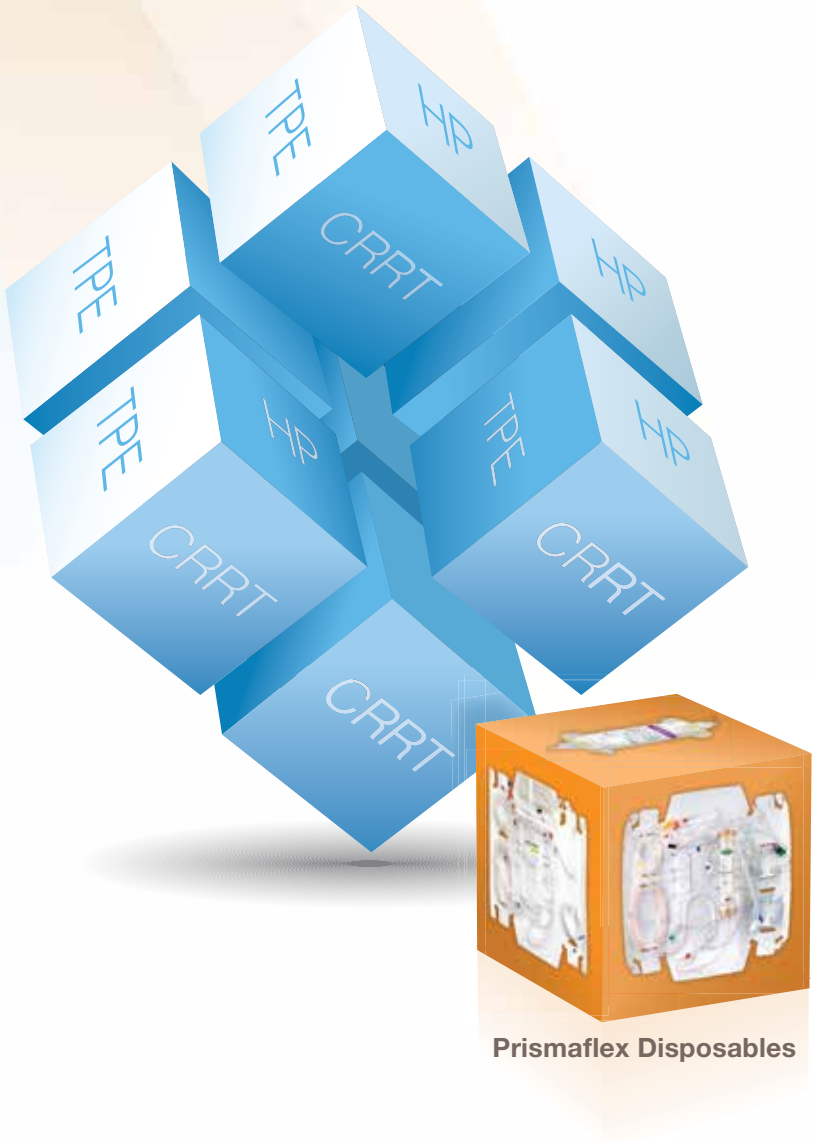
Baxter

Prismaflex disposable sets

An integral piece of acute therapy.



Prismaflex Disposables

POWERED BY prismaflex

Making possible personal.

Prismaflex CRRT sets

The **Prismaflex** CRRT sets are disposable, extracorporeal circuits for use with the **Prismaflex** system. They consist of a hollow fiber haemofilter/dialyser (filter) and tubing system. Different filter sizes and membranes are available. The filter is permanently connected to color-coded lines for easy identification.

The **Prismaflex** set is provided with a specific small volume deaeration chamber in which blood does not appear to mix with the replacement liquid the majority of the time; this specific shape configuration avoiding air-blood contact in the chamber is designed to minimize risks of clotting. A 5-liter bag is provided to be used to collect effluent liquids.

