Therapeutic Plasma Exchange Tubing

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MODELS:

multiFiltratePRO TPE

INSTRUCTIONS FOR USE

Please read the following instructions carefully.

GENERAL INFORMATION

General description of the product

The therapeutic plasma exchange tubing (multiFiltrate PRO TPE) is intended to be used and compatible with an extracorporeal blood purification system multiFiltratePRO device.
multiFiltratePRO TPE is intended for single use.
multiFiltratePRO TPE is designed to provide extracorporeal blood treatment of patients who need therapeutic plasma exchange due to various diseases.
multiFiltratePRO TPE is composed by the arterial line / access line (RED line), venous line / return line (BLUE line), filtrate line (YELLOW line) and plasma line (WHITE line).

The product is pyrogen free.

Sterilization

multiFiltratePRO TPE is ETO sterilized.

COMPOSITION

Tubes: medical grade soft-PVC.
Connectors and other components: Acrylonitrile butadiene styrene (ABS), Polybutylene Terephthalate (PBT), Polycarbonate (PC), Hydrophobic Acrylic Copolymer membrane, Polypropylene (PP), Polytetrafluoroethylene (PTFE), Polyvinylchloride (PVC), Silicone, Polyisoprene (PHE), Thermoplastic elastomer (TPE).

INTENDED PURPOSE AND RELATED DEFINITIONS

Intended purpose

Channeling of blood and fluid in an extracorporeal treatment.

Medical indication

Conditions requiring the exchange of blood plasma via TPE.

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).

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.
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, cardiac arhytmia, cardiac arrest)
- 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 for other devices and drugs used in the therapy.
Refer to the multiFiltratePRO device Instructions for Use 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.
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 ETO 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 multiFiltratePRO device Instructions for Use for more information of general contraindications for extracorporeal blood purification.

PERFORMANCE CHARACTERISTICS

Refer to the multiFiltratePRO device Instructions for Use for essential performance parameters.

METHOD OF ADMINISTRATION

Handling Instructions

Refer to the multiFiltratePRO device Instructions for Use of the regarding how to handle the disposable during set-up, priming, treatment and reinfusion. Also, the Instructions for Use of other disposables such as the plasma filter must be taken into account.

Preparation

- Refer to the multiFiltratePRO device Instructions for Use 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.
- multiFiltratePRO TPE is intended to be used and compatible with multiFiltratePRO device (refer to label) and shall be used only after appropriate instruction or training.
- The infusion administration lines should be clamped, except when needed.
- Unpack and connect the multiFiltratePRO TPE 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 multiFiltratePRO device. All the other relevant specifications of the device apply.

Treatment

- To ensure correct functionality of the bubble catchers, fill to about 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.
- The disposable has 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 multiFiltratePRO device Instructions for Use for the termination of the treatment and also to the "Disposal" Section of the present Instructions for Use.
- Close all clamps on the multiFiltratePRO TPE 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 multiFiltratePRO TPE 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 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 tubes).
- Make sure 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 multiFiltratePRO TPE 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).
- 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).
- 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 are fitting 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, 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. 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 close to the luer-lock connection site remains completely free of nutrition solution.

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.

SYMBOLS USED ON LABELS

MD	Medical Device
UDI	Unique Device Identifier
	Patient information website
LATEX	Latex-free
STERILE EO	Sterile, Sterilized using ethylene oxide
MAX TIME / VOLUME	Replace the Bloodline after maximum usage time or pumped blood volume as indicated on the primary package
	Pump segment diameter / length
	Blood Priming Volume
	Units
5°C 50°C	Temperature limit
	Do not use if package is damaged
	Refer to the instructions
	Non-pyrogenic
SBS	Sterile barrier system
	Do not re-use
	Caution (Consult the Instructions for Use for important cautionary information such as warnings and precautions)
LOT	Batch code
REF	Catalogue number
	Date of manufacture
	Expiry date

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 multiFiltratePRO TPE.

DATE OF REVISION OF TEXT

2023/07

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
Else-Kröner-Str. 1, 61352 Bad Homburg
GERMANY ✆ +49 6172 609-0
www.freseniusmedicalcare.com/en/product-information

Manufacturer/Registrant: Fresenius Medical Care AG
Address of Manufacturer/Registrant: Else-Kröner-Str. 1, 61352 Bad Homburg, GERMANY
Manufacturing Address(es): No: 16, Liman Serbest Bölgesi Mahallesi, 07070 Antalya, TURKEY
Agent / After-Sale Service Provider in China: Fresenius Medical Care (Shanghai) Co., Lt
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
Registration Certificate No./Product Technical Requirements No.: GuoXieZhuJin20223100504
Date of Manufacture: See outer package
Shelf life: 3 years
Version No: 20223100504-V2

