Polyethersulfone Hollow Fiber Hemodialyzer

Operation Instruction

Single use, NOT FOR REUSE
DO NOT use the product if the packing bag is damaged
Read the operation instruction before usage
Validity: three years

Digitally signed by Moraru Grigore
Date: 2024.01.12 17:42:36 EET
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Location: Moldova

[GENERAL INFORMATION]

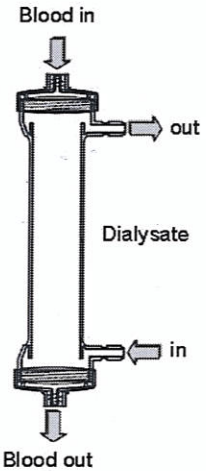
INDICATIONS: The Polyethersulfone Hollow Fiber Hemodialyzer is designed for single use in acute and chronic renal failure hemodialysis and hemodiafiltration treatment.

CONTRAINDICATIONS: There is no absolute contraindication, but it should be used with caution in the following cases: allergy to materials; severe intracranial hemorrhage; severe shock which is difficult to be corrected by drugs; severe myocardial disease with refractory heart failure; severe active bleeding; mental disorders cannot be treated with hemodialysis.

PRECAUTIONS: (1) The intended users are patients with acute and chronic renal failure, the use of the product must comply with the requirements of relevant operation instructions, laws and regulations of the medical department, and should only be used by trained doctors or nurses. (2) After connecting to the bloodline, the dialyzer should be aseptic operation and used as soon as possible. (3) The Maximum trans-membrane pressure is 66.5kpa (500mmhg), and unnecessary pressure should be avoiding to the bloodline and dialyzer to prevent leakage and falling off of the connecting parts. (4) The operator should strictly obey the manufacturer's recommended procedures, warnings and precautions. (5) Intended patient population: recommend for adults only. The safety and efficacy of the Polyethersulfone hollow fiber hemodialyzer for pregnant patients have not been established. (6) When the flow rate of the product is lower than the recommended rate or the product is not used in accordance with the instructions, the performance will be reduced. (7) It is suggested to test blood routine, renal function, blood electrolyte and other indicators once a month. (8) The product should be used together with dialyzer machine, bloodline and dialysate. These equipment and consumables must meet the national and international standards. In case of complications affecting the stability of the patient's condition, the treatment should be stopped. (9) The duration of device life use is 4h. (10) The dialysate should meet the be ISO 13485 and MDD/MDR.

WARNING: (1) The device can only be used on the machines equipped with precise ultrafiltration control. If not, the high water flux capability of high flux membranes with an ultrafiltration coefficient ≥ 90ml/kPa•h may cause membrane break. (2) Dialysate supply system without degassing shall not be used. Air entering the extracorporeal circuit during dialysis can result in serious injury. Check the security of all extracorporeal connections prior to the initiation of dialysis and periodically throughout the treatment. The venous drip chamber should be continuously monitored with a level detector. (3) The device should be used with caution in patients who allergy to materials otherwise may cause allergy reaction. (4) The device should be used with caution in patients who under severe intracranial hemorrhage and severe active bleeding otherwise may aggravate bleeding. (5) The device should be used with caution in patients who severe shock which is difficult to be corrected by drugs otherwise may cause hypotension. (6) The device should be used with caution in patients who under refractory heart failure otherwise may aggravate heart failure. (7) The device should be used with caution in patients who under mental disorders otherwise may delay treatment. (8) The device is single use, not for reuse. If were to be re-used will lead to patient infection. (9) In rare cases, hypersensitivity reactions to the dialyzer or other parts in the extracorporeal circuit may occur during hemodialysis. If occurs, the source of the hypersensitivity should be identified and the material of the extracorporeal circuit should be excluded from future treatments for the patient. With severe reactions, dialysis must be discontinued and aggressive first line therapy must be initiated.

