6008 CAREset-R product family

INSTRUCTIONS FOR USE

Please read the following instructions carefully.

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)

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

Sterilization

The 6008 CAREset-R product family is e-beam sterilized.

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), Isoprene Rubber (IR), Styrene Ethylene Butylene Styrene (SEBS), Styrene-Butadiene Copolymer (SBC), Thermoplastic elastomer (TPE), Polyethylene Terephthalate (PET), Polytetrafluoroethylene (PTFE).

INTENDED PURPOSE AND RELATED DEFINITIONS

Intended purpose

Channeling of blood and fluid in an extracorporeal 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.

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.

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

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 BVMR 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 Instruc- tions 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

- 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 termina- tion 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.
- 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).

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• 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.

Operating time

• The maximum application time is 12 hours. The disposable must be replaced after the maximum usage time 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 age:
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

REF	Catalogue number
MD	Medical Device
UDI	Unique Device Identifier
	Patient information website
STERILE R	Sterile fluid path Sterilized using irradiation
	Pump segment diameter / length
	Blood Priming Volume
MAX 12h	Replace the Cassette system after maximum 12 hours
LATEX	Latex-free
	Units
+4°C +25°C	Temperature limit
	Do not use if package is damaged
SBS	Sterile barrier system
LOT	Batch code
	Manufacturer
	Use-by date
	Date of manufacture
	Caution
2	Do not re-use
	Consult instructions for use
	Non-Pyrogenic

Quantity : See package

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.

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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

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