血浆置换用管路

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型号、规格：
multiFiltratePRO TPE

使用说明书
请仔细阅读以下说明。

基本信息

产品概述
血浆置换用管路预期用于配合兼容的体外血液净化系统multiFiltratePRO设备使用。
血浆置换用管路仅供一次性使用。
血浆置换用管路用于因各种疾病需要进行血浆置换的患者的体外循环血液治疗。
血浆置换用管路由动脉管路(红色管路)、静脉管路(蓝色管路)、滤过液管路(黄色管路)和血浆管路(白色管路)组成。
血浆置换用管路无热原。

灭菌
血浆置换用管路使用环氧乙烷(ETO)灭菌。

产品组成
管路：医用级软PVC。
连接器和其他组件：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)、疏水性丙烯酸共聚物膜、聚丙烯(PP)、聚四氟乙烯(PTFE)、聚氯乙烯(PVC)、硅树脂、聚异戊二烯(PHE)、热塑性弹性体(TPE)。

预期用途和相关说明
预期用途
本产品与连续性血液净化设备，血浆滤过器，废液袋和动静脉穿刺针配套使用，用于对体重40Kg以上的患者进行 TPE(治疗性血浆置换)治疗。
医学适应症
需要通过TPE进行血浆置换的病症
预期患者人群
制造商规定设备旨在用于治疗体重40 kg及以上、任何年龄的患者，需考虑设备和所用的一次性用品的规定技术数据(例如：输送速率、注入量)。
预期用户群体和预期环境
本一次性用品只能由经过适当培训、拥有正确运行和操作设备相关的知识和经验，且可通过证据显示其经过指导的个人使用。
本一次性用品可在专业医疗保健机构中适合进行透析的诊疗室运行。
请务必遵守规范性法规和当地法规。

副作用
在当前的文献中报告的副作用如下，这些副作用仅会偶尔发生：
- 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、心律失常、心脏骤停)
- 凝血障碍(例如血小板减少症)
- 栓塞(空气栓塞、血栓栓塞)
- 细菌感染
- 体温过低
- 溶血
- 超敏反应或类似超敏反应的反应(例如呼吸困难、心肺骤停、低血压、荨麻疹、潮红、瘙痒、腹痛、恶心、抽搐和神志不清)。

其他副作用可能是治疗中使用的其他器械和药物的特有副作用。
有关治疗相关副作用的更多信息，请查阅multiFiltratePRO设备的使用说明书。

严重事件报告
如发现任何与器械相关的严重事件(包括本说明书中未列出的副作用)，应立即通知治疗医师。在欧盟范围内，用户须向标签上的制造商 (🏭) 和实施治疗所在地的欧盟成员国主管机构报告与器械相关的任何严重事件。
严重事件可以是直接或间接导致患者、用户或其他人员死亡，患者、用户或其他人员的健康状态发生暂时或永久性严重恶化，或严重公共健康威胁的任何事件。

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ETO残留有超敏反应。
在严重的情况下，必须停止治疗，不应将血液回输给患者，而应启动适当的急救医疗措施。

治疗相关禁忌症
有关体外血液净化的一般禁忌症，请查阅multiFiltratePRO设备的使用说明书了解更多信息。

性能特征
有关基本性能参数，请查阅multiFiltratePRO设备的使用说明书。

使用方法
操作说明
有关在设置、预充、治疗和回输期间一次性用品的操作说明，请查阅multiFiltratePRO设备的使用说明书。此外，必须考虑其他一次性用品(如血浆滤过器)的使用说明书。

准备
· 请查阅multiFiltratePRO设备的使用说明书，了解一次性用品在使用就绪之前或使用期间需进行的任何准备性操作的细节信息，以及有关验证一次性用品是否正确安装的信息。
· 血浆置换用管路预期用于配合兼容的multiFiltratePRO设备使用(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。
· 除需要使用时，应夹紧输注管路。
· 在无菌条件下，打开包装并连接血浆置换用管路，请勿接触开放式连接器。
· 应当根据设备上相应的标记，遵循颜色代码使用相应管路。
· 根据设备的使用说明书操作泵和泵夹。
· 拧紧所有密封帽，确保所有连接器和盖帽均已固定。
· 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和培训(如果适用)对一次性用品进行灌注和冲洗。
· Fresenius Medical Care一次性用品可以耐受在与相应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规范均适用。

