English

DORA®

CE 0197

Tubing Sets for Hemodialysis

Instruction for Use

Manufacturer has been granted certificate of ISO 13485
Performed standard is ISO 8637-2

1. Material

The major components of this product are made from medical-grade PVC, PP, PE and other medical-grade macromolecule materials. And it is free of latex. All these materials are possible to contact blood directly or indirectly.

2. Product configuration and Feature

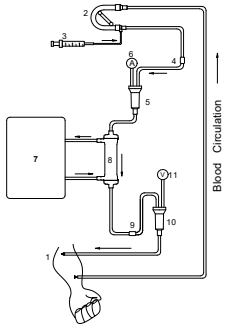
This product consists of a red Arterial line and a blue Venous line, the tubing is soft, transparent, smooth and non-kink, which ensure the good liquidity of the tubing. The filter in the venous chamber can prevent the blood clot going into patient's vein.

3. Indication for use

This product is intended to connect with the dialyzer to the patient in dialysis treatment. It is applicable to all dialysis patients.

4. Recommended usage method

1) Take out the product from the pouch, the arterial and venous connectors should be connected correctly with the dialyzer's arterial and venous ports respectively.
2) Priming using physiological saline (or online prepared dialysate), removing all of the air from the product and the dialyzer.
3) Ensure the product is full of saline (or online prepared dialysate), and with no air in any part, then stop the pump and close all the clamps in the product.
4) Recheck all the connectors, make sure all of the connectors are tight.
5) Start treatment referring to the dialyzer instruction for use.
6) The typical bloodline circuit 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)

7) Termination procedure:

- For reinfusion and completion of the treatment, follow the instruction on the dialysis machine in use.
- 500mL saline or substitution fluid 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.

8) Discard it to the designated collection container.

5. Transportation and storage

Please avoid crash or exposure to rain, snow or direct sunlight during transportation. Store it in 0℃~40℃, well-ventilated indoor place with relative humidity no more than 80%, without corrosive gas. Store away from chemicals and moist articles.

6. Precautions in use

1) This product should be used under the supervision of a physician or adequately trained personnel.
2) Use aseptic technique throughout connection, priming and treatment. The validity period is three years after the sterilization day. Please check the expiration date prior to use. Do not use any expired product.
3) Fluid pathway is sterile and non-pyrogenic, sterilized by irradiation. Do not use the product if the pouch is damaged or the protective caps fall out of the pouch.
4) Tear open the pouch and pick out the product carefully.
5) This product is intended to be used with A.V. Fistular needle, dalysis catheter, dialyzer and dialysis machine. Make sure the product is compatible with the devices which are equipped with standard luer lock. The safety of the connection to dialyzers should be guaranteed. Do not use this product if the dialyzer connectors of this product cannot fit for the dialyzer. Make sure that all of connectors are tight to prevent blood leakage or any air entry, otherwise readjustment should be performed. In case no improvement is made, replace with another new one. The product should be properly installed to the dialysis machine to prevent kinking during treatment.
6) The access port is accessed with a hypodemic syringe having a diameter of 0.8mm or less.
7) This product is for single use only and reuse is strictly prohibited. Reuse or 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 waste.
8) The transducer protector of this product should be kept dry/without any type of fluids. Make sure that a transducer protector must be installed on each pressure monitoring line, connected to dialysis machine prior to patient use and it must be replaced if wetted by saline or contaminated by blood.
9) This product contains DEHP (Di-2-ethylhexyl phthalate). Attention should be paid when this product is used for pregnant women, lactating women, infants and children.
10) All of the disinfectant used for this product have no special contraindications.
11) To prevent the potential of air infustion during treatment, ensure the normal use of the air-capture chamber, whose level marking should below 1cm of the upper limit.
12) Locking connectors might separate if either the male or female part is exposed to a lubricant, which is transfered from a lubricated needless valve.
13) This product should be compatible with device which is equipped with air detector. The device should be prevented from the contamination of blood. The air detector will not detect air introduced by a syringe through an access port distal to the air detector.
14) The actual blood flow rate might differ from the blood flow rate indicated by the machine and that the difference might change with time.
15) If abnormal conditions arise during the dialysis, such as bubbles, foreign matter, blood leak, or clotting, etc., proper measures shall be taken according to doctor's advice.
16) If serious incident occurs, please inform the manufacturer or local competent authority.
17) There are no known contraindications of this product. General contraindications for hemodialysis apply.
18) Please refer to the actual labeling for the model, volume of blood pathway, applicable machine, shelf life, batch code, etc.

7. After sales service

Please keep the original packaging for any investigation on product quality.

8. Symbol

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

9. Parameter

Positive pressure (mmHg)	Negative pressure (mmHg)	Blood flowrate limitations
500	-500	500ml/min

EC REP <EU Representative>

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⚠ Keep this instruction for use after all of the products in this carton are used up.

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