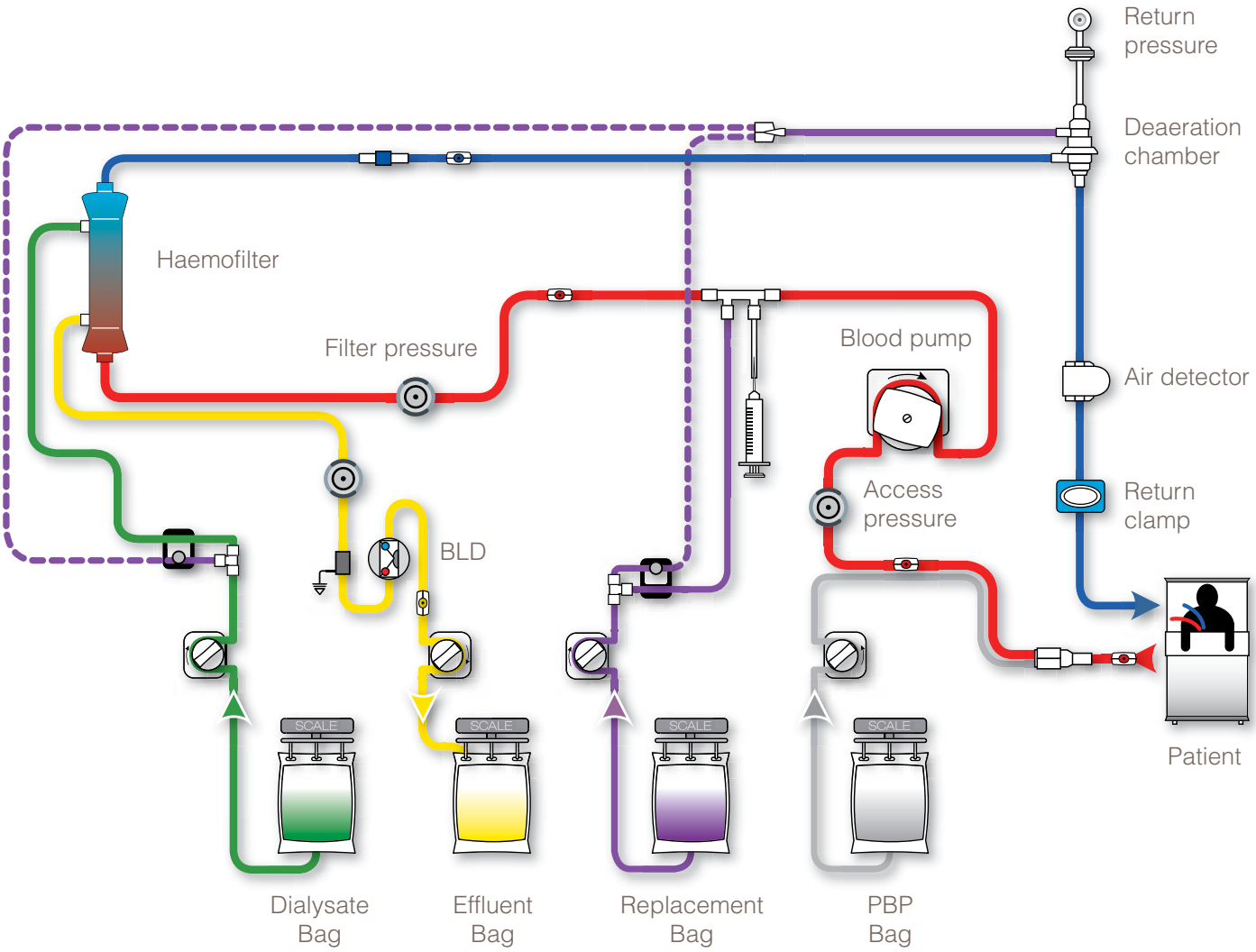
Other sterile 5- and 9-liter bags and sterile, pyrogen-free spikes can be ordered separately.

