Mozarc medical

Technical Data Sheet
BL 250 KIT 0075 CVVH

for Carpediem™ cardio renal pediatric dialysis emergency machine

Product Information

The Carpediem procedure pack is captive to use on the Carpediem™ system. This procedure pack is composed by the Carpediem preassembled device 0075 manufactured by Bellco S.r.l. and a 10 mL Luer Lok™* BD Plastipak syringe, that is manufactured by Becton Dickinson S.A.

The Carpediem preassembled device 0075 is sterile, single use, extracorporeal circuit and consists of a hemofilter and tubing lines, that are permanently connected, and three 3-litre waste bags. The hemofilter consists of a cylindrical body that contains a bundle of hollow fibers made of high permeability polysulfone. In the Carpediem preassembled device 0075, the hemofilter is connected to a blood access line, a blood return line, an infusion line, an effluent outlet line, and includes a heparin infusion line (figure 2).

The 10 mL Luer Lok™* BD Plastipak syringe is sterile, single use and inserted with its primary packaging in the procedure pack.

Figure 1. BL 250 KIT 0075 CVVH for Carpediem™ system

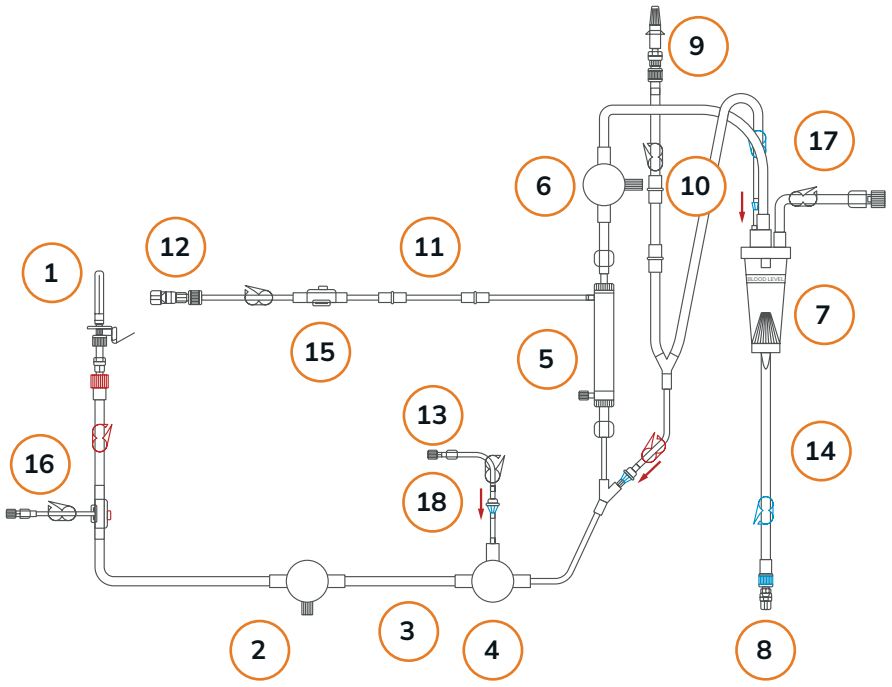

Figure 2

Legend

1) Arterial line Luer lock
2) Arterial pressure dome
3) Blood pump segment
4) Pre-filter pressure dome
5) Filter
6) Venous pressure dome
7) Venous chamber
8) Venous line Luer lock
9) Infusion line Luer lock
10) Infusion pump segment
11) Effluent pump segment
12) Effluent line Luer lock
13) Heparin line Luer lock
14) Venous return line
15) Effluent line with sampling port
16) Arterial service line
17) Venous service line
18) Heparin line

Applicable Therapies

The Carpediem preassembled device is indicated with the Carpediem™ system in extracorporeal blood treatment of pediatric patients weighing 2.5 kg or more with acute kidney injury, fluid overload and / or electrolyte disorders, requiring, hemofiltration (CVVH) or ultrafiltration / fluid removal (SCUF).

