FRESENIUS MEDICAL CARE

ENGLISH en **Instructions for Use – Extracorporeal Bloodlines for Blood Purification**

ZHONGWEN zh-cn **使用说明书—血液净化体外循环血路**

en INSTRUCTIONS FOR USE

Extracorporeal Bloodlines for Blood Purification

Models:

6008 CAREset-R
6008 CAREset BVM-R
6008 CAREset L-R
6008 CAREset BVM L-R

Please read the following instructions carefully.

SYMBOLS USED ON LABELS

Symbol	Meaning	Symbol	Meaning
MD	Medical Device		Sterile Barrier System
UDI	Unique Device Identifier		Consult instructions for use or consult electronic instructions for use
	Patient information website		Non-pyrogenic
STERILE R	Sterile Sterilized using irradiation		Do not re-use
	Pump segment diameter/ length		Caution (Consult the Instructions for Use for important cautionary information such as warnings and precautions)
	Blood Priming Volume	LOT	Batch code
LATEX	Latex-free	REF	Catalogue number
	Units		Date of manufacture
5°C 30°C	Temperature limit		Expiry date
	Do not use if package is damaged		

Product composition

Product model	Product composition
6008 CAREset-R	Pump tube, System tube, Dialyzer connector, Patient connector, Arterial injection port, Venous injection port, Cassette (Body, Connectors, Foil, Coagel catching disk, Check valve, Evacuation membrane), Heparin tube, Luer Lock Female Connector, Rinse port adapter, Clamp, Cap
6008 CAREset BVM-R	Pump tube, System tube, Dialyzer connector, Patient connector, Arterial injection port, Venous injection port, Cassette (Body, Connectors, Foil, Coagel catching disk, Check valve, Evacuation membrane), Heparin tube, Luer Lock Female Connector, Rinse port adapter, Clamp, Cap, BVM Cuvette

zh-cn 使用说明书

血液净化体外循环血路

型号、规格：

6008 CAREset-R
6008 CAREset BVM-R
6008 CAREset L-R
6008 CAREset BVM L-R

请仔细阅读以下说明。

标签所用符号

符号	含义	符号	含义
MD	医疗器械		无菌屏障系统
UDI	医疗器械唯一标识		查阅使用说明
	患者信息网站		无热原
STERILE R	产品无菌 使用辐射灭菌		不得二次使用
	泵管直径/长度		警告（表示用户需要查阅使用说明的重要警告信息，比如警告信息和防范措施）
	血液预充容量	LOT	批次代码
LATEX	不含胶乳	REF	产品编号
	数量		生产日期
5°C 30°C	温度极限		失效日期
	如包装破损切勿使用		

产品组成

产品型号	产品组成
6008 CAREset-R	泵管，PVC 管，透析接头，患者接头，动脉采样口，静脉采样口，盒式管路（包括一体式盒体，接头，背膜，血块过滤器，单向阀，疏水膜），肝素管路，鲁尔接头，预冲接头，管路夹，保护帽
6008 CAREset BVM-R	泵管，PVC 管，透析接头，患者接头，动脉采样口，静脉采样口，盒式管路（包括一体式盒体，接头，背膜，血块过滤器，单向阀，疏水膜），肝素管路，鲁尔接头，预冲接头，管路夹，保护帽，BVM 液体槽

6008 CAREset L-R	Pump tube, System tube, Dialyzer connector, Patient connector, Arterial injection port, Venous injection port, Cassette (Body, Connectors, Foil, Coagel catching disk, Check valve, Evacuation membrane), Heparin tube, Luer Lock Female Connector, Rinse port adapter, Clamp, Cap		6008 CAREset L-R	泵管，PVC 管，透析接头，患者接头，动脉采样口，静脉采样口，盒式管路（包括一体式盒体，接头，背膜，血块过滤器，单向阀，疏水膜），肝素管路，鲁尔接头，预冲接头，管路夹，保护帽
6008 CAREset BVM L-R	Pump tube, System tube, Dialyzer connector, Patient connector, Arterial injection port, Venous injection port, Cassette (Body, Connectors, Foil, Coagel catching disk, Check valve, Evacuation membrane), Heparin tube, Luer Lock Female Connector, Rinse port adapter, Clamp, Cap, BVM Cuvette		6008 CAREset BVM L-R	泵管，PVC 管，透析接头，患者接头，动脉采样口，静脉采样口，盒式管路（包括一体式盒体，接头，背膜，血块过滤器，单向阀，疏水膜），肝素管路，鲁尔接头，预冲接头，管路夹，保护帽，BVM 液体槽

