Baxter

PRISMAFLEX System M60/M100/M150

Hemofilter Sets

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PRISMAFLEX System M60/M100/M150 Sets

Preconnected Hemofilter Sets with the AN 69 Dialyzer Membrane for CRRT

The PRISMAFLEX Set is indicated for use only with the PRISMAFLEX Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

This set is intended for use in the following veno-venous therapies: SCUF; CVVH; CVVHD; CVVHDF.

All treatments administered via the PRISMAFLEX Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

The PRISMAFLEX M100 & M150 Sets should be restricted to patients with a body weight greater than 30 kg (66 lb). The pediatric use of the PRISMAFLEX M60 Set should be restricted to children with a body weight greater than 11 kg (24 lb) with respect to extracorporeal blood volume.

The M150, M100 and M60 hemofilter sets are designed for prescription flexibility on the PRISMAFLEX System. Both set configurations are created with the AN 69 Dialyzer Membrane and can be used to perform all CRRT therapies (SCUF, CVVH, CVVHD and CVVHDF).

General data

	PRISMAFLEX M60 Set	PRISMAFLEX M100 Set	PRISMAFLEX M150 Set
Weight	780 g	800 g	860 g
Overall dimensions	27 x 22 x 9 cm	27 x 22 x 9 cm	27 x 22 x 9 cm
Blood volume in set ± 10 %	93 ml	152 ml	189 ml
Minimal patient weight	11 Kg	30 Kg	30 Kg

Materials

- AN 69 HF hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer
- Filter housing and headers: Polycarbonate
- Filter potting compound: Polyurethane
- Tubing material: plasticized polyvinyl chloride (PVC)
- Cartridge: PETG
- Sterilization mode: EtO (ethylene oxide)
- Not made with natural rubber latex
- Contains DEHP, which may pose risks to infant development

Filter operating specifications

- Maximum TMP* (mmHg/kPa): 450/60
- Maximum blood pressure (mmHg/kPa): 500/66.6
- Minimum blood flow rate:
  PRISMAFLEX M60 Set: 50 ml/min
  PRISMAFLEX M100 Set: 75 ml/min
  PRISMAFLEX M150 Set: 100 ml/min

Filter data

- Nominal physical characteristics
  - Effective surface area:
    PRISMAFLEX M60 Set: 0.6 m^2
    PRISMAFLEX M100 Set: 0.9 m^2
    PRISMAFLEX M150 Set: 1.5 m^2
  - Fiber internal diameter (wet): 240 µm
  - Fiber wall thickness: 50 µm

Sieving coefficient

- (bovine plasma, Pc 60 g/l, T = 37°C)
  Urea = 1, Creatinine = 1, Vitamin B12 = 1, Inulin = 0.95, Myoglobin = 0.55, Albumin <0.01

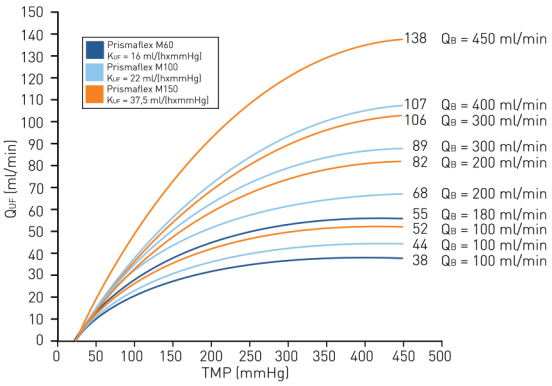
In vitro performances

- Blood priming volume in filter ±10%:
  PRISMAFLEX M60 Set: 42 ml
  PRISMAFLEX M100 Set: 66 ml
  PRISMAFLEX M150 Set: 105 ml
- Blood pressure drop (in post dilution mode)
  (bovine blood, Hematocrit 32%, Pc*** = 60 g/l, T = 37°C)

	PRISMAFLEX M60 Set	PRISMAFLEX M100 Set	PRISMAFLEX M150 Set
Q_B** = 100 ml/min - Q_{UF}**** = 1 l/h	47 mmHg	31 mmHg	20 mmHg
Q_B** = 180 ml/min - Q_{UF}**** = 2 l/h	91 mmHg	60 mmHg	—
Q_B** = 300 ml/min - Q_{UF}**** = 2 l/h	—	73 mmHg	51 mmHg
Q_B** = 400 ml/min - Q_{UF}**** = 2 l/h	—	105 mmHg	64 mmHg
Q_B** = 450 ml/min - Q_{UF}**** = 2 l/h	—	—	70 mmHg

CVVH Performances

- "In vitro" ultrafiltration with blood (in post-dilution)
  (values ±15%) (Continuous venovenous hemofiltration)
  (Bovine blood at 37°C, Hematocrit 32%, Pc*** 60 g/l).



CVVHD Clearances

- Clearances versus inlet dialysate flow rate
  (Continuous venovenous hemodialysis) (Saline, T = 37°C).

	PRISMAFLEX M60 Set Q_B** = 100 ml/min Q_{UF}**** = 0 ml/min			PRISMAFLEX M100 Set Q_B** = 150 ml/min Q_{UF}**** = 0 ml/min				PRISMAFLEX M150 Set Q_B** = 200 ml/min Q_{UF}**** = 0 ml/min			
QD l/h ml/min	1 17	2.5 42	4 67	1 17	2.5 42	4 67	8 133	1 17	2.5 42	4 67	8 133
Urea (±10%)	17	39	54	17	41	63	95	17	42	66	117
Vitamin B12 (±20%)	14	23	28	16	30	37	45	17	37	49	64
Inulin (±20%)	12	17	19	14	23	26	30	16	31	37	45

*Transmembrane pressure.
**Access blood flow rate.
***Protein concentration.
****Ultrafiltration flow rate (1).
(1)The ultrafiltration flow rate is the "patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate."

Ordering information

	Factory ID	Code No.	No. Units/Box
PRISMAFLEX M60 Set	8353510	106696	4
PRISMAFLEX M100 Set	8353520	106697	4
PRISMAFLEX M150 Set	8353584	109990	4
SP414 - 5-liter bag	6032957	106690	50
SP418 - 9-liter bag	6033765	107650	30

Contact your local Baxter sales representative to learn more about the product.
For Customer Support, call 800-525-2623.

Rx Only. For the safe and proper use of the devices mentioned herein, please refer to the *Instructions for Use*.

www.baxter.com
USMP/MG120/14-0003(2) 1000 01/16

59.2 poz.

Prismaflex sets with the AN 69 ST membrane for CRRT

Prismaflex ST60, ST100, ST150 sets

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Prismaflex ST60 Set / ST100 Set / ST150 Set

The **Prismaflex** set is indicated for use only with the **Prismaflex** Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both. This set is intended for use in the following veno-venous therapies: SCUF, CVVH, CVVHD, CVVHDF.