Depending on the configuration of the manual clamps, this device can perform the following treatments:

- **Continuous Veno-Venous Hemofiltration (CVVH),** a continuous form of hemofiltration with infusion of replacement fluid upstream (pre-infusion) or downstream (post-infusion) from the hemofilter. The solute transmembrane transport mechanism is convection. The ultrafiltrate is partly or completely replaced with an appropriate replacement fluid in order to obtain effective reduction of the solute concentration and effective fluid balance.

- **Slow Continuous Ultrafiltration (SCUF),** a treatment based solely on slow plasma water removal. It is generally used to manage patients who have fluid overload and / or are immune to pharmacologic treatment and may also have concomitant renal damage. The goal of the treatment is to achieve effective and safe correction of fluid overload. The solute concentration cannot be reduced using this treatment. SCUF treatment may be performed by programming CVVH therapy with an infusion volume equal to 0 mL.

Intended Use

Carpediem procedure pack for CVVH (Continuous Veno-Venous Hemofiltration) therapy.

Codes Available

CFN Procedure Pack	Procedure Pack Name	Medical Device Code	Medical Device Name	Medical Device Manufacturer	EMDN / CND[1]	GMND[1]
IB0595510	BL250 KIT 0075 CVVH	IB0580800	Carpediem preassembled device 0075	Bellco S.r.l. Via Camurana 1 41037 Mirandola (MO) Italy. CE0123	EMDN: Z12090385	61674
		305959	BD Plastipak™* Syringe 10 mL Luer-Lok™*	Becton Dickinson S.A. Camino de Valdeoliva, s / n 28750 San Agustín del Guadalix, Madrid, Spain. CE0318	CND: A020102020102	47017

[1] The EMDN, CND and GMDN indicated in the table above refer to the Carpediem preassembled device 0075 and Plastipak™* Syringe 10 mL Luer-Lok™*

Sterilization method and validity

The Carpediem procedure pack is non-sterile and non-pyrogenic and has a shelf life of 3 years.

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

In particular, the Carpediem preassembled device 0075 and the syringe are sterile and non-pyrogenic. Their sterilizing agent is ethylene oxide and they cannot be re-sterilized. The shelf life of a preassembled device is 3 year and the syringe is 5 years.

Technical Characteristics

The technical characteristics of the Carpediem procedure packs components are reported below.

Carpediem Preassembled device 0075

Bloodlines	
Components	**Materials**
Tubing lines	Polyvinyl chloride (PVC)
Blood pump segment	Polyvinyl chloride (PVC)
Infusion pump segment	Polyvinyl chloride (PVC)
Heparin line	Polyvinyl chloride (PVC)
Pressure transducer membrane	Silicon rubber
Tube adapter	Polyvinyl chloride (PVC)
Line connector	Polyvinyl chloride (PVC) Methylmethacrylate acrylonitrile butadiene styrene (MABS)
Pressure traducer holder	Polyvinyl chloride (PVC)
Venous chamber	Polyvinyl chloride (PVC)
Venous chamber filter	Polyethylene (PE)
Filter connector	Polyvinyl chloride (PVC)
Access port	Polyvinyl chloride (PVC) Isoprene Polypropylene (PP)
Clamps	Polypropylene (PP)
INF / UF luer connector ring	Polycarbonate (PC)
Venous drip chamber service line cap	High density Polyethylene (HDPE)
INF Y connector	Polyvinyl chloride (PVC)
One-way valve	Silicon rubber Methylmethacrylate acrylonitrile butadiene styrene (MABS)
Port caps	Polypropylene (PP)
Vented spike	Acrylonitrile butadiene styrene (ABS) Low density polyethylene (LDPE) Linear low density polyethylene (LLDPE) Acrylic Polyamide (PA Polyvinyl chloride (PVC)
Unvented spike	Acrylonitrile butadiene styrene (ABS) Low density polyethylene (LDPE)
INF / UF luer connector	Polyvinyl chloride (PVC)

