FRESENIUS MEDICAL CARE

ENGLISH en **Instructions for Use – Tubing Systems for Continuous Blood Purification**

ZHONGWEN zh-cn **使用说明书—连续性血液净化管路**

en INSTRUCTIONS FOR USE

Tubing Systems for Continuous Blood Purification

Models:

multiFiltratePRO HDF
multiFiltratePRO Ci-Ca HD
multiFiltratePRO Ci-Ca HDF
Adapter Hansen male / Luer-lock male

Please read the following instructions carefully.

Refer to product or packaging label for:
- Type / Code of Bloodline/Tubing system
- Manufacturer and model of the machine for which the product is intended
- Applicable symbols
- Arterial / Access / Inlet Line (RED); Venous / Return / Outlet Line (BLUE); Filtrate Line (YELLOW); Dialysate Line (GREEN); Substituate Line / Plasma Line (WHITE)

zh-cn 使用说明书

连续性血液净化管路

型号、规格：

multiFiltratePRO HDF
multiFiltratePRO Ci-Ca HD
multiFiltratePRO Ci-Ca HDF
Adapter Hansen male / Luer-lock male

请仔细阅读以下说明。

以下信息参考产品或者包装标签：
- 连续性血液净化管路的类型/代码
- 产品预期使用的机器的制造商和型号
- 适用标识
- 动脉/引出/入口管路（红色）；静脉/返回/出口管路（蓝色）；滤过液管路（黄色）；透析液管路（绿色）；置换液管路/血浆管路（白色）

SYMBOLS USED ON LABELS

Symbol	Meaning	Symbol	Meaning
MD	Medical Device		Do not use if package is damaged
UDI	Unique Device Identifier		Consult instructions for use or consult electronic instructions for use
	Patient information website		Non-pyrogenic
LATEX	Bloodline/Tubing systems does not contain any natural Latex		Single Sterile Barrier System
STERILE EO	Sterile, Sterilized using ethylene oxide		Do not re-use
MAX TIME / VOLUME	Replace the Blood line after maximum usage time or pumped blood volume as indicated on the primary package		Caution (Consult the Instructions for Use for important cautionary information such as warnings and precautions)
	Pump segment diameter	LOT	Batch code
	Blood Priming Volume	REF	Catalogue number
	Units		Date of manufacture
5°C 30°C	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed)		Expiry date
	Manufacturer		

标签所用符号

符号	含义	符号	含义
MD	医疗器械		如包装破损切勿使用
UDI	医疗器械唯一标识		查阅使用说明
	患者信息网站		无热原
LATEX	连续性血液净化管路不包含任何天然乳胶		单层无菌屏障系统
STERILE EO	产品无菌，经环氧乙烷灭菌		不得二次使用
MAX TIME / VOLUME	在达到初级包装上指示的最长使用时间或泵送血容量后，需要更换连续性血液净化管路		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）
	泵管内径	LOT	批次代码
	血液预充容量	REF	产品编号
	数量		生产日期
5°C 30°C	温度极限（表示医疗器械可安全暴露的环境的温度限制）		失效日期
	制造商		

Product composition

Product model	Product composition
multiFiltratePRO Ci-Ca HD	Arterial/venous tubing system, Filtrate tubing system, Dialysate tubing system, Citrate tubing (located in arterial tubing system) and calcium tubing system (located in venous tubing system)
multiFiltratePRO Ci-Ca HDF	Arterial/venous tubing system, Filtrate tubing system, Dialysate tubing system, Substitute tubing system, Citrate tubing (located in arterial tubing system) and calcium tubing system (located in venous tubing system)
multiFiltratePRO HDF*	Arterial/venous tubing system, Filtrate tubing system, Dialysate tubing system, Substitute tubing system
Adapter Hansen male/Luer-lock male	Cap, PVC tube, Connector Hansen male

* multiFiltratePRO HDF model: dialysate tubing and substitute tubing share one feed line.

