# Medtronic

### **TECHNICAL DATA SHEET**

# Bicompartmental dialysis solution for continuous renal replacement therapy



## Indication for use

Intended for use as a dialysis solution in Continuous Renal Replacement Therapy.

### **Description**

This bag is a bicarbonate based dialysis solution packaged in a ready to mix, sterile, non-pyrogenic, bi-chambered solution container system. One chamber contains the acidic solution and one chamber contains the basic solution. At the point of use, the membrane between the two chambers is broken, and the acidic and basic solutions are mixed to form the final ionic composition of the solution to be used in the Continuous Renal Replacement Therapy (CRRT) treatment.

The solution is offered in bi-chambered volumes of 500+1500 ml. The chemical composition of the final solution is located in the table below.

### **Formulation**

Solution A		
	g/l	
$C_6H_{12}O_6\;H_2O$	4.40	
KCI	0.75	
CaCl <sub>2</sub> 2H <sub>2</sub> O	0.88	
MgCl <sub>2</sub> 6H <sub>2</sub> O	0.61	
HCI 37%	1.18	
WFI q.s.	1000 ml	

Solution B	
	g/l
NaCl	8.18
NaHCO <sub>3</sub>	3.92
WFI q.s.	1000 ml

Final solution	
Ca <sup>2+</sup>	1.5 mmol/l
HCO <sub>3</sub> ·	32 mmol/l
K <sup>+</sup>	2.5 mmol/l
PO <sub>4</sub> <sup>3-</sup>	0
Mg <sup>2+</sup>	0.75 mmol/l
Na⁺	140 mmol/l
CI-	115 mmol/l
C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	5.55 mmol/l
Theoretical Osmolarity	297.3 mOsm/l

# **Packaging specifications**

# A. Primary packaging

Flexible bag of non-PVC material (Nexcel<sup>™</sup> film). It is a non-reusable, bi-chambered bag; 500 ml for Solution A, 1500 ml for Solution B, to be mixed before use.

The bi-chambered bag is equipped with three different systems: breakable cone, blind closure, and injection port (latex-free rubber).

# B. Secondary packaging

Vacuum packaging with double-layer barrier film PP/PA.

# C. UOM packaging

Cardboard box containing four (4) bags of 500 ml + 1500 ml bi-chambered bags.



# Ordering information

Capital		
CFN code	Description	UOM
IB7010200	Carpediem™ machine	1 EA
LB22B2685	Biegler Warmer BW685	1 EA

Disposables/consumables				
IB0595510	BL 250 Hemofiltration kit 0075 for Carpediem™	4/CT		
IB0595540	BL 250 Hemofiltration/Hemodialysis Kit 015 for Carpediem $^{\! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! $	4/CT		
IB0595550	BL 250 Hemofiltration/Hemodialysis Kit 025 for Carpediem™	4/CT		
IB0930250/MD087	HMB32 - ml 500 + 1500	4/CT		
IB0507007	3 I non-sterile waste bags	20/CT		
FP4600203	Biegler Warmer tubing set	20/CT		

### Not for use in the U.S.

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