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ELISIO™

SYNTHETIC HEMODIALYZER

Instructions for Use

Prior to use, please read the Instructions for Use carefully.

Indications

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

Contraindications

There are no special contraindications for use of our dialyzer for dialysis. Patients indicating allergic reactions to polyethersulfone 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.
- Follow these instructions and those of the dialysis machine supplier.
- 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 about the administration and dose and the administration time of the drugs.
- Do not reuse this product since this is a single-use product.
- The foreseeable risks in association with re-use of the product are:
  - Infection by contamination,
  - Deterioration of solute removal performance and ultrafiltration performance,
  - Exposure of patients and/or technicians to residual medicinal agents such as disinfectant used for product reuse, and/or adverse effects of residual medicinal agents on them, and
  - Damage of hollow fiber and/or leakage.
- Do not expose this product to chemical solvents, such as bleach and alcohols.
- 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, hypertension, hypotension and/or cardiac arrhythmia during the use of this product, take appropriate measures according to a physician's instructions.
- Commonly seen side effects (hypotension, hypertension, headache and nausea which are sometimes with hypovolemia or hypervolemia) can be minimized 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 ;
  (1) have a history of hypotension with hemodialysis,
  (2) have inflammatory reaction, allergic reaction, hypersensitivity, or increase in the immunity by infections,
  (3) take hypotensive drugs such as inhibitor of angiotensin converting enzyme and calcium antagonist,
  (4) use this product for the first time.

Caution

Caution should be employed against excessive water removal. Use of accurate UF control system is required. Do not use on non-de-aerated dialysis fluid delivery systems. Confirm that the dialysate does not contain pyrogens in order to prevent transfer of pyrogens 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 air mix-in and contamination during rinsing / priming operations.
- Start dialysis immediately after rinsing / priming operations.
- Rinsing / priming should be carried out under the following conditions according to this "Instructions for Use":
  - Blood side : Rinsing 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 the integrity of the blood line and dialyzer.
- Administration of Heparin
  Systemic or regionalized heparinization may need to be administered based on instructions from attending physician.

2.Caution in use

- Continuously monitor the pressure 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 during blood recovery to minimize the risk of air embolisms.
- 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

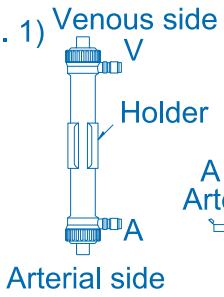
- Store at 0 to 35 °C avoiding exposure to direct sunlight, severe vibration, high humidities and dry places.

Instructions for Use

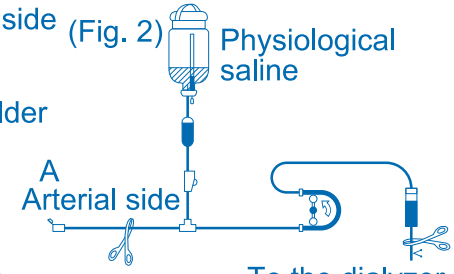
I.Rinsing / priming

(1)Take the dialyzer out of the package and set it to the holder so that the venous side is directed upward. (Fig. 1)

(Fig. 1)

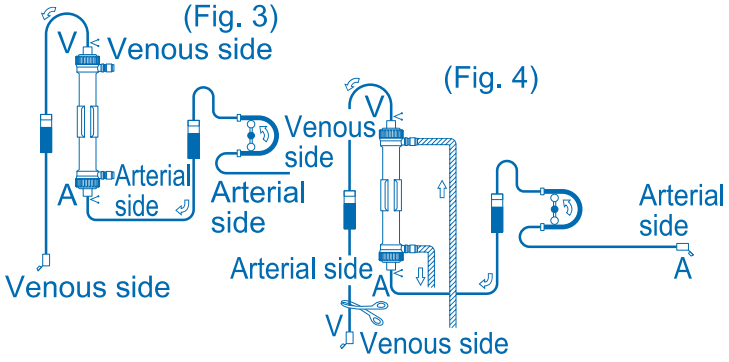


(Fig. 2)



(2)Connect the arterial and venous dialyzer connector to 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).