Structure diagram of compositions of 6008 CAREset-R product family

6008 CAREset-R 产品系列各组成部分结构示意图

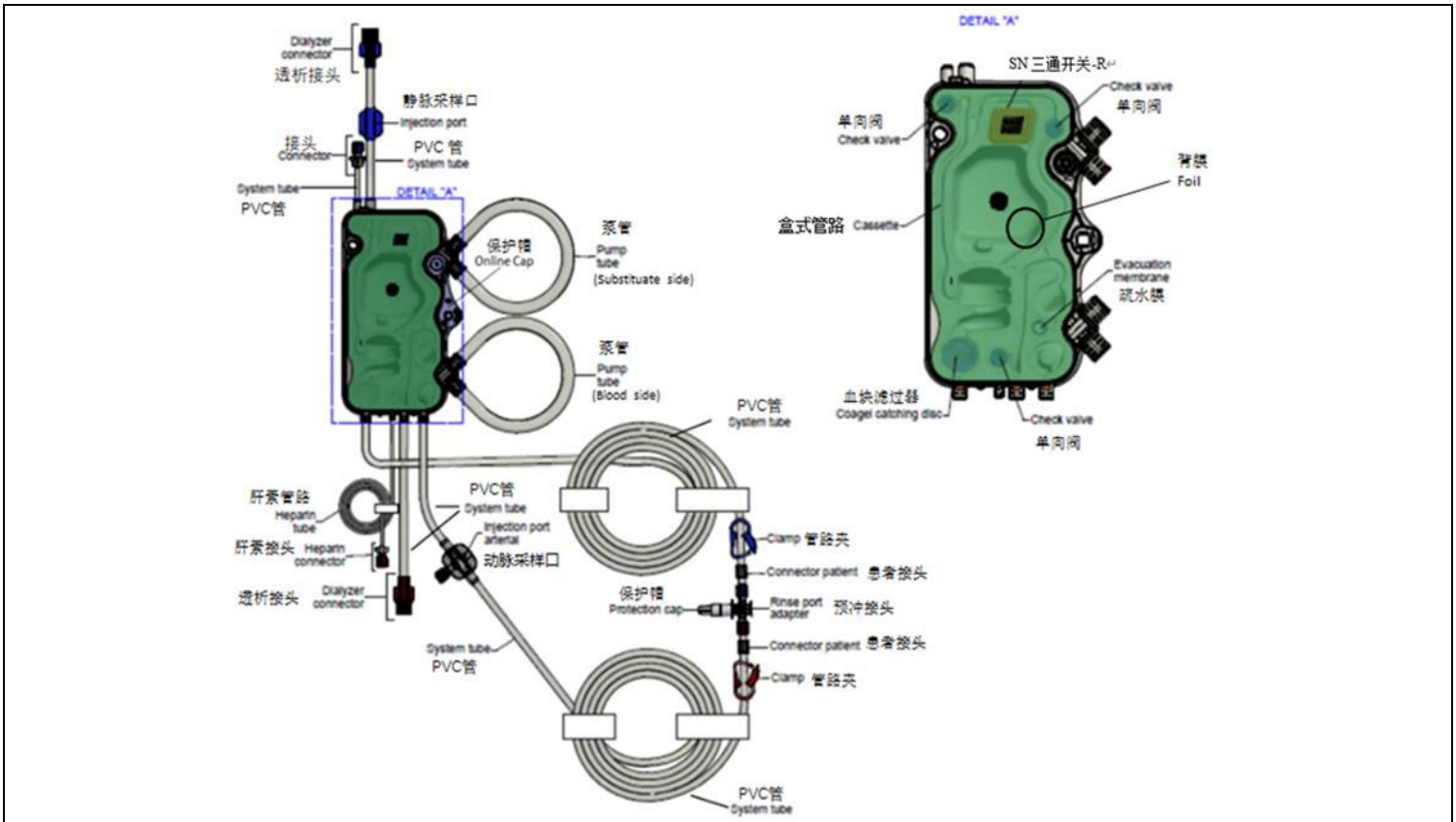

Figure 1 6008 CAREset-R/6008 CAREset L-R representative drawing

图 1 6008 CAREset-R/6008 CAREset L-R 结构图

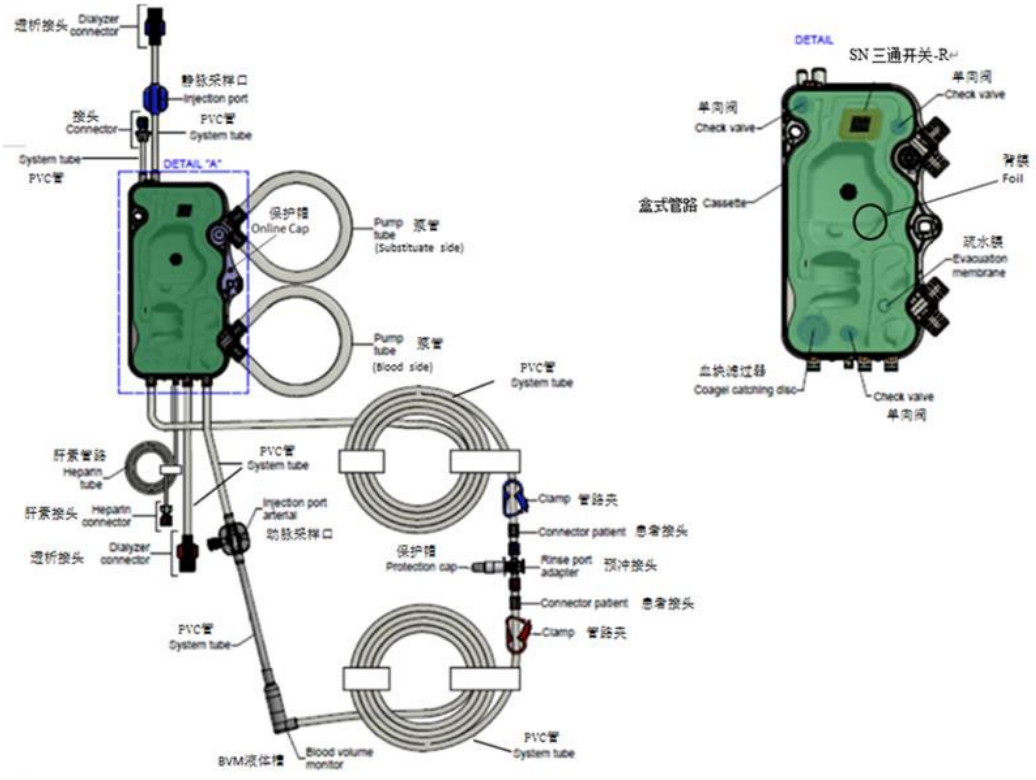

Figure 2 6008 CAREset BVM-R/6008 CAREset BVM L-R representative drawing

图 2 6008 CAREset BVM-R/6008 CAREset BVM L-R 结构图

GENERAL INFORMATION

General description of the product

The 6008 CAREset-R product family is intended to be used and is compatible with 6008 hemodialysis system for extracorporeal blood purification (refer to label). Intermittent (not continuous) dialysis modalities can be performed with the 6008 CAREset-R product family.
The 6008 CAREset-R product family is intended for single use.
The 6008 CAREset-R product family is designed to provide extracorporeal blood treatment to patients suffering from renal insufficiency.
The 6008 CAREset-R disposables consist of a rigid cassette which is the main component of the disposable and delivers fluid paths on the arterial line (RED) and venous line (BLUE) of the blood circuit as well as connection to a substituate fluid path. Connected to the cassette are different lines to deliver the pumping functionality as well as the blood flow from and to the patient and the dialyzer.

The variants of the 6008 CAREset-R product family are:

- 6008 CAREset-R
- 6008 CAREset BVM-R (with BVM cuvette)
- 6008 CAREset L-R (version with an increase of the tube length of arterial and venous line to the dialyzer to connect the cassette system with FX-series and F-series dialyzers).