治疗
· 为确保气泡捕获器的正确功能，填充至顶部以下约1 cm。这可避免液体接触疏水性滤器，以及空气进入体外循环。如果液体到达并接触传感器保护器(TP)内的疏水性滤器，则必须更换一次性用品。
· 一次性用品包含连接到压力测量系统的额外接口，可用其连接新的压力测量管路(作为Fresenius Medical Care产品系列中的附件提供)。
· 请勿使用注射器将压力测量管路中的液体推回，这可能损坏TP中的薄膜，进而导致污染。如果液体可能通过TP，则在治疗完成后检查设备是否存在污染。如果发生污染，则在下一次使用之前，设备必须停止使用，并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，检查并在必要时恢复管路和组件的正确位置。
· 与其他产品连接之前，请对无保护帽的相应接入部位进行消毒。

回输
· 请参考multiFiltratePRO设备的使用说明书查看终止治疗的相关内容，以及本使用说明书的“废弃处置”部分。
· 在取出一次性用品之前，请关闭血浆置换用管路上的所有管路夹，以降低液体泄漏的风险。

警告和注意事项

警告
· 本一次性用品只能由经过适当培训、拥有正确运行和操作设备相关的知识和经验，且可通过证据显示其经过指导的个人使用。
· 血浆置换用管路仅供一次性使用。只有在一次性使用时才能确保所有接口的正常功能。重复使用可能对患者和操作员造成危险(性能受损、污染)。
· 切勿在失效日期及之后使用(参考标签)。
· 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)，请勿使用。
· 确保将所有管路和气泡捕获器正确安装到相应的位置。避免一次性用品发生扭结或闭塞，以免细胞血液成分发生机械和化学损伤。
· 出于卫生和功能原因，建议仅在准备前方可插入管路系统，使得治疗前的准备和循环时间尽可能接近治疗开始的时间并且遵照适用的指南。
· 在无菌条件下连接血浆置换用管路，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，并先使其风干再进行连接。
· 应在临床使用之前确定消毒剂(推荐使用的消毒剂除外)与接入部位的相容性。
· 负压过大可能导致泵管部分变瘪，进而导致实际血流量显著低于设备上所指示的流量。
· 一次性用品的最低使用温度为18°C(64°F)。
· 请勿使用带斜面针尖、直径大于20G(针管外径小于等于0.9 mm)的针来穿刺采样口(如存在)。
· 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彩色(蓝、红)连接螺母。不得向该连接器内部施加拧紧扭矩。在连接后，检查是否对相关组件进行了牢固拧接。
· 确保与设备直接连接的组件/管路恰当合适，并确保所有盖帽和所有锁紧型接头均牢固并正确拧紧(尤其是患者接口、透析器接口、设备和溶液袋接口)。
· 在预充阶段和治疗期间，检查一次性用品的扭结和泄漏情况，必要时，采取纠正措施(例如：拧紧鲁尔锁连接)，或者进行更换。
· 为避免空气栓塞，请确保将患者静脉管路正确插入设备的气泡探测器中。
· 必须特别注意气泡捕获器的安装和血液水平。确保压力波动不会导致血液接触疏水性滤器，或者空气进入体外循环。
· 在血液回路的静脉管路气泡捕获器下游，如果观察到可见凝块形成(“白色条带”)，则更换一次性用品，例如：在钙输注管路并入血液回路的位置。
· 清洗液和消毒剂可能损坏一次性用品所用的材料。如此则无法再保证使用安全性和性能，且制造商对此不承担任何责任。
· 所用塑料可能与药物或消毒剂不相容(例如：当与pH>10的水溶液接触时，聚碳酸酯制成的接头可能出现裂纹)。
· 如将营养液注入到该血液回路中，液态油脂可能弄湿与饲喂系统连接的鲁尔锁接头，进而可能削弱所用塑料材料的性能。在连接饲喂系统的过程中，确保在鲁尔锁接头处附近的输注管路始终保持完全没有营养液的状态。

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，必须更换一次性用品。

材料和物质相关的特别说明
CMR物质和内分泌干扰物质
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
遵循产品标签上的指示。防止受潮、受冻和过热。
废弃处置
确保按照当地法规安全处置任何未使用的产品或废料。

与血液或其他人源物质接触的材料可能具有传染性。采取必要的预防措施并根据当地有关(潜在)传染性物质的法规，处置此类材料。

标签所用符号

MD	医疗器械
UDI	医疗器械唯一标识
	患者信息网站
LATEX	不含天然胶乳
STERILE EO	产品无菌，使用环氧乙烷灭菌
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，需要更换血液回路
	泵管直径/长度
	血液预充容量
	数量
5°C 50°C	温度极限
	若包装破损，请勿使用
	查阅使用说明
	无热原
SBS	无菌屏障系统
	不得二次使用
	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)
LOT	批次代码
REF	产品编号
	生产日期
	失效日期

保证
制造商对于任何误用、操作不当、不符合使用说明书和警示说明，以及制造商交付血浆置换用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
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.

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注册证号/产品技术要求编号：国械注进20223100504
生产日期：见产品外包装
有效期：3年
说明书版本号：20223100504-V2