Technical Data Sheet

BL 250 KIT 015 and 025 CVVH-CVVHD

for Carpediem™ Cardio Renal Pediatric Dialysis Emergency Machine

Product Information

The Carpediem procedure packs are captive to use on the Carpediem system. These procedure packs are composed by Carpediem preassembled device 015 or Carpediem preassembled device 025 manufactured by Bellco S.r.l and a 10 mL Luer Lok™* BD Plastipak syringe, that is manufactured by Becton Dickinson S.A.

Each Carpediem preassembled device is sterile, single use, extracorporeal circuit and consists of a dialyzer and tubing lines, that are permanently connected, and three 3-liter waste bags. The dialyzer consists of a cylindrical body that contains a bundle of hollow fibers made of high permeability polyethersulfone.

The two Carpediem preassembled devices have different hollow-fiber dialyzer sizes (HCD 015 and HCD 025), but they have same tubing line configuration: a blood access line, a blood return line, a dialysate / 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 015 CVVH / CVVHD for Carpediem system, as example

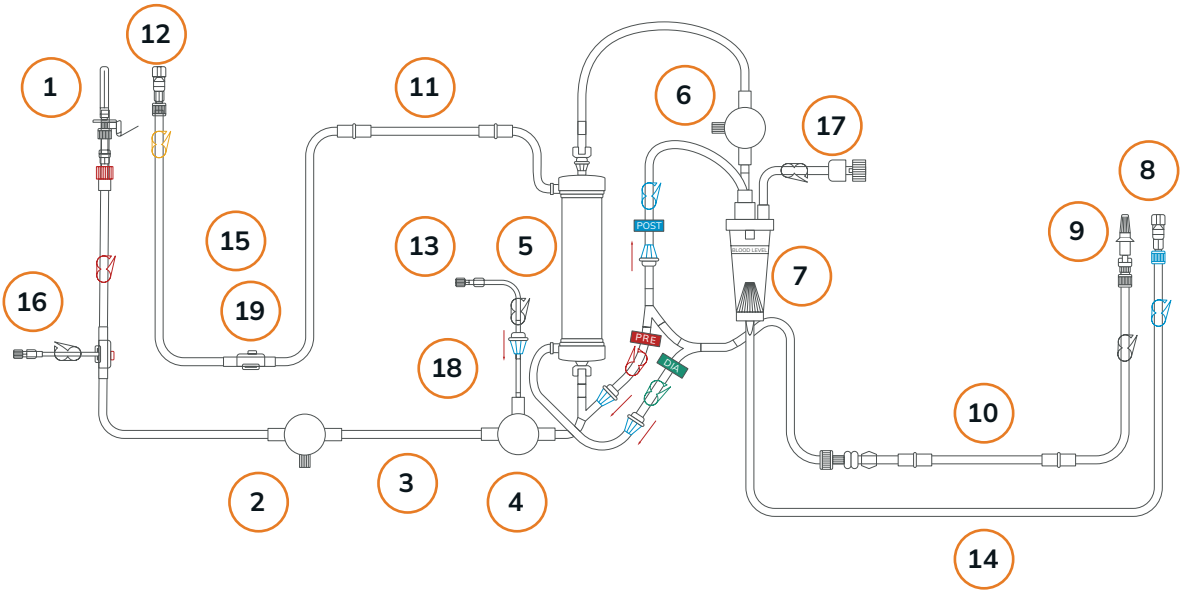

Figure 2

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 / dialysis line Luer lock
10) Infusion / dialysis pump segment
11) Effluent pump segment
12) Effluent line Luer lock
13) Heparin line Luer Lock
14) Venous return line
15) Effluent line
16) Arterial service line
17) Venous service line
18) Heparin line
19) Effluent line sampling port

Applicable Therapies

The Carpediem preassembled devices are indicated for use with the Carpediem system in extracorporeal blood treatment for pediatric patients weighing 2.5 kilograms or more with acute kidney injury, fluid overload and / or electrolyte disorders, requiring hemofiltration (CVVH), hemodialysis (CVVHD) or ultrafiltration / fluid removal (SCUF).

Depending on the configuration, these devices can perform the following treatments:

- **Continuous Veno-Venous Hemodialysis (CVVHD),** a continuous form of hemodialysis characterized by a slow dialysate flow with respect to the blood flow in the dialysate compartment of the hemodialyzer. The main solute transmembrane removal mechanism is diffusion.

- **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 packs for CVVH (Continuous Veno-Venous Hemofiltration) and CVVHD (Continuous Veno-Venous Hemodialysis) therapies.