Hemofilter Model		HCD 0075
Hemofilter Surface area (m^2)		0.075 ± 0.010
Hemofilter Fiber wall thickness (µm)		50
Hemofilter Fiber internal diameter (µm)		250
Hemofilter Blood compartment priming volume (mL)		5
Hemofilter Maximum TMP (mmHg)		500
Hemofilter Maximum blood flow (mL / min)		50
Hemofilter Maximum infusion flow (mL / min)		2.5
Hemofilter Blood compartment pressure drop[1] (mmHg)	Q_B 10 mL / min	21
	Q_B 50 mL / min	40
Hemofilter Total length[2] (mm)		128
Total priming volume preassembled device (mL)		26

[1] Bovine blood: Hct = 32 ± 3%, protein = 60 ± 5 g / L

[2] Hemofilter outer body characteristic

Hemofilter HCD 0075	
Components	**Materials**
Membrane	Polysulfone
Housing	Copolyester
Header	Copolyester
Potting	Polyurethane

3-litre Waste Bag	
Components	**Materials**
Film	Polyvinyl chloride (PVC) DOP free
Tube	Polyvinyl chloride (PVC) DOP free
Joint female Luer lock	Polyvinyl chloride (PVC)
Vented male cone cap	Polypropylene (PP)
Clamp	Polypropylene (PP)

Syringe - Plastipak™* / Syringe 10 mL Luer-Lok™*

Syringe[1]	
Components	**Materials**
Syringe Barrel	Polypropylene (PP)
Barrel lubricant	Medical grade silicon
Plunger	Polypropylene (PP)
Plunger colorant	PE / F
Stopper	Polyisoprene black rubber or Black TPE Copolymer
Scale	Ink / Dissolvent

[1] Technical data provided by the manufacturer Becton Dickinson S.A in data sheet EMEA-SOP039-F1

Performance

The measurements are taken in accordance with EN ISO 8637-1.† 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 different ISO standard mentioned in the document are in current revision.

Hemofilter - HCD 0075

Ultrafiltration Coefficient - K_{uf} (mL / h*mmHg)[1]	
Q_B 10 mL / min	Q_B 50 mL / min
2.4	2.7

Hemofilter Sieving Coefficient	
Inulin	1.0
Myoglobin	0.72
Albumin	0.005

[1] Bovine blood: Hct= 32 ± 3%, protein = 60 ± 5 g / L

Packaging

Model	Primary packaging		
	Pouch material	Tray	Pouch weight (g)
Carpediem preassembled device 0075	Polyester / Polypropylene (PET / PP) Medical grade paper 60g / m^2	Polypropylene (PP)	30

Model	Secondary Packaging - Box				
	Single Box	Weight[1] (kg)	Multiple Box	Weight[2] (kg)	UOM
BL250 KIT 0075 CVVH	White colored Rippled Cardboard 4 mm – KBM / 222 / B Dimensions: 560 x 377 x 71 mm	0.7	Avana colored Rippled Cardboard 4 mm Dimensions: 582 x 382 x 297 mm	4.0	4 / CT

[1] Single box's weight

[2] Multiple box's weight

Storage and Disposal Conditions

Storage conditions: store at temperatures between +5 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 device and 10 mL Luer Lok™* BD Plastipak syringe for Carpediem™ machine have been performed according to ISO 10993-1[1] and related applicable standard series.

Biocompatibility tests are the responsibility of the manufacturer of the medical devices inside the procedure packs.

Disclaimer

Carpediem Preassembled Device 0075 is a non-active, non-invasive, class IIb CE0123 medical device manufactured by Bellco S.r.l.

BD Plastipak syringe is a medical device manufactured by Becton Dickinson S.A.

They are included in the Carpediem Procedure Pack.

For technical details regarding BD Plastipak™* Syringe 10 mL Luer-Lok™* contact the manufacturer Becton Dickinson S.A.

Important: Please refer to the package inserts for complete instructions, contraindications, warnings and precautions in your respective geography.

Mozarc Medical
EMEA Regional Headquarters
Via Varesina, 162
20156 Milano MI, Italy

emeacontactus@mozarcmedical.com
mozarcmedical.com/products/emea-en/
LinkedIn