Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

SCD-PED INSTRUCTIONS FOR USE

Rx only

HUMANITARIAN DEVICE: Authorized by Federal law for use in the treatment of pediatric patients ≥ 10kg with acute kidney injury due to sepsis or a septic condition on antibiotic therapy and requiring renal replacement therapy. The effectiveness of this device for this use has not been demonstrated.

- **Read Instructions for Use. Failure to follow Instructions for Use may result in patient harm, injury, or serious adverse reactions.**
- **Additional equipment and supplies are required to use this device.**

PRODUCT DESCRIPTION

The SeaStar Medical Selective Cytopheretic Device for Pediatrics (SCD-PED) consists of a SCD-PED Cartridge and SCD Blood Tubing Set (collectively trade name QUELIMMUNE™) connected in-line to an existing hemodialysis delivery system's extracorporeal continuous kidney replacement therapy (CKRT) circuit with regional citrate infusion to maintain a circuit post-SCD ionized calcium level of less than 0.40 mmol/L.

The term 'SCD-PED' refers to both the SCD-PED Cartridge and SCD Blood Tubing Set.

Each SCD-PED Cartridge and SCD Blood Tubing Set are intended for continuous use for up to 24 hours. The SCD-PED Cartridge and SCD Blood Tubing Set are to be replaced:

- Every 24 hours of use throughout the duration of therapy;
- Any time the SCD-PED Cartridge inhibits CKRT circuit function per normal CKRT criteria;
- With every CKRT circuit change.

Figure 1: The SCD-PED Cartridge is a single use, hollow fiber synthetic membrane cartridge.

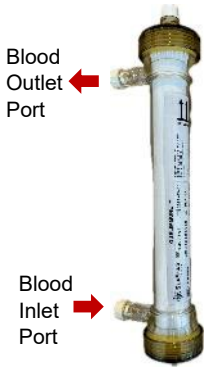
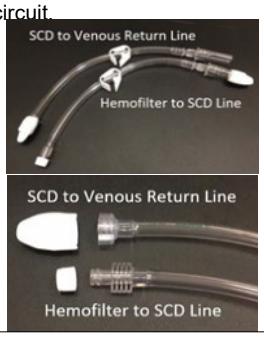


Figure 2: The SCD Blood Tubing Set is an ethylene oxide sterilized, single use tubing set designed to connect the SCD-PED Cartridge to the post-CKRT filter segment of the CKRT circuit.



INDICATIONS FOR USE

The SCD-PED is intended to treat pediatric patients (weight ≥ 10 kg and age ≤ 22 years) with acute kidney injury (AKI) due to sepsis or a septic condition on antibiotic therapy and requiring renal replacement therapy (RRT).

CONTRAINDICATIONS

Use of the SCD-PED as a standalone unit to provide any renal replacement therapy or fluid and electrolyte management therapy is contraindicated.

The SCD-PED cartridge and SCD Blood Tubing Set should not be used on patients who have a known allergy to any of the components in this product.

⚠WARNINGS

1. Carefully read all warnings, precautions, and instructions before use. Follow all operating, maintenance, and installation procedures as described in this document.
2. The blood flow path in the SCD-PED is non-sterile.
3. Operating procedures are to be performed only by trained and qualified clinicians/personnel.
4. The target post-SCD ionized calcium level during SCD-PED therapy is less than 0.40 mmol/L.
5. The CKRT device and disposables must be operated by trained personnel according to the instructions for use provided by the manufacturer.
6. The use of anything other than the SCD Blood Tubing Set provided by SeaStar Medical may result in patient injury.
7. Do not modify the SCD-PED Cartridge or the SCD Blood Tubing Set in any way.
8. Carefully inspect barriers of all items prior to use. Do not use item if barrier is damaged.
9. The SCD-PED Cartridge and SCD Blood Tubing Set are single use sets. Do not sterilize or reuse

the SCD-PED Cartridge. Do not re-sterilize or reuse the SCD Blood Tubing Set.

