Indications

Our dialyzer is indicated for patients having acute or chronic renal failure when dialysis prescribed by the physician.

Contraindications

There are no special contraindications for use of our dialyzer for dialysis. Patients indicating allergic reactions to polysulfone membranes should not be dialyzed with this product.

Warning

• Use this product according to instructions of a physician who is well familiar with the patient’s condition.
• Do not use for any other purposes than dialysis.
• If any abnormalities such as foam generation or mixture, blood leakage, blood coagulation and hemolysis occurred during the use of this product, take appropriate measures according to a physician’s instructions.
• In case drugs including an anticoagulant are administered before or during use of this product, follow a physician’s instructions regarding the administration and dose and the administration time of the drugs.
• Do not reuse this product since this product is disposable.
• The foreseeable risks in association with reuse of the product are:
  - Infection by contamination.
  - Deterioration of solute removal performance and ultrafiltration performance.
  - Exposure of patients or/and technicians to residual medical agents such as disinfectant used for product reuse, and/or adverse effects of residual medical agents on them.
  - Damage of hollow fiber and/or leakage.
• Do not expose this product to chemical solvents, such as strong acids and bases.
• Residual disinfectant in product may cause adverse patient reactions.
• If the patient exhibits any abnormal symptoms such as discomfort, pruritus, urticaria, peripheral and facial edema, respiratory arrest, facial flush, erythema, asthmatic reaction, hypotension, hypotension and/or cardiac arrhythmia during the use of this product, take appropriate measures according to a physician’s instructions.
• Commonly seen side effects (hypertension, hypotension, headache and nausea which are sometimes with hypovolemia or hypervolemia) can be avoided by careful management of the patient fluid and electrolyte balance, as well as the dialysis condition (blood flow rate and ultrafiltration rate).
• During dialysis, constantly monitor the patients who:
  - Have a history of hypertension with hemodialysis.
  - Have inflammatory reaction, allergic reaction, hyperreactivity, or increased in the immunity by infections.
  - Take hypotensive drugs such as inhibitor of angiotensin converting enzyme and calcium antagonist.
• Use this product for the first time.

Caution

Caution should be employed against excessive water removal. Use of accurate UF control system is required. Confirm that no pyrogen is contained in dialysate in order to prevent transfer of pyrogen from dialysate to blood.

1. Caution before use

• Do not use if the package is broken or if the product is damaged.
• Do not use if blood port tip protectors are not in place.
• Unpack immediately before use.
• Avoid mix-in and contamination during rinsing/priming operations.
• Start dialysis immediately after rinsing/priming operations.
• Rinse/priming should be carried out under the following conditions according to this “Instructions for Use”:
  - Blood side: Rinse and priming with physiological saline at a flow rate of 200 ml/min (not less than 500 ml).
  - Dialysate side: Verify conductivity and temperature, and rinse with dialysate at a flow rate of 500 ml/min for about 3 minutes.
• Check integrity of the blood line and dialyzer.
• Administration of Heparin: Systematic or regional heparinization may need be administered based on instructions from attending physician.

2. Caution in use

• Continuously monitor the blood in the blood line and check for blood leakage during dialysis.
• Avoid contamination during blood sampling and blood recovery, carefully.
• Set TMP alarm (max. 500 mmHg).
• Avoid air embolism during blood recovery.
• Do not apply excessive pressure to the blood line, the dialyzer and their connections.

3. Caution after use

• Single use only. Dispose of the dialyzer immediately after use.
• Dispose of the used blood lines and dialyzer by any means suitable for avoiding contamination.

4. Caution for storage

• Store at 0 to 35 °C avoiding exposure to direct sunlight, severe vibration, high humidities and dry places.

Instructions for Use

1. Rinsing/priming

• Take the dialyzer out of the package and set it to the holder so that the venous side is directed upward. (Fig.1)
• Connect the arteriovenous dialyzer connector to the dialyzer. Connect the arterial patient line to physiological saline bag (Fig.2). Start arterial blood pump at a flow rate of 200 ml/min (not less than 500 ml) (Fig.3).
• Stop the blood pump; rotate the dialyzer for 180 degree. Put the dialysate connectors to the dialyzer (dialysate inlet at the venous blood side, dialysate outlet at the arterial blood side) (Fig.4). Make sure of deagglutination the dialysate part of the dialyzer. Start running through dialysate at a flow rate of about 500 ml/min.
• Stop the blood pump; make sure that the blood compartment is free of air-bubbles and filled with physiological saline. The preparations for dialysis is complete.