(Fig. 3)



(Fig. 4)

(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 degassing the dialysate part of the dialyzer. Start running through dialysate at a flow rate of about 500 ml/min.

(4) Restart 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.

[Leakage test]

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

(1)Fully prime the arterial and venous lines and the dialyzer with physiological saline by operating the blood pump ; then stop the pump operation.

(2)Clamp the arterial line near the dialyzer and the distal end of the venous line with forceps.

(3)Place 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. Remove the forceps from the arterial and venous lines. While running dialysate at a flow rate of about 500 ml/min, operate the blood pump at a flow rate of about 50 ml/min.

(2)Confirm that no air bubbles remain in venous header or venous blood line.

(3)Fully prime the arterial and venous lines including the dialyzer with blood by operating the blood pump, and then stop the pump operation. Clamp the distal end of the venous line with forceps.

(4)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 low flow rate.
Take care not to apply excessive pressure to the lines and the dialyzer to avoid leakage from the dialyzer and separation of each of the connections.

(5)After confirming that there are no bubbles in the arterial and venous headers, 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 dialysate pressure to about 0 mmHg. (This is to avoid blood coagulation due to dehydration.)
(2)Set UF rate carefully to avoid excessive water removal according to patients' 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 port 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 transport, 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 reuse of our dialyzer, we will not be responsible for the injury or damage of any nature.
(5)We will not be responsible for any injury or damage caused by use of our dialyzer after the expiry date mentioned on the label or packages.

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PERFORMANCE DATA [1]

Clearance [2]

(mL/min)	Qb/Qd(mL/min)	ELISIO™-H 09H	11H	13H	15H	17H	19H	21H	25H	ELISIO™-M 11M	13M	15M	17M	19M	21M	ELISIO™-L 11L	13L	15L	17L	19L	21L
Urea [3]	200/500	190	193	196	198	198	199	200	200	190	192	194	196	197	198	188	192	194	195	196	197
	300/500	246	257	272	278	285	288	291	294	248	256	264	270	276	281	242	251	261	267	273	277
	400/500	278	298	316	326	337	345	348	363	285	298	309	318	327	334	275	290	301	314	322	332
Creatinine [4]	200/500	177	184	191	196	197	198	199	200	181	185	189	192	195	198	176	182	187	191	194	195
	300/500	218	233	250	259	268	273	275	285	226	236	244	251	257	263	213	227	236	246	252	260
	400/500	242	261	280	296	306	314	326	342	251	266	279	290	300	309	234	252	265	280	289	302
Phosphate [5]	200/500	163	171	178	184	188	192	195	196	156	163	170	176	181	186	146	153	161	167	171	176
	300/500	200	213	230	241	254	258	265	276	183	198	211	221	231	240	165	182	194	205	214	221
	400/500	223	246	265	275	292	305	314	329	202	219	233	246	257	267	184	204	216	230	244	254
Vitamin B_{12} [6]	200/500	116	128	140	150	157	164	166	178	99	109	118	125	132	138	81	92	101	109	115	121
	300/500	134	148	165	180	190	200	206	224	111	123	134	143	151	158	93	107	117	124	135	143
	400/500	139	161	181	194	211	222	228	247	113	128	140	151	161	170	98	110	124	135	143	154
Inulin [7]	200/500	81	86	96	102	110	119	124	153	—	—	—	—	—	—	—	—	—	—	—	—
	300/500	89	94	102	112	121	132	145	171	—	—	—	—	—	—	—	—	—	—	—	—
	400/500	92	96	109	118	129	139	151	182	—	—	—	—	—	—	—	—	—	—	—	—
Myoglobin [8]	200/500	58	63	74	84	91	101	104	116	—	—	—	—	—	—	—	—	—	—	—	—
	300/500	61	68	80	90	98	107	111	126	—	—	—	—	—	—	—	—	—	—	—	—
	400/500	63	76	84	94	107	113	122	137	—	—	—	—	—	—	—	—	—	—	—	—
KUF (mL/hr/mmHg)		53	59	64	67	74	76	82	93	15	17	20	22	25	27	11	14	16	18	20	22
KoA Urea (mL/min)		746	861	1010	1145	1265	1415	1569	2157	717	812	916	1045	1103	1239	689	801	888	1010	1083	1239

