ELISIO™-HX

SYNTHETIC HEMODIALYZER

Instructions for Use

Be familiar with instructions specified in this document before use.

Caution: Prescription use only

Indications for Use: The ELISIO™-HX dialyzer is indicated for patients with chronic kidney failure who are prescribed intermittent hemodialysis. It provides an expanded solute removal profile with increased removal of various middle molecules (up to 45 kDa) that may play a pathologic role in the uremic clinical syndrome. This dialyzer is not intended for hemofiltration or hemodiafiltration therapy. The total extracorporeal blood volume for this dialyzer and the set should represent less than 10% of the patient's blood volume.

Contraindications: Do not use ELISIO™-HX dialyzer for HDF (hemodiafiltration) or HF (hemofiltration). Patients with a history of allergic reactions to polyethersulfone should not be treated using this product.

Limitations: Water and dialysate should comply with quality standards such as ANSI/AAMI RD62 and ISO 23500. Failure to monitor and maintain water and dialysate quality may result in patient exposure to levels of bacterial or endotoxin contamination capable of causing infection and/or pyrogenic reactions.

Handling and Storage: Do not store at extreme temperature and/or humidity, avoid direct exposure to sunlight and vibrations.

Warnings and Precautions: Refer to specific procedures for additional warnings and precautions. This product is intended for single use only. Reuse or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity. Ineffective removal of residual disinfectants may lead to adverse patient reactions. Do not expose fibers to bleach.

Adverse Reactions:

Common risks associated with dialysis include:

- Low blood pressure (hypotension)
- Muscle cramps
- Itching
- Sleep problems
- Anemia (low number of red blood cells that can cause headaches, inability to concentrate, tiredness, fatigue, and shortness of breath, with risk of heart attack or heart failure. May require a blood transfusion)
- Bone disease
- High blood pressure (hypertension)
- Fluid overload (hypervolemia) or low fluid volume (hypovolemia)
- Inflammation of the membrane surrounding the heart (pericarditis)
- High potassium levels (hyperkalemia) or low potassium levels (hypokalemia)
- Access site complications
- Amyloidosis (proteins in blood are deposited on joints and tendons)
- Depression
- Headaches
- Air embolism (air in the bloodstream)
- Infections (including bloodstream and access-site information)
- Pyrogen reactions (e.g., fever with chills, nausea, hypotension suggestive of endotoxin exposure)
- Nausea
- Vomiting
- Dizziness
- Dyspnea

There may be risks that are unknown.

Risks of the ELISIO™-HX dialyzer

- Low albumin levels (proteins in the blood) / Expanded removal of molecules up to 45 kDa may lead to increased removal of essential proteins in this size range. Clinicians should consider this possibility when prescribing the device for expanded solute removal.
- Low vitamin B_{12} levels (which can cause tiredness, weakness and difficulty with memory)
- Expanded removal of molecules up to 45 kDa may lead to increased removal of certain drugs. Clinicians should consider this when prescribing the device and make any necessary dosing adjustments.
- Itching
- Hives
- Low blood pressure (hypotension)
- High blood pressure (hypertension)
- Skin redness
- Swelling of the face and/or extremities
- Decreased or low platelets (parts of the blood that help form clots)
- Abnormal rhythm of the heart
- Serious breathing problems such as asthma attack or stopping breathing
- Allergic reaction

If you have had an allergic reaction to Polyethersulfone, you should not receive HD with the ELISIO™-HX dialyzer.

Air Embolism: Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued, and the blood must not be returned to the patient. If any abnormalities such as foam generation, blood leakage, blood coagulation and hemolysis occurred during the use of this product, take appropriate measures according to a physician's instructions.

Hypersensitivity Reactions: It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.

High Permeability Dialyzers: Use of the ELISIO™-HX Dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Dialysate Fluid: Use of an in-line conductivity monitor is recommended. To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure

1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. If applicable, the inlet (arterial) and outlet (venous) drip chambers must be at manufacturer's recommended fill level at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure.
5. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
6. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure: Do not use if the package is broken or if the product is damaged. Do not use if the blood port tip protectors are not in place. Unpack immediately before use.

Initial Assembly: Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line, heparin line (if applicable) to the dialysis machine and dialyzer.