All line connectors are compatible with the ISO 594/1 & 2 international standards concerning conical fittings.

The fluid pathways of the **Prismaflex** set are sterile and pyrogen-free.

- Same circuit set for all CRRT therapies/modalities
- Only one type of circuit for pre &/or post dilution
- Bar code for set recognition by the machine
- Integrated pre-blood pump infusion for regional anticoagulation (citrate)
- DEHP-free materials in blood path
- Different tubing diameters for a broad range of blood flow rates

Prismaflex sets for CRRT



*DEHP-free: materials in direct or indirect blood contact are DEHP free

AN 69 surface modified and coated with heparin

Prismaflex sets for CRRT

Prismaflex M sets

Description:

CRRT and continuous fluid management with **Prismaflex** system in acute renal failure, fluid overload or both.

PRODUCT CODE	ORDER NUMBER	FILTER SIZE	EXTRACORPOREAL BLOOD VOLUME / MINIMUM PATIENT WEIGHT	MATERIALS	SHELF LIFE	STERILISATION METHOD
M60 M60 CKT	106696 115305	0.6 m^2	93 ml / 11 kg	- AN 69 membrane - PVC - Latex-free - DEHP free*	2 years	EtO
M100 M100 CKT	106697 115306	0.9 m^2	152 ml / 30 kg			
M150 M150 CKT	109990 115307	1.5 m^2	189 ml / 30 kg			

Prismaflex ST sets

Description:

CRRT and continuous fluid management with **Prismaflex** system in acute renal failure, fluid overload or both.

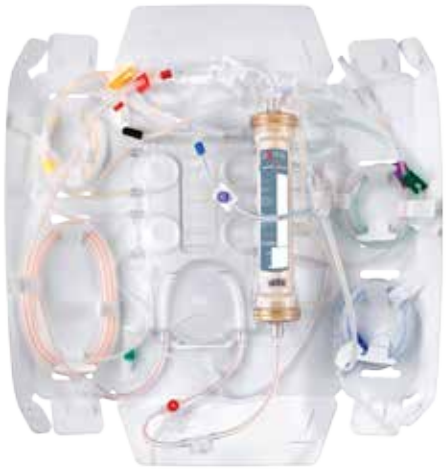
PRODUCT CODE	ORDER NUMBER	FILTER SIZE	EXTRACORPOREAL BLOOD VOLUME / MINIMUM PATIENT WEIGHT	MATERIALS	SHELF LIFE	STERILISATION METHOD
ST60 ST60 CKT	107643 115308	0.6 m^2	93 ml / 11 kg	- AN 69 ST membrane - PVC - Latex-free - DEHP free*	2 years	EtO
ST100 ST100 CKT	107636 115309	1.0 m^2	152 ml / 30 kg			
ST150 ST150 CKT	107640 115310	1.5 m^2	189 ml / 30 kg			

*DEHP-free: materials in direct or indirect blood contact are DEHP free

oXiris set

Description:

CRRT and continuous fluid management with **Prismaflex** system in acute renal failure, fluid overload or both.



PRODUCT CODE	ORDER NUMBER	FILTER SIZE	EXTRACORPOREAL BLOOD VOLUME / MINIMUM PATIENT WEIGHT	MATERIALS	SHELF LIFE	STERILISATION METHOD
oXiris	112016	1.5 m^2	189 ml / 30 kg	- AN 69 surface modified and coated with heparin - PVC - Latex-free - DEHP free*	2 years	EtO
oXiris CKT	955255					

Prismaflex HF sets

Description:

CRRT and continuous fluid management with **Prismaflex** system in acute renal failure, fluid overload or both.