10. Log or note the lot number of the SCD-PED Cartridge(s) used on a patient in that patient's Electronic Medical Record (EMR) for tracking purposes.
11. During the prime and operation procedures, observe closely for blood/fluid leakage at all circuit connections. If tightening the connections does not stop leakage, immediately replace the SCD-PED Cartridge and the SCD Blood Tubing Set. Leakage can cause blood loss or air entry/air embolism.
12. To prevent contamination, the SCD-PED Cartridge and the SCD Blood Tubing Set must be connected and primed using aseptic technique immediately after opening the packaging and removing caps to make the connections. Use aseptic technique when handling all connections and replacing the SCD-PED Cartridge and the SCD Blood Tubing Set. Universal precautions should be followed to ensure the safety of the patient and clinician.
13. In the event that a patient decompensates (per the treating physician's clinical judgment) within 2 hours of a new SCD-PED Cartridge initiation, SCD-PED therapy should be terminated, and a blood sample should be obtained from the patient and cultured for aerobic, anaerobic, and fungal organisms.
14. Store the SCD-PED Cartridge in a dry place, between 5 °C (41 °F) and 30 °C (86 °F). The upper limit for the SCD Blood Tubing Set is 50 °C (122 °F), with no lower limit specified.

⚠ PRECAUTIONS

1. Used SCD-PED Cartridges and SCD Blood Tubing Sets are considered biohazardous materials. Handle and dispose in accordance with hospital policy/procedure and applicable local, state, and federal laws and regulations.
2. Carefully inspect the SCD-PED Cartridge and the SCD Blood Tubing Set prior to use. Do not use the SCD-PED Cartridge and/or the SCD Blood Tubing Set if the package is damaged or if the lines are kinked, or if there is any visual evidence of cracks, breakage, or contamination.
3. The CKRT circuit with SCD-PED Cartridge and SCD Blood Tubing Set connected must be anticoagulated with a continuous citrate infusion during SCD-PED therapy.
4. Prevent entry of air into the SCD-PED Cartridge or the SCD Blood Tubing Set during set up and priming.
5. Use of SCD-PED with dialysis modalities other than CKRT (i.e., intermittent hemodialysis or peritoneal dialysis) has not been studied.

ADVERSE REACTIONS

Five adverse reactions were observed in more than one instance across the two pediatric SCD studies (SCD-PED-01 [16 subjects enrolled] and SCD-PED-02 [6 subjects enrolled]). Those adverse reactions include six instances of hypotension across three subjects, four instances of hypothermia across two subjects, four instances of tachycardia across three subjects, two instances of hyperglycemia across two subjects, and two instances of thrombocytopenia across two subjects.

SPECIFICATIONS

Table 1: SCD- PED Cartridge Specifications

Applicable Membrane Surface Area	0.98 m^2
Applicable Priming Volume	115 mL
Applicable Max Blood Flow Rate	300 mL/min
Maximum TMP	600 mmHg

Table 2: SCD-PED Blood Tubing Set Specifications

Priming Volume	35 mL

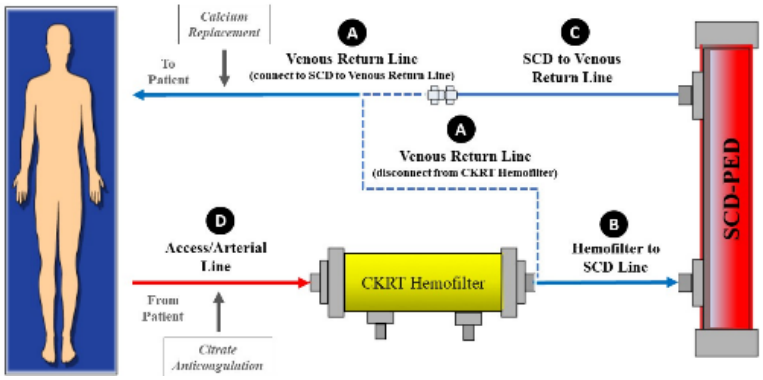


Figure 3: SCD-PED Therapy Set-up

PROCEDURES

A. GATHER SUPPLIES

Supplied with QUELIMMUNE:

