INSTRUCTIONS FOR USE

Haem-O-Flux (Dialyzer)

Materials : Housing: Polypropylene, Potting material : Polyurethane, O-ring: Silicone, Polyether Sulfone.

Indications : Dialyzers are designed for single use in acute and chronic haemodialysis treatment.

Contraindications : Contraindications are unknown. Generally, contraindications for haemodialysis are applicable. The dialyzer should only be used as directed by qualified healthcare professionals.

Side-effects : In rare cases hypersensitive reactions may occur during haemodialysis treatment. In severe cases dialysis must be discontinued and the appropriate medication initiated. The dialyzer is Gamma sterilised and thus contains no sterilisation residues.

Anticoagulation : It is recommended to introduce an anticoagulant to the extracorporeal circuit. Nature, amount and method of application of an anticoagulant must be prescribed by the responsible physician. Coagulation should be monitored by a standard clotting time test.

INSTALLATION, SET - UP, WASHING
Extract the dialyzer from its individual wrapping and check that the protectors are correctly in place. Place the dialyzer vertically in its holder with arterial side ("BLOOD INLET") facing downwards. Prepare one litre of isotonic salt solution (0,9% NaCl) with addition of heparin (between 4000 and 5000 UI sodium heparin). Place the arterial and vein lines on the monitor in accordance with the manufacturer's instructions. Clamp the arterial line and connect it to the container with the heparin solution, connect the tip of the vein line to a sterile recipient. Proceed to purge the arterial line to eliminate air by clamping below the arterial expansion chamber (or after the pump unit, if the line has not such part fitted). Continue purging the blood circuit by turning the blood pump between 100 and 150 ml/min, alternatively clamping and releasing the arterial and vein lines to eliminate the air from the blood circuit. Stop the pump once 500 ml heparinized solution has passed. ATTENTION: no air must enter the dialyzer's blood compartment.

PATIENT CONNECTION – HAEMODIALYSIS
Once the blood and dialysis liquid compartments are filled and degassed, the patient can be connected to arterial and venous blood line.

ATTENTION : if the patient is not connected immediately, the ultra filtration losses must be compensated in order to maintain the level of the vein bubble trap. If the priming liquid has remained in the dialyzer for some time, heparin salt solution must be pumped through again immediately before connecting up the patient in order to flush the dialyzer and the blood lines completely. Proceed to connect the patient according to the doctor's instructions. Connect the arterial line to the to the vascular access, avoiding entry of air. Allow the blood to enter the blood circuit (pump speed 100 ml/min). Connect the vein line close to the vascular access. Adjust the blood pump and the flow of the dialyzer liquid to the desired settings and the negative pressure or ultra filtration flow as well as the relevant parameter on the haemodialysis monitor in accordance with manufacturer's recommendations.

HEPARINIZATION
The patient should be heparinized in accordance with the doctor's instructions.

END OF TREATMENT
Prepare 500 ml of sterile isotonic 0,9% NaCl solution. Reduce the flow of the ultrafiltrate to the minimum and stop the blood pump. Clamp the arterial line and connect it quickly to the container with the isotonic solution, taking care that no air is allowed in. Switch the blood pump on again at 100 ml/min. Clamp the vein line intermittently below the bubble trap. Once restitution is complete, stop the blood pump, clamp the vein line as close as possible to the patient and disconnect it, disposing of the dialyzer and lines

ATTENTION : Air must not be allowed to enter the extracorporeal circuit.

PRECAUTIONS
During haemodialysis treatment, a null ultrafiltrate flow can only occur when there is positive pressure in the dialysis liquid when compared to blood pressure. The use of a minimal ultrafiltrate flow allows the risk to be reduced. Should there be a considerable accumulation of foam or micro-bubbles in the arterial part of the circuit, it is a good suggestion to invert the dialyzer in order to eliminate them. Care must be taken to reduce the amount of the physiological solution injected into the patient to the minimum, at the connection stage.