- 6008 CAREset BVM L-R (6008 CAREset L-R with BVM cuvette)
- 6008 CAREset Low Volume-R and 6008 CAREset Low Volume BVM-R (pediatric disposable)

Note: 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R are not registered in China. And Single Needle mode is not applicable in China.

Product Blood Priming Volume:
6008 CAREset-R: 115 mL
6008 CAREset BVM-R: 122 mL
6008 CAREset L-R: 128 mL
6008 CAREset BVM L-R: 135 mL

The 6008 CAREset-R product family is pyrogen-free.

Sterilization

The 6008 CAREset-R product family is e-beam sterilized. For sterility test control, the test solution is collected by flushing the fluid path.

COMPOSITION

Tubes: medical grade soft-PVC.
Connectors and other components: Acrylonitrile butadiene styrene (ABS), Liquid silicone rubber (LSR), Polycarbonate (PC), Polyethylene (PE), Polypropylene (PP), Polyvinylchloride (PVC), Polyisoprene rubber (IR), Styrene Ethylene Butylene Styrene (SEBS), Styrene-Butadiene Copolymer (SBC), Polyethylene Terephthalate (PET), Polytetrafluoroethylene (PTFE).

INTENDED PURPOSE AND RELATED DEFINITIONS

Intended purpose

Channeling of blood and fluid in an extracorporeal treatment.

Intended Application

The 6008 CAREset-R product family is intended to be used and is compatible with 6008 hemodialysis system for extracorporeal hemodialysis, hemofiltration, hemodiafiltration and isolated ultrafiltration treatment.

Medical indication

Renal insufficiency requiring renal replacement therapy.