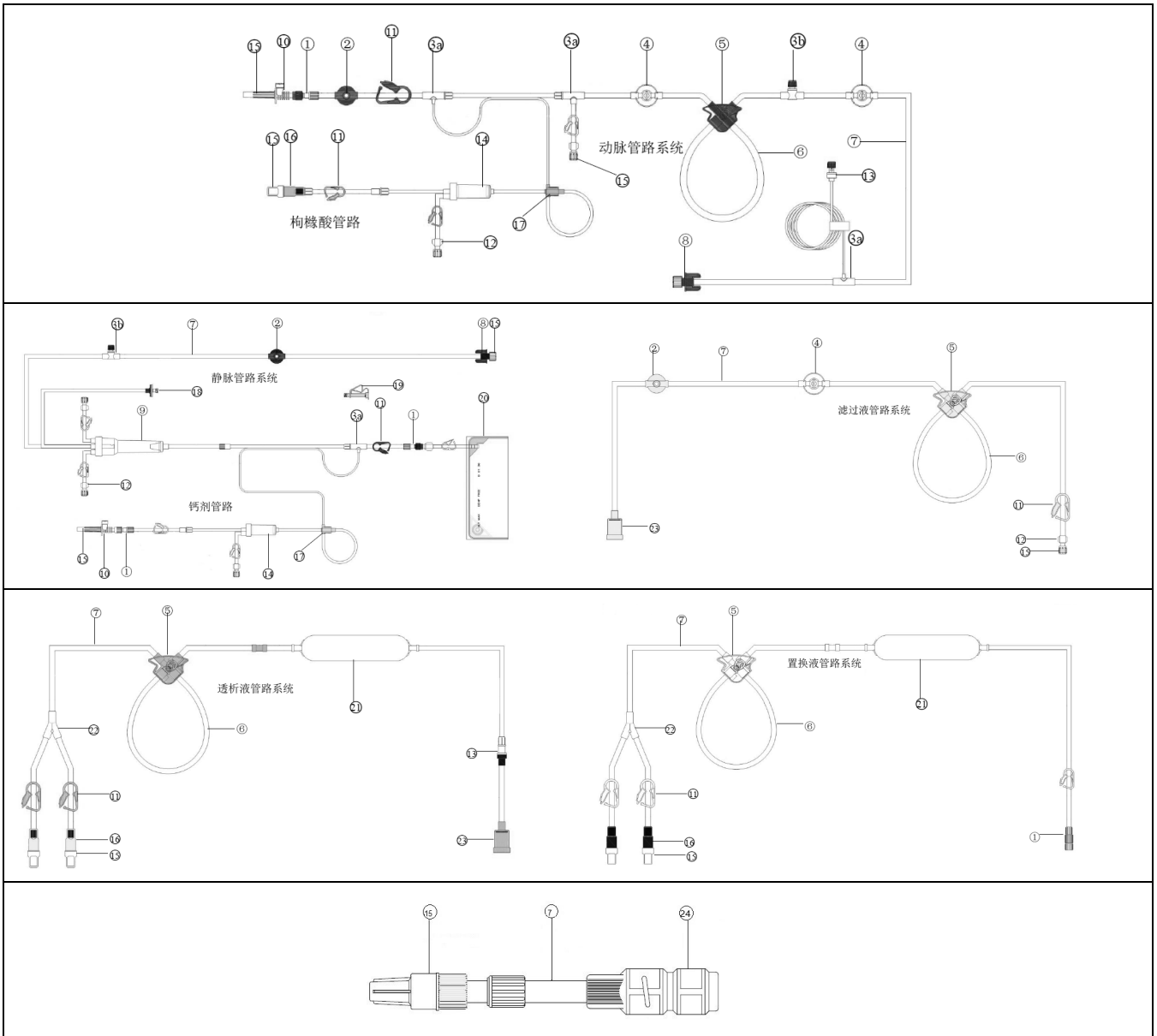
产品组成

产品型号	产品组成
multiFiltratePRO Ci-Ca HD	动/静脉管路系统、滤过液管路系统、透析液管路系统、枸橼酸（位于动脉管路系统）及钙剂管路系统（位于静脉管路系统）
multiFiltratePRO Ci-Ca HDF	动/静脉管路系统、滤过液管路系统、透析液管路系统、置换液管路系统、枸橼酸（位于动脉管路系统）及钙剂管路系统（位于静脉管路系统）
multiFiltratePRO HDF*	动/静脉管路系统、滤过液管路系统、透析液管路系统、置换液管路系统
Adapter Hansen male/Luer-lock male	盖帽、PVC 管路、接头