SIDE EFFECTS: Potential side effects include, but are not limited to, the following: Leakage, Allergic Reactions, Infection, Hemolysis and bleeding, Myocardial infarctions, Clotting, Congestive heart failure, Strokes, Peripheral arteries disease/ critical limb ischemia, Disequilibrium Syndrome, Joint Pain, Hypotension, Hypertension, Intradialytic muscle cramp, Infection, Chest tightness/Chest pain, Mortality.



HEPARINIZATION: It is recommended that the patient be systemically heparinized before beginning extracorporeal circulation. In addition, the total amount of heparin should be taken care not to exceed the prescription. During dialysis, the dosage of heparin are the responsibility of the attending physician.

STERILE/NON-PYROGENIC: The dialyzer is sterilized by Gamma ray. The product is non-pyrogenic.

MEDICAL PERFORMANCE CLAIM: This product is a sterile disposable device, which support the use of hemodialysis machine and extracorporeal circulation tube, apply to hemodialysis therapy of patients with acute or chronic renal failure, function as blood purification to remove small molecule toxins or metabolic wastes(such as urea, creatinine, phosphate, vitamin B12 and so on), middle molecule and macromolecule toxins or metabolic wastes (such as β2-microglobulin) and excess water, simultaneously adjust the water, electrolyte and acid-base balance of patients.

RECOMMENDED STORAGE: Store in a dry place with ventilated, clean, non-corrosive air within the temperature of 0~40°C.

PREPARATION FOR DIALYSIS

• Install the arterial and venous bloodlines on the dialyzer. Note: Refer to the instructions of hemodialysis machine for use in setting up bloodlines.

• Connection of fluid infusion tube: In the front replacement hemodialysis, the fluid infusion tube is connected to the port of the arterial bloodline; In the post replacement hemodialysis, the fluid infusion tube is connected to the fluid supply port of the venous bloodline. It should be noted that for post replacement HDF, if the water content in the blood is too much reduced, the risk of coagulation during extracorporeal circulation is increased, and the blood water content should be controlled.

• Aseptically connect a 1 liter bag sterile saline solution with a clamped dialysis priming set. Be sure the connection is secure.

• Set the pump speed of 80~100 mL/min. Prime the arterial bloodline, dialyzer and venous bloodline with saline.

• Flush the dialyzer and blood lines with 500 mL sterile saline solution.

• Verify that the dialysate is within the prescribed conductivity limits with a calibrated conductivity monitor.

• Rotate the dialyzer so the venous end is down. Attach the dialysate lines to the dialyzer. Fill the dialysate with the dialyzer in the venous end down position. Then turn the dialyzer back to the arterial end down position and place back in dialyzer holder.

• Then set the dialysate flow at 200 to 300 mL/min to purge all the visible air from the dialyzer and bloodlines.

• Do not infuse the recirculated saline into the patient. Discard the recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to the patient.

• If the hemodialysis machine was chemically disinfected or sterilized prior to patient use, be sure to test for the absence of germicide residuals.

INITIATION OF DIALYSIS

• Stop the blood pump, clamp the dialysis priming set and the arterial and venous bloodlines.

• Aseptically attach the ends of the bloodlines to the patient's arterial and venous access. Open the arterial and venous bloodline clamps and the clamps on the patient access.

• Increase the blood pump speed slowly to the prescribed blood flow rate. Be sure to monitor the arterial and venous blood pressures carefully during this process to note any possible flow restrictions or inappropriate pressure readings.

• Once the prescribed blood flow rate has been achieved, set the prescribed ultrafiltration rate.

DURING THE DIALYSIS TREATMENT

• If a blood leak occurs during the treatment, the operator should take measures as directed by a physician.

• Air entering the extracorporeal circuit during dialysis is a very serious event and should be avoided. A routine check of all connections prior to initiation of dialysis and periodically throughout the dialysis treatment is recommended.

• Constantly monitor the venous drip chamber. If air gets into the venous line during the treatment, the dialysis must be discontinued without returning any of the blood mixed with air.