Intended patient population

The 6008 hemodialysis system including the 6008 CAREset-R product family is specified for the treatment of patients with chronic renal insufficiency and with a dry weight of more than 40 kg. The LOW VOLUME software option of the 6008 device allows treatment of patients with a dry weight between 10 kg and 40 kg with all the 6008 CAREset-R product family variants.
Low Volume disposable: the 6008 CAREset Low Volume-R and 6008 CAREset Low Volume BVM-R may only be used in combination with the LOW VOLUME software option of the 6008 device.

Note: Dry weight 40kg is a precise description on patient weight.

Intended user group and intended environment

The disposable must only be used by individuals with the appropriate training, knowledge, and experience on the proper operation and handling and for whom proof of instruction can be shown.
Operation in rooms suitable for dialysis located in professional healthcare facilities. Normative and local regulations must be observed.

SIDE EFFECTS

Occasional occurrence of the following treatment-related side effects is reported in current literature:
Acute urticaria, Anxiety, Blood loss, Cardiac arrhythmia, Cardiac tamponade, Clotting, Cramps, Depressive symptoms, Dialysis disequilibrium syndrome, Dialyzer reactions, Falls, Fever, Headache, Hemolysis, Hypotension, Impaired quality of life, Itching, Micro air embolisms, Nausea, Pain (chest and back), Restlessness, Seizures, Shivering, Sleep disturbance, Thirst, Vomiting.
Observe the package inserts enclosed with the hemodialysis concentrates and dialyzers, etc. To reduce possible side effects of the treatment, the therapy specification should be customized for each patient.
Additional side effects when blood or colloids are used to prime the extracorporeal circuit, e.g. for small children: acid-base and electrolyte imbalances; haemodynamic complications.

Reporting of serious incidents

If any serious incident occurs in relation to the device, including those not listed in this leaflet, the treating physician shall be informed immediately. Within the EU the user must report any serious incident that has occurred in relation to the device to the manufacturer according to labelling ( ) and the competent authority of the EU Member State in which the treatment is performed.
A serious incident can be any incident that directly or indirectly leads to the death of a patient, user or other person; to the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; or a serious public health threat.

基本信息

产品概述

6008 CAREset-R 产品系列用于且适于与 6008 血液透析设备配合使用进行体外血液净化（请参阅标签）。使用 6008 CAREset-R 产品系列可以进行间歇性（非连续）透析模式的治疗。
6008 CAREset-R 产品系列仅供一次性使用。
6008 CAREset-R 产品系列用于肾功能不全患者的体外血液治疗。
6008 CAREset-R 一次性产品包括一个硬质透析盒，它是一次性产品的主要组件，构成血液回路动脉管路（红色）和静脉管路（蓝色）中的液体通路，并可连接至 置换 液体通路。各种不同管路会连接至该透析盒，以提供泵送功能以及输送从患者和透析器流出以及流入患者和透析器的血液。

6008 CAREset-R 产品系列的不同版本包括：

- 6008 CAREset-R
- 6008 CAREset BVM-R（配置 BVM 管）
- 6008 CAREset L-R（该版本增加了连接透析器的动脉和静脉管路的管长，以连接透析盒系统与 FX 系列和 F 系列透析器）。
- 6008 CAREset BVM L-R（6008 CAREset L-R，配置 BVM 管）
- 6008 CAREset Low Volume-R 和 6008 CAREset Low Volume BVM-R（儿童用一次性产品）

注意：6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R这两个版本未在中国注册。同时在中国不适用单针模式。
产品血液预充容量：
6008 CAREset-R: 115 mL
6008 CAREset BVM-R: 122 mL
6008 CAREset L-R: 128 mL
6008 CAREset BVM L-R: 135 mL

6008 CAREset-R 产品系列不含热原。

灭菌

6008 CAREset-R 产品系列是电子束灭菌产品。采用测试液冲洗液路进行无菌质控测试。

成分

管路：医用级软 PVC。
接头和其他组件：丙烯腈-丁二烯-苯乙烯共聚物(ABS)、液体硅橡胶 (LSR)、聚碳酸酯 (PC)、聚乙烯 (PE)、聚丙烯 (PP)、聚氯乙烯 (PVC)、聚异戊二烯橡胶 (IR)、苯乙烯-乙烯-丁烯-苯乙烯嵌段共聚物 (SEBS)、苯乙烯-丁二烯嵌段共聚物 (SBC)、、聚对苯二甲酸乙二醇酯 (PET)、聚四氟乙烯 (PTFE)。

预期用途和相关说明

预期用途

在体外治疗中输送血液和液体。

适用范围

该产品与血液透析设备配合使用， 用于体外血液透析、血液滤过、血液透析滤过及单纯超滤治疗。

医学适应症

肾功能不全，需要肾脏替代治疗。

预期患者人群

6008 血液透析设备（包括 6008CAREset-R 产品系列在内）专用于治疗慢性肾功能不全和干体重超过 40kg 的患者。使用 6008 仪器的 LOWVOLUME 软件选件，可以对干体重在 10kg 和 40kg 之间的患者进行治疗，所有 6008CAREset-R 系列产品均可。

