INSTRUCTIONS FOR USE

CAUTION:

- Products should be stored at room temperature
- Single-use only; Do not reuse or alter this set
- Do not resterile
- If blood should leak in any part of the Blood line set during operating, replace entire set immediately

HEMODIALYSIS BLOOD TUBING SET WITH 3 MODELS: V06203/BLT; V06203-BLS; DiaStream®BL

INDICATIONS FOR USE

- Hemodialysis Blood Tubing Set is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer. The suitability of a particular bloodline/hemodialyzer configuration is the responsibility of the physician.
- Hemodialysis Blood Tubing Set is intended for transfer blood from patient to the hemodialyzer via the arterial blood tubing and from the hemodialyzer back to the patient via the venous blood tubing.
- Hemodialysis Blood Tubing Set is intended for use on adults only
- Hemodialysis Blood Tubing Set is intended to be used with hemodialysis machines listed in the last page

CONTRAINDICATIONS

- None Known

WARNINGS

- Product sterilized by ethylene oxide gas (EtO). STERILE | EO
- Store in cool dry place. Protect from moisture, freezing, and excessive heat.
- Read, understand and follow all warnings, precautions and instructions contained in this document before attempting treatment. Failure to do so may result in patient injury or death.
- Remove all paper tape as necessary before use.
- Do not use the device if package is damaged
- Do not use the device if the protective end caps are not in place
- Do not use Hemodialysis Blood Tubing Set if damaged or if parts are missingas the blood pathway is no longer sterile and non-pyrogenic.
- Always use aseptic technique when making or breaking any fluid path connection.
- Do not expose Hemodialysis Blood Tubing Set connections to a lubricant. Exposure could cause connections to separate resulting in patient injury or death.
- Ensure all connections are secure before use and monitor for leaks regularly during patient use. Blood leaks can result if connections are not secure.
- Lack of detection may allow air to enter Hemodialysis Hemodialysis Blood Tubing Set resulting in patient injury or death.
- Do not infuse recirculated saline into patient. Discard recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to patient.
- Do not perform Air rinse-back at termination of dialysis..
- Do not exceed 600 mL/min blood flow rate.
- Do not exceed arterial or venous pressures of -300 mmHg or +500
- Hemolysis may occur at elevated negative or positive pressures. Excessive negative pressure may cause partial collapse of the pump segment resulting in an actual blood flow substantially less than indicated on the hemodialysis machine.
- Arterial pressures must always be monitored. Check bloodline and patient access when excessive arterial pressures are noted. Deficiencies in access flow or improper position of the fistula needles, bloodline, or catheter may cause reduced blood flow that can result in increased negative pressures.
- Potential consequences of not detecting inadequate pressure include hemolysis and vascular access complications.
- Clotting may result from inadequate heparinization, inappropriate fluid removal and stagnant blood flows.
- **Ensure there are no kinks in the bloodline tubing during set-up and patient use. Significant hemolysis of red blood cells can occur in kinked blood tubing, especially in the post pump arterial tubing segment.**
- All Hemodialysis Blood Tubing Set clamps must be used either completely open or completely closed. These clamps are not intended to regulate the flow of fluids.
- Use of catheters, AVF needle sets or other devices not compatible with this set may result in blood/air leakage or accidental disconnection, air embolus, significant blood loss, patient injury or death. Multiple patient treatments with temporary or permanent catheters may deform such catheter's luer connectors from compliance with ISO 80369-7 at the time of treatment, which would make them incompatible with this set. Use of incompatible connectors with this set may result in blood loss, patient injury or death.
- Adhere to the facility's procedure for securing the blood tubing/access device connections to the patient. Taping should be secure despite potential changes in the patient's position or stress on the set tubing or blood access device.
- Do not use this Hemodialysis Blood Tubing Set for therapies longer than 10 hours.
- If patient shows any sign of hypersensitivity reaction, immediately discontinue treatment and initiate appropriate medical intervention. A history of allergies is an indication for careful monitoring of hypersensitivity reactions.
- This set must be used only by qualified medical personnel fully trained in its use, qualified under state and federal regulations and under the direct supervision of a licensed physician.
- Do not open shipping carton with any sharp instrument. Sharp instruments may cut set within carton, causing blood/air leakage which may result in patient injury or death.
- Do not over-tighten arterial and venous Transducer Protectors (TP) to machine. Twist connectors into the threaded machine monitor until secure and finger tight. Over-tightening may cause the connector to crack, resulting in inaccurate pressure readings an.