TERMINATION OF DIALYSIS

• When the dialysis treatment is completed, turn the blood pump off, clamp on the arterial bloodline. Pull out the puncture needle or indwelling needle from the fistula of the patient and connect it to the saline bag to recover the blood.

• Remove the clamp on the arterial bloodline. Start the blood pump and rinsing the blood in the tube and the dialyzer.

• Once the blood has been returned to the patient, turn the blood pump off. Clamp the arterial and venous bloodlines and the patient's arterial and venous access. Aseptically disconnect the arterial and venous bloodlines from the patient's access.

• Discard the extracorporeal circuit in an appropriate biohazard waste receptacle. References: 29CFR, 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state and local codes.

[SYMBOLS]

LOT	Batch code	REF	Catalogue number		Do not re-use
EC REP	Authorized representative in the European Community	STERILE	Sterile		Do not use if package is damaged
	Date of manufacture	STERILE R	Sterilized using irradiation		Non-pyrogenic
	Use-by date		Consult instructions for use		

[COMPONENTS OF THE PRODUCT]

Components	Materials
Membrane	Polyethersulfone (PES)
Sealing compound	Polyurethane (PUR)
Housing; End Cap	Polycarbonate (PC): High-Flux Polyethersulfone Hollow Fiber Hemodialyzer; Low-Flux Polyethersulfone Hollow Fiber Hemodialyzer Polypropylene (PP): Hollow Fiber Membrane Hemodialyzer; Hollow Fiber Dialyzer; Hollow Fiber Hemodiafilter
Sealing ring	Silicon rubber (SIR)
Blood compartment connections	ISO 8637
Dialysis fluid connections	ISO 8637
Sterilization Method	Gamma ray

[WARRANTY]

The manufacturer guarantees that the dialyzer has been manufactured in accordance with its specifications and in compliance with the GMP regulatory guidelines.

Products with manufacturing defects will be replaced if the defect is reported with details of the lot number.

The manufacturer will 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 dialyzer.

[MANUFACTURER INFORMATION]

Chengdu OCI Medical Devices Co., Ltd.

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[EUROPEAN REPRESENTATIVE]

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【Technical data】Technical specifications of Hollow Fiber Membrane Hemodialyzer

Hemodialyzer Model	OCI-HD13M			OCI-HD15M			OCI-HD16M			OCI-HD17M			OCI-HD18M			OCI-HD19M			OCI-HD20M			OCI-HD21M			OCI-HD23M			OCI-HD25M		
Surface area (m^2)	1.3			1.5			1.6			1.7			1.8			1.9			2.0			2.1			2.3			2.5		
Blood flow range (mL/min)	200~400																													
Dialysate flow range (mL/min)	500~800																													
Ultrafiltration coefficient (mL/h•mmHg)	39			48			57			60			63			64			67			69			73			77		
Clearance (mL/min)±10% Q_D = 500 mL/min																														
Q_B (mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea	180	259	292	184	264	305	186	267	312	188	270	318	190	274	325	192	277	332	195	280	340	196	283	348	200	289	358	205	295	364
Creatinine	164	239	259	168	243	265	170	245	268	173	248	271	175	250	274	178	252	277	180	255	280	182	258	283	186	264	289	190	270	295
Phosphate	164	244	284	172	248	290	176	250	293	179	253	296	182	256	298	185	259	300	188	262	304	191	265	308	197	271	316	203	277	324
Vitamin B_{12}	129	159	168	135	165	176	138	168	180	140	171	185	142	173	188	144	175	192	147	178	196	150	181	200	156	187	208	162	193	216
Clearance (mL/min)±10% Q_D = 800 mL/min																														
Q_B (mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea	182	265	295	187	271	315	190	274	325	192	277	332	194	280	338	196	283	344	198	286	350	200	289	356	202	295	366	208	297	374
Creatinine	165	244	260	171	248	270	174	250	275	177	253	273	180	256	280	183	258	283	186	260	286	189	262	289	195	266	295	201	270	301
Phosphate	168	247	294	176	253	298	180	256	300	183	259	303	186	262	305	189	265	307	192	268	310	195	271	313	201	277	319	207	283	325
Vitamin B_{12}	133	165	170	139	171	182	142	174	188	145	177	192	147	180	196	149	182	200	152	186	204	155	190	208	161	198	216	167	206	224
Pressure drop blood (Q_B=300mL/min)	≤13.5			≤13.5			≤13.5			≤13.5			≤13.5			≤13.5			≤13.5			≤13.5			≤13.5			≤13.5		
Priming volume (ml)	84			90			95			101			106			112			120			126			136			146		
Maximum pressure of use	500 mmHg / 66.5kPa																													