注意: 干体重40kg为患者体重的准确描述。

预期用户群体和预期环境

只有在正确操作和处理方法方面经过适当培训、拥有相应知识和经验且可以出示培训证明的人员才能使用本一次性产品。
在专业医疗场所内适合透析的房间操作。必须遵守规范性和地方性法规。

副作用

据当前文献报告，偶尔会发生以下与治疗相关的副作用：
急性荨麻疹、焦虑、失血、心律失常、心包填塞、血凝块、痉挛、抑郁症状、透析平衡失调综合征、透析反应、跌倒、发热、头痛，溶血、低血压、生活质量受损、瘙痒、微空气栓塞、恶心、疼痛（胸部和背部）、躁动、癫痫发作、寒颤、睡眠障碍、口渴、呕吐。
阅读血液透析浓缩液和透析器等随附的使用说明书。为了减少治疗可能产生的副作用，应为每位患者制定个性化治疗方案。
使用血液或胶体灌注体外回路时（如对儿童）的额外副作用：酸碱和电解质失衡；血液动力学方面的并发症。

严重事故报告

如果发生与仪器有关的任何严重事故，包括本说明书中未列出的事故，应立即告知治疗医生。在欧盟范围内，用户必须将发生的任何与仪器有关的严重事故报告给制造商（根据标签 ）和执行治疗所在欧盟成员国的主管部门。
严重事故指导致以下后果的任何事故：直接或间接致使患者、用户或其他人死亡；患者、用户或其他人的健康状况发生暂时性或永久性的严重恶化；出现严重的公共健康威胁。

CONTRAINDICATIONS
Therapy related contraindication
Refer to the Instructions for Use of the 6008 hemodialysis system for more information of general contraindications for extracorporeal blood purification.

PERFORMANCE CHARACTERISTICS
Refer to the Instructions for Use of the 6008 hemodialysis system for essential performance parameters.

METHOD OF ADMINISTRATION
Handling Instructions
The 6008 CAREset Low Volume-R and 6008 CAREset Low Volume BVM-R can be used only in combination with the LOW VOLUME software option.
Refer to Instructions for Use of the 6008 hemodialysis system regarding how to handle the 6008 CAREset-R product family during preparation, treatment and reinfusion. Also, the Instructions for Use of the dialyzer must be considered.
Check the compatibility and safety of the connections (Luer lock) to the patient, to the dialyzer and to syringes or infusion systems.

Preparation
- The 6008 CAREset-R product family are intended to be used and is compatible with 6008 hemodialysis system (refer to label) and shall be used only after appropriate instruction or training.
- The 6008 CAREset-R product family must be used in combination with Fresenius Medical Care dialyzers of the FX- or F-series.
- When using F-series dialyzers, the 6008 CAREset L-R or 6008 CAREset BVM L-R must be used in order to avoid kinking.
- Ensure that the F-series dialyzer is correctly centered in the dialyzer holder to avoid kinking of the upper blood line by swiveling the monitor and to avoid kinking of the lower blood line by height adjustable dialysis beds or chairs.
- Ensure that the position of the venous insertion site / sampling site is correct for use and the arterial insertion site / sampling site is closed.
- Tighten all closure caps and ensure that all connectors and caps are secured.
- Connect the 6008 CAREset-R product family variants aseptically without touching open connectors.
- Color codes should be followed and used in line with the corresponding markings on the 6008 hemodialysis device.
- Fill and rinse the disposable in accordance with the Instructions for Use of the device or supplemental Instructions for Use for additional options, and training, if applicable.
- The Fresenius Medical Care disposable is designed to withstand the maximum and minimum manufacturer's recommended pressures and flow rates generated in use with the respective 6008 hemodialysis system. All the other relevant specifications of the device apply.

Additional information for Low Volume Treatment
- When using the 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R it is recommended to use the dedicated Low Volume dialyzer holder from FMC to prevent the blood line from kinking.
- The BTM cannot be used in combination with a 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R. This is due to the fact that the blood line diameters of the 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R are much smaller than that of the standard 6008 CAREset-R. Therefore, the BTM sensor will not work.
- The 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R must be used in combination with the specific software to perform low volume treatments. The recommended blood flow rate range is 30 ml/min to 150 ml/min. Refer to the Instructions for Use of the 6008 hemodialysis system for additional information and limitation regarding patient body weight.
- Take care not to pull the thin segments of the patient lines during preparation or removal of the 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R in order to avoid damaging the cassette and the lines.