Specifications [9]

	ELISIO™-H 09H	11H	13H	15H	17H	19H	21H	25H	ELISIO™-M 11M	13M	15M	17M	19M	21M	ELISIO™-L 11L	13L	15L	17L	19L	21L
Effective Surface Area [10] (m2)	0,9	1,1	1,3	1,5	1,7	1,9	2,1	2,5	1,1	1,3	1,5	1,7	1,9	2,1	1,1	1,3	1,5	1,7	1,9	2,1
Priming Volume [11] (mL)	62	70	85	95	105	115	130	149	68	80	91	108	115	128	69	81	91	104	114	127
Effective Length [12] (mm)	212	228	245	259	271	281	290	305	228	245	259	271	281	290	228	245	259	271	281	290
Inner Diameter [13] (µm)	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200	200
Membrane Thickness [14] (µm)	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
Maximum TMP [15] (mmHg)	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500
Pressure Drops [16] Qb/Qd (mL/min)	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500	200/500
Pressure Drops [16] Blood [17]/Dialysate [18] (mmHg)	59/22	56/24	54/32	52/29	51/31	51/28	49/26	47/24	58/23	56/27	54/25	53/27	52/24	50/22	58/22	56/26	53/24	50/30	49/29	47/22

In-Vitro Test Conditions [19] (ISO 8637-1)

Clearance : Qd 500mL/min, Qf 10mL/min
KUF : Bovine Blood [20] (Hct 32±2%, Protein [21] 60g/L, 37°C), Qb 300mL/min
KoA : Qb 300mL/min, Qd 500mL/min, Qf 0mL/min

Sieving Coefficient [22] *

Vitamin B_{12}	0,989
Inulin	0,926
Myoglobin	0,223
Albumin [23]	0,002

Membrane [24]
Housing [25]
Potting compound [26]
Sterilization [27]

POLYNEPHRON™
Polyethersulfone [28]
Polypropylene [29]
Polyurethane [30]
Gamma Ray [31]

* Typical values measured with ELISIO-15H, with bovine plasma, protein 60g/L, at 37°C

In-Vitro Test Conditions [19] (ISO 8637-1)

Clearance : Qd 500mL/min, Qf 10mL/min
KUF : Bovine Blood [20] (Hct 32±2%, Protein [21] 60g/L, 37°C), Qb 300mL/min
KoA : Qb 300mL/min, Qd 500mL/min, Qf 0mL/min

Membrane [24]
Housing [25]
Potting compound [26]
Sterilization [27]

POLYNEPHRON™
Polyethersulfone [28]
Polypropylene [29]
Polyurethane [30]
Gamma Ray [31]

In-Vitro Test Conditions [19] (ISO 8637-1)

Clearance : Qd 500mL/min, Qf 10mL/min
KUF : Bovine Blood [20] (Hct 32±2%, Protein [21] 60g/L, 37°C), Qb 300mL/min
KoA : Qb 300mL/min, Qd 500mL/min, Qf 0mL/min

Membrane [24]
Housing [25]
Potting compound [26]
Sterilization [27]

POLYNEPHRON™
Polyethersulfone [28]
Polypropylene [29]
Polyurethane [30]
Gamma Ray [31]

Recommended connectors for blood ports Acc.to ISO 8637-1
Recommended connectors for dialysate ports Acc.to ISO 8637-1

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the POLYNEPHRON Polyethersulfone membrane, and in the manufacture of the device. Therefore, the values given are for approximate only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived.