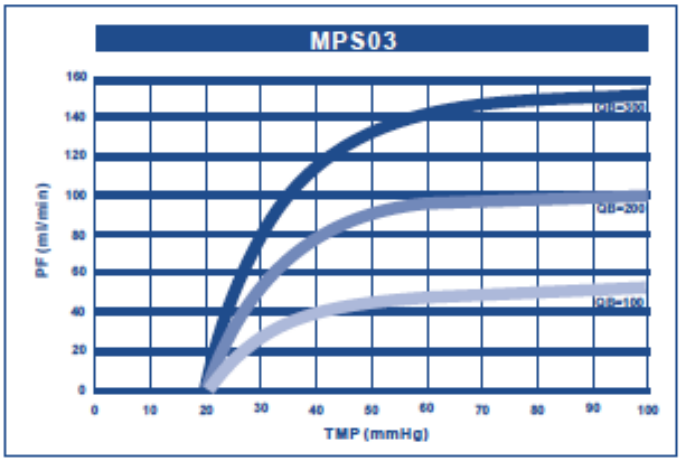
The measurements in the following chart are in accordance with EN ISO 8637-3. The table indicates the nominal values of the individual models obtained from random sampling at the end of the production process.

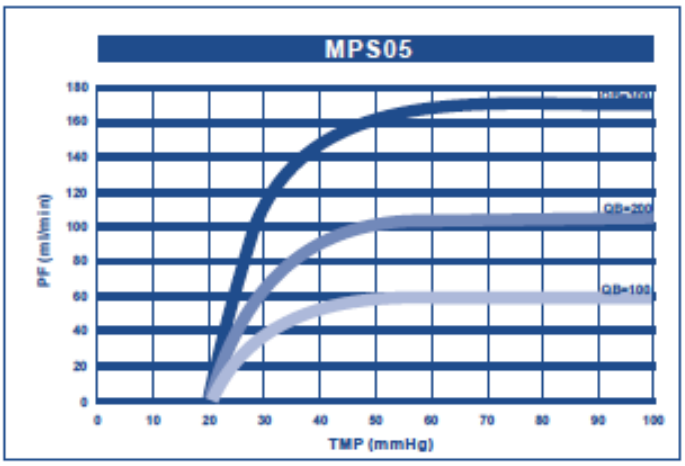
		MICROPLAS MPS03	MICROPLAS MPS05	MICROPLAS MPS07
Sieving coefficient	Albumin	~1	~1	~1
	IgM	~1	~1	~1
	B-Lipoproteins	~1	~1	~1

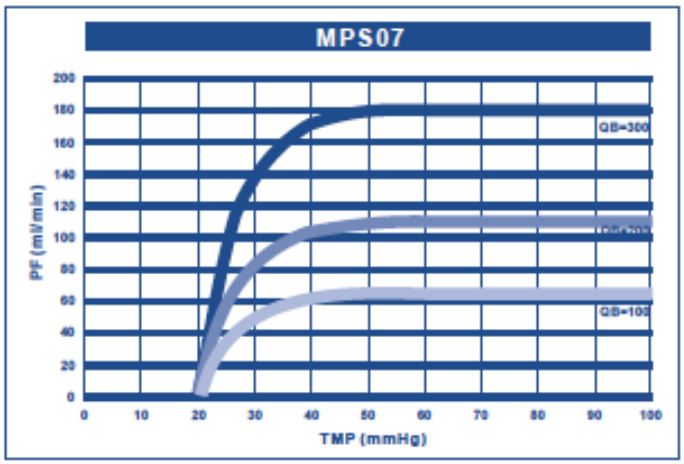
	MICROPLAS MPS03	MICROPLAS MPS05	MICROPLAS MPS07
Pressure drop blood compartment[5]	<50 mmHg	<40 mmHg	<30 mmHg

[5] Q_b = 100mL/min

The filtration fraction is in relation to TMP and Qb as shown in the following graphs:







Packaging

Model	Primary packaging – Pouch	
	Material	Pouch weight (g)
MICROPLAS MPS03 MICROPLAS MPS05 MICROPLAS MPS07	Nylon (oriented polyamide)/Polypropylene envelope transparent with medical paper Dimension of pouch: 40 x 11 cm	8.3
	Medical Paper includes a sealing layer of Polypropylene Dimension of Medical Paper: 12.4 x 4.6 cm	

Model	Secondary packaging – Box		
	Box	Weight[6] (kg)	Pcs/ Box[7]
MICROPLAS MPS03	Individual box – Kraftliner white top, medium and testliner with configuration Rippled Cardboard – Micro Flute – 1.7mm Dimensions: 32 x 8 x 8 cm	0.2	1
	Generic box – Kraftliner, uso semichimica and fluting with configuration Rippled Cardboard – BC Flute – 6.5mm Dimensions: 41.0 x 34.2 x 24.8	4.2	15
MICROPLAS MPS05	Individual box – Kraftliner white top, medium and testliner with configuration Rippled Cardboard – Micro Flute – 1.7mm Dimensions: 32 x 8 x 8 cm	0.3	1
	Generic box – Kraftliner, uso semichimica and fluting with configuration Rippled Cardboard – BC Flute – 6.5mm Dimensions: 41.0 x 34.2 x 24.8	4.3	15
MICROPLAS MPS07	Individual box – Kraftliner white top, medium and testliner with configuration Rippled Cardboard – Micro Flute – 1.7mm Dimensions: 32 x 8 x 8 cm	0.3	1
	Generic box – Kraftliner, uso semichimica and fluting with configuration Rippled Cardboard – BC Flute – 6.5mm Dimensions: 41.0 x 34.2 x 24.8	4.6	15

[6] Box weight filled with products

[7] There are fifteen individual boxes with in one MICROPLAS Plasmafilter, included in a generic box.

Storage and disposal conditions

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

Dispose of the device in accordance with the regulations in force.

Biocompatibility

Biocompatibility tests of the MICROPLAS Plasmafilters have been performed according to EN ISO 10993-1 and related applicable standard series.

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