Treatment
- Refer to the operating programs of instruction for use of the 6008 hemodialysis system for treatment related information.
- Ensure that the arterial and the venous blood lines are completely air free.
- After manipulation of lines ore use of components during treatment check and, if necessary, restore the correct position of the lines and components.
- Close the arterial insertion site / sampling site after usage and close the Luer connector with a sterile closure cap.
- The venous insertion line should be closed with a sterile closure cap except when in use
- Disinfect the corresponding access sites without protective cap prior to connection with other products.

Reinfusion
- Refer to the Instructions for Use of the 6008 hemodialysis system for the termination of the treatment and also to the “Disposal” Section of the present Instructions for Use.
- Close all clamps on the 6008 CAREset-R product family variants before removing the disposable to reduce the risk of fluid leakage.
- During ONLINE reinfusion, medication via the arterial insertion site is forbidden and the site must be closed. The medication must be administered via the venous insertion site or directly via the vascular access afterwards. The arterial insertion site has to be closed prior the reinfusion.

WARNINGS AND PRECAUTIONS
Warnings
- The disposable must only be used by individuals with the appropriate training, knowledge, and experience of the proper operation and handling and for whom proof of instruction can be shown.
- The 6008 CAREset-R product family is intended for single use. The correct function of all interfaces is ensured only for single use. Re-use may be hazardous to both patient and operator (e.g. impaired performances, contamination).
- Do not use after use-by date (refer to label).
- If the carton is damaged, check the products contained carefully. Do not use if the sterile package is damaged, if the protective or closure caps are not in place, or if there is any visible damage on the finished products (e.g. kinked lines).
- Make sure all lines and chambers are correctly inserted into the respective holders. Avoid kinking or occluding the disposable in order to avoid mechanical and chemical damage to cellular blood constituents.
- For hygienic and functional reasons, it is recommended that the selected 6008 CAREset-R product family variants are only inserted immediately prior to the treatment time, thereby keeping the preparation and circulation times nearer to the beginning of the treatment and in compliance with applicable guidelines.
- Connect the 6008 CAREset-R product family variants aseptically without touching open connectors.

禁忌症
治疗相关禁忌症
有关体外血液净化一般禁忌症的更多信息，请参阅 6008 血液透析设备使用说明书。

性能特征和临床益处
有关基本性能参数，请参阅 6008 血液透析设备的使用说明书。
肾功能不全患者体外血液治疗的临床益处包括通过排毒和控制液体和电解质平衡来预防该疾病发生其他致命性的进展。
使用方法
操作说明
6008 CAREset Low Volume-R 和 6008 CAREset Low Volume BVM-R 仅能与 LOW VOLUME 软件选件配合使用。
请参阅 6008 血液透析设备使用说明书，了解如何在准备、治疗和再输注过程中操作 6008 CARESET-R 产品系列。此外，必须参考透析器的使用说明书。
检查与患者、透析器、注射器或输注系统连接的接口（螺口）的兼容性和安全性。

准备
- 6008 CAREset-R 产品系列用于且适于与 6008 血液透析设备配合使用（请参阅标签），应仅在经过适当的指导或培训后使用。
- 6008 CAREset-R 产品系列必须与 FX 或 F 系列的 Fresenius Medical Care 透析器配合使用。
- 使用 F 系列透析器时，必须避免 6008 CAREset L-R 或 6008 CAREset BVM L-R 产生扭结。
- 确保 F 系列透析器正确位于透析器支架的中央，以避免在转动监视器时扭结上方血液管路，并避免在调节透析床或椅子高度时扭结下方血液管路。
- 确保静脉插入部位/采样部位的位置正确可用，且动脉插入部位/采样部位已关闭。
- 拧好所有盖帽，确保所有接头和盖帽均已拧紧。
- 不接触外露的接头，在无菌条件下连接各种 6008 CAREset-R 产品系列版本。
- 应遵循颜色标记并按照 6008 血液透析仪器上的相应标记使用。
- 根据仪器使用说明书或附加选件的补充使用说明书以及培训内容（如适用），灌注和冲洗一次性产品。
- Fresenius Medical Care 一次性产品设计可以承受制造商建议的最大和最小压力和流量（与相应的 6008 血液透析设备配合使用时）。仪器的所有其他相关说明均适用。

Low Volume 治疗的附加信息
- 使用 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R 时，建议使用专用的 FMC Low Volume 透析器支架，以防止血液管路发生扭结。
- BTM 不能与 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R 配合使用。这是因为 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R 的血液管路直径比标准 6008 CAREset-R 的血液管路直径小得多。因此，BTM 传感器将不起作用。
- 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R 必须与特定软件配合使用，才能进行低容量治疗。建议的血液流速范围为 30 ml/分钟至 150 ml/分钟。有关患者体重的更多信息和限制，请参阅 6008 血液透析设备的使用说明书。
- 在准备或拆卸 6008 CAREset Low Volume-R / 6008 CAREset Low Volume BVM-R 时，小心不要拉扯患者管路的细段，以免损坏透析盒和管路。