FEATURES

- Compatible with listed hemodialysis machines at final page.
- Priming volume: arterial: min 96 mL, max 117mL; venous: min 70mL, max 82mL
- Bloodline path tubing (arterial and venous): **4.6mm I.D., 6.8 mm O.D.**
- Bloodline pump segments**: 6.6mm, 8.0 mm I.D.**
- Bloodline provided with color coded components: **Red** on the arterial side and **Blue** on the venous side.
- Attached priming set with or without Y-injection site.
- Arterial and Venous with or without Injection Sites
- Arterial and Venous with or without Transducer Protectors (TP)
- Heparin Line (if applicable)
- Arterial with or without pillow

The bloodline is part of the extracorporeal circuit by which blood is transported from the patient through a hemodialyzer (for cleansing), and back to the patient. The pump segment in the bloodline interfaces to the blood pump rotor mechanism on the hemodialysis machine that drives the flow of blood through the circuit. The bloodline contains interfaces to the hemodialysis machine safety mechanism to ensure proper operation. These include monitor lines for the monitoring of the arterial and venous pressures, as well as a venous chamber for the detection of air in the blood path.

PRECAUTIONS

Dialysis Treatment Precautions:

1. Before initiation verify:
   a. The air detector clamp is engaged.
   b. The venous drip chamber is positioned and secured correctly in the venous level detector.
   c. The absence of any air bubbles in the extracorporeal circuit.
   d. Monitor lines and Hemodialysis Blood Tubing Set clamps are open.
   e. All connections are secure. For proper connection between fistula needle/catheter and bloodline:
      1. Firmly insert the male luer of the bloodline into the female luer of the fistula needle. See figure 1a

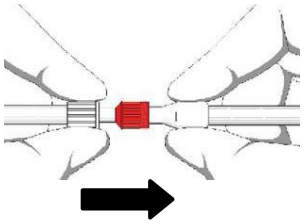

Figure 1a: Fistula Needle Connection: Insertion Technique.

2. Twist the colored collar of the bloodline in the direction shown while holding the female luer of the fistula needle or catheter to secure the connection. See figure 1b.

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2. During Treatment:

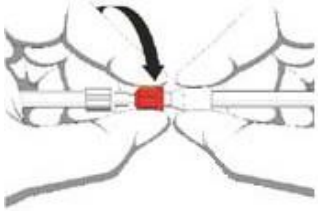


Figure 1b: Fistula Needle Connection: Securing Technique.

   a. Periodically check the extracorporeal circuit for any evidence of possible separation or leaks.
   b. Do not allow the access or bloodline connections to be covered witha blanket or clothing during the treatment.
   c. Maintain fluid level in arterial chamber at approximately 90% full and venous chamber at approximately 70% full. Levels may rise or dropduring the treatment due to changes in pressure or flow rate. Readjust levels as needed. Air leaks will also cause the chamber levels to fluctuate.
   d. Monitor arterial and venous pressures. Pressure readings which are clinically inappropriate for treatment (i.e.: 0 mmHg) must be addressed immediately and may indicate a clamped, loose, kinked or disconnected monitor line or wet Transducer Protector (TP). If blood samples are required, they can be drawn from the Arterial and Venous Injection Sites or needleless site..
   e. Periodically monitor rate of heparin delivery to ensure proper dosage.
3. During Completion of the Treatment:
   a. Maintain a proper fluid level in chambers to ensure that no air is returned to the patient.
   b. To complete termination procedure, refer to machine, dialyzer and manufacturer instructions, physician prescription, and/or facility protocol.

NOTE: Air rinse-back at termination of dialysis is not recommended

4. Actual blood flow rate may differ from the blood flow rate indicated by the machine and may change with time.
5. Properly dispose of the extracorporeal circuit after termination of dialysis.

