

CRIT-LINE CLiC Disposable Blood Chamber Instructions For Use

FOR USE WITH PN: **CL10041021**

FOR USE WITH THE CRIT-LINE CLiC INSTRUMENT. STERILE DISPOSABLE. FOR SINGLE USE ONLY.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE ON OR BY THE ORDER OF A LICENSED PHYSICIAN.

DO NOT USE IF PACKAGE HAS BEEN COMPROMISED.

UNIT IS NON-PYROGENIC, STERILE IN UNOPENED, UNCOMPROMISED PACKAGE. USE IMMEDIATELY AFTER OPENING.

DO NOT EXCEED ARTERIAL OR VENOUS PRESSURES OF -300 mm Hg OR +500 mm Hg RESPECTIVELY.

DO NOT EXCEED 600 ml/min BLOOD FLOW RATE. INTERNAL BLOOD VOLUME IS 1.8ML, CHAMBER LENGTH: 3.33 INCHES.

DEVICE CONNECTIONS ARE COMPATIBLE WITH BLOOD LINES AND DIALYZERS THAT USE CONNECTIONS COMPLIANT WITH ISO 594.

GENERIC NAMES OF MATERIALS THAT DIRECTLY OR INDIRECTLY CONTACT BLOOD ARE AVAILABLE UPON REQUEST.

STERILIZATION METHOD: GAMMA RADIATION . STORAGE TEMP: 0°C TO 45°C. SHORT TERM SHIPPING TEMP: -25°C TO 60°C.

Indications for Use: The CRIT-LINE CLiC Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment.

INSTRUCTIONS FOR USE

A. Inserting the blood chamber into the dialysis tubing prior to priming

- During setup, before priming, attach the blood chamber in the dialysis blood circuit on the arterial end of the dialyzer as shown in FIGURE 1.
 - Remove the blood chamber from its sterile package.
 - Remove the red cap from the dialyzer attachment end of the blood chamber.
 - Attach the Dialyzer end of the blood chamber to the arterial fitting (top) of the dialyzer. (see FIGURE 2 & 3)
 - Push the dialyzer end of the blood chamber into the hard plastic end of the dialyzer.
 - Twist blood chamber by the soft plastic tabs to engage connector.

CAUTION: Do not twist blood chamber by lens or body (see FIGURE 3)
 - Remove the red winged plug and attach the arterial blood tubing end of the blood chamber to the twist lock of the arterial blood tubing set.
 - Push the twist lock connector into the arterial end of the blood chamber.
 - Twist the tubing set connector to engage tubing set connector.
- Complete remaining connections of the blood lines as instructed by the Dialysis Machine Manufacturer.
- Support blood line to create blood line loop above the blood chamber and prevent kinking (see DETAIL A of FIGURE 1).
- Prime the blood circuit as instructed by the Dialysis Machine Manufacturer.
- Carefully check for leaks in all components and at all connections before introducing blood into the dialysis circuit.

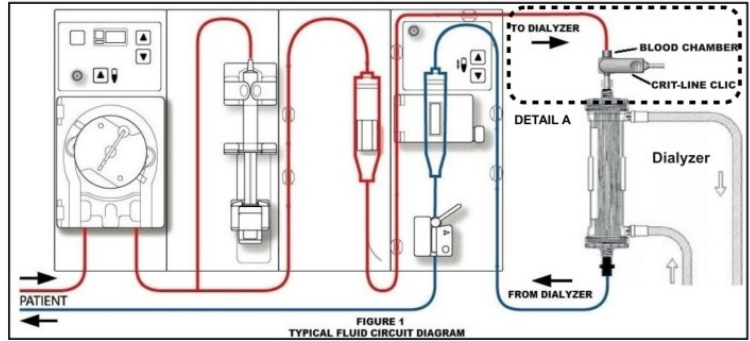


FIGURE 1
TYPICAL FLUID CIRCUIT DIAGRAM

B. Observing the blood chamber when the pump is initially turned ON and throughout the treatment

Important Notice: To ensure patient safety, periodically verify that both blood chamber connections (blood line and dialyzer) are secure and leak free throughout the prescribed treatment.

If a blood leak is observed, don appropriate PPE, turn off blood pump, carefully push down on leaking connection and tighten the connection (see FIGURE 2), turn on blood pump and check for leaks.

If the leak does not stop with tightening the connections, replace blood line and blood chamber.

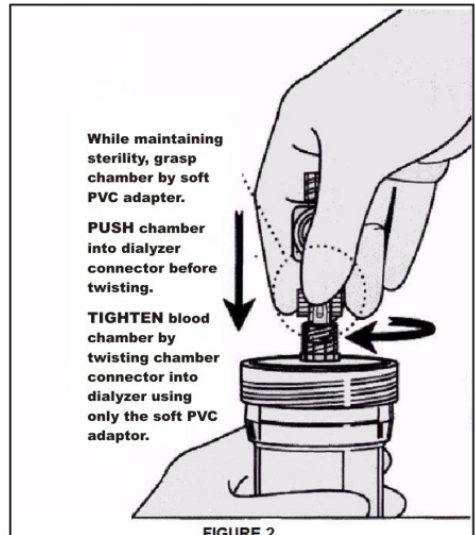


FIGURE 2

C. Connecting the sensor clip to the blood chamber

- Place the sensor clip of the CLiC Instrument on the blood chamber lens. Attach sensor clip such that it is opposite the blood line loop created in step A3. This will reduce blood line connection problems.
- Refer to the start-up instructions for the CLiC Instrument.

D. Disposing of the Crit-Line CLiC Blood Chamber

- Dispose of the blood chamber at the completion of the monitored session.

WARNING: DO NOT reuse the blood chamber.
- Used blood chambers must be properly disposed of in biological waste containers.

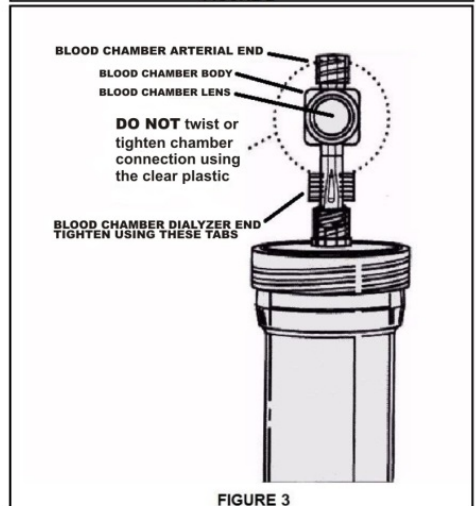


FIGURE 3



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