Priming:

1. Place the dialyzer in a vertical position. Connect the arterial and venous blood lines to the respective dialyzer blood ports.
2. Attach priming solution and prime the dialyzer at a flow rate of 100 mL/min.
3. Attach the dialysate connectors to the dialyzer following the counter-current flow, red (arterial) blood line end to red dialysate connector end and blue (venous) bloodline end to blue dialysate connector end.
4. Prime the blood compartment, ensuring it has been rinsed with at least 300 mL of priming solution and there are no visible air bubbles.
5. Prime the dialysate compartment of the dialyzer.
6. Recirculate the extracorporeal circuit with at least 200 mL of priming solution. Verify the blood and dialysate compartments are full and free of air bubbles.
7. Clamp the arterial and venous lines near the patient connector.

Caution: When the priming procedure has been completed, and the extracorporeal circuit is free of air, set the ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure. This will minimize the ultrafiltration of priming solution from the dialyzer between the time when the circuit is primed and treatment is to commence. If for any reason the treatment procedure is not started immediately following the completion of priming, the priming solution in the circuit should be replaced with fresh priming solution prior to the initiation of treatment if applicable.

Treatment Procedure: Refer to the Warnings and Precautions section for additional statements. Specific directions should be given by the attending physician.

Caution: Operation of the dialyzer at a zero net ultrafiltration rate or at extremely low net ultrafiltration rates may cause the dialysate-side pressure to exceed the blood-side pressure in a portion of the dialyzer. Because the likelihood of reverse ultrafiltration of nonsterile dialysate into the blood is increased under these conditions, the ultrafiltration rate must be carefully adjusted as directed by a physician.

Administration of Heparin: Systemic or regionalized heparinization may need to be administered based on instructions from the attending physician.

Initiation of Treatment: For extracorporeal circuit configuration, refer to Figure 1.

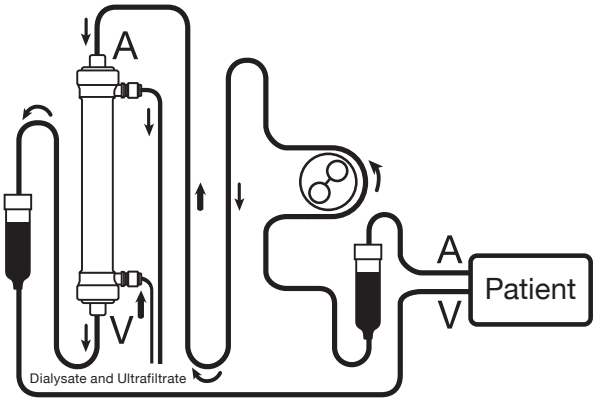

Figure 1 - Extracorporeal Circuit for Hemodialysis Treatment.

WARNING: Carefully observe the outlet (venous) drip chamber as blood enters. If blood appears hemolyzed, clamp the outlet (venous) set and simultaneously shut off the blood pump. Clamp the inlet (arterial) set. If dialysate fluid is used, verify that the dialysate mixture is proportioned correctly and properly formulated, then explore other causes (e.g. dialysate overtemperature, improper priming fluids). Purge all incompatible fluid from the dialyzing fluid path. The blood must not be returned to the patient. When cause has been determined and corrected, discard the dialyzer and sets. Set up a new dialyzer and sets.

- Connect the arterial access port to the arterial set patient connector. Connect the venous access port to the venous set patient connector.
- Remove the clamps from the patient's access and the arterial patient connector, then remove the venous patient connector clamp. Coordinate the start of the blood pump with this action. Start the blood pump.

Treatment Monitoring: If monitoring the post-pump arterial pressure during treatment, a continuing rise in post-pump arterial pressure may indicate an obstruction in the dialyzer or extracorporeal circuit. Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, constant monitoring using a blood leak detector on the dialysate fluid line or ultrafiltrate line, and visual inspection of the system, is recommended. If a blood leak occurs, an attempt may be made (at the discretion of the attending physician) to return blood from the extracorporeal system to the patient (see Termination of Treatment). If the decision is made not to return the blood to the patient, clamp the venous set and simultaneously stop the blood pump. Clamp the arterial set. Discard the dialyzer and sets.

Termination of Treatment:

WARNING: Any air that was trapped inadvertently in the dialyzer during priming and treatment may be dislodged. Carefully monitor the level of the venous drip chamber at all times. Air rinsing of blood at the termination of treatment is not recommended.

1. Stop the blood pump and clamp venous and arterial sets and arterial access
2. Separate the arterial set from the arterial access and connect the arterial set to a source of sterile priming solution.
3. Open the clamps on the fluid administration set, the arterial set, and the venous set and increase the blood pump setting slowly to return the blood to the patient.

4. Rinse priming solution through the blood tubing until the fluid in the venous set is as clear as desired.
5. Stop the blood pump and clamp the venous set and the venous access. Separate the venous set from the venous access.
6. Discard dialyzer and all other disposable equipment in accordance with appropriate biohazardous material disposal practices.
7. Provide appropriate care to the patient's vascular access as prescribed by the physician.

WARRANTY CLAUSE

NIPRO warrants that ELISIO-HX is designed and manufactured in accordance with the written specification for ELISIO-HX applicable to the specific model purchased by the user and in compliance with current applicable industry standards, and regulatory requirements.

The warranty above is in lieu of and to the exclusion of any other warranty, whether written or oral, express or implied, statutory or otherwise, and there are no warranties of merchantability, or fitness or other warranties, which extend beyond those described above.

NIPRO's sole liability to the purchaser for breach of warranty, and purchaser’s sole remedy, shall be to replace ELISIO-HX for which a valid claim is presented. Nipro shall not be liable for any consequential or incidental loss, damage, injury, or expense directly or indirectly arising or resulting from the breach of any warranty herein.

NIPRO shall not be liable for any damage, loss or injury caused by the reuse of ELISIO-HX misuse, improper, handling, noncompliance with warnings and instructions, damage caused by events occurring after the product is released, failure to ensure that the product is in proper condition before use, or any warranty given by independent distributors.

THERE ARE NO ADDITIONAL WARRANTIES, EITHER EXPRESSED OR IMPLIED, ARISING OUT OF THE SALE OF THIS PRODUCT OTHER THAN THOSE CONTAINED HEREIN.

PERFORMANCE

In-Vitro Data: 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 approximation only. See in-vitro test conditions for explanatory materials related to the test conditions from which the data was derived.

WARNING: ELISIO™-HX dialyzers must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Clearance (mL/min)		**ELISIO™-15HX**				**ELISIO™-17HX**				**ELISIO™-19HX**				**ELISIO™-21HX**			
Surface area (m^2)		1.5				1.7				1.9				2.1			
	Qd \ Qb	200	300	400	500	200	300	400	500	200	300	400	500	200	300	400	500
Potassium (K)(39 Da)	500	92	130	153		94	131	158		93	134	163		93	137	163	
	800			172	194			174	203			178	203			182	210
Urea (60 Da)	500	197	275	327		198	281	338		199	287	348		200	290	355	
	800			357	410			369	428			377	441			382	450
Phosphate (95 Da)	500	186	241	272		190	252	286		194	261	299		196	268	310	
	800			305	340			321	359			335	374			344	387
Creatinine (113 Da)	500	190	255	297		194	266	310		197	275	321		198	280	331	
	800			332	372			345	389			356	403			362	413
Vitamin B_{12}(1.4kDa)	500	150	179	196		159	192	210		167	203	223		174	214	235	
	800			213	233			232	251			247	269			258	281
Inulin (5.2 kDa)	500	116	136	153		127	152	165		131	161	186		137	175	194	
	800			168	186			187	209			203	221			217	235
Cytochrome C (12 kDa)	500	93	104	110		102	115	122		109	123	133		114	128	138	
	800			124	130			137	143			145	155			157	165
Myoglobin (17 kDa)	500	92	100	108		102	110	119		112	122	130		121	132	142	
	800			113	121			127	136			140	149			152	162
IL-6 (25 kDa)	500	56	62	64		56	62	67		70	64	81		72	72	84	
	800			68	68			74	79			80	75			88	91
TNFα (51 kDa)	500	40	33	53		45	54	52		54	53	70		58	66	60	
	800			50	62			61	53			67	77			66	76
Ultrafiltration Coefficient (mL/hr/mmHg)		68				75				78				83			
Priming Volume (mL)		90				102				114				125			
Pressure Drop (mmHg)	Blood (mL/min)	200		500		200		500		200		500		200		500	
	Dialysate (mL/min)	500		800		500		800		500		800		500		800	
	Blood Compartment	80		182		79		181		77		174		76		173	
	Dialysate Compartment	34		37		35		39		31		34		31		36	
Sieving Coefficient	Vitamin B_{12}	1.07															
	Inulin	1.00															
	Myoglobin	0.86															
	Albumin	<0.01															

ELISIO™-HX Dialyzer Technical Information	
Hollow Fiber Membrane Polymer:	POLYNEPHRON (Polyethersulfone)
Inner Diameter:	200 microns
Membrane Thickness:	40 microns
Maximum TMP:	500 mmHg
Header:	Polypropylene
Housing:	Polypropylene
Potting Compound:	Polyurethane
Sterilization:	Gamma Irradiation
Blood flow range:	200-500 mL/min
Dialysate flow range:	500-800 mL/min