* multiFiltratePRO HDF型号：透析液管路和置换液管路共用一段供液管

Structure diagram of compositions of tubing systems for continuous blood purification

连续性血液净化管路各组成部分结构示意图



Arterial tubing system	动脉管路系统
Citrate tubing	枸橼酸管路
Venous tubing system	静脉管路系统
Calcium tubing	钙剂管路
Filtrate tubing system	滤过液管路系统
Dialysate tubing system	透析液管路系统
Substitute tubing system	置换液管路系统

1	Male luer lock	1	外圆锥接头
2	Injection Site	2	采样口
3a	T-connector (without antisphon valve)	3a	T 型接头（不带单向阀）
3b	T-connector (with antisphon valve)	3b	T 型接头（带单向阀）
4	Pressure Dome	4	压力探测器
5	Alpha Clip	5	钳形接头
6	Pump Tube	6	泵管（血路）
			泵管（液路）
7	PVC Tube	7	PVC 管
8	Dialyser Connector	8	透析器接头
9	Venous Chamber	9	静脉气体捕获器
10	Spike	10	穿刺器
11	Clamp	11	管路夹
12	Female luer lock	12	内圆锥接头
13	Antisphon Valve	13	单向阀
14	Drip Chamber	14	滴斗
15	Caps	15	盖帽
16	HF Male Connector	16	置换液接头
17	Pump Clip	17	固定器
18	Transducer Protector	18	传感器保护器
19	Recirculation connector	19	冲洗接头
20	Drainage Bag	20	收集液袋
21	Heat Chamber	21	加热囊
22	Y connector	22	Y 形接头
23	Filter adapter	23	滤器接头
24	Connector Hansen male	24	接头

GENERAL INFORMATION
General description of the product
Bloodline/Tubing systems are intended to be used and compatible with an extracorporeal blood purification system multi (Version multiFiltratePRO) device.

Bloodline/Tubing systems are intended for single use.

This product is sterile and pyrogen free.

Sterilization
This product is ethylene oxide sterilized (EO).

COMPOSITION
Tubes: medical grade soft-PVC.
Connectors and other components: Acrylonitrile butadiene styrene (ABS), Polybutylene Terephthalate (PBT), Polycarbonate (PC), Polyamide (PA), Polyethylene (PE), Polyethylene Terephthalate Glycol-modified (PETG), Polypropylene (PP), Polytetrafluoroethylene (PTFE), Polyvinylchloride (PVC), Silicone, Polyhydroxy Ether (PHE), Thermoplastic Elastomer (TPE), Polyethylene High-Density (HDPE), Methyl Methacrylate Acrylonitrile Butadiene Styrene (MBS).
INTENDED PURPOSE AND RELATED DEFINITIONS
Intended purpose
Channeling of blood and fluid in an extracorporeal treatment.

Intended Application
Bloodline/Tubing systems are intended for extracorporeal blood purification. multiFiltratePRO HDF model can be used in CVVH, CVVHD and CVVHDF treatment modes, multiFiltratePRO Ci-Ca HD model can be used in CVVHD mode, and multiFiltratePRO Ci-Ca HDF model can be used in CVVHDF treatment mode. The Adapter Hansen male/Luer-lock male model is used with the multiFiltratePRO HDF model for pre post CVVH treatment mode.

Medical Indication
- Acute kidney injury leading e.g., to severe electrolyte disturbances and/or severe acid-base-balance disturbance requiring continuous renal replacement therapy
- Volume overload requiring continuous renal replacement therapy
- Intoxications requiring continuous renal replacement therapy

Intended patient population
The devices have been specified by the manufacturer for the purpose of treating patients with a body weight of 40 kg and more, irrespective of their age, under consideration of the specified technical data of the device and the single-use items used (e.g., delivery rates, fill volumes).