General Data

	Prismaflex ST60 set	**Prismaflex** ST100 set	**Prismaflex** ST150 set
Weight	795 g	830 g	905 g
Overall dimensions	27 x 22 x 9 cm	27 x 22 x 9 cm	27 x 22 x 9 cm
Blood volume in set ± 10 %	93 ml	152 ml	189 ml
Minimal patient weight	11 kg	30 kg	30 kg

Materials

AN 69 ST hollow fiber:
- Acrylonitrile and sodium methallyl sulfonate copolymer
- Surface treatment agent: Polyethylene imine

Filter housing and headers: Polycarbonate

Filter potting compound: Polyurethane

Tubing material: Plasticized polyvinyl chloride (PVC)

Cartridge: PETG

Sterilization mode: EtO (ethylene oxide)

Filter operating specifications

Maximum TMP* (mmHg/kPa)	450/60
Maximum blood pressure (mmHg/kPa)	500/66.6

Range of blood flow rate:
Prismaflex ST60 set: 50–180 ml/min
Prismaflex ST100 set: 75–400 ml/min
Prismaflex ST150 set: 100–450 ml/min

Filter data

Nominal physical characteristics

Effective surface area:
Prismaflex ST60 set: 0.6 m^2
Prismaflex ST100 set: 1 m^2
Prismaflex ST150 set: 1.5 m^2

Fiber internal diameter (wet)	240 µm
Fiber wall thickness	50 µm

In Vitro Performances

Blood priming volume in filter ±10%

Prismaflex ST60 set: 44 ml
Prismaflex ST100 set: 69 ml
Prismaflex ST150 set: 105 ml

Blood pressure drop (in post dilution mode)

(Bovine blood, Hematocrit 32%, Cp*** = 60 g/l, T = 37°C)

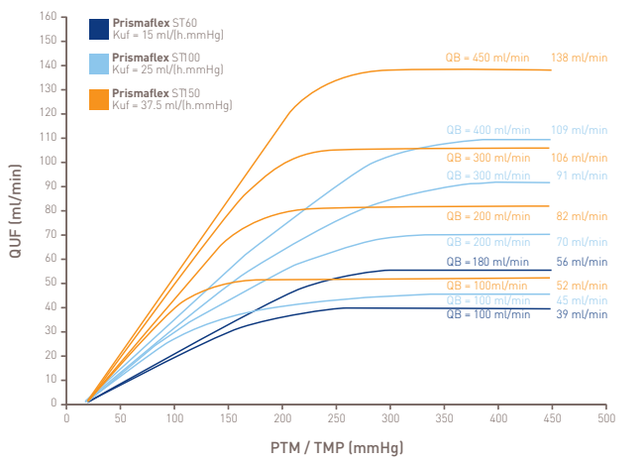
	Prismaflex ST60 set	**Prismaflex** ST100 set	**Prismaflex** ST150 set
Q_B** = 100 ml/min - Q_{UF}**** = 1l/h	46 mmHg	31 mmHg	20 mmHg
Q_B = 180 ml/min - Q_{UF} = 2l/h	84 mmHg	55 mmHg	–
Q_B = 300 ml/min - Q_{UF} = 2l/h	–	79 mmHg	51 mmHg
Q_B = 400 ml/min - Q_{UF} = 2l/h	–	100 mmHg	64 mmHg

Sieving coefficient

Q_B** = 100 ml/min, Q_{UF}**** = 20 ml/min
(Bovine plasma, Cp 60 g/l, T = 37°C)
Urea = 1, Creatinine = 1, Vitamin B_{12} = 1, Inulin = 0.96, Myoglobin = 0.58, Albumin <0.01

CVVH performances

"In vitro" ultrafiltration with blood (in post-dilution)
(values ±20%) (Continuous venovenous hemofiltration)
(Bovine blood at 37°C, Hematocrit 32%, Cp*** 60 g/l).



CVVHD clearances

Clearances versus inlet dialysate flow rate
(Continuous venovenous hemodialysis) (Saline, T = 37°C).

	Prismaflex ST60 set Q_B** = 100 ml/min Q_{UF}**** = 0 ml/min			**Prismaflex** ST100 set Q_B** = 150 ml/min Q_{UF}**** = 0 ml/min				**Prismaflex** ST150 set Q_B** = 200 ml/min Q_{UF}**** = 0 ml/min			
Q_D l/h ml/min	1 17	2.5 42	4 67	1 17	2.5 42	4 67	8 133	1 17	2.5 42	4 67	8 133
Urea (±10%)	17	40	56	17	41	63	97	17	42	66	117
Vitamin B_{12} (±20%)	15	26	30	16	32	41	50	17	38	51	68
Inulin (±20%)	13	19	22	15	26	30	35	16	33	40	49

*Transmembrane pressure.
**Access blood flow rate.
***Protein concentration.
****Ultrafiltration flow rate [1].
[1]The ultrafiltration flow rate is the "patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate".

Ordering Information

	Code N°	N° units/box
Prismaflex ST60 set **Prismaflex** ST60 set CKT	107643 115308	4
Prismaflex ST100 set **Prismaflex** ST100 set CKT	107636 115309	4
Prismaflex ST150 set **Prismaflex** ST150 set CKT	107640 115310	4
5-liter effluent bag	115959 (SP414) or 114423 (A6001)	40 (SP414) 50 (A6001)
9-liter effluent bag	107650 (SP418)	30

Sweden:
Baxter Medical AB
Box 63,
164 94 Kista
T: 08-632 64 00
www.baxter.se

Denmark:
Baxter A/S
Tobaksvejen 2A
2860 Søborg
T: 4816 6400
www.baxter.dk

Finland:
Baxter Oy
PL 119,
00181 Helsinki
T. (09) 8621 111
www.baxter.fi

Norway:
Baxter AS
Gjerdrumsvei 11
0484 Oslo
T: 22 58 48 00
www.baxter.no

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SE/MG120/16-0003, NO/MG120/16-0004, FI/MG120/16-0003, DK/MG120/16-0003

Baxter
Oxiris

59.3 poz.

OXIRIS Set

The OXIRIS Set has been Authorized by the FDA for the indication to treat patients with COVID-19 infection.

The OXIRIS Set is indicated for use only with the **PRISMAFLEX** control unit or with the **PRISMAX** control unit.