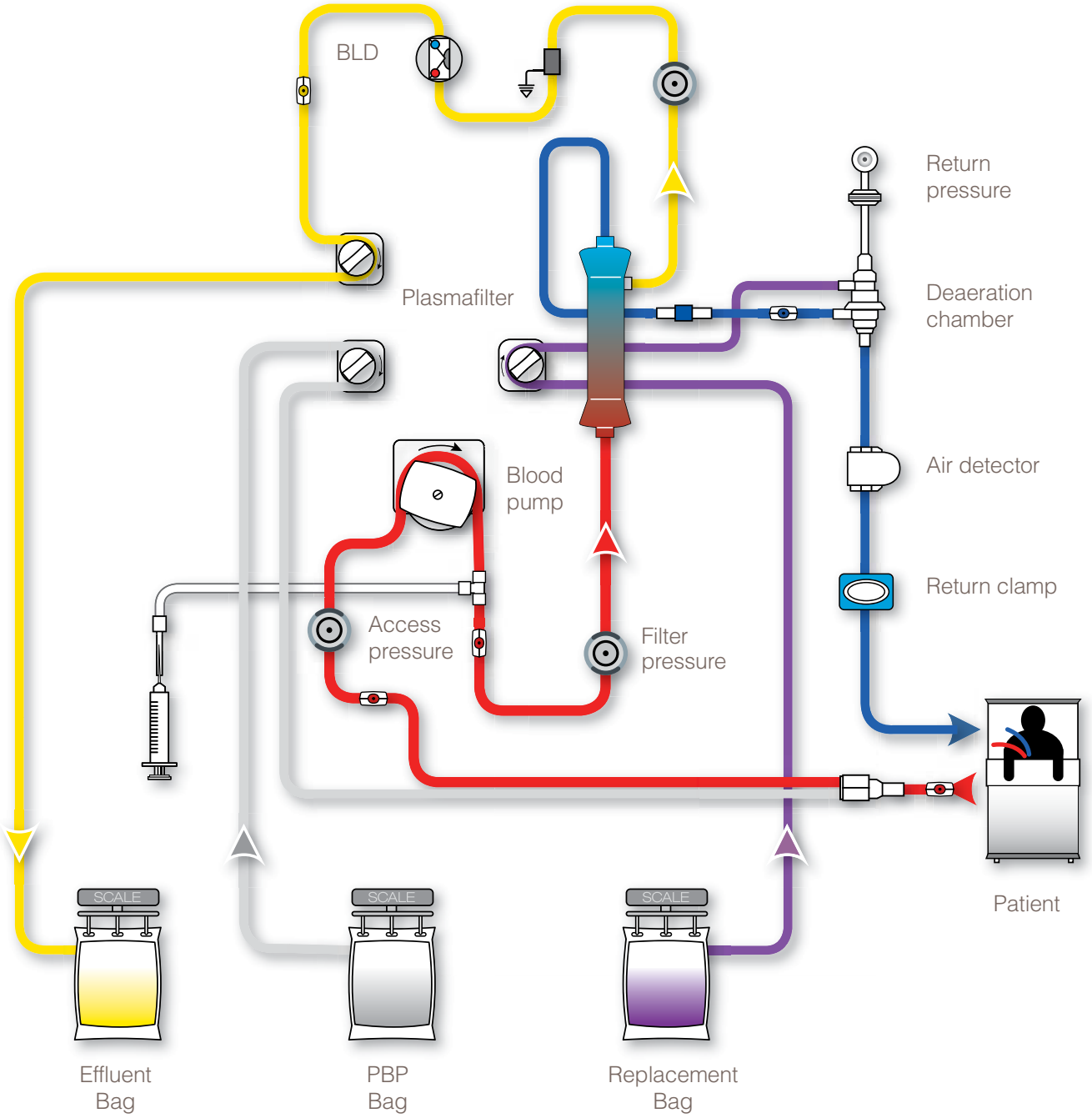
PRODUCT CODE	ORDER NUMBER	FILTER SIZE	EXTRACORPOREAL BLOOD VOLUME / MINIMUM PATIENT WEIGHT	MATERIALS	SHELF LIFE	STERILISATION METHOD
HF20 HF20 CKT	109841 115313	0.2 m^2	60 ml / 8 kg	- PAES membrane - PVC - Latex-free - DEHP free*	3 years	EtO
HF1000 HF1000 CKT	107140 115311	1.1 m^2	165 ml /30 kg			
HF1400 HF1400 CKT	107142 115312	1.4 m^2	186 ml / 30 kg			