治疗
- 有关治疗的相关信息，请参考6008血液透析设备的使用说明书中运行程序的相关内容。
- 确保动脉和静脉血液管路内完全没有空气。
- 在治疗过程中操纵管路或使用组件后，检查管路和组件是否处于正确位置，并在必要时恢复正确位置。
- 使用后关闭动脉插入部位/采样部位，并使用无菌盖帽关闭螺口接头。
- 应使用无菌盖帽关闭静脉插入管路，使用时除外
- 在与其他产品连接之前，请先对没有保护盖的相应接入部位进行消毒。

回输
- 有关终止治疗的信息，请参阅 6008 血液透析设备的使用说明书以及本使用说明书的“处置”一节。
- 拆卸一次性产品之前，请关闭各种 6008 CAREset-R 产品系列版本上的所有夹具，以降低液体泄漏的风险。
- ONLINE 再输注时，禁止通过动脉插入部位给药，且必须关闭该部位。必须通过静脉插入部位或随后直接通过血管通道给予药物。在再输注之前，必须关闭动脉插入部位。

警告和注意事项
警告
- 只有在正确操作和处理方法方面经过适当培训、拥有相应知识和经验且可以出示培训证明的人员才能使用本一次性产品。
- 6008 CAREset-R 产品系列仅供一次性使用。仅一次性使用才能确保所有接口的正确功能。重复使用可能对患者和操作人员都有害（如性能下降、污染）。
- 如果产品已过有效期（参见标签），请勿使用。
- 如果包装盒损坏，请仔细检查其中的产品。如果无菌包装损坏、保护帽或盖帽未就位或成品上有任何明显损坏（如管路扭结），请勿使用。
- 确保所有管路和腔室正确插入相应的夹持器。避免扭结或堵塞本一次性产品，以免对血液细胞成分造成机械性和化学性破坏。
- 出于卫生和功能原因，建议仅在临治疗前插入所选的 6008 CAREset-R 产品系列版本，这样可以使准备和循环时间更接近治疗开始，并符合适用的指南。
- 不接触外露的接头，在无菌条件下连接各种 6008 CAREset-R 产品系列版本。
- 在与其他产品连接之前，请使用 70% 酒精消毒无保护帽的接入部位，以降低感染风险，并在连接前待其干燥。
- 在临床使用之前，应确定消毒剂（建议的消毒剂之外）是否适用于接入部位。

- Disinfect with 70% alcohol access sites without protective cap prior to the connection with other products to reduce the risk of infection and let it dry before the connection.
- The compatibility of disinfectants (other than those recommended) with access sites shall be determined prior to clinical use.
- Excessive negative pressure may cause partial collapse of the blood pump segment resulting in an actual blood flow substantially less than indicated on the device.
- Minimum temperature of use of the disposable is 18° C (64° F).
- Do not use needles with a diameter larger than 20 gauge to puncture injection sites.
- In case of blood leakages at the hydrophobic membranes of the 6008 CAREset (evacuation port, Single-Needle port) at the end of the treatment, the 6008 hemodialysis device has to be taken out of service and cleaned as per manufacturer's recommendation.
- To ensure a secure connection between patient access and blood line, hold and screw the colored (blue, red) coupling nut on the bloodline only. Do not apply the screwing torque to the inner part of the connector. After the connection, check that the components are firmly screwed together.
- Do not touch the substituate connector during unpacking and mounting of the 6008 CAREset-R product family variants.
- Inspect the extracorporeal circuit during priming and treatment. If there are kinked lines or leakages, take measures (e.g. tighten connectors) or change the 6008 CAREset-R product family variants, if necessary.
- To avoid air embolism, make sure that the patient lines are correctly inserted into the 6008 hemodialysis system's air bubble detectors (arterial line: left side, venous line: right side).
- During ONLINE reinfusion, medication via the arterial insertion site is forbidden and the site must be closed. This can cause a risk of air infusion to the patient.
- · Cleansing solutions and disinfectants may damage materials employed for the 6008 CAREset-R product family. Safety and performance of use can no longer be guaranteed, and the manufacturer assumes no liability.
- The plastics used can be incompatible with drugs or disinfectants (e.g. connectors made of polycarbonate can develop cracks when in contact with aqueous solutions with pH > 10).
- If nutritional solutions are administered into the bloodline, wetting of the Luer lock connection with lipidic fluids can weaken the properties of the plastic material used. Make sure that during the connection, the infusion line close to the Luer lock connection site remains completely free of nutrition solution.
- The system contains large-size packaging, foils and small parts which should be kept away from children.
- Children can be strangled by lines; lay lines in such a manner that they do not pose a danger to children.

Treatment time
- The treatment time shall follow China hemodialysis standard treatment practice.