OXIRIS SET

OXIRIS SET GENERAL DATA	
Weight	890 g
Overall Dimensions	27 x 22 x 9 cm
Blood volume in set ± 10 %	193 ml
Minimal patient weight	30 kg

Materials

OXIRIS hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer + PolyethyleneImine (surface treatment agent) + heparin grafted (4500+/-1500 IU/m²)

Filter housing and headers: Polycarbonate

Filter potting compound: Polyurethane

Tubing material: Plasticized polyvinyl chloride (PVC)

Cartridge: PETG

Sterilization mode: EtO (ethylene oxide)

Filter operating specifications	
Maximum TMP* (mmHg/kPa)	450/60
Maximum blood pressure (mmHg/kPa)	500/66.6
Range of blood flow rate	100-450 ml/min

Filter data	
Nominal physical characteristics:	
Effective surface area	1.5 m²
Fiber internal diameter (wet)	240 µm
Fiber wall thickness	50 µm

IN VITRO PERFORMANCES

CVVHD clearances

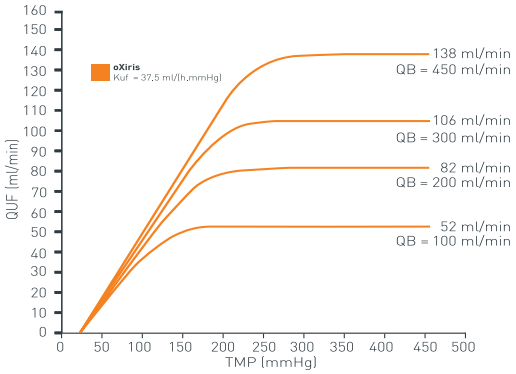
Clearances versus inlet dialysate flow rate
(Continuous veno-venous hemodialysis) (Saline, T = 37°C).

	OXIRIS set Q_B** = 200 ml/min Q_{UF}**** = 0 ml/min			
QD l/h ml/min	1 17	2.5 42	4 67	8 133
Urea (±10%)	17	42	66	117
Vitamin B_{12} (±20%)	17	38	51	68
Inulin (±20%)	16	33	40	49

*Transmembrane pressure.
**Access blood flow rate.
***Protein concentration.
****Ultrafiltration flow rate[1].
[1] The ultrafiltration flow rate is the "patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate".

CVVH performances[1]

"In vitro" ultrafiltration with blood (values ±15%)
(Continuous veno-venous hemofiltration)
(Bovine blood at 37°C, Hematocrit 32%, Cp*** 60 g/l).
Ultrafiltration is controlled by the **PRISMAFLEX** system and is independent of the ultrafiltration coefficient (KUF)



Sieving coefficient

(Bovine plasma, Cp 60 g/l, T = 37°C)
Q_B =100 ml/min, Q_{UF} = 20 ml/min

Urea	1
Vitamin B_{12}	1
Inulin	0.96
(Human plasma, Cp 60 g/l, T=37°C)	
Myoglobin	0.70
Albumin	<0.0045

Cytokine adsorption

Cytokine adsorption removal rate (%)[2]
(human plasma, Cp 60 g/l, 37°C)
Q_B = 150 ml/min, Q_{UF} = 0 ml/min

IL-10 (± 10%)	96
IL-6 (± 10%)	84
HMGB-1 (± 10%)	94
TNF-α (± 30%)	82

[2]Removal Rate expressed at t=120 min with a theoretical initial IL-10, IL-6, HMGB-1 and TNF-α respective concentration of 500 pg/ml, 1500 pg/ml, 30 ng/ml and 250 pg/ml.

Endotoxin adsorption

Lipopolysaccharide adsorption removal rate (%)[3]
(human plasma, Cp 60 g/l, 37°C)
Q_B = 150 ml/min, Q_{UF} = 0 ml/min

LPS (± 20%)	75

[3]Removal Rate expressed at t=120 min with an initial LPS concentration after stabilization of 50±10 EU/ml
Cp: Protein concentration
RR: removal rate
IL-10: Interleukin-10
IL-6: Interleukin-6
HMGB-1: High-mobility group box 1
TNF-α: Tumor necrosis factor – α
LPS: Lipopolysaccharide

ORDERING INFORMATION

	Code N°	N° units/box
OXIRIS S set	955503	4

1. Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. Adsorption removal rate obtained in vitro are likely to differ from in vivo results. Adsorption characteristics change with the duration of observation.

OXIRIS

Emergency Use Authorization for the United States

The OXIRIS Set has been Authorized by the FDA for the indication to treat patients with COVID-19 infection.

The OXIRIS Set has been authorized by FDA under EUA200164.

The OXIRIS Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the OXIRIS set under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Intended Use for Patients with COVID-19

The OXIRIS Set is indicated for use only with the PRISMAFLEX control unit or with the PRISMAX control unit.

It is intended to treat patients 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure in need of blood purification, including continuous renal replacement therapy, to reduce pro-inflammatory cytokine levels, who have any one of the following conditions:

- Early acute lung injury (ALI)/early acute respiratory distress syndrome (ARDS);
- Severe disease, such as:
  - dyspnea,
  - respiratory frequency ≥ 30/min,
  - blood oxygen saturation ≤ 93%,
  - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or
  - lung infiltrates >50% within 24 to 48 hours; or
- Life-threatening disease, defined as:
  - respiratory failure,
  - septic shock, and/or
  - multiple organ dysfunction or failure

The use of OXIRIS is contraindicated (as mentioned in the IFU) when:

- Patients present a known allergy to heparin or have type II thrombocytopenia caused by heparin (HIT Syndrome type II)
- A drug used simultaneously with OXIRIS is contraindicated per its Instructions for use

Relative contraindications (individual risk/benefit to be determined by treating physician) for the use of OXIRIS include:

- The inability to establish vascular access to safely perform CRRT/ hemoperfusion (SCUF; CVVH; CVVHD; CVVHDF)
- Severe hemodynamic instability
- Known hypersensitivity to any component of the OXIRIS Set

This set is intended for use in the following veno-venous therapies: SCUF; CVVH; CVVHD; CVVHDF.

All treatments administered with the OXIRIS Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

Rx Only. For safe and proper use of the devices mentioned herein, please refer to the Instructions for Use.

For more information, please contact your Baxter representative.

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Baxter HealthCare, One Baxter Parkway, Deerfield, IL 60015

USMP/MG146/20-0001 04/20

59.4 poz.

Prismaflex HF20 set

Prismaflex set for CRRT in low body weight patients.
The **Prismaflex** HF20 set should be used only for patients with a body weight above 8kg (18lbs).