基本信息
产品概述
连续性血液净化管路预期用于配合兼容的连续性血液净化设备 multi（Version multiFiltratePRO）使用。

连续性血液净化管路仅供一次性使用。

本产品无菌无热原。

灭菌
本产品经过环氧乙烷灭菌 (EO)。

产品组成
管路：医用级软 PVC。
接头和其他组件：丙烯腈丁二烯苯乙烯 (ABS)、聚对苯二甲酸丁二醇酯 (PBT)、聚碳酸酯 (PC)、聚酰胺 (PA)、聚乙烯 (PE)、乙二醇改性聚对苯二甲酸乙二醇酯 (PETG)、聚丙烯 (PP)、聚四氟乙烯 (PTFE)、聚氯乙烯 (PVC)、硅树脂、聚羟基醚 (PHE)、热塑性弹性体 (TPE)
、高密度聚乙烯 (HDPE)、甲基丙烯酸甲酯丙烯腈丁二烯苯乙烯(MBS)。

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
本产品适用于连续性血液净化治疗，multiFiltratePRO HDF型号可用于CVVH，CVVHD和CVVHDF三种治疗模式， multiFiltratePRO Ci-Ca HD型号可用于CVVHD模式，multiFiltratePRO Ci-Ca HDF型号可用于CVVHDF治疗模式。Adapter Hansen male/Luer-lock male型号与multiFiltratePRO HDF型号一起使用，可用于前-后CVVH治疗模式。

医学适应证
- 需要连续性肾脏替代治疗的急性肾损伤，如导致严重的电解质紊乱和/或严重的酸碱平衡失调
- 需要连续性肾脏替代治疗的容量超负荷
- 需要连续性肾脏替代治疗的中毒

预期患者人群
制造商指定该器械旨在用于治疗体重不低于 40 kg、任何年龄的患者，需考虑设备和所用的一次性产品的规定技术数据（例如：输送速率、注入量）。

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

SIDE EFFECTS
Occasional occurrence of the following side effects is reported in current literature:
- Hypotension
- Blood loss (e.g. hypovolemia, and hypovolaemic shock, hypotension, anaemia)
- Coagulation disorders (e.g. thrombocytopenia)
- Embolism (air-, thrombo-)
- Bacterial infection
- Hypothermia
- Haemolysis
- Hypersensitivity or hypersensitivity-like reactions (e.g. dyspnea, cardiopulmonary arrest, hypotension, urticaria, flushing, itching, abdominal pain, nausea, convulsions and unconsciousness).

Additional side effects might be specific to other devices and drugs used in the therapy.
Refer to the Instructions for Use of the multi (Version multiFiltratePRO) device for more information on treatment related side effects.

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. When the device is used outside the EU, the serious incident in relation to the device should also be reported to the local authority where 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 treat.

CONTRAINDICATIONS
Product related contraindications
Hypersensitivity to any of the material of the tubings as listed under composition or to ethylene oxide residues.
In severe cases the treatment must be discontinued, the blood should not be returned to the patient, and appropriate emergency medical treatment should be initiated.

Therapy related contraindication
Refer to the Instructions for Use of the multi (Version multiFiltratePRO) device for more information of general contraindications for extracorporeal blood purification.

PERFORMANCE CHARACTERISTICS
Refer to the Instructions for Use of the multi (Version multiFiltratePRO) device for essential performance parameters.

METHOD OF ADMINISTRATION
Handling Instructions
Refer to the Instructions for Use of the multi (Version multiFiltratePRO) device of the regarding how to handle the disposable during set-up (e.g. selection of treatment type), priming, treatment and reinfusion. Also, the Instructions for Use of other disposables such as the haemofilter, plasmafilter must be taken into account.