Particular notes on materials and substances
CMR substances and endocrine-disrupting substances
For SVHC information according to Article 33 of Regulation (EC) No. 1907/2006 ("REACH") please use this page: www.freseniusmedicalcare.com/en/svhc.

Special precautions for storage
Follow the indication of the product label. Protect from moisture, freezing and excessive heat.

Disposal
Ensure safe disposal of any unused product or waste material in accordance with local regulations.
Materials that have been in contact with blood or other material of human origin may be infectious. Dispose of such materials by taking the necessary precautionary measures and in accordance with local regulations for (potentially) infectious materials.

WARRANTY
The manufacturer shall not be liable for any misuse, improper handling, non compliance with Instructions for Use and cautionary notes and for any damage incurred subsequent to the manufacturer's delivery of the 6008 CAREset-R product family.

DATE OF REVISION OF TEXT
10/2023 Second Modified

For the electronic version of instruction for use (e-IFU), please use this page:
www.freseniusmedicalcare.com/en/product-information.

INFORMATION ON THE MANUFACTURER
Legal manufacturer

FRESENIUS MEDICAL CARE CE 0123
Fresenius Medical Care AG
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Germany +49 6172 609-0
www.freseniusmedicalcare.com/en/product-information

Registrant/Manufacturer: Fresenius Medical Care AG

Address of Registrant/Manufacturer: Else-Kröner-Str. 1, 61352 Bad Homburg, Germany

Telephone of Registrant/Manufacturer: +49 6172 609-0

- 过大的负压可能会导致血液泵段部分凹陷，从而导致实际血流明显低于仪器上的指示值。
- 本一次性产品的最低使用温度为 18° C (64° F)。
- 切勿使用直径大于 20 号的针头刺穿注射部位。
- 如果在治疗结束时 6008 CAREset 的疏水膜（排出口、单针口）发生血液泄漏，则必须停止使用 6008 血液透析仪器，并根据制造商的建议进行清洁。
- 为确保患者通路与血液管路牢固连接，仅将有色（蓝色、红色）连接螺母连接并固定在血液管路上。切勿将扭力施加至接口的内侧。连接后，检查组件是否牢固地拧在一起。
- 请勿在 6008 CAREset-R 产品系列版本的拆开包装和安装过程中接触到 substituate 接头。
- 在灌注和治疗过程中检查体外回路。如果存在管路扭结或泄漏，请采取措施（如拧紧接头）或在必要时更换 6008 CAREset-R 产品系列版本。
- 为避免出现空气栓塞，请确保患者管路正确插入 6008 血液透析设备的气泡检测器（动脉管路：左侧，静脉管路：右侧）。
- ONLINE 再输注时，禁止通过动脉插入部位给药，且必须关闭该部位。否则会存在将空气注入患者的风险。
- 清洗液和消毒剂可能会损坏 6008 CAREset-R 产品系列所用的材料。如若使用，则无法再保证产品的安全性和性能，对此制造商不承担任何责任。
- 使用的塑料可能不宜接触药物或消毒剂（例如，当接触 pH 值 > 10 的水溶液时，聚碳酸酯制成的接头可能会出现裂纹）。
- 如果在血液管路中加入营养溶液，脂质液体润湿螺口接头后会削弱所用塑料材料的性能。连接期间，确保靠近螺口接头连接部位的输注管路完全不会接触营养溶液。
- 本系统包含大尺寸包装、箔纸和小部件，应远离儿童。
- 儿童可能会被管路勒死；以不会对儿童造成危险的方式布置管路。

治疗时间
- 应按照中国血液净化操作规程使用本一次性产品。

关于材料和物质的特别说明
致癌、致突变、致生殖毒性物质和干扰内分泌的物质
有关欧盟委员会第 1907/2006 号法规（"REACH"）第 33 条规定的 SVHC 信息，请访问此网页：www.freseniusmedicalcare.com/en/svhc

关于储存的特殊注意事项
按照产品标签上的说明操作。防止受潮、受冻和过热。

废弃处理
务必按照当地法规安全处置任何未使用的产品或废弃材料。
与血液或其他人源性物质接触的物质可能具有传染性。采取必要的预防措施并根据当地针对（潜在）传染性物质的法规处置此类物质。

保证
对于任何错误使用、不当处理、不遵守使用说明书和警示说明的情况，以及在制造商交付 6008 CAREset-R 产品系列后发生的任何损坏，制造商概不负责。

说明书修订日期
2023年10月第2次修订

有关电子版使用说明书 (e-IFU)，请访问此网页：
www.freseniusmedicalcare.com/en/product-information.

生产企业信息
法定生产企业

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Medical Device Registration Certificate No./Product Technical Requirements No.: GuoXieZhuJin20233100280

Date of Manufacture: See outer package

Shelf life: 1 years

Version No：20233100280-V2

生产地址：No: 16, Liman Serbest Bölgesi Mahallesi, 07070 Antalya, TURKEY

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