Filtrate bag 10 L (CN)

en

INSTRUCTIONS FOR USE

Please read the following instructions carefully.

GENERAL INFORMATION

General description of the product

The filtrate bag is an unsterile product; it consists of tubes, connectors, cap, clamp and fluid bag.

The product is intended to be used in combination with an extracorporeal acute blood purification system multiFiltrate and multiFiltratePRO.

COMPOSITION

Materials: Tube: medical grade soft-PVC; Connectors and other components: PP, PVC, ABS, PE.

INTENDED PURPOSE

Medical purpose

This product is used as a container to collect the clinical waste such as dialysate/body fluids at hospitals/clinics in combination with Fresenius Medical Care CRRT (Continuous Renal Replacement Therapy) devices multiFiltrate and multiFiltratePRO during CRRT treatment, haemoperfusion procedures or therapeutic plasma exchange.

This product is used as ancillary device for collecting waste fluid during HD/F treatment.

Intended patient population

The bags have been specified by the manufacturer for the purpose of treating patients irrespective of their age and body weight, under consideration of the specified technical data of the medical device and the single-use items used (e.g., delivery rates, fill volumes).

Intended user/environment

The disposable may 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 suitable rooms in professional health care facilities. Normative and local regulations must be observed.

SIDE EFFECTS

No specific side effect due to the use of Filtrate bag is known.

Side effects related to the multiFiltrate and multiFiltratePRO must be taken into account. Please refer to the Instructions for Use (IFU) of multiFiltrate and multiFiltratePRO for more information on the 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 user is established.

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

There are no contraindications known for Filtrate bag 10L.

For general contraindications onextracorporeal blood purification therapies, please refer to the Instructions for Use of multiFiltrate and multiFiltratePRO.

PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

Filtrate Bag 10L has to be used in combination with multiFiltrate and multiFiltratePRO during CRRT treatments haemoperfusion procedures and therapeutic plasma exchange.

METHOD OF ADMINISTRATION

Handling Instructions

Before use

Refer to the Instructions for Use of the multiFiltratePRO and multiFiltrate device.

Handling

The product is intended to be used in combination with an extracorporeal acute blood purification system multiFiltrate and multiFiltratePRO.

Open the package to get the product, hang filtrate bag onto the hooks of the lower scales, remove the luer cap, connect the male Luer-Lock with the Filtrate Line (multiFiltrate filtrate line "F") according to Instructions for Use for multiFiltrate and multiFiltratePRO device.

Upon completion of solution collection, enable the function "bag change" and close the clamp, according to Instructions for Use for multiFiltrate and multiFiltratePRO Syctem.

Discard the used product and material waste as described in the "Disposal" Section of this IFU.

Where present, the available stopcock can be used to empty the bag after disconnection from the multiFiltrate and multiFiltratePRO device.

Intended application time

The maximum application time is 72 hours (equal to the maximum application time of multiFiltrate and multiFiltratePRO tubing systems for extracorporeal acute blood purification).

Termination

Refer to the Instructions for Use of the multiFiltratePRO and multiFiltrate device for the termination of the treatment and also to the "Disposal" Section of the present Instructions for Use.

WARNINGS AND PRECAUTIONS

Warnings

Do not use the product if there is damage to the bag or components.

If the carton is damaged, check the products contained carefully. Do not use if the 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).

Do not use one filtrate bag for different patients.

Do not use after use-by date (refer to label).

Inspect the extracorporeal circuit for kinking and leaks during the priming phase and treatment, taking corrective measures or exchanging the disposable as necessary.

The system contains large-size packaging and foils that can cause choking, and which should be kept away from children.

Particular notes on materials and substances

There is no hypersensitivity to the bag system or any of the materials known.

One or more components contain in a concentration > 0.1 mass% according to Article 33 and 59 (1, 10) of Regulation (EC) No. 1907/2006 ("REACH"): – 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

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

The dialysate waste may be contaminated with pathogenic agents of transmittable diseases; thus, the bag must be considered to be potentially infectious.

The accredited organization is liable for the safe disposal of the product. Any unused product or waste material shall be disposed of in accordance with local requirements and in accordance with local requirements for potentially contaminated materials.

SYMBOLS USED ON LABELS

MD	Medical Device
UDI	Unique Device Identifier
	Patient information website
LATEX	Latex-free
MAX 72 h / 1250 l	Exchange the Bloodline/Tubing System after maximum usage time or pumped blood volume as indicated on the primary package
	Units

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 bloodlines.