CLOTTING
If the dialyzer becomes clotted, leading to a drop pressure in the vein line, the dialyzer and the blood lines must be changed and the vascular access rinsed with heparin solution. Should the vascular access devices become clotted, shown by a drop in pressure in the arterial line and/or increased pressure in the vein line, disconnect the blood lines and replace the vascular access devices. It is also preferable to change the dialyzer and the blood lines as well.

BLOOD LEAKS
If any leak occur during treatment, disconnect the arterial line and return the blood to the patient, maintaining the ultrafiltrate flow in order to avoid potential contamination. Then, change the dialyzer and the blood lines. If necessary, inject physiological solution to compensate patient's blood loss.

ENTRY OF AIR
If there is a considerable entry of air into the dialyzer, it should be changed. In order to prevent any risk of infusing air into the patient, it is necessary to use a dialysis machine equipped with an air detector in accordance with current regulations.

HYPERSENSITIVITY
If the patient shows symptoms of hypersensitivity: nausea, discomfort, weak flushes, excessive perspiration, breathing difficulties and, in certain cases, HBP and cardiac arrest, treatment should be suspended.

MINOR REACTIONS
Nausea, cephalea and HBP can be avoided if the dialysis session is conducted correctly assuring: good hydro-electrolytic balance and appropriate blood flow.

IMPORTANT RECOMMENDATIONS
The dialyzer must be flushed as described above. It is important to respect the recommended priming procedures and to use a correctly degassed dialysis liquid in accordance with national and international standards. Do not use in system where the dialysis liquid has not been degassed. In order to avoid all risks of bacterial endotoxin contamination, we recommend the use of water and dialysis concentrate which meet the specifications of current standards. Certain solvents or other chemicals may damage the dialyzer. It is vital to have Medica's authorization before using such products. The following products are specifically prohibited :
aromatic, halogen, aliphatic and ketone-based solvents.

ATTENTION: Due to obligatory ultrafiltration, a zero ultrafiltration cannot be achieved without a risk of infusing dialyzing fluid into the blood stream and/or the risk of obstruction the blood pathway.
Due to the performance characteristics of membrane dialyzer, it is convenient to use haemodialysis controlled ultrafiltration monitor to avoid the risk of backfiltration.

Warnings/Cautions
Use only if package is intact, sealing caps are in place and the dialyzer is undamaged. Dialyzers must not be used after expiry date (see label). Each dialyzer is checked for integrity prior to leaving the factory. If a blood leak should arise, the dialyzer must be exchanged. The dialyzer is intended for single-use only. Re-use may be hazardous to both the patient and operator. Cleansing solutions and disinfectants may damage materials employed for the housing, potting and membrane. Safety of use can no longer be guaranteed and the manufacturer assumes no liability. The product should be used only by a qualified healthcare professionals. Do not re-sterilize. Discard the set after single use. The product should be replaced and disposed of as per facility approved protocol or CDC guidelines. Store in between 5° to 35° C, avoid excessive heat, protect from direct sunlight and moisture. Poly Medicure Limited will not be responsible for any direct incidental or consequential damages resulting from reuse of product.


Cautions


See Instructions for use

Product reference/Art. No.


For single use only

Do not Resterilize


Do not use if packaging or product has been damaged or contaminated

Batch Number


Date of Manufacturing


Use by / Expiry date

Sterilised using irradiation


Manufactured by


Non-Pyrogenic

Storage Condition


Keep Away from Sunlight


Keep Dry

Medical Devices

European Authorised Representative

POLYMED

POLY MEDICURE LTD.
Plot No. 33-34, Sector 68, IMT, Faridabad,
Haryana-121004, India,
Web : www.polymedicure.com,
Contact customer care executive: +91-129-4287053,
Email: customercare@polymedicure.com,
Address: Same as above

Not made with Bisphenol A.
Not made with DEHP plasticizer.

EU REP Obelis s.a.,
Boulevard Général Wahis 53,
1030, Brussels, BELGIUM.
Tel : +(32) 2. 732.59.54
E-mail : mail@obelis.net

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