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Prismaflex HF20 set

The **Prismaflex** set is indicated for use only with the **Prismaflex** control unit equipped with software version 4.00 or later in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

General Data

	Prismaflex HF20 Set
Weight	664 g
Overall dimensions	27 x 22 x 9 cm
Blood volume in set (±10%)	60 ml
Required volume for priming	500 ml
Materials	
PAES hollow fiber: Polyarylethersulfone	
Housing and headers: Polycarbonate	
Potting compound: Polyurethane	
Tubing material: Plasticized polyvinyl chloride (PVC)	
Cartridge: PETG	
Filter operating specifications	
Maximum TMP* (mmHg/kPa)	500/67
Maximum blood pressure (mmHg/kPa)	500/67
Minimum blood flow rate:	20 ml/min
Maximum blood flow rate:	100 ml/min
*Transmembrane pressure	
Filter data	
Nominal physical characteristics	
Effective surface area	0.2m²
Fiber internal diameter (wet)	215 µm
Fiber wall thickness	50 µm
Blood priming volume (filter only)	17 ml

In Vitro Performance Specifications†

Blood pressure drop (post-dilution)			
(Bovine blood, Q_{UF}*** = 0 l/h Htc**** 32%, Cp***** 60 g/l, 37°C)			
Q_B** = ml/min	20	50	100
Blood pressure drop (post dilution) mmHg	25	37	59

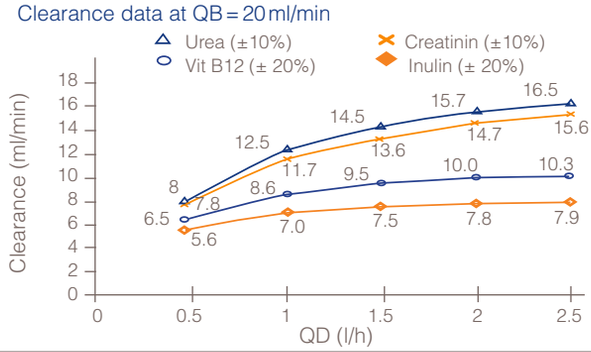
**Blood flow rate
***Ultrafiltration flow rate
****Hematocrit
*****Protein Concentration
†Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions.

Sieving coefficient
(Bovine plasma, Cp 60 g/l, T = 37°C) Q_B**= 50 ml/min, Q_{UF}*** = 10 ml/min Solute = SC, Urea = 1, Vitamin B12 = 1, Inulin = 0.92, Albumin <0.01

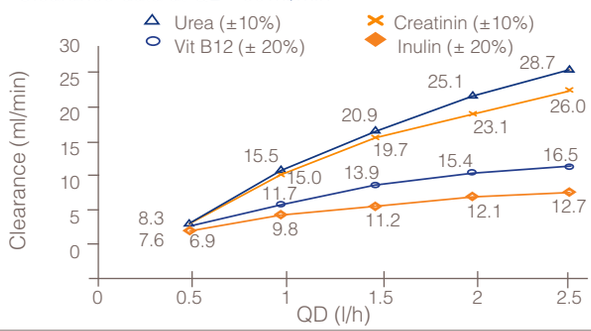
CVVHD clearances

(Continuous veno-venous hemodialysis). Clearances versus inlet dialysate flow rate (37°C) variable QD, variable QB, Q_{UF} = 0 ml/min

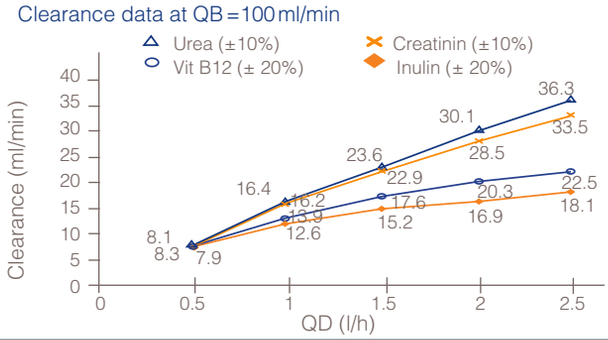
Clearance data at QB = 20 ml/min



Clearance data at QB = 50 ml/min

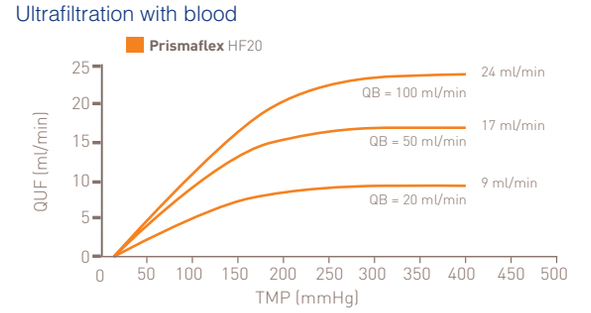


Clearance data at QB = 100 ml/min



CVVH performances

Ultrafiltration with blood



In vitro ultrafiltration with blood (values ± 20%). (Bovine blood at 37°C, Hct 32%, Protein concentration 60 g/l). Ultrafiltration is controlled by the **Prismaflex** system and is independent of the ultrafiltration coefficient (KUF).

Ordering Information

	Code N°	N° units/box
Prismaflex HF20 set	109841	4

Sweden:
Baxter Medical AB
Box 63,
164 94 Kista
T: 08-632 64 00
www.baxter.se

Denmark:
Baxter A/S
Tobaksvejen 2A
2860 Søborg
T: 4816 6400
www.baxter.dk

Finland:
Baxter Oy
PL 119,
00181 Helsinki
T: (09) 8621 111
www.baxter.fi

Norway:
Baxter AS
Gjerdrumsvei 11
0484 Oslo
T: 22 58 48 00
www.baxter.no

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NORD/MG31/18-0001 06/2018

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Prismaflex TPE 1000 and TPE 2000 Sets

Pre-connected sets for plasmafiltration

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Prismaflex TPE 1000 and TPE 2000 Sets

General Data

	Prismaflex TPE 1000 set	**Prismaflex** TPE 2000 set
Weight	680 g	760 g
Blood volume in set ± 10 %	71 ml	125 ml
Blood volume in plasmafilter	23 ml ±10%	41 ml ±10%
Minimal patient weight	9 kg	adult

Materials
Plasmafilter hollow fiber: Polypropylene
Filter housing and headers: Polycarbonate
Filter potting compound: Polyurethane
Tubing material: Plasticized polyvinyl chloride (PVC)
Cartridge: PETG
Sterilization mode: EtO (ethylene oxide)

Filter operating specifications
Maximum blood flow rate: **Prismaflex** TPE 1000 set: 180 ml/min **Prismaflex** TPE 2000 set: 400 ml/min
Minimum blood flow rate: **Prismaflex** TPE 1000 set: 50 ml/min **Prismaflex** TPE 2000 set: 100 ml/min
Maximum TMPa* (mmHg/kPa):

	Prismaflex TPE 1000 set	**Prismaflex** TPE 2000 set
Q_B** = 50 ml/min	100 mmHg - 13.3 kPa	–
Q_B** = 100 ml/min	140 mmHg - 18.7 kPa	120 mmHg - 16 kPa
Q_B** = 180 ml/min	190 mmHg - 25.3 kPa	–
Q_B** = 200 ml/min	–	171 mmHg - 22.8 kPa
Q_B** = 250 ml/min	–	193 mmHg - 25.7 kPa
Q_B** = 400 ml/min	–	246 mmHg - 32.8 kPa

Filter data	
Nominal physical characteristics	
Effective surface area: **Prismaflex** TPE 1000 set: 0.15 m² **Prismaflex** TPE 2000 set: 0.35 m²	
Fiber internal diameter (wet):	330 µm
Fiber wall thickness:	150 µm