1. SCD-PED Cartridge
2. SCD Blood Tubing Set (includes 2 Luer Adapters)
3. SeaStar Medical Humanitarian Device Label
4. SCD Securing Bracket/Holder
   - Prismaflex: SCD Securing Bracket with attached zip-ties and adhesive strips
   - PrisMax: dual clamp holder
5. Hemostats

Not supplied with QUELIMMUNE:

1. HF20/HF1000/HF1400 Hemofilter Tubing Set
2. (3) 1-liter bags of sterile 0.9% Normal Saline solution for infusion
3. Zero Calcium Bicarbonate Solution
4. Free flow gravity IV Tubing Set
5. Gambro Accessory 'Y' Connector S-660-C for calcium chloride infusion
6. Additional Gambro Accessory 'Y' Connector S-660-C for citrate infusion (if using a separate IV infusion pump)
7. Pressure Bag
8. 20 mL syringe
9. Sterile blue disposable towels
10. Sterile alcohol wipes
11. MX560 tubing adapter (only if prescribed blood flow will be < 100 ml/min)

B. SET UP & PRIMING THE SCD-PED

1. Attach the SCD Securing Bracket to the side of CKRT machine if using Prismaflex CKRT machine. Skip this step if using PrisMax CKRT machine.
   - The SCD Securing Bracket can be secured to the right side of the Prismaflex machine using the pre-attached adhesive strips (see Figure 4, Figure 5, and Figure 31 as an example), or it can be attached to an adjacent IV pole using the included releasable zip-ties. Follow the instructions closely to ensure a secure, safe attachment.
   - Important: To allow the adhesive strips to properly bond, attach the bracket to the CKRT machine and leave for one hour prior to use.

Figure 4: The SCD Securing Bracket uses releasable zip-ties. To release the zip-tie, simply push the small tab and open.

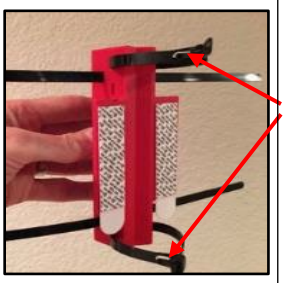


Figure 5: Attach bracket vertically to the right-facing side of the Prismaflex machine using the pre-attached adhesive strips.

If present, remove the two zip-ties that would have been used for IV pole mounting (they are not required when bracket is attached to the side of the machine).

Clean the side of the Prismaflex machine with an alcohol wipe in the area where the bracket will be attached and allow surface to dry. Remove the paper backing from the adhesive strips. Place the SCD Securing Bracket on the Prismaflex machine.

Press firmly on the adhesive strips for 30 seconds. Wait 1 hour before use to allow the adhesive to properly bond.

2. Remove the SCD-PED Cartridge from the packaging and place on a sterile blue towel. Keep in place all caps as provided (blood port caps and end caps). Visually inspect the SCD-PED Cartridge as described in the Precautions section of this document.