*DEHP-free: materials in direct or indirect blood contact are DEHP free

Prismaflex TPE sets

The **Prismaflex** TPE sets are disposables for Therapeutic Plasma Exchange. Plasma exchange on the **Prismaflex** system is obtained by plasmafiltration, with simultaneous infusion of a replacement solution. Plasma is filtered (removed) through the large-pore membrane of a plasmafilter, while fresh plasma or other types of colloid solutions are infused post-plasmafilter to replace the plasma removed.

- 2 sizes of plasmafilters are available.



*DEHP-free: materials in direct or indirect blood contact are DEHP free

Prismaflex TPE sets

Description:

Intended for use with the **Prismaflex** system in therapeutic plasma exchange, thus in diseases where removal of plasma components is indicated.

PRODUCT CODE	ORDER NUMBER	FILTER SIZE	EXTRACORPOREAL BLOOD VOLUME / MINIMUM PATIENT WEIGHT	MATERIALS	SHELF LIFE	STERILISATION METHOD
TPE1000 TPE1000 CKT	107143 115314	0.15 m^2	71 ml / 9 kg	- Membrane Polypropylene - PVC - Latex-free - DEHP free*	3 years	EtO
TPE2000 TPE2000 CKT	107144 115315	0.35 m^2	125 ml / adults			