DIRECTIONS FOR USE

WARNING: Review all warnings and precautions in this document before performing directions listed below.

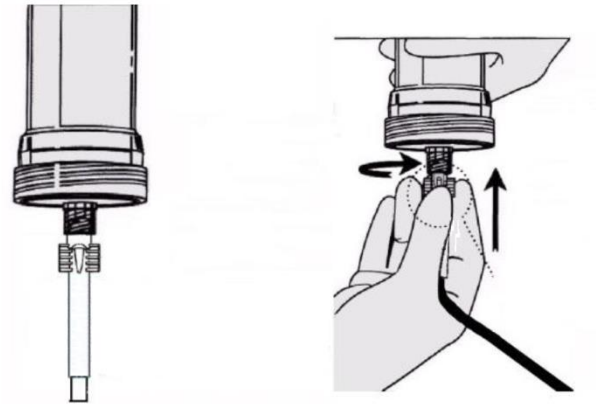
Setup Bloodline:

Dialyzer:

1. Push the dialyzer into holder arterial end down, with the clamp in the middle of the dialyzer. Position dialysate ports to the right, facing outwards away from the machine.

Arterial Line:

1. Close the arterial chamber site clamp.
2. Close heparin line clamp.
3. Place the arterial drip chamber into the holder.
4. Insert blood pump segment into blood pump. Close door.
5. Connect the dialyzer end of the arterial line to the bottom/arterial port of the dialyzer. Ensure connection to the port is finger tight. See Figures 2a and 2b.
6. Connect monitor line to arterial pressure port with a transducer protectorand verify the line is unclamped. Aseptically place the patient end of thearterial line into priming bucket clip.



Figures 2a and 2b

Venous Line:

1. Close the venous chamber access site big clamp.
2. Roll the venous drip chamber into the venous level detector with filter below sensor heads. See Figure 3. Close and latch door.
3. Connect the venous line dialyzer connector to the top/venous port of the dialyzer. Ensure connection to the port is finger tight.
4. Connect monitor line to venous pressure port with a transducer protector and verify the line is unclamped.
5. Aseptically place patient end of the venous line into priming bucket clip.

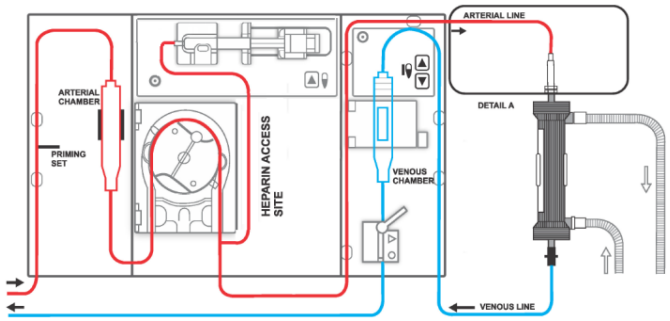


Figure 3: Bloodline/Machine Interface of Hemodialysis Machine

6. Perform Prime Extracorporeal Circuit, Recicuration and start dialysis according to standard procedure.
7. After completing 1 dialysis treatment, dispose of the product and adhere to nation instruction's policy for safe disposal of all medical waste

GENERAL INFORMATION

1. Generic names of materials that directly or indirectly contact the fluid path are available to the user upon request.
2. This product is not made with free-latex, Non-Phthalate
3. This product is sterilized by ethylene oxide gas (EtO)

***List of compatible hemodialysis machines:**

- Toray Yuga, Toray TR-321/TR-FX
- Kawasumi PHX 2100
- Fresenius 4008 Series, Fresenius 4008S/E, Fresenius 2008S/4008B/5008S
- Gambro AK95/96, Gambro AK-95/AK-200, Gambro AK Series/Phoenix,
- Nikkiso DBB05/DBB26/DBB27
- Nefron 2028,
- Baxter Tina Models1000/1550/550,
- JMS
- Nipro Surdial/Surdial-53/Diamax
- BBraun Dialog/Dialog Plus
- ACH-10
- IQ21