English

CE 0197

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Hollow Fiber Dialyzer
(PF Series)
Instructions for Use

Please read the Instructions for Use carefully before using the product.

Indication for use: DORA Hollow Fiber Dialyzer can be used for the hemodialysis treatment of acute and chronic renal failure. It is applicable to all dialysis patients.

Contraindications: No absolute contraindication for hemodialysis treatment. In case of any complication that would affect the stable condition, appropriate medical actions under the supervision of a physician or adequately trained personnel should be taken.

Cautions and Warnings:

- The dialysate and the blood should flow in counter-current.
- The maximum flow rate of dialysate is 800mL/min.
- **DO NOT** use on non-degas dialysate delivery systems.
- During the treatment, the transmembrane pressure shall not exceed 66kPa (500mmHg).
- The blood flow rate shall not be lower than 150mL/min, but not higher than 500mL/min.
- Use an aseptic technique when preparing the circuit and the dialyzer for use to avoid contamination.
- DORA Hollow Fiber Dialyzer shall be used under certain medical supervision or adequately trained personnel. To avoid bacterial and pyrogenic contamination, it is suggested to use together with hemodialysis machine, dialysis water, concentrated solution and dialysate which are in accordance with the international standards.
- The fluid pathways (blood and dialysate) is sterile and non-pyrogenic, sterilized by irradiation. **DO NOT** use the expired product. **DO NOT** use the device if package is damaged or if protective caps are not in place.
- This dialyzer is for single use and reuse is strictly prohibited. Reprocessing of this product may lead to adverse patient reactions and/or device failure.It should be discarded according to laws and regulations relevant to disposal of clinical medical waste so as to prevent infection.
- If abnormal conditions arise during the dialysis, such as bubbles, foreign matter, blood leak, or clotting, proper measures shall be taken according to doctor's advice.
- If complications arise during the dialysis treatment, such as (but not limited to) hypotension; hypertension, air embolism, cramps, headache, nausea, shivers, fever, thirst; angina, arrhythmia, or hemolysis, proper measures shall be taken according to physician's or adequately trained personnel's advice.
- Please use only with ultrafiltration controlling dialysis system.
- Do not use expired products. Please check the expiration date on label before use.
- Ensure the connection between bloodline and dialyzer is stricltly tight. Do not use this product if the bloodline connectors cannot fit for the dialyzer. During the treatment check that all of connectors are tight to prevent blood leakage or any air entry.
- If the device is used below a blood flow rate of 150mL/min, below a dialysate flow rate of 500mL/min, it may have diminished performance.
- If serious incident occurs,please inform the manufacturer or local competent authority.

Instructions for Installation

- Take out the dialyzer from the pouch, and check whether the dialyzer and its components are in good condition.
- Set up the dialyzer vertically to the holder.
- Make sure the dialyzer stays firmly in the holder.

Recommended usage method

1. Priming

- Prepare no less than 500mL normal saline or dialysate and add appropriate amount of heparin if needed under physician's prescription.
- Place the arterial line and the venous line onto the dialysis machine according to the instructions for use of the extracorporeal blood circuit.
- Connect the arterial line,the venous line and the dialyzer.
- Control the flow rate of blood pump within 80~100mL/min, use normal saline or dialysis fluid until totally remove air from blood line and blood compartment of the dialyzer. The direction of normal saline or online dialysis fluid flow is arterial line→dialyzer→venous line, and counter-current is forbiddened.
- Turn the flow rate up to 200~300mL/min, connect the dialysate connector to the dialyzer, and remove all air from the dialysate compartment.

Note: Check for the presence of air in the blood circuit before patient connection and run extra priming/ recirculation/ ultrafiltration if any air may remain.

2. Anticoagulation

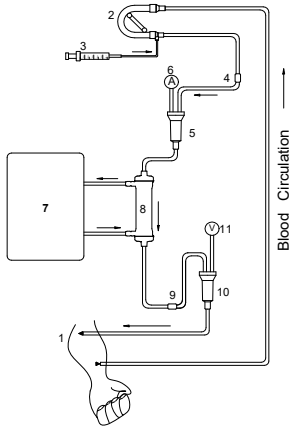
- Carry out the anticoagulation according to prescription.

3. Termination of Treatment

- For reinfusion and completion of the treatment, follow the instruction on the dialysis machine in use.
- 500mL saline or substitution is normally sufficient to an adequate blood reinfusion. Turn off the blood pump and disconnect the patient's venous line.