In-Vitro Test Conditions: Testing was performed in compliance with the evaluation standard for dialyzer performance per ISO 8637-1	
Clearance Temperature:	37°C
Ultrafiltration Rate:	0 mL/min
Ultrafiltration Coefficient Test Solution:	Bovine Blood
Hematocrit:	32%
Blood flow:	300 mL/min
Priming Volume Test Solution:	Water
Pressure Drop:	50 mmHg TMP
Sieving Coefficients determined after plasma recirculation exposure	
Blood Flow:	300 mL/min
Ultrafiltration Rate:	60 mL/min

Clinical Data: (ELISIO™-15HX, ELISIO™-17HX, ELISIO™-19HX, ELISIO™-21HX) [NCT07058909]
A prospective, single-arm, open-label pivotal clinical study was conducted to evaluate safety and effectiveness of the ELISIO™-HX in adult patients with chronic kidney disease who are suitable candidates for high-flux hemodialysis (HD). A total of 22 participants were enrolled with 13 participants completing 36 treatments per protocol. Participants were on average 55 years of age, and the most common racial group was Black or African American, 38% were women. Average time on renal replacement therapy was 68.4 months (5.7 years) for the safety analysis cohort. The primary objectives of the study were to show that the pre-dialysis albumin levels are not affected using the ELISIO-HX and that the performance of the high permeability hemodialyzer series ELISIO™-HX, improves the clearance rate of middle molecular weight lambda(λ) free light chain (FLC). The primary safety endpoint was the change in serum level of albumin (65 kDa) from baseline (last blood draw post-dialysis with ELISIO-H) to last blood draw post-dialysis after 36 treatments with ELISIO-HX. The primary efficacy endpoint was the reduction ratio (RR) of lambda (λ) FLC (45 kDa) at the last blood draw post-dialysis after 36 treatments compared to baseline (last blood draw post-dialysis with ELISIO-H). There were no Serious Adverse Events (SAEs) related to the device.

Primary Outcomes	**Mean (SD)**	**95% CI**
Albumin (66kDa)(g/dL) Change in serum level from baseline to post-dialysis after 36 treatments	-0.04 (0.419)	-0.29, 0.21
Lambda free light chains (λ-FLC; 45kDa)(mg/L) Mean Reduction ratio (RR) from baseline to post-dialysis after 36 treatments	-11.20 (15.237)	-20.41, -1.99

Secondary outcomes (n=13).

Mean Reduction ratio (RR) from baseline to post-dialysis after 36 treatments	**Mean (SD)**	**95% CI**
Necrosis Factor alpha (TNFα; 51 kDa) (pg/mL)	-16.45 (26.824)	-32.65, -0.24
Complement Factor D (CFD; 27 kDa) (ng/mL)	-21.53 (9.355)	-27.18, -15.87
Interleukin 6 (IL-6; 25 kDa) (pg/mL)	18.80 (59.495)	-17.15, 54.75
κ FLC (23 kDa) (mg/L)	-12.85 (14.155)	-21.41, -4.30
Myoglobin (~17 kDa) (ng/mL)	-17.06 (32.954)	-36.98, 2.85
β2-microglobulin (β2-MG; 11.6 kDa) (mg/L)	-8.83 (13.916)	-17.24, -0.42
Change from baseline to post-dialysis after 36 treatments		
Factor VII (50 kDa) (ng/mL)	-29.3 (53.72)	-61.8, 3.2
Protein C (53-62 kDa) (%)	-7.0 (19.94)	-19.1, 5.1
Vitamin A (mg/L)	-0.095 (0.1628)	-0.194, 0.003
nPNA (nPCR) (g/kg/d)	0.136 (0.6872)	-0.280, 0.551
Kt/V	-0.054 (0.1776)	-0.161, 0.054

The reduction ratio of λ-FLC from baseline to 12 weeks was -11.20% (95% CI: -20.41%, -1.99%) indicating improved removal of λ-FLC after treatment with ELISIO-HX over baseline treatment with ELISIO-H. Secondary endpoints showed trends towards enhanced clearance of a range of middle molecules including TNFα (51 kDa), Complement Factor D (27 kDa), κ-FLC (23 kDa), and β2-Microglobulin (11.6 kDa). Kt/V remained consistent and within adequate levels throughout the study. There was no significant impact of the treatment on quality of life.

STERILE R

℞ ONLY

UF Control This device must be used on dialysis machines with an ultrafiltration controller or an accurate balancing system.

Not made with BPA NON-Bisphenol-A

Not made with DEHP NON-Bis(2-ethylhexyl) phthalate

HDF **Not for use with HDF**

www.nipro.com/symbols_glossary/

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