Preparation
- Refer to the Instructions for Use of the multi (Version multiFiltratePRO) device for details on any preparatory handling of the disposable before it is ready for use or during its use and information to verify if the disposable is properly installed.
- The Bloodline/Tubing systems are designed for machines for extracorporeal blood purification multiFiltrate or multi (version: multiFiltratePRO) (refer to label) and shall be used only after appropriate instruction or training. Use only Bloodline/Tubing systems approved for the selected therapy.
- The infusion administration lines should be clamped, except when needed.
- Unpack and connect the Bloodline/Tubing systems aseptically without touching open connectors.
- Colour codes should be followed and used in line with the corresponding markings on the device.
- Handle pumps and pump clips in accordance to the Instructions for Use of the device.
- Tighten all closure caps and ensure that all connectors and caps are secured.
- 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.
- 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 multi (Version multiFiltratePRO) device**.** All the other relevant specifications of the device apply.

Treatment
- In cases where the extracorporeal volume of the circuit consists of a significant amount of the patient's circulating blood volume, as well as in anaemic and/or haemodynamically unstable patients, priming the circuit with blood or blood substitution fluid may be considered.
- To ensure correct functionality of the bubble catchers, fill to about

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医务人员才能使用本一次性产品。
本一次性产品可在专业医疗机构中适合进行血液净化治疗的诊疗室使用。
请务必遵守规范性法规和当地法规。

治疗相关并发症
据当前文献报告，偶尔会出现以下治疗相关并发症：
- 低血压
- 失血（例如血容量过低和低血容量性休克、低血压、贫血）
- 凝血功能障碍（例如血小板减少）
- 栓塞（空气栓塞、血栓栓塞）
- 细菌感染
- 低体温症
- 溶血
- 过敏或类过敏的反应（例如呼吸困难、心跳呼吸骤停、低血压、荨麻疹、潮红、瘙痒、腹痛、恶心、抽搐和意识丧失）。

其他相关并发症可能由治疗中所用的其他器械和药物所致。
有关治疗相关并发症的更多信息，请查阅 multi（Version multiFiltratePRO）设备的使用说明书。

严重事故报告
如果发生与器械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器械有关的严重事故报告给标签指明的制造商（🏭）和实施治疗所在欧盟成员国的主管部门。如器械在欧盟范围外使用，则同时用户必须将发生的任何与器械有关的严重事故报告给实施治疗所在地的当地主管部门。
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。

禁忌症
产品相关禁忌症
对产品组成部分中所列的任何管路材料或对环氧乙烷残留物有过敏反应。
在严重的情况下，必须停止治疗，不应将血液回输给患者，还应启动适当的紧急医学治疗。

治疗相关禁忌症
有关体外血液净化的一般禁忌症的更多信息，请查阅multi（Version multiFiltratePRO）设备使用说明书。

性能特征
有关基本性能参数，请参阅multi（Version multiFiltratePRO）设备使用说明书。

使用方法
操作说明
请参阅multi（Version multiFiltratePRO）设备使用说明书，了解如何在设置（例如：选择治疗类型）、预充、治疗和回输过程中操作本一次性产品。此外，还必须考虑其他一次性产品（如血液透析滤过器、血液滤过器）的使用说明书。

准备
- 请参阅 multi（Version multiFiltratePRO）设备使用说明书，了解有关本一次性产品在可以使用前或使用期间的任何准备操作的详细信息，以及验证本一次性产品是否正确安装的信息。
- 连续性血液净化管路专门用于进行体外血液净化的设备 multi（Version multiFiltratePRO）（参见标签），而且仅在相关人员接受了适当指导或培训后方可使用。仅使用批准用于选定治疗的连续性血液净化管路。
- 除需要使用时，应夹紧输注管路。
- 在无菌条件下，打开包装并连接连续性血液净化管路，请勿接触暴露的接头。
- 应当根据机器上相应的标记，遵循颜色代码使用相应管路。
- 按照设备的使用说明书操作泵和泵夹。
- 拧紧所有密封帽，确保所有接头和盖帽均已连接牢固。
- 根据设备的使用说明书或针对附加选项的补充使用说明书以及培训内容（如适用）灌注和冲洗本一次性产品。
- 费森尤斯公司一次性产品可以耐受在与相应multi（Version multiFiltratePRO）设备配合使用时生成的最大和最小的制造商建议的压力和流量。设备的所有其他相关说明均适用。

治疗
- 如果体外回路容量占用患者的大量循环血容量，或用于贫血和/或血液动力学不稳定的患者，则可考虑使用血液或血液置换液预充回路。
- 为确保气体捕获器正常工作，请灌注至顶部下方约 1 cm 处。这可避免液体接触疏水性过滤器以及空气进入体外循环。如果液体到达并接触到传感器保护器 (TP)

1 cm below the top. This avoids fluid contacting the hydrophobic filter as well as air entering the extracorporeal circuit. In the event that fluid reaches and comes into contact with the hydrophobic filter within the Transducer Protector (TP) the disposable must be replaced.
- Bloodline/Tubing systems that have the possibility of an additional connection intended to be connected to the pressure measurement system. This can be used to connect a new pressure measurement line (available as an accessory in the Fresenius Medical Care product range).
- Do not push back the fluid in the pressure measurement line by using a syringe. This might damage the membrane in the TP and thus lead to contamination. In the event that fluid might have passed through the TP, check the device for contamination after treatment is completed. If contamination has occurred, the device must be taken out of service and disinfected according to the manufacturer's recommendations before further use.
- After the manipulation of lines or the usage of components during the treatment check and, if necessary, restore the correct position of the lines and components.
- Disinfect the corresponding access sites without protection cap prior the connection with other products.

Reinfusion
- Refer to the Instructions for Use of the multi (Version multiFiltratePRO) device for the termination of the treatment and also to the "Disposal" Section of the present Instructions for Use.
- Close all clamps on the Bloodline/Tubing systems before removing the disposable to reduce the risk of fluid leakage.

WARNINGS AND PRECAUTIONS
Warnings
- 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.
- The Bloodline/Tubing systems are intended for single use only. 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 on and after expiry date (refer to label).
- If the carton is damaged, check the contained products 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 tubes).
- Make sure that all tubes 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 tubing systems are inserted immediately before preparation only, thereby keeping the preparation and circulation times nearer the commencement of the treatment and in compliance with applicable guidelines.
- Connect the Bloodline/Tubing systems aseptically without touching open connectors.
- Disinfect with 70% alcohol access sites without protection 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 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).
- To ensure a secure connection between patient access and blood line, hold and screw the colored (blue, red) coupling nut on the blood line 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.
- Make sure that the components/tubes in direct interface with the device fit properly, and ensure that all caps and all screw-lock joints are secure and properly tightened (particularly those of the patient connections, the dialyzer connections, the device and the solution bags connections).
- Inspect the disposable for kinking and leaks during the priming and treatment phase and taking corrective measures (e.g. tightening Luer-Lock connection) or exchanging it as necessary.
- To avoid air embolism, make sure that the return patient line is correctly inserted into the device's air bubble detector.
- Careful attention must be given to the installation and blood level of the bubble catchers (see above). Make sure that due to pressure fluctuation neither the blood contacts the hydrophobic filter nor air enters the extracorporeal circuit.
- Change the disposable if a visible clot formation ("white strip") is seen in the blood line downstream of the return line bubble catcher, for instance at the point where the calcium infusion line merges into the blood line.
- Cleansing solutions and disinfectants may damage materials employed for the disposable. 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 blood line, wetting of the luer-lock connection to the feeding system with lipidic fluids can weaken the properties of the plastic material used. Make sure that during the connection of the feeding system, the infusion line