*DEHP-free: materials in direct or indirect blood contact are DEHP free

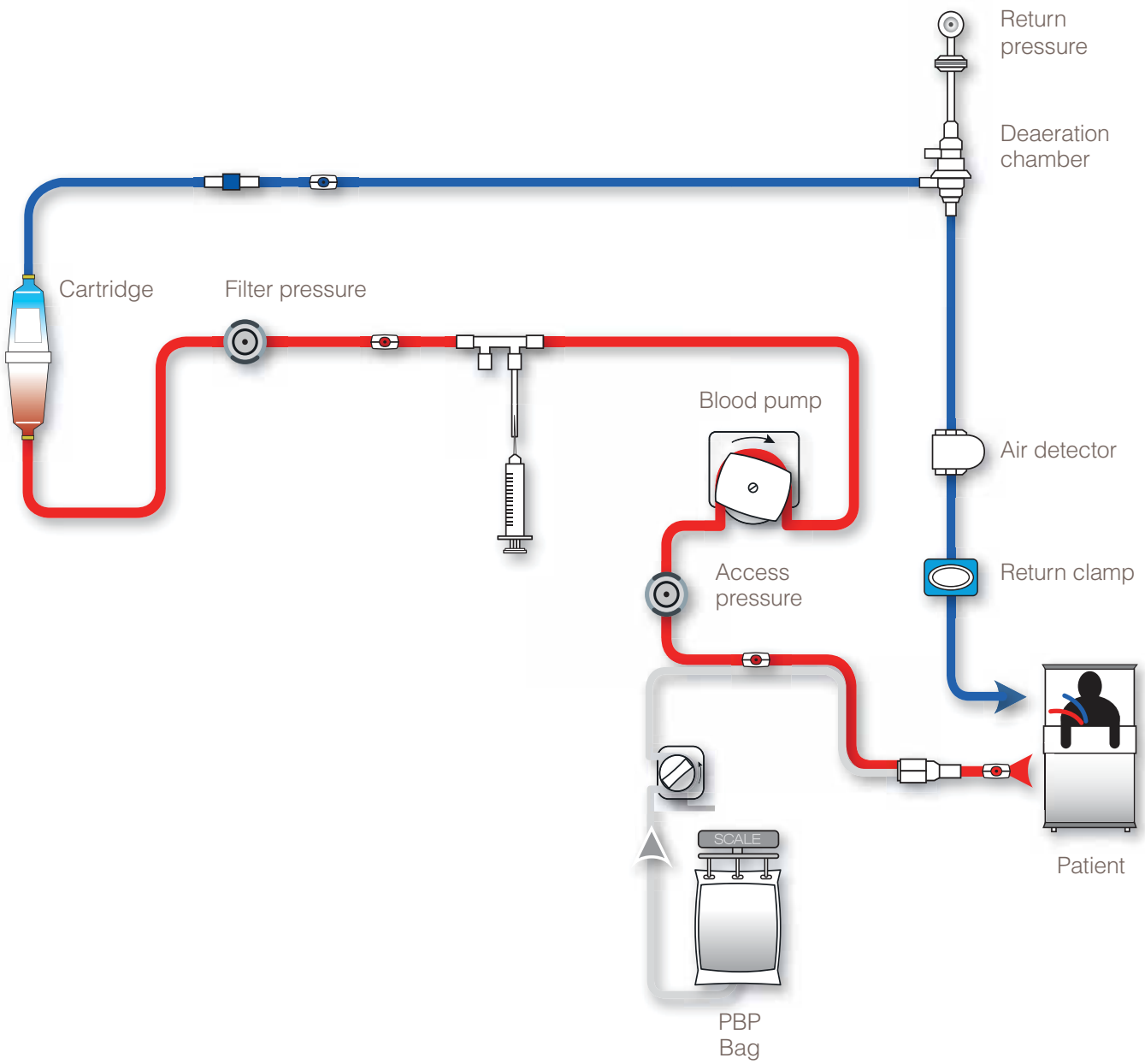
Other Prismaflex kits/sets

Adsorba kits and Hemoperfusion set (HP-X)

Haemoperfusion is a blood purification therapy provided by means of an extracorporeal purification device. The patient's blood is directed through the **Prismaflex** disposable HP line set, passes the HP device, and the cleansed blood is then returned back to the patient.

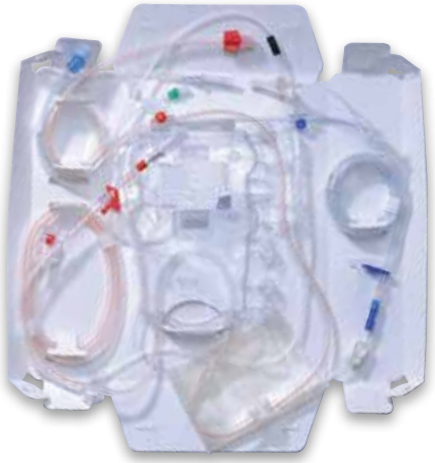
No fluid removal occurs.

A range of different HP devices is supported for use with the **Prismaflex** system. These include hemoperfusion cartridges in which toxic substances and/or drugs are adsorbed from the plasma as the patient's blood is perfused through an adsorption column.



*DEHP-free: materials in direct or indirect blood contact are DEHP free

Prismaflex Adsorba kits



Description:

Disposable kits designed to perform hemoperfusion therapies using the **Prismaflex** monitor. The kit consists of an extracorporeal circuit (hemoperfusion set) and an **Adsorba** cartridge; there are two sizes of cartridges available: **Adsorba** 150 C and **Adsorba** 300 C.

The **Adsorba** cartridge contains cellulose-coated activated carbon. The cartridge is filled with physiological saline solution and sterilised.

