Hemoset™ BLOOD LINES

INSTRUCTION FOR USE

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Set up the dialyzer and blood lines as per instructions provided with the dialyzer and blood lines.

1. Remove blood lines from primary packing and connect arterial (red) and venous (blue) lines to the blood pump, monitoring equipment, dialysis machine and dialyzer. Ensure that pump segment is not kinked or twisted.
2. Connect the monitoring lines to the pressure monitors utilizing transducer protectors or insert the arterial pillow into the arterial pressure monitor.
3. Make sure that all the connection are secure before proceeding.
4. Insert the bubble trap or line into the air detector.
5. Prime the system according to the dialyzer manufacturer's direction sheet.
6. Adjust drip chamber levels to 3/4 or guide line of the chamber using a sterile syringe connected to the level adjustment line.
7. Check blood lines carefully making sure that all the connection are secure and there is no leaks in the blood lines.
8. Initiate dialysis in accordance with dialyzer, equipment and delivery system manufacturer's instructions.

Note:

1. Connectors (Blue & Red) to dialyzer is designed by requirement of Harmonised Standard. See IFU of dialyzer & confirm blood parts.
2. Connectors to vascular access devices and ancillary components (including Transducer Protector) are designed by 6% Luer taper lock fitting.
3. Informations for pump segment & Hemodialysis machine is described on the individual package.

II. WARNINGS & CAUTIONS

1. This blood lines is for a single use only. Do not reuse. Reuse reprocessing of a single use device may lead to contamination and compromised device function and device integrity.
2. Do not use if the package is damaged.
3. Do not exceed arterial or venous pressures of -300 mmHg or +500mmHg, respectively.
4. Maximum operating pressure for the transducer protector is +500mmHg.
5. Do not use the blood lines for blood flow rates that exceeds 500ml/min.
6. Use only with dialyzer, dialysis machine, catheters or AVF needles, and other devices which have locking connectors compliant with ISO 80369-7 and ISO 8637-2 when connected with this set.
7. If the machine or machines for which the extra-corporeal blood lines is intended is not indicated on the individual package perform the fitting test prior to use.
8. Aseptic technique is required throughout set up and use.
9. Inspection prior to use and constant monitoring during the dialysis procedure is required in order to insure the product is in proper conditions for use.
10. Watch carefully for leaks during priming and use. The use of air bubble detector is required.
11. Continuously monitor for air in the set during treatment.
12. Air entering the extra-corporeal blood circuit may cause fatal embolism. Use of an air detector is recommended, in any cases, continually observe the bubble trap for adequate blood level (at least filled to 3/4 or guideline of the drip chamber).
13. Leakage at joints, connections or any point on the extra-corporeal circuit may cause blood loss or air embolism. Observe carefully for leaks before & during treatment and take corrective measures as necessary.
14. Avoid kinking or occlusion of tubing during treatment. Excessive pressure may damage the extra-corporeal circuit or blood access site, or may cause disconnection and/ or blood loss.
15. Fluid in the monitoring line should be avoided.
16. Keep the infusion line clamped except when administering fluid.
17. Serrated metal hemostats can cut or break heparin lines & should not be used with these blood lines.
18. The actual blood flow rate might differ from the blood flow rate indicted by the machine and the differences might change with time.
19. Keep level adjustment lines clamped except when adjusting the drip chamber level.
20. There may be slight variations in the vascular access devices and connectors provided by different manufacturers. Check to make certain that vascular access utilized is sealed and taped securely. Failure of connectors to fit tightly can results in serious blood loss or air embolism.
21. If the external transducer protector becomes wetted by saline or if blood shall be included, replace it immediately and inspect it. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine and check for contamination after the treatment is completed.
22. Do not use any needle larger than 20 gauge to puncture blood sample injection site.
23. Make sure that all connections are firm & secure.
24. Immediately prior to puncture, thoroughly disinfect the puncture site (rubber, injection site).
25. Pay special attention to crack of this set when using the disinfectant including alcohol.
26. Do not store at extreme temperature & humidity.
27. The set's priming volume is indicated on the individual package.
28. Do not use the device if protective end caps are not in place.

III. INDICATIONS

This blood lines is indicated for use during Hemodialysis to provide access to a patient's blood. When used in Hemodialysis, It is part of an artificial kidney system for treatment of patients with renal failure or toxaemic conditions. The compatibility of available configurations is the responsibility of the physician in charge.

IV. CONTRAINDICATIONS

As this blood lines is not, in itself, a medical treatment device, there is no absolute contraindications to its use. Use of this blood lines is contraindicated if it does not provide the features required in the instructions for use of the dialysis machine.

REF	Reference No.
LOT	Lot No./Batch No.
	Manufacturer
	Date Of Manufacturing
	Use By / Expiry Date
STERILE EO	Sterilised By Ethylene Oxide
	Do Not Reuse
	Do Not Resterilize
	Non-Pyrogenic
	Do Not Use If Package Is Damage
	Caution
	Consult Instructions For Use
EC REP	Authorised Representative In The European Community
10°C 45°C	Temperature Limit

DEHP FREE

LATEX **LATEX FREE**

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AW/IFU_1617, REV:00, DT 03-02-2022