Ordering Information

	Code N°	N° units/box
Prismaflex TPE 1000 set **Prismaflex** TPE 1000 set CKT	107143 115314	4
Prismaflex TPE 2000 set **Prismaflex** TPE 2000 set CKT	107144 115315	4

In Vitro Performances

Blood pressure drop ±30%

(Bovine blood, Htc***32%, Protein concentration 60 g/l, 37°C)

	Prismaflex TPE 1000 set	**Prismaflex** TPE 2000 set
Q_B** = 50 ml/min	14 mmHg - 1.9 kPa	–
Q_B** = 100 ml/min	29 mmHg - 3.9 kPa	25 mmHg - 3.3 kPa
Q_B** = 180 ml/min	52 mmHg - 6.9 kPa	–
Q_B** = 200 ml/min	–	51 mmHg - 6.8 kPa
Q_B** = 250 ml/min	–	64 mmHg - 8.5 kPa
Q_B** = 400 ml/min	–	101 mmHg - 13.5 kPa

*Arterial transmembrane pressure
**Access blood flow rate
***Hematocrit

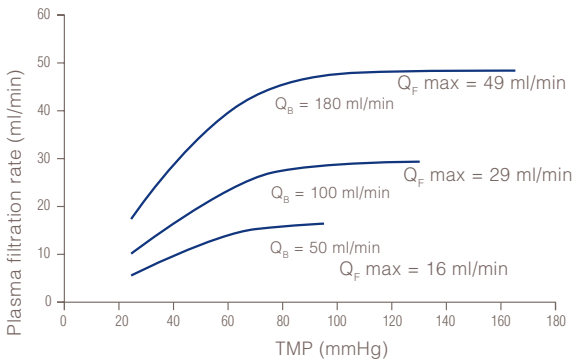
Sieving coefficient

(In vivo data, 19 treatments)
Albumin = 0.97, IgG = 1, Apolipoprotein B = 0.95, IgM = 0.92

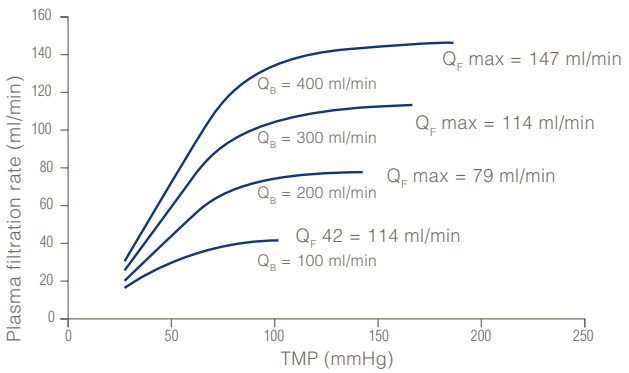
Plasma filtration with blood

In vitro, values ±20%
(Bovine blood at 37°C, Htc 32%, Protein concentration 60 g/l)
Plasma filtration is controlled by the **Prismaflex** system.

Prismaflex TPE 1000 set



Prismaflex TPE 2000 set



Sweden:
Baxter Medical AB
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www.baxter.se

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T: 4816 6400
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00181 Helsinki
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www.baxter.fi

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Gjerdrumsvei 11
0484 Oslo
T: 22 58 48 00
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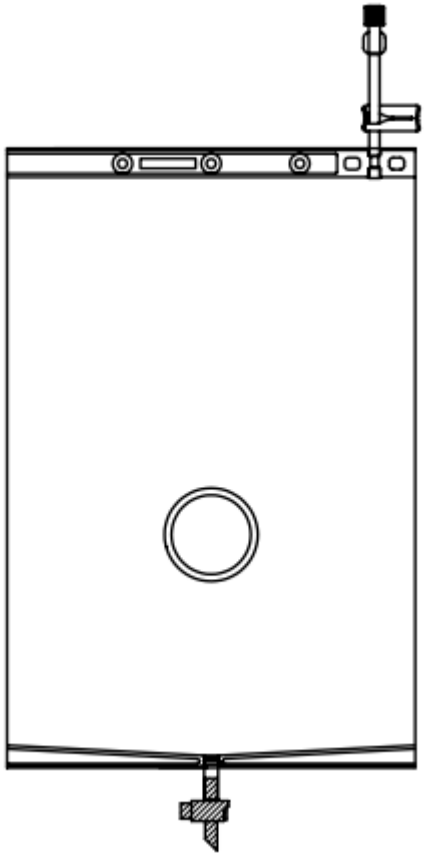
SE/MG120/16-0002, NO/MG120/16-0003, FI/MG120/16-0002, DK/MG120/16-0002

59.6 poz.



Produkto pavadinimas

Produktnamn	SP-418
Beställningsnummer	107650

Produkto kodas

Produktbeskrivning	Tömningspåse
Produkto aprašymas	
Access	
Behandlingstyp	
Maskintyp	
Längd	
Volym	9 liter
Mjukgörare	DEHP-fri
Sterilisering	EtO
Förpackningsstorlek	30 st.

Surinkimo maišas

Tūris

Be DEHP

Eto sterilizacija

Baxter

PRISMAFLEX System M60/M100/M150

Hemofilter Sets

Making possible personal.

PRISMAFLEX System M60/M100/M150 Sets

Preconnected Hemofilter Sets with the AN 69 Dialyzer Membrane for CRRT

The PRISMAFLEX Set is indicated for use only with the PRISMAFLEX Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

This set is intended for use in the following veno-venous therapies: SCUF; CVVH; CVVHD; CVVHDF.

All treatments administered via the PRISMAFLEX Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

The PRISMAFLEX M100 & M150 Sets should be restricted to patients with a body weight greater than 30 kg (66 lb). The pediatric use of the PRISMAFLEX M60 Set should be restricted to children with a body weight greater than 11 kg (24 lb) with respect to extracorporeal blood volume.

The M150, M100 and M60 hemofilter sets are designed for prescription flexibility on the PRISMAFLEX System. Both set configurations are created with the AN 69 Dialyzer Membrane and can be used to perform all CRRT therapies (SCUF, CVVH, CVVHD and CVVHDF).