PRODUCT CODE	ORDER NUMBER	EXTRACORPOREAL BLOOD VOLUME	MATERIALS	SHELF LIFE	STERILISATION METHOD
Adsorba 150 kit	107642	140 ml + 107 ml	- Activate charcoal - PVC - Latex-free - DEHP free*	2 years (3 years each but 2 years for kit)	- steam (**Adsorba**) - EtO (set)
Adsorba 300 kit	107641	260 ml + 107 ml			

*DEHP-free: materials in direct or indirect blood contact are DEHP free

Other Prismaflex kits/sets

Prismaflex HP-X set

Description:

Set of blood lines intended for extracorporeal circulation of blood on the **Prismaflex** control unit equipped with software 7.00 or later when selecting “HP mode” and designed to be connected to blood purification devices.

PRODUCT CODE	ORDER NUMBER	EXTRACORPOREAL BLOOD VOLUME	MATERIALS	SHELF LIFE	STERILISATION METHOD
HP-X	Not available as stand alone	108 ml	- Tubes PVC - Latex-free - DEHP free*	3 years	EtO

*DEHP-free: materials in direct or indirect blood contact are DEHP free

EUMP/MG120/16-0017 05/2016

Prismaflex sets for CRRT

Prismaflex M Sets

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
M60 M60 CKT	106696 115305	4
M100 M100 CKT	106697 115306	4
M150 M150 CKT	109990 115307	4

Prismaflex ST Sets

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
ST60 ST60 CKT	107643 115308	4
ST100 ST100 CKT	107636 115309	4
ST150 ST150 CKT	107640 115310	4

Prismaflex oXiris Sets

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
oXiris	112016	4
oXiris CKT	955255	4

Prismaflex HF Sets

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
HF20 HF20 CKT	109841 115313	4
HF1000 HF1000 CKT	107140 115311	4
HF1400 HF1400 CKT	107142 115312	4

Other **Prismaflex** kits/sets

Prismaflex TPE Sets

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
TPE1000 TPE1000 CKT	107143 115314	4
TPE2000 TPE2000 CKT	107144 115315	4

Prismaflex Adsorba Kits

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
Adsorba 150 kit	107642	1
Adsorba 300 kit	107641	1

Prismaflex HP-X Set

PRODUCT CODE	ORDER NUMBER	UNITS PER BOX
HP-X	Not available as stand alone	1

www.baxter.com

Baxter Healthcare/Gambro Lundia AB, Magistratsvägen 16, SE-220 10 Lund, SWEDEN
t: 46 46 16 90 00

Baxter

GAMBRO

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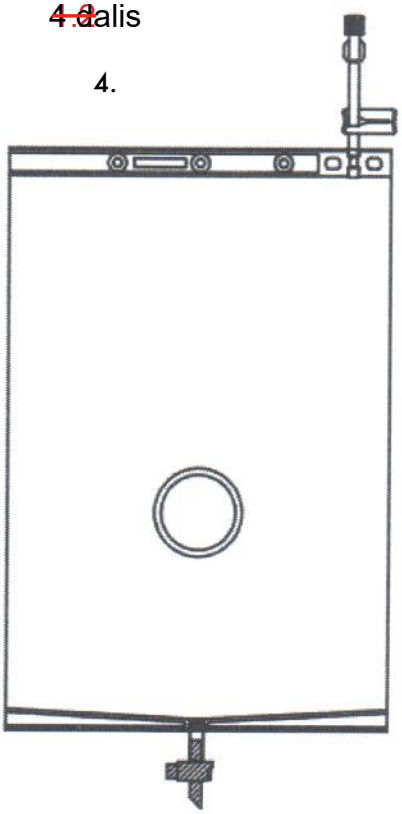