内的疏水性过滤器，则必须更换本一次性产品。
- 如果血液回路/管路系统中存在额外的可与压力测量系统连接的接头，则可以通过该接头连接新的压力测量管路（在费森尤斯公司产品系列中作为独立售卖的附件提供）。
- 切勿使用注射器将压力测量管路中的液体推回，这可能会损坏 TP 中的薄膜，进而导致污染。如果液体有可能已通过 TP，请在完成治疗后检查设备是否受到污染。如果受到污染，则必须停止使用该设备，并在进一步使用之前，根据制造商的建议对设备进行消毒。
- 在治疗过程中对管路进行操作或使用组件后，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
- 与其他产品连接之前，请先对无保护帽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 multi（Version multiFiltratePRO）设备使用说明书，亦请参阅本使用说明书的"废弃处理"一节。
- 拆卸一次性产品之前，请闭合连续性血液净化管路上的所有夹具，以降低液体泄漏的风险。

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。
- 连续性血液净化管路仅供一次性使用。只有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（例如性能下降、污染）。
- 如果产品已到达及超过失效日期（参考标签），请勿使用。
- 如外箱损坏，请仔细检查里面的产品。如无菌包装受损，或者保护帽或密封帽未在正确位置，或者成品存在任何明显损坏（例如管路扭结），不得使用。
- 确保将所有管路和气体捕获器正确安装到相应的位置。避免一次性产品发生扭结或闭塞，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，建议仅在准备的前一刻方可插入管路系统，使得治疗前的准备和循环时间更接近治疗开始的时间并且符合适用的指南。
- 在无菌条件下连接连续性血液净化管路，请勿接触开放式连接器。
- 在与其他产品连接之前，请使用 70%酒精对无保护帽的接入部位进行消毒以降低感染的风险，并在干燥后进行连接。
- 在临床使用前，应确定消毒剂（推荐使用的消毒剂除外）是否适用于接入部位。
- 负压过大可能会导致泵管部分变瘪，进而导致实际血液流量明显低于设备上的指示值。
- 本一次性产品的最低使用温度为 18°C（64°F）。
- 为了确保患者通路与血液回路之间实现牢固连接，仅需握住并拧动在血液回路上的有色（蓝，红）连接螺母。切勿将扭力施加至接口的内侧。在连接后，检查组件是否已牢固拧接。
- 确保与仪器直接连接的组件/管路正确安装，并确保所有盖帽和所有螺纹锁定接头均牢固且正确拧紧（尤其是用于连接患者的外圆锥接头、透析器接头、和溶液袋接口）。
- 在预冲阶段和治疗期间，检查本一次性产品是否扭结和漏液，必要时可采取纠正措施（例如：拧紧螺口接头连接），或更换产品。
- 为避免空气栓塞，确保将患者回路正确插入设备的气泡检测器中。
- 必须特别注意气体捕获器的安装和血液水平（见上文）。确保压力波动不会导致血液接触到疏水性过滤器，或者空气进入体外循环。
- 在血液回路的静脉管路气体捕获器下游，如果观察到可见凝块形成（"白色条带"），例如：在钙输注管路汇入血液管路处，请更换本一次性产品。
- 清洗液和消毒剂可能会损坏本一次性产品所用的材料。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。
- 所用塑料可能与药物或消毒剂不相容（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）。
- 如果在血液回路中加入营养溶液，脂质液体可能弄湿与输液系统连接的螺口接头，进而可能削弱所用塑料材料的性能。连接输液系统期间，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。

close to the luer-lock connection site remains completely free of nutrition solution.

Warnings: injection sites

- Do not use needles with a beveled tip and a diameter larger than 20 gauge (outer needle diameter to be 0.9 mm or less) to puncture injection sites (if present).

Warnings: needle-free access sites

- Needleless access sites are labelled with the following:

- Use a Luer lock syringe to activate the needle-free access site. Do not use sharp needles to puncture the needle-free access site septum. Their use can lead to leaks or air entering the fluid pathway. Refer to the warning labels present on the finished product.
- Do not connect the syringe used for the needle-free access site to other parts of the finished product — if the syringe comes into contact with lubricant, it could become disconnected and lead to patient injury or death.

Operating time

- The maximum application time is 72 hours. The disposable must be replaced after the maximum usage time or respectively after a specific blood volume pumped as indicated on the primary packaging.

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 Bloodline/Tubing systems.

DATE OF REVISION OF TEXT

2023-07 Fifth Modified

A digital version of this document is available on the following website: www.freseniusmedicalcare.com/en/product-information.

INFORMATION ON THE MANUFACTURER
Legal manufacturer

FRESENIUS MEDICAL CARE CE 0123
Fresenius Medical Care AG
Else-Kröner-Str. 1, 61352 Bad Homburg
GERMANY ✆ +49 6172 609-0
www.freseniusmedicalcare.com/en/product-information

Registrant/Manufacturer: Fresenius Medical Care AG

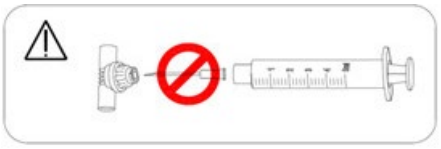
Address of Registrant/Manufacturer: Else-Kröner-Str.1, 61352 Bad Homburg, GERMANY

警告：注射部位

- 切勿使用带有斜面针尖且直径大于 20 号（针头外径应不超过 0.9 mm）的针来穿刺注射部位（如果存在）。

警告：无针接入部位

- 无针接入部位带以下标记：



- 使用螺口注射器匹配连接无针接入部位。切勿用锋利的针头刺穿无针接入部位的隔膜。否则，可能导致泄漏或空气进入液体通路。请参阅成品上的警告标签。
- 切勿将用于无针接入部位的注射器连接至成品上的其他部分——如果注射器接触润滑剂，它可能断开并导致患者受伤或死亡。

使用时间

- 最长使用时间是 72 小时。在最长使用时间之后，或者泵送了初级包装上所指示的特定血容量之后必须更换本一次性产品。

材料和物质相关的特别说明

致癌、致突变、致生殖毒性物质和干扰内分泌的物质

如需了解欧盟委员会（EC）第1907/2006号法规（"REACH"）第33条规定的SVHC信息，请访问以下页面：www.freseniusmedicalcare.com/en/svhc。

贮存的特别注意事项

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

制造商对于任何误用、操作不当、不遵守使用说明书和警示说明的情况，以及在制造商交付连续性血液净化管路后发生的任何损坏不承担任何责任。

说明书修订日期

2023年07月第5次修订

如需获取使用说明书的电子版本（e-IFU），请访问页面：www.freseniusmedicalcare. com/en/product-information。

生产企业信息
生产企业

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注册人/生产企业名称： Fresenius Medical Care AG
费森尤斯医药用品股份公司

注册人/生产企业住所： Else-Kröner-Str.1, 61352 Bad Homburg, GERMANY

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

Manufacturing Address(es): Via Crema 8 26020 Palazzo Pignano (CR), ITALY; No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya，TURKEY; Stegne 11 Ljubljana 1000, SLOVENIA

Agent / After-Sale Service Provider in China: Fresenius Medical Care (Shanghai) Co., Ltd.

Address of Agent/After-Sale Service Provider: Section A, Building 01, No. 439 Futexi Road 1st, China (Shanghai) Pilot Free Trade Zone

Telephone Number of Agent/After-Sale Service Provider: 021-61152800

Medical Device Registration Certificate No./Product Technical Requirements No.: GuoXieZhuJin20203100035

Date of Manufacture: See outer package

Shelf life: 3 years

Version No：20203100035-V5

注册人/生产企业联系方式：+49 6172 609-0

生产地址： Via Crema 8 26020 Palazzo Pignano (CR), ITALY; No: 16, Liman Serbest Bölgesi Mahallesi 07070 Antalya, TURKEY; Stegne 11 Ljubljana 1000, SLOVENIA

代理人/售后服务单位名称：费森尤斯医药用品（上海）有限公司

代理人/售后服务单位住所：中国（上海）自由贸易试验区富特西一路 439 号 01 号楼第 A 部位

代理人/售后服务单位联系方式：021-61152800

医疗器械注册证号/产品技术要求编号：国械注进20203100035

生产日期：见产品外包装

有效期：3年

说明书版本号：20203100035-V5

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