2. Operation

- [Leakage test]

It is recommended to perform the following operations before connecting the dialysate lines to the dialyzer:

1. Priming the arterial and venous lines and the dialyzer with physiological saline by operating the blood pump: stop the pump operation.
2. Clamp the arterial line near the dialyzer and the distal end of the venous line with forceps.
3. Release the clamped distal end about 1 m below the dialyzer and remove the forceps. (This results in application of a negative pressure of about 70 mmHg to the blood compartment of the dialyzer.)
4. Examine whether or not continuous bubble formation is observed in the venous header to check for leakage from the dialyzer, if observed, replace the dialyzer with a new one.

II. Start of dialysis

(1) Prepare the blood access site and connect to the arterial line and venous lines.
(2) While running at a flow rate of about 500 ml/min, operate the blood pump at a flow rate of about 50 ml/min.
(3) Confirm that no air bubbles remain in venous header or venous blood line.
(4) Start the blood pump operation, clamp the distal end of the venous line with forceps.
(5) Prepare the blood return site and connect to the venous line. After confirming that there are no bubbles in the line, remove the forceps from the line. After checking that there are no forceps on the lines and no line folding, operate the blood pump at a flow rate.
(6) Take care not to apply excessive pressure to the lines and the dialyzer to avoid leaving from the dialyzer and separation of each of the connections.
(7) After confirming that there are no bubbles in the arterial and venous heads, turn the dialyzer 180° to allow removal of bubbles from dialysate. If bubbles are detected in the venous header before the turning, run blood at a prescribed flow rate for 5 to 10 minutes with the venous side kept upward.

III. Operations during dialysis

(1) If stopping the blood pump is required during dialysis due to insufficient blood flow, lower the dialysis pressure to about 0 mmHg. (This is to avoid blood coagulation due to dehydration.)
(2) Keep UF rate carefully to avoid excessive water removal according to patient’s needs. Reduce the blood flow rate if disequilibrium syndrome is suspected.
(3) If blood leakage is suspected, judge by testing dialysate sampled from the dialysate outlet part of the dialyzer using occult blood reaction test paper. If a leakage is detected, reduce UF rate to minimum rate according to the institutional protocol, stop the dialysate supply and recover blood, then replace the dialyzer with a new one.

IV. Dialysis termination and blood recovery

(1) Stop the blood pump, clamp the arterial line and remove the line from the arterial blood access site, then connect the line to the physiological saline vial for blood recovery.
(2) Unclamp the arterial line and run physiological saline to rinse out the blood from the arterial and venous lines and the dialyzer.
(3) After the blood recovery, discard the arterial and venous lines and the dialyzer. Do not reuse them.

Performance

The performance of the hemodialyzer varies with types. Refer to respective catalogues and performance data sheet.

Guarantee

(1) Non-pyrogenic.
(2) Our dialyzer is manufactured under strict quality control and the quality is assured. If the dialyzer is defective (broken package, damaged dialyzer), however, it shall be replaced with a new one at our cost upon return of the broken package or damaged dialyzer. We will not be responsible, however, for the injury on a patient or any person or the damage to any object that is attributed to transportation, storage and operation in your institution.
(3) If a patient or any person is injured or any object is damaged by use of our dialyzer, we will not be responsible for the injury or damage unless we are clearly identified as being at fault.
(4) If a patient or any person is injured or any object is damaged by wear of our dialyzer, we will not be responsible for the injury or damage of any nature.
(5) We will not be responsible for injury or damage caused by the use of our dialyzer after the expiry date mentioned on the label or packaging.

NON PYROGENIC

NON PYROGENIC
## ELISIO™-M PERFORMANCE DATA

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<th>Clearance (^2) (mL/min)</th>
<th>Qb (^3) (mL/min)</th>
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<th>13M</th>
<th>15M</th>
<th>17M</th>
<th>19M</th>
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## Specifications \(^9\)

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## In-Vitro Test Conditions (EN1283)

- Clearance: Qd 500mL/min, Qf 10mL/min
- KUF: Bovine Blood \(^{20}\) (Hct 32±2%, Protein \(^{21}\) 60g/L, 37°C), Qb 300mL/min

**Membrane** \(^{24}\)
**Housing** \(^{25}\)
**Potting compound** \(^{26}\)
**Sterilization** \(^{27}\)

**POLYNEPHRON™**
**Polypropylene** \(^{28}\)
**Polyurethane** \(^{29}\)
**Gamma Ray** \(^{30}\)