INSTRUCTIONS FOR USE

BLOOD LINES WITH 3 MODELS:
V06203/BLT; V06203-BLS; DiaStream®BL)

CAUTION:

- Products should be stored at room temperature
- Single-use only; Do not reuse or alter this set, if reuse it will be cross-infection
- Do not re-sterile
- If blood should leak in any part of the Blood lines set during operating, replace entire set immediately
- 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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer or Authorized Representative and competent authority of the Member State in which the serious accident is established

  * Note:
- Review all warning and precaution in IFU on website: www.perfectmedical.com.tw

INDICATIONS FOR USE

- Blood lines 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.
- Blood lines 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.
- Blood lines is intended for use on adults only
- The bloodline is intended for acute and chronic hemodialysis therapy.
- Blood lines 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

- Remove all paper tape as necessary before use.
- Do not use Blood lines if damaged or if parts are missing as the blood pathway is no longer sterile and non-pyrogenic.
- Do not expose Blood lines connections to a lubricant. Exposure could cause connections to separate resulting in patient injury or death.
- Lack of detection may allow air to enter Blood lines resulting in patient injury or death.
- Do not exceed 600 mL/min blood flow rate.
- Do not exceed arterial or venous pressures of -300 mmHg or +500 mmHg, respectively.
- 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.
- 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.
- 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.
- Actual blood flow rate may differ from the blood flow rate indicated by the machine and may change with time but not exceed 10%
- Do not use this bloodline for therapies longer than 10 hours.
- Do not use the device if packaging is damaged or information of product not correct.
- Do not use the device if the protective caps are not inplace.

- Ensure all connections are secure before use and ensure no tubing kinks, stretched or twisted during setup and patient use. significant hemolysis of red blood cells can occur in kinked blood tubing especially in the post pump arterial tubing segment. Blood leak can result if connections are not secure.
- During recirculation intermittently pinch and release the bloodline between the blood pump segment and dialyzer to help purge air.
- Do not infuse recirculated saline into the patient.
- Do not allow the access or bloodline connection to be covered with a blanket or clothing during the treatment.
- Air leak will also cause the chamber levels to fluctuate.
- Pressure reading which are clinically inappropriate for treatment (ie: 0mmHg) must be addressed immediately and may indicate a clamped, loose, kinked or disconnect monitor line or wet transducer protector.
- Maintain a proper fluid level in chamber to ensure that no airf is returned to the patient.
- Discard the Bloodline in an appropriate biohazard waste receptacle.
- Always use aseptic technique when making or breaking any fluid path connection.
- Do not perform Air rinse-back at termination of dialysis..
- 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.
- All Blood lines clamps must be used either completely open or completely closed. These clamps are not intended to regulate the flow of fluids.
- 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.
- 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.
- 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 Injection Sites or needleless site
- Arterial and Venous with or without Transducer Protectors (TP) or 0.2 micron hydrophobic filter
- Heparin Line
- 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.

Ancillary equipment required but not provided are the following:
- Arterial/Venous (AV) Fistulas Needles (not required for catheter patients)
- Sterile Normal Saline
- Hemodialyzer

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 Blood lines 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

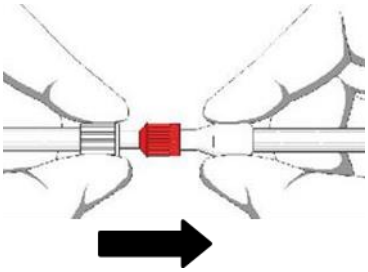


Figure 1a: Fistula Needle Connection: Insertion Technique.

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.

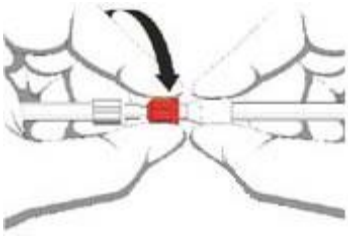


Figure 1b: Fistula Needle Connection: Securing Technique.

2. During Treatment:

a. Periodically check the extracorporeal circuit for any evidence of possible separation or leaks.

b. Maintain fluid level in arterial chamber at approximately 90% full and venous chamber at approximately 70% full. Levels may rise or drop during the treatment due to changes in pressure or flow rate. Readjust levels as needed. Air leaks will also cause the chamber levels to fluctuate.

c. 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..