DATE OF REVISION OF TEXT

01/2021

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

Fresenius Medical Care AG & Co. KGaA
Else-Körner-Str. 1, 61352 Bad Homburg
GERMANY ✆ +49 6172 609-0
www.freseniusmedicalcare.com/en/product-information

透析用废液袋　型号、规格：Filtrate bag 10 L

zh-cn

使用说明书

请仔细阅读以下说明。

基本信息

产品概述

废液袋为非无菌产品；由管路，接头，保护帽、管路夹以及液体袋组成。该产品与急性体外血液净化系统multiFiltrate 和multiFiltratePRO 配合使用。

成分

材料：管路：医用级软质PVC；接头和其他部件：PP、PVC、ABS、PE。

预期用途

医疗用途

本产品主要供临床医院做透析液/体液等临床废物收集容器使用，用于在CRRT（连续性肾脏替代治疗）、血液灌流程序或治疗性血浆置换的实施过程中配合Fresenius Medical Care CRRT器械multiFiltrate和multiFiltratePRO使用。

作为血液透析/滤过治疗用配件，在透析治疗期间，用于废液的收集。

适用患者人群

制造商规定此废液袋旨在用于治疗各个年龄段和体重范围的患者，但需考虑医疗器械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/环境

一次性用品只能由经过适当培训、拥有有关正确操作和处理的知识和经验，且可通过证据显示其经过指导的个人使用。

在专业医疗护理机构的相应房间中使用。务必遵守规范性法规和当地法规。

副作用

尚无由于Filtrate透析用废液袋的使用而导致的已知特别副作用。

必须考虑与multiFiltrate和multiFiltratePRO系统相关的副作用。请参考multiFiltrate和multiFiltratePRO的使用说明书（IFU）获取有关副作用的更多信息。

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，用户须根据标签 (🏭) 向制造商报告并向用户所在的欧盟成员国的主管当局报告所发生的与器械有关的任何严重事件。

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

10 L Filtrate透析用废液袋尚无已知的禁忌症。

如需了解体外血液净化治疗的一般禁忌症，请参考multiFiltrate和multiFiltratePRO的使用说明书。

性能特征和临床受益

10 L Filtrate透析用废液袋在用于CRRT治疗、血液灌流程序或治疗性血浆置换中时必须配合multiFiltrate和multiFiltratePRO使用。

使用方法

操作说明

使用前

请参考multiFiltratePRO和multiFiltrate器械的使用说明书。

操作

该产品与急性体外血液净化系统multiFiltrate和multiFiltratePRO配合使用。

打开包装，取出产品，将废液袋悬挂在下方天平的钩子上，取下圆锥接头保护套，按照multiFiltrate和multiFiltratePRO器械的使用说明书将外圆锥接头与滤过液管路（multiFiltrate滤过液管路“ F”）连接。

完成溶液收集后，请按照multiFiltrate和multiFiltratePRO系统的使用说明书启用“废液袋更换”功能并合上止流夹。

按照本使用说明书“废弃处置”一节的内容，对用过的产品和材料废物进行丢弃。

如带有排液旋塞阀，则可在断开与multiFiltrate和multiFiltratePRO器械的连接后，使用提供的旋塞阀来排空废液袋。

预期使用时间

最长使用时间为72小时（等于用于急性体外血液净化的multiFiltrate和multiFiltratePRO管路系统的最长使用时间）。

终止治疗

请参考multiFiltratePRO和multiFiltrate器械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”一节。

警告和注意事项

警告

如贮液袋或其它部件有损，请勿使用本品。

如外箱损坏，请仔细检查里面的产品。如包装受损，或者保护套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。

请勿将一个废液袋用于不同的患者。

请勿在超过有效期后使用本品（参见标签）。

请在预充阶段和治疗期间，检查体外循环血路是否存在扭结和泄漏，并在必要时采取纠正措施或者更换一次性用品。

该系统包含可能引起窒息的大尺寸包装和铝箔，应远离儿童放置。

材料和物质相关的特别说明

无已知的对废液袋系统或任何材料的超敏反应。

根据欧盟委员会（EC）第1907/2006号法规（“REACH”）第33条和第59条（1，10）的规定，一种或多种成分所含浓度〉 0.1%（质量）：2-乙基己基-10-乙基-4,4-二辛基-7-氧代-8-氧杂-3,5-二硫杂-4-锡杂十四烷酸（DOTE）

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

透析液废液可能受到可传播疾病的病原体污染；因此，必须将废液袋视为具有潜在传染性。

由经认证的组织负责对本品进行安全地废弃处置。所有未使用的产品或废料均应按照当地要求以及当地对潜在污染材料的要求进行废弃处置。

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
MAX 72 h / 1250 l	按照内包装标识的指示达到最长使用时间或泵血量时需更换管路系统
	个数

保证

对于任何误用、不当操作、不遵守使用说明书和警示说明的情况以及在制造商交付血路管后发生的任何损坏，制造商概不负责。

文本修订日期：2021年1月

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.

制造商信息

法定制造商

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CE

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GERMANY ✆ +49 6172 609-0
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批准文号：

产品备案号/产品技术要求编号：国械备20170452号

备案人/生产企业名称：Fresenius Medical Care AG & Co. KGaA 费森尤斯医药用品股份及两合公司

注册地址：Else-Körner-Str. 1, 61352 Bad Homburg, GERMANY

电话：+49 （0）6172/609-0

生产地址：10th of Ramadan city, B4 No 174, Egypt

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

地址：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

电话：021-61152800