General data

	PRISMAFLEX M60 Set	PRISMAFLEX M100 Set	PRISMAFLEX M150 Set
Weight	780 g	800 g	860 g
Overall dimensions	27 x 22 x 9 cm	27 x 22 x 9 cm	27 x 22 x 9 cm
Blood volume in set ± 10 %	93 ml	152 ml	189 ml
Minimal patient weight	11 Kg	30 Kg	30 Kg

Materials

- AN 69 HF hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer
- Filter housing and headers: Polycarbonate
- Filter potting compound: Polyurethane
- Tubing material: plasticized polyvinyl chloride (PVC)
- Cartridge: PETG
- Sterilization mode: EtO (ethylene oxide)
- Not made with natural rubber latex
- Contains DEHP, which may pose risks to infant development

Filter operating specifications

- Maximum TMP* (mmHg/kPa): 450/60
- Maximum blood pressure (mmHg/kPa): 500/66.6
- Minimum blood flow rate:
  PRISMAFLEX M60 Set: 50 ml/min
  PRISMAFLEX M100 Set: 75 ml/min
  PRISMAFLEX M150 Set: 100 ml/min

Filter data

- Nominal physical characteristics
  - Effective surface area:
    PRISMAFLEX M60 Set: 0.6 m^2
    PRISMAFLEX M100 Set: 0.9 m^2
    PRISMAFLEX M150 Set: 1.5 m^2
  - Fiber internal diameter (wet): 240 µm
  - Fiber wall thickness: 50 µm

Sieving coefficient

- (bovine plasma, Pc 60 g/l, T = 37°C)
  Urea = 1, Creatinine = 1, Vitamin B12 = 1, Inulin = 0.95, Myoglobin = 0.55, Albumin <0.01

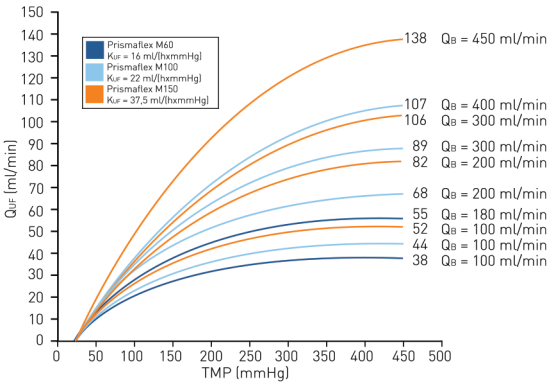
In vitro performances

- Blood priming volume in filter ±10%:
  PRISMAFLEX M60 Set: 42 ml
  PRISMAFLEX M100 Set: 66 ml
  PRISMAFLEX M150 Set: 105 ml
- Blood pressure drop (in post dilution mode)
  (bovine blood, Hematocrit 32%, Pc*** = 60 g/l, T = 37°C)

	PRISMAFLEX M60 Set	PRISMAFLEX M100 Set	PRISMAFLEX M150 Set
Q_B** = 100 ml/min - Q_{UF}**** = 1 l/h	47 mmHg	31 mmHg	20 mmHg
Q_B** = 180 ml/min - Q_{UF}**** = 2 l/h	91 mmHg	60 mmHg	—
Q_B** = 300 ml/min - Q_{UF}**** = 2 l/h	—	73 mmHg	51 mmHg
Q_B** = 400 ml/min - Q_{UF}**** = 2 l/h	—	105 mmHg	64 mmHg
Q_B** = 450 ml/min - Q_{UF}**** = 2 l/h	—	—	70 mmHg

CVVH Performances

- "In vitro" ultrafiltration with blood (in post-dilution)
  (values ±15%) (Continuous venovenous hemofiltration)
  (Bovine blood at 37°C, Hematocrit 32%, Pc*** 60 g/l).



CVVHD Clearances

- Clearances versus inlet dialysate flow rate
  (Continuous venovenous hemodialysis) (Saline, T = 37°C).

	PRISMAFLEX M60 Set Q_B** = 100 ml/min Q_{UF}**** = 0 ml/min			PRISMAFLEX M100 Set Q_B** = 150 ml/min Q_{UF}**** = 0 ml/min				PRISMAFLEX M150 Set Q_B** = 200 ml/min Q_{UF}**** = 0 ml/min			
QD l/h ml/min	1 17	2.5 42	4 67	1 17	2.5 42	4 67	8 133	1 17	2.5 42	4 67	8 133
Urea (±10%)	17	39	54	17	41	63	95	17	42	66	117
Vitamin B12 (±20%)	14	23	28	16	30	37	45	17	37	49	64
Inulin (±20%)	12	17	19	14	23	26	30	16	31	37	45

*Transmembrane pressure.
**Access blood flow rate.
***Protein concentration.
****Ultrafiltration flow rate (1).
(1)The ultrafiltration flow rate is the "patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate."

Ordering information

	Factory ID	Code No.	No. Units/Box
PRISMAFLEX M60 Set	8353510	106696	4
PRISMAFLEX M100 Set	8353520	106697	4
PRISMAFLEX M150 Set	8353584	109990	4
SP414 - 5-liter bag	6032957	106690	50
SP418 - 9-liter bag	6033765	107650	30

59.6 poz.

Contact your local Baxter sales representative to learn more about the product.
For Customer Support, call 800-525-2623.

Rx Only. For the safe and proper use of the devices mentioned herein, please refer to the *Instructions for Use*.

www.baxter.com
USMP/MG120/14-0003(2) 1000 01/16

Poz. 59.7 Magistralė kalcio druskų infuzijai Prismaflex aparatu

Calcium Line for Prismaflex® – CA 250

Prismaflex® is a trademark of Gambro Lundia AB

GAMBRO®

IFU Revision Date: Mar 2010

INSTRUCTION FOR USE
Calcium Line for Prismaflex® – CA 250

Caution!
Read the instructions carefully before using this product.

INTENDED USE

The Calcium Line for Prismaflex is a medical device to be used only with the Prismaflex Control Unit software version 5.0 or later for performing the "Citrate-calcium via Prismaflex syringe pump" anticoagulation method. Carefully read the Prismaflex Operator's Manual and on-line screen instructions. All treatments administered via the Calcium Line for Prismaflex must be prescribed by a physician.

CONTRAINDICATIONS AND ADVERSE REACTIONS

There are no known contraindications or adverse reactions to the use of the Calcium Line for Prismaflex if used as indicated in the intended use section above.

CAUTIONS AND WARNINGS

1. 

The lines must be stored in a dry place, between 5°C (41°F) and 30°C (86°F).

2.  Do not store in direct sunlight.

3.  Expiration date of the product is shown on the packaging.

4.  Do not use an individual unit if package is damaged.

5. In order to reduce the risk of disease transmission, the use of protective clothing (gloves, glasses, masks, etc.) by nurses, doctors, and other medical staff is recommended when handling the Calcium Line for Prismaflex.

6. Before using the Calcium Line for Prismaflex check that all caps are in place.

7. The Calcium Line for Prismaflex must be used as soon as the packaging and the protective caps have been removed.

8. Before starting, and also during the treatment using Calcium Line for Prismaflex, ensure that the check valve is in place and all connections are secure.

9. The minimum temperature for use is 20°C (68°F).

10. The Calcium Line for Prismaflex is sterile and non-pyrogenic. Use an aseptic technique when installing the line and throughout the treatment.

11. Make sure the Calcium Line for Prismaflex and the patient's vascular access are not kinked.

12. Verify safe operation of the system comprising the Prismaflex machine, any accessories and the Calcium Line for Prismaflex during set up.

13. The safe connection of the Calcium Line for Prismaflex shall be performed by skilled personnel only or under the supervision of the medical officer in charge.

