BIOTEQ Hemodialysis Blood Tubing Set

INSTRUCTIONS

(1) INTENDED USE:

A. Intended Purpose:

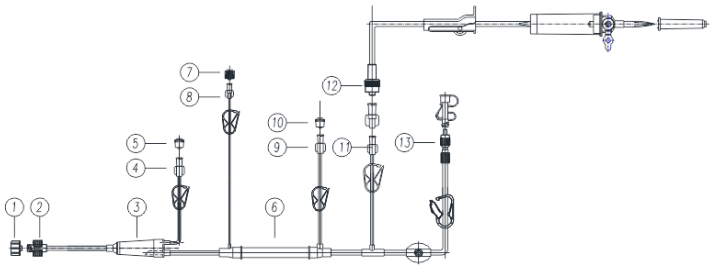
"BIOTEQ" Hemodialysis Blood Tubing Set is intended for use as an extracorporeal blood circuit to set up a one-way fluid pathway between patient and dialyzer.

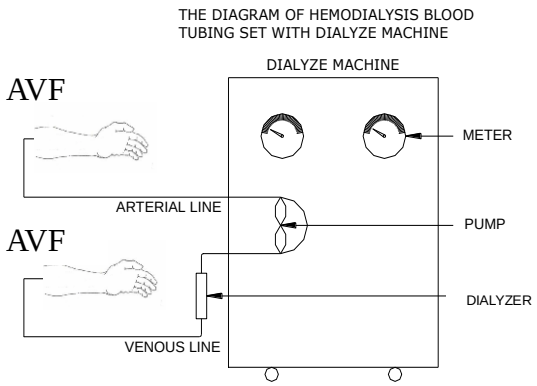
B. Intended Population:

- Intended Users:
  "Bioteq" Hemodialysis Blood Tubing Set shall be manipulated by a trained registered professional Nephrology physician and nurse.
- Intended Patient:
  "Bioteq" Hemodialysis Blood Tubing Set is indicated for patients that have the indications related to Renal Failure, Acid-base problems, Electrolyte problems, Intoxications, and Overload fluid. Uncooperative or hemodynamically unstable patients are contraindications of hemodialysis. This device is used for adult patients only. Pregnant patients should be evaluated the benefit-risk by Nephrology physicians before using.

(2) INSTRUCTION MENU:

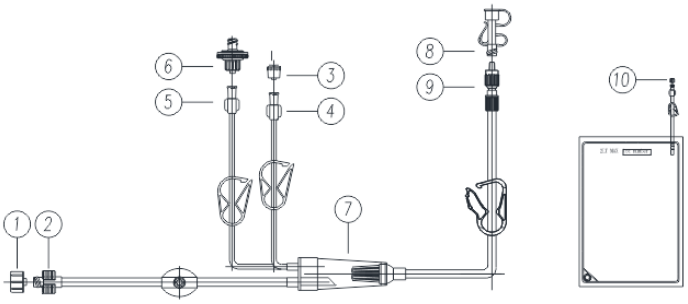
Arterial line:〔BT-102 Series〕





A. Removes cap ① and connect ② to dialyzer's arterial site.
B. Set pump line ⑥ to blood pump site.
C. Set the drip chamber ③ to the drip chamber holder.
D. Removes cap⑤ if the air in tube need to remove.
E. Removes cap ⑦ and connect female lure lock ⑧ to syringe which filled with heparin.
F. Removes cap ⑩ and connect Transducer protector (if have,) to Machine.
G. Removes cap⑪ and connect IV set ⑫ to normal saline
H. Connect recirculation connector ⑬and venous line when priming process.
I. Remove recirculation connector⑬ connect to A.V fistula needle arterial site, which the blood will be extracted.

Venous line:〔BT-102 Series〕



A. Removes cap ① and connect ② to dialyzer's venous site.
B. Set the drip chamber ⑦ to drip chamber holder.
C. Removes cap ③ if the air in tube need to remove.
D. Removes cap ⑤ and connect Transducer protector ⑥ to Machine.
E. Remove recirculation connector ⑧ and connect patient connector ⑨ to A.V fistula needle venous site, which the blood returns to patient.
F. Removes cap ⑩ and connect lure lock ⑨ into Collection Bag when collecting waste solution. Not need to measure.

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INSTRUCTIONS

(3) PRECAUTION:

1. Avoid collision when handling or storing this product, and do not store at extreme temperature, humidity and sunlight, store between $+15^0$c and $+25^0$c.
2. Unpack and operate under aseptic conditions.
3. Connections should be checked before priming procedure.
4. This product should be connected to dialyzer or dialysis machine. Do not use if the product is not using in the dialysis process.
5. Collection of discard products should be performed according to the medical infection waste programs.
6. This product does not contain DEHP,BBP,DBP,DNOP, DINP, and DIDP plasticizer.
7. Red color connector adapt artery tubing. Blue color connector adapt venous tubing.
8. **Complications:** Hypotension, Cramps, Nausea Vomiting, and Headache

(4) WARNING: ⚠

1. Do not use If the package is damaged and the protected caps aren't in place.
2. Leakage at joints, connections or any point on the extra-corporeal circuit may cause blood loss or air embolism. Observe carefully for leakage before and during treatment and take corrective measures as necessary.
3. U.S. Federal Law restricts the sale of the device to use under physician's prescription only.
4. Hemodialysis Blood Tubing Set is intended for single use. The reprocessing and reuse of single-use products pose the risk of bacterial growth, and contamination. Faulty clean, re-sterilization and tests may allow the transmission of infectious disease between patients; may alter device's mechanical properties and thus risk product failure. It is the end user's responsibility to read and understand the important warnings and to ensure the single use of medical devices. Do not reuse. Hemodialysis Blood Tubing Set is single patient use only and MUST be replaced for each patient.
5. Avoid kinking or occluding of tubing during treatment. Excessive pressure may damage the extra-corporeal circuit or blood access site, or may cause disconnects and /or blood loss.
6. Air entering the extra-corporeal blood circuit may cause air embolism. Use if air detector is recommended, in any case, continually observe the bubble trap under adequate blood level (at least filled 2/3).
7. To avoid using the serrated metal hemostats that could cut or break heparin lines of these blood tubing sets.
8. The maximum working pressure cannot exceed 0.66kgf/cm2 (500mmHg).

(5) MANUFACTURER:

BIOTEQUE CORPORATION
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STERILE EO

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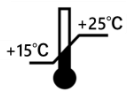
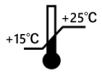
FOR SINGLE USE



	Caution
	Catalogue number
	Batch code
	Date of manufacture
	Use-by date
	Manufacturer
	Do not re-use
	Authorized representative in the European community
	Sterilized using ethylene oxide
	Consult instructions for use
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Temperature limit
	CE mark
	Fragile,handle with care
	Do not resterilize