3. During Completion of the Treatment:

a. To complete termination procedure, refer to machine, dialyzer and manufacturer instructions, physician prescription, and/or facility protocol.

b. Use a 21 gauge or smaller conventional metal needle to access the Injection site or Injection site Y type for administration purpose.

c. Use a standard male luer syringe connect to needleless access site to administration medication. Insert male luer syringe straight into the injection site and twist using a clockwise motion; twist counter clockwise to disbanded

d. To disinfect injection site, use 70% alcohol or 10% povidone iodine solution

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 but note exceed 10%. The machine blood pump setting displayed may not represent actual blood flow. Actual blood flow is affected by arterial and venous pressures, hematocrit, AV fistula needle size and other factors.

DIRECTION FOR USE

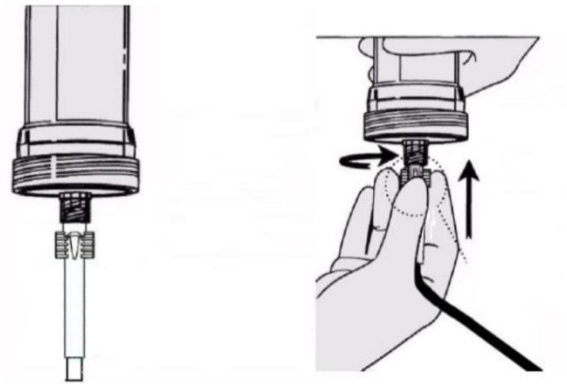
+ Prepared before use:
- Check package and confirm information of product before use;
- Open pouch, check status of the protective caps, remove all paper tape as necessary before use;

+ Setup device:
- Connecting bloodline with Hemodialysis machine and Hemodialyzer filter.

SETUP PRECAUTION:

Arterial Line:

- Close the arterial chamber site clamp.
- Close heparin line clamp.
- Place the arterial drip chamber into the holder.
- Insert blood pump segment into blood pump. Close door.
- 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.



Figures 2a and 2b

- Connect monitor line to arterial pressure port with a transducer protector and verify the line is unclamped. Aseptically place the patient end of the arterial line into priming bucket clip.

Venous Line:

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

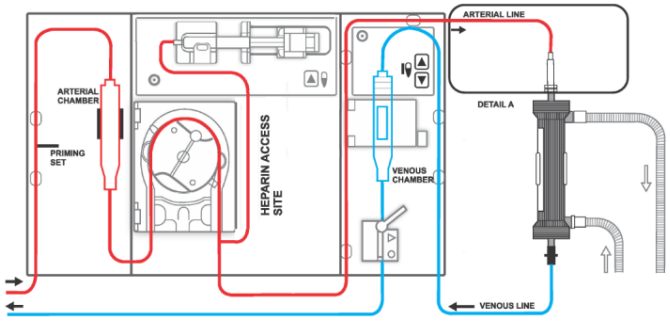


Figure 3: Bloodline/Machine Interface of Hemodialysis Machine

- Filling saline solution into bloodline, connect the arterial patient end connector to the recirculation connector of the venous patient end of the Blood line and perform exclude air bubbles.

+ Treatment process:
- Discard recirculated saline and fill the bloodline with fresh saline prior to connecting to patient.
- Connect the patient, set treatment parameter as prescribed, monitor line and bloodline clamps are open. Initiate treatment per unit protocol.
- Periodically check the Blood line for any evidence of possible separation or leak.
- Maintain fluid level in arterial chamber at approximately 90% full and venous chamber at approximately 70% full.
- Monitor arterial and venous pressures.
- Periodically monitor rate of heparin delivery to ensure proper dosage.

+ Completion of treatment:
- Return the blood in the patient end of the bloodline back to the patient, aseptically disconnect the patient's arterial and venous access.
- Discard the bloodline according to unit policy

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

NOTICE

Any the incident that directly or indirectly led, might have led or might lead to any of "the death of a paitent, user or other person; the pemporary or permanent serious deterioration of a patient's, user's or other person's state of health; a serious public health threat" should be reported to the manufacturer and the competent authority in which incident occurred.