14. Watch carefully for leaks during priming and use.

15. All connections must be checked carefully throughout the treatment to prevent any misconnection, leakage or disconnection issues that could result in potential patient injuries such as blood loss, air embolism or fluid imbalance.

16. During the treatment, it should be regularly checked that the line is not kinked or obstructed in order to prevent any risk of electrolytic imbalance for the patient.

17. Presence of DEHP in the PVC tube should be taken into special consideration in the treatment of children who have not yet reached puberty, pregnant women and nursing mothers because these patient groups exhibit an increased sensitivity.

18. Use only drugs compatible with PVC.

19.  The Calcium Line for Prismaflex is intended for single use only. Discard it after use, following local laws and regulations for potentially contaminated equipment.

20. The Calcium Line for Prismaflex must not be reused in order to avoid bacteriological contamination and possible performance decrease.

21. Stability and performance of this device is guaranteed by the manufacturer only if it is intact and prepared as recommended for single use only.

OTHER SYMBOLS USED ON THE PRODUCT LABELING

	Consult Instructions For Use
	Date of Manufacture
LOT	Batch code
DEHP	The material used for the manufacture of this specific medical device contains Di-2-ethyl hexyl phthalate (DEHP)
	Keep dry

	Manufacturer
REF	Catalogue number
STERILE R	The Calcium Line for Prismaflex is sterilized by irradiation
NO LATEX	The product doesn t contain latex or its derivatives.
	Fragile, handle with care

INSTRUCTIONS FOR USE AND RECOMMENDATIONS

Use the Calcium Line for Prismaflex by following the detailed on-line instructions provided by the Prismaflex Control Unit. Additional information is available in the Prismaflex Operator's Manual.

a) Unpack and remove the protective caps
b) Follow online-instructions on the Prismaflex screen for the following steps:
   - Connection of the line to the Prismaflex syringe
   - Automatic priming of the line by the Prismaflex system
   - Connection of the line to the patient
c) Remove eventual air bubbles before use

Please refer to Prismaflex Operator's Manual for more information on the "Citrate-calcium via Prismaflex syringe pump" anticoagulation method and calcium infusion.

SPECIFICATIONS

(1) Line: The Calcium Line for Prismaflex is compliant with the applicable parts of the DIN EN ISO 8536 standard
   Pump line ISO 8536-9-SPL- P
   - Length: 2500 mm
   - Inner diameter: 0.59 mm
   - Storage volume at 40°C (104°F): 0.7 mL
(2) Luer-lock connectors: Both male Luer and female Luer-lock connectors comply with the following standards: EN 20594-1 and EN 1707.
(3) Check valve is compliant with the applicable parts of the DIN EN ISO 8536 standard.
(4) Slide clamp
(5) "Calcium" tags

The materials in direct or indirect contact with blood are: Acrylonitrile Butadiene Styrene (ABS), high and low density polyethylene (HDPE, LDPE), plasticized Polyvinylchloride (PVC), Styrene Acrylonitrile (SAN), silicone.

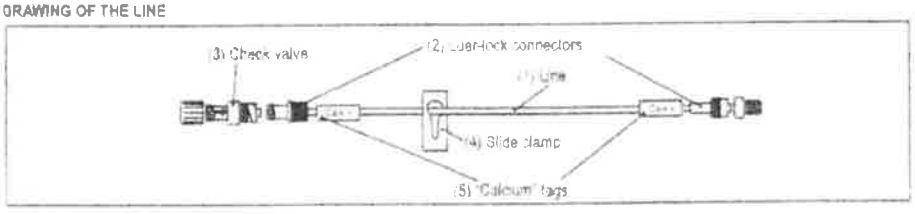
WARRANTY AND LIMITATION OF LIABILITY

a) The manufacturer Medizintechnik Promedt GmbH, warrants that the lines have been manufactured in accordance with their specifications and in compliance with DIN EN ISO 13485 and other regulatory requirements.
b) Medizintechnik Promedt GmbH Quality system is working in accordance with DIN EN ISO 13485 as it is assessed by the Notified Body MEDCERT
c) The manufacturer shall not be held responsible for failure to use the lines with the dialysis machines they have been specifically designed for
d) The manufacturer shall not be liable for any misuse, improper handling, non compliance with warnings and instructions, damage arising from events after the manufacturer's release of the lines, failure or omission to inspect the lines before use in order to insure that they are in proper condition, or any warranty given by independent distributors or dealers.
e) The manufacturer is Medizintechnik Promedt GmbH, Kleiner Moorweg 4, 25436 Tornesch, Germany.

CE 0482

Sponsor for Australia: Gambro Pty Ltd, Suite 2, Level 4, 62 Norwest Blvd, Baulkham Hills NSW 2153, Australia

DRAWING OF THE LINE



Kalcio linija *Prismaflex*® – CA 250

Prismaflex® yra „Gambro Lundia AB“ priklausantis prekės ženklas.

Naudojimo instrukcijos 3

Naudojimo instrukcijos peržiūrėtos 2010 m. kovo.

Naudojimo instrukcijos
Kalcio linija *Prismaflex*™ CA 2.5/0
Prismaflex™ yra „Gambro Lundia AB" priklausantis prekės ženklas.

Perspėjimas!
Prieš naudodami produktą atidžiai perskaitykite šias instrukcijas.

NAUDOJIMO PASKIRTIS
Prismaflex kalcio linija yra medicininis prietaisas, kuris gali būti naudojamas tik su *Prismaflex* 5.0 ar vėlesne kontrolinio bloko kompiuterinės programos versija darbui citrato kalcio per *Prismaflex* švirkšto siurblį antikoaguliacijos metodu. Atidžiai perskaitykite *Prismaflex* naudotojo vadovą ir nuorodas, pateikiamas ekrane vykstant procesui. *Prismaflex* kalcio linija teikiamą gydymą turi išrašyti gydytojas.

KONTRAINDIKACIJOS IR NEPAGEIDAUJAMOS REAKCIJOS
Jokių žinomų *Prismaflex* kalcio linijos naudojimo kontraindikacijų ar nepageidaujamų reakcijų nėra, jei prietaisas naudojimas pagal paskirtį.