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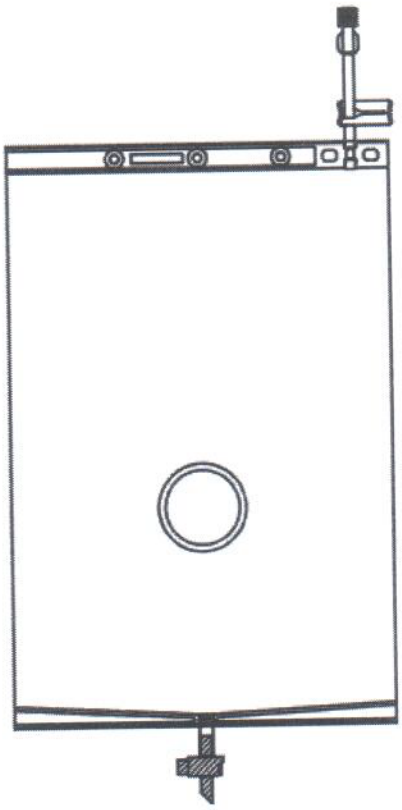
Product name	SP-418
Order number	107650

Product description	Effluent bag
Access	
Treatment type	CRRT
Machine type	PrismaFlex
Lenght	
Volume	9 liter
Softener	DEHP-free
Sterilization method	EtO
Package	30 pcs

GAMBRO



Produkto pavadinimas	SP-418
Užsakymo numeris	107650

Produkto aprašas	Nuotekų surinkimo maišas
Prieiga	
Terapijos tipas	CRRT
Aparato tipas	PrismaFlex
Ilgis	
Tūris	9 litrai
Plastifikatorius	Be DEHP (dietilheksilftalatų)
Sterilizacijos būdas	EtO (etileno oksidu)
Pakuotė	30 vnt.

Aš, vertėjas (
esu susipažin
nustatyta bau

Parašas .....


VERTĖJŲ BIURAS „MAGISTA"
TRANSLATION SERVICE
VILNIUS, LIETUVA
Susiūlta, sunum
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~~5.3~~ 5. dalis

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. Sterility 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
PHT 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.

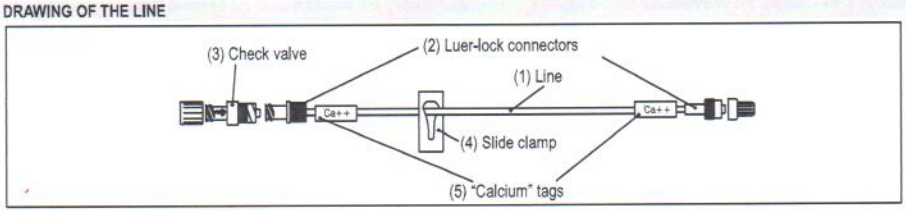
WARRANTY AND LIMITATION OF LIABILITY

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. kovą.

Naudojimo instrukcijos
Kalcio linija *Prismaflex*®*-CA 250*
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 PIEMONĖS 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 liniją patikrinkite, ar savo vietose visi dangteliai.
7. *Prismaflex* kalcio linija turi būti naudojama iškart, kai tik atidaroma pakuotė ir nuimami dangteliai.
8. Prieš pradėdami 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 liniją ir gydydami laikykitės aseptikos taisyklių.
11. Patikrinkite, ar *Prismaflex* kalcio linija ir paciento kraujagyslės nesulinkusios.
12. Įrengdami pasirūpinkite, kad sistema, susidedanti iš *Prismaflex* aparato, priedų ir *Prismaflex* kalcio linijos, veiktų saugiai.
13. *Prismaflex* kalcio liniją 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 procesą 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 tikrinama, ar linija nesulinkusi ar neužsikimšusi.
17. Jei PVC vamzdelyje yra DEHP, tokie vamzdeliai turi būti ypač atsargiai naudojami vaikams iki brendimo laikotarpio, nėščioms ir žindančioms moterims, nes šių grupių pacientai yra jautresni.
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 liniją 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
Vidinis skersmuo: 0,59 mm
Laikymo tūris, kai temperatūra 40 °C (104 °F): 0,7 ml
2) *Luer-Lock* jungtys: ir lizdinė, ir kištukinė *Luer-Lock* jungtys atitinka EN 20594-1 ir EN 1701 standartus.

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

4) Slankioji veržlė.

5) Kalcio antgaliai.

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LINIJOS BRĖŽINYS

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