Codes Available

CFN Procedure Pack	Procedure Pack Name	Medical Device Code	Medical Device Name	Medical Device Manufacturer	EMDN / CND[1]	GMND[1]
IB0595540	BL250 KIT 015 CVVH / CVVHD	IB0580804	Carpediem preassembled device 015	Bellco S.r.l. Via Camurana 1 41037 Mirandola (MO) Italy. CE0123	EMDN: Z12090385 Z12090285	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
IB0595550	BL250 KIT 025 CVVH / CVVHD	IB0580805	Carpediem preassembled device 025	Bellco S.r.l. Via Camurana 1 41037 Mirandola (MO) Italy. CE0123	EMDN: Z12090385 Z12090285	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 devices 015 and 025 and Plastipak™* Syringe 10 mL Luer-Lok™*

Sterilization method and validity

The Carpediem procedure packs are non-sterile and non-pyrogenic their shelf life is of 3 years.

The shelf life of the procedure packs are determined by the component with the shortest shelf life.

In particular, the Carpediem preassembled devices 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 015 and 025

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 transducer 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)

Dialyzer Model		HCD 015	HCD 025
Dialyzer Surface area[1] (m^2)		0.16	0.29
Fiber wall thickness (µm)		30	30
Fiber internal diameter (µm)		200	200
Blood compartment priming volume (mL)		11	20
Maximum TMP (mmHg)		500	500
Maximum blood flow (mL / min)		50	50
Maximum dialysate flow (mL / min)		10	10
Blood compartment pressure drop[2] (mmHg)	Q_B 10 mL / min	19	22
	Q_B 50 mL / min	32	35
Dialysis fluid compartment pressure drop[3] (mmHg)	Q_D 10 mL / min	10	17
Total length[4] (mm)		128	140
Total priming volume preassembled device (mL)		32	41

[1] Medium value ± 10% according with IFU

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

[3] Dialysis fluid: NaCl = 0.9%

[4] Dialyzer outer body characteristic

Dialyzer	
Components	**Materials**
Membrane	Polysulfone
Housing	Copolyester
Header	Copolyester
Potting	Polyurethane
O-ring[1]	Silicone Rubber

[1] Only for 025

3-liter 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 performance data provided refers to in-vitro tests performed in accordance with ISO 8637-1. The values indicated are to be considered approximate and may be 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.

Dialyzer model	In Vitro clearance[1] (mL / min)															
	Urea				Creatinine				Phosphates				Vitamin B12			
	Q_B 5	Q_B 10	Q_B 20	Q_B 50	Q_B 5	Q_B 10	Q_B 20	Q_B 50	Q_B 5	Q_B 10	Q_B 20	Q_B 50	Q_B 5	Q_B 10	Q_B 20	Q_B 50
HCD 015	2.8	4.2	5.6	7.8	2.9	4.3	5.7	7.8	3.0	4.4	5.5	7.7	3.0	4.3	5.0	6.5
HCD 025	2.6	4.0	5.4	7.2	2.8	4.2	5.8	7.5	2.8	4.3	5.8	7.2	2.9	4.3	5.5	6.7

[1] In vitro clearance: Q_D = 10 mL / min, Q_F = 0 mL / min; saline solution: NaCl = 0.9%

Dialyzer model	Clearance at maximum Q_F and Q_D (mL / min)[1]			
	Urea	Creatinine	Phosphates	Vitamin B12
HCD 015[2]	10.6	10.7	10.6	9.2
HCD 025[3]	10.9	11.1	11.1	10.5

[1] Saline solution: NaCl = 0.9%, Q_D = 10 mL / min

[2] Q_F = 14 mL / min, Q_B = 50 mL / min, Q_D = 10 mL / min

[3] Q_F = 15 mL / min, Q_B = 50 mL / min, Q_D = 10 m L / min

Ultrafiltration Coefficient - K_{uf} (mL / h*mmHg)[1]			
Dialyzer model			
HCD 015		HCD 025	
Q_B 10 mL / min	Q_B 50 mL / min	Q_B 10 mL / min	Q_B 50 mL / min
4.8	9.8	9.0	22.1

Dialyzer Sieving Coefficient		
Marker	HCD 015	HCD 025
Inulin	0.8	0.8
Myoglobin	0.34	0.34
Albumin	0.002	0.002

[1] Bovine blood: Hct = 32 ± 3%, protein = 6 0 ± 5 g / L

Packaging

Model	Primary packaging		
	Pouch material	Tray	Pouch weight (g)
BL250 015 KIT 015 CVVH / CVVHD	Polyester / Polypropylene (PET / PP) Medical grade paper 60g / m^2	Polypropylene (PP)	30
BL250 025 KIT 025 CVVH / CVVHD	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 015 KIT 015 CVVH / CVVHD	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: 590 x 390 x 324 mm	4.0	4 / CT
BL250 025 KIT 025 CVVH / CVVHD	White colored Rippled Cardboard 4 mm – KBM / 222 / B Dimensions: 560 x 377 x 71 mm	0.8	Avana colored Rippled Cardboard 4 mm Dimensions: 590 x 390 x 324 mm	4.4	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: after its use, the preassembled device and all the connected components must be disposed of in accordance with the guidelines or procedures in force in the hospital / clinic for dangerous hospital medical waste.

Biocompatibility

Biocompatibility tests of the preassembled devices and syringe for Carpediem system 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 Devices 015 and 025 are non-active, non-invasive, class IIb CE medical devices 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.

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