In vitro performance: T = 37°C

Ultrafiltration coefficients: Anticoagulated bovine blood with a haematocrit of (32±3)% and a protein content of (60±5)g/L

In vitro results are likely to differ from in vivo results

The performance might change with the duration of observation

【Technical data】Technical specifications of Hollow Fiber Dialyzer

Hemodialyzer Model	OCI-HD110L			OCI-HD130L			OCI-HD140L			OCI-HD150L			OCI-HD160L			OCI-HD170L			OCI-HD180L			OCI-HD190L			OCI-HD200L			OCI-HD210L			OCI-HD230L		
Surface area (m^2)	1.1			1.3			1.4			1.5			1.6			1.7			1.8			1.9			2.0			2.1			2.3		
Blood flow range (mL/min)	200~400																																	
Dialysate flow range (mL/min)	500~800																																	
Ultrafiltration coefficient (mL/h•mmHg)	10			12			13			13			14			16			17			21			24			25			28		
Clearance (mL/min)±10% Q_D = 500 mL/min																																		
Q_B (mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea	176	224	262	178	227	266	180	230	270	182	233	274	185	235	278	187	238	284	190	242	290	192	246	295	194	250	300	195	254	305	197	262	315
Creatinine	166	207	239	168	211	243	170	215	247	172	218	251	175	220	255	178	223	260	182	227	265	185	231	270	188	235	275	191	239	280	197	247	290
Phosphate	147	177	200	151	181	205	155	185	210	158	188	215	160	191	220	164	195	222	168	200	225	170	205	232	172	210	240	174	215	248	178	225	264
Vitamin B_{12}	97	105	119	100	109	122	103	113	125	106	116	128	108	118	130	114	124	140	120	130	150	125	135	155	130	140	160	135	145	165	145	155	175
Clearance (mL/min)±10% Q_D = 800 mL/min																																		
Q_B (mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea	181	245	272	182	250	281	185	255	290	187	259	298	189	263	305	191	266	313	193	269	322	195	272	326	197	275	330	199	278	334	203	284	342
Creatinine	176	230	265	178	234	270	180	238	275	182	242	280	184	245	285	186	247	290	188	250	295	190	255	297	192	260	300	194	265	303	198	275	309
Phosphate	152	180	215	156	185	220	160	190	225	164	195	230	167	200	235	169	203	238	171	207	242	173	211	246	175	215	250	177	219	254	181	227	262
Vitamin B_{12}	104	117	132	108	121	136	112	125	140	116	128	143	120	130	145	122	138	152	125	145	160	130	150	165	135	155	170	140	160	175	150	170	185
Pressure drop blood (Q_B=300mL/min)	≤12			≤12			≤12			≤12			≤12			≤12			≤12			≤12			≤12			≤12			≤12		
Priming volume (ml)	72			80			85			90			95			101			106			112			118			123			145		
Maximum pressure of use	500 mmHg / 66.5kPa																																	

In vitro performance: T = 37°C

Ultrafiltration coefficients: Anticoagulated bovine blood with a haematocrit of (32±3)% and a protein content of (60±5)g/L

In vitro results are likely to differ from in vivo results

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