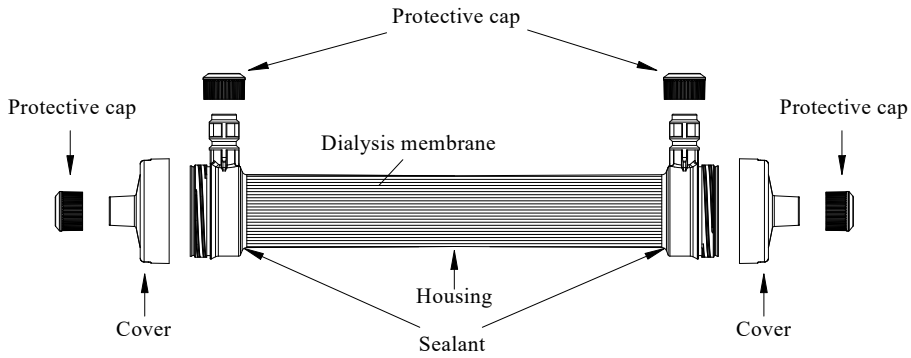
Note: DO NOT turn off the air monitor system before blood returns completely to prevent the air flowing into the patient from the blood line.

A typical connection diagram



1. Patient
2. Arterial Blood Pump
3. Heparinization
4. Access Port of the Arterial Line (Red)
5. Arterial Drip Chamber
6. Transducer Protector (Arterial Pressure)
7. Dialysis Machine
8. Hemodialyzer
9. Access Port of the Venous Line (Blue)
10. Venous Drip Chamber
11. Transducer Protector (Venous Pressure)

	Do not re-use	STERILE R	A sterile fluid path that has been sterilized using irradiation		Fluid path is non-pyrogenic
	Date of manufacture		Manufacturer		Temperature limit
LOT	Batch code		Use-by date		This end up
REF	Catalogue number		Keep dry		Fragile, handle with care
	Do not use if package is damaged		Keep away from sunlight		Consult instructions for use
	Caution		Humidity limitation	EC REP	Authorized representative in the European Community
CE	CE marking				



Main Structure:

Component	Housing	Dialysis Membrane	Cover	Sealant	Protective Cap
Material	Polypropylene	PES Membrane	Polypropylene	Polyurethane	Polyethylene

Product Performance: This dialyzer has reliable performance, which can be used for hemodialysis. The basic parameters of product performance and the laboratory data of this series will be provided as follows for reference.

Note: The laboratory data of this dialyzer was measured according to the standards ISO 8637-1.

These data represent typical *in vitro* performance. *In vivo* performance will differ due to the patient's blood composition and clinical settings.

Model	B-14PF			B-16PF			B-18PF			B-20PF			B-22PF			B-24PF		
Product ref.	B-14PF			B-16PF			B-18PF			B-20PF			B-22PF			B-24PF		
Test Conditions: Q_D = 500 mL/min, Temperature: 37℃±1℃, Q_F =10 mL/ min																		
Clearance / Q_B (mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea (mL/min)	189	251	281	191	259	290	193	266	300	195	274	311	197	284	321	198	291	330
Creatinine (mL/min)	180	232	260	183	244	275	186	256	287	189	267	299	192	280	311	195	286	322
Phosphate (mL/min)	179	228	267	185	240	280	190	250	292	192	260	305	195	272	317	197	281	329
Vitamin B_{12} (mL/min)	114	132	142	123	148	158	130	162	175	138	177	188	146	190	202	153	201	214
Pressure drop of blood compartment (mmHg)	<50	<70	<90	<45	<65	<85	<40	<60	<80	<40	<55	<75	<40	<55	<75	<40	<55	<75
KUF (mL/hr/mmHg) Q_B=300 mL/min, TMP=100 mmHg	21			23			26			29			33			36		
Priming volume (mL)	85			98			110			125			137			150		
Effective membrane area (m^2).	1.4			1.6			1.8			2.0			2.2			2.4		

Special Storage Conditions and Methods: Please avoid crash and exposure to rain, snow, and direct sunlight during transportation. Please store it in a well-ventilated indoor place with storage temperature of 0℃～40℃, with relative humidity no more than 80%. Store away from chemicals and humid articles.

Shelf life: please refer to the actual labeling.

After-sale service: Please keep the original packaging for any investigation on product quality.

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Keep this Instruction for Use after all of the products in this carton are used up.

Date: 11/04/2020

Made in China

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