ATSARGUMO PRIEMONĖS IR PERSPĖJIMAI
1. Linija turi būti laikoma sausoje vietoje, nuo 5 °C (41 °F) iki 30 °C (86 °F) temperatūroje.
2. Nelaikykite tiesioginėje saulės šviesoje.
3. Produkto galiojimo laikas nurodytas ant pakuotės.
4. Nenaudokite prietaiso, jei pažeista pakuotė.
5. Norint sumažinti ligos perdavimo riziką, slaugytojams, gydytojams ir kitam medicinos personalui dirbant su *Prismaflex* kalcio linija rekomenduojama naudoti apsaugines priemones (pirštines, akinius, kaukes ir kt.).
6. Prieš naudodami *Prismaflex* kalcio linija patikrinkite, ar savo vietose visi dangteliai.
7. *Prismaflex* kalcio linija turi būti naudojama iškart, kai tik atidaroma pakuotė ir nuimami dangteliai.
8. Prieš pradedami naudoti ir gydydami užtikrinkite, kad visi apsauginiai vožtuvai būtų savo vietose, o jungtys patikimai sujungtos.
9. Minimali prietaiso naudojimo temperatūra yra 20 °C (68 °F).
10. *Prismaflex* kalcio linija yra sterili ir nepirogeniška (nesukelia karščiavimo). Įrengdami linija ir gydydami laikykitės aseptikos taisyklių.
11. Patikrinkite, ar *Prismaflex* kalcio linija ir paciento kraujagyslės nesutrikusios.
12. Įrengdami pasirūpinkite, kad sistema, susidedanti iš *Prismaflex* aparato, priedų ir *Prismaflex* kalcio linijos, veiktų saugiai.
13. *Prismaflex* kalcio linija gali saugiai prijungti tik įgudęs personalas arba personalas, prižiūrimas atsakingo medicinos darbuotojo.
14. Pripildydami ir naudodami atidžiai stebėkite, ar nėra nuotėkio.
15. Per visą gydymo proceso turi būti atidžiai stebimos visos jungtys, siekiant išvengti netinkamo sujungimo, nuotėkių ar atsijungimo, galinčių sukelti žalą pacientui, pavyzdžiui, kraujo netekimą, oro emboliją ar skysčių pusiausvyros sutrikimus.
16. Siekiant išvengti paciento elektrolitų pusiausvyros sutrikimų rizikos, gydant turi būti reguliariai tikrinamas, ar linija nesalinkusi ar neužsikimšusi.
17. Jei PVC vamzdeliuose yra DEHP, tokie vamzdeliai turi būti ypač atsargiai naudojami vaikams iki brendimo laikotarpio nėščioms ir žindančioms moterims, nes šių grupių pacientai yra jautriausi.
18. Naudokite tik tuos vaistus, kurie gali būti naudojami su PVC.

19. *Prismaflex* kalcio linija yra vienkartinė. Po naudojimo ją išmeskite, remdamiesi šalyje galiojančiomis taisyklėmis ir teisės aktais, kuriais reguliuojamas galinčių būti užterštų prietaisų išmetimas.
20. Siekiant išvengti bakterinės taršos ir nepakankamo efektyvumo, *Prismaflex* kalcio linijos negalima naudoti pakartotinai.
21. Šio prietaiso sterilumą ir tinkamą darbą gali garantuoti tik gamintojas ir tik tuomet, jei prietaisas nepažeistas ir pagal rekomendacijas paruoštas naudoti vieną kartą.

KITI ŽENKLINANT PRODUKTĄ NAUDOJAMI SIMBOLIAI
Skaitykite naudojimo instrukcijas
Pagaminimo data
Serijos numeris
Gaminant šį specifinį medicinos prietaisą naudotas di-2-etilo heksilo ftalatas (DEHP)
Laikykite sausoje vietoje

Gamintojas
Katalogo numeris
Prismaflex kalcio linija sterilizuota radiacijos būdu
Produktas neturi latekso ar jo darinių
Trapus, naudokite atsargiai

NAUDOJIMO INSTRUKCIJOS IR REKOMENDACIJOS
Prismaflex kalcio linija naudokite pagal vykstant procesui *Prismaflex* kontroliniame bloke pateikiamas išsamias instrukcijas. Papildomos informacijos galima rasti *Prismaflex* naudotojo vadove.

a) Išpakuokite ir nuimkite apsauginius dangtelius.
b) Laikykitės per *Prismaflex* procesą šiais etapais pateikiamų instrukcijų:
linijos prijungimas prie *Prismaflex* švirkšto;
automatinis linijos pripildymas, atliekamas *Prismaflex* sistemos;
linijos prijungimas prie paciento.
c) Prieš naudodami pašalinkite susidariusius oro burbuliukus.

Norėdami gauti daugiau informacijos apie citrato kalcio per *Prismaflex* švirkšto siurblį antikoaguliacijos metodą ir kalcio infuziją, skaitykite *Prismaflex* naudotojo vadovą.

SPECIFIKACIJOS
1) Linija *Prismaflex* kalcio linija atitinka taikytinas DIN EN ISO 8536 standarto dalis.
Siurblio linija ISO 8536-9-SPL-P
Ilgis: 2500 mm
Vidaus skersmuo: 0,59 mm
Laikomo tūris, kai temperatūra 40 °C (104 °F): 0,7 ml
2) *Luer-Lock* įrangtys ir uždanga: *Luer-Lock* įrangtys atitinka EN 20594-1 ir EN 1707 standartus.

3) Patikrinkite, ar vožtuvas atitinka taikytinas DIN EN ISO 8536 standarto dalis.

4) Slankioji veržlė.

5) Kalcio antgaliai.

Tiesiogiai ar netiesiogiai su krauju kontaktuojančios medžiagos: akrilo nitrilo butadieno stirenas (ABS), mažo ir didelio tankio polietilenas (HDPE, LDPE), plastifikuotas polivinilchloridas (PVC), stireno akrilo nitrilas (SAN), silikonas.

GARANTIJA IR ATSAKOMYBĖS APRIBOJIMAI

a) Gamintojas, „Medizintechnik Promedt GmbH", garantuoja, kad pagamintos linijos atitinka specifikacijas ir DIN EN ISO 13485 bei kitus reguliuojančius teisės aktus.
b) „Medizintechnik Promedt GmbH" kokybės užtikrinimo sistema atitinka DIN EN ISO 13485, tai įvertino atsakingoji institucija MEDCERT.
c) Gamintojas neatsako už linijos naudojimą su šiai linijai neskirtais dializės aparatais.
d) Gamintojas neatsako už netinkamą naudojimą ar netinkamą elgesį su prietaisu, perspėjimų ir atsargumo priemonių nesilaikymą, žalą, kuri padaroma linijoms po pagaminimo ir išleidimo, už linijų netikrinimą ar netinkamą tikrinimą prieš naudojimą, siekiant užtikrinti tinkamą būklę, arba atsakomybę, kurią prisiima nepriklausomi platintojai ar prekiautojai.
e) Gamintojas yra „Medizintechnik Promedt GmbH", Kleiner Moorweg 4, 25436 Tornesch, Vokietija.

Rėmėjas Australijoje: „Gambro Pty Ltd", Suite 2, Level 4, 62 Norwest Blvd, Baulkham Hills NSW 2153, Australija.

LINIJOS BRĖŽINYS

3 Apsauginis vožtuvas 2 *Luer-Lock* jungtys
1 Linija
4 Slankioji veržlė
5 Kaleio antgaliai

Aš, vertėjas (-a) .....
esu susipažinęs (usi) su LR BK 235 straipsniu, kuriame nustatyta baudžiamoji atsakomybė už netelisingą vertimą.

Parašas .....