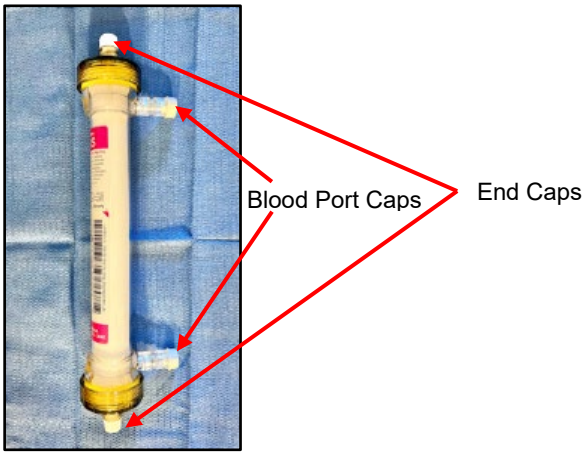
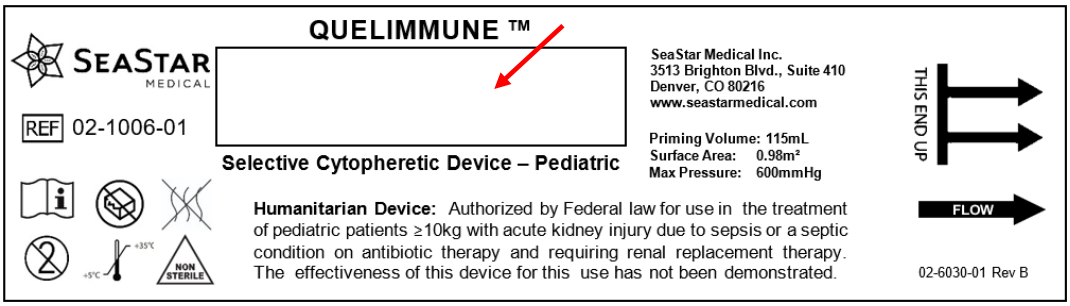


Figure 6: SCD-PED Cartridge on a sterile blue towel with caps labeled

3. Hold the SCD-PED Cartridge horizontally with the red border of the manufacturer's label positioned along the upper edge of the SCD-PED Cartridge (Figure 7).

Figure 7: SCD-PED Cartridge

4. Affix the SeaStar Medical Humanitarian Device Label (PN:02-6030-01) over the original manufacturer's label, so that the manufacturer's Reference Number, Lot Number, Manufacture Date, and Expiration Date appear through the opening of the new label as shown below (red arrow):



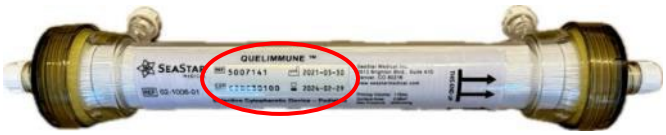


Figure 8: Label and SCD-PED Cartridge with Label Affixed

5. Remove the SCD Blood Tubing Set from the packaging and place on a sterile blue towel. Keep white end caps in place until lines are ready to connect to the SCD-PED Cartridge (Figure 9).

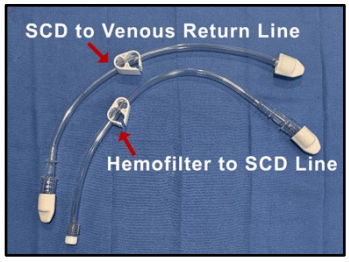


Figure 9:

Identify the SCD to Venous Return Line and the Hemofilter to SCD Line.

6. Hold the SCD-PED Cartridge vertically with the label arrows facing up. Remove the cap from the blood outlet port of the SCD-PED Cartridge located on the upper side of the SCD-PED Cartridge (Figure 10).
   - To facilitate ease of attachment, the SCD-PED Cartridge may be placed on a hard flat surface covered with a sterile towel.

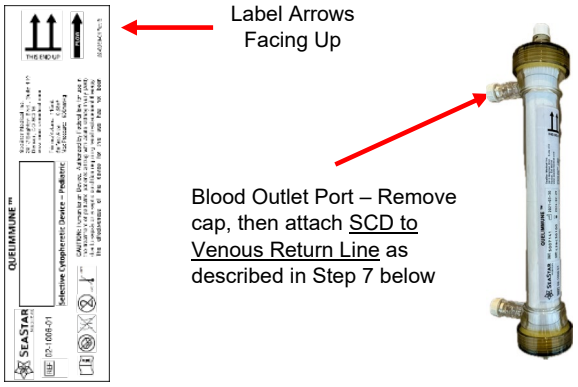


Figure 10: Humanitarian Device Label and SCD-PED Cartridge Orientation

7. Connect the SCD to Venous Return Line to the blood outlet port of the SCD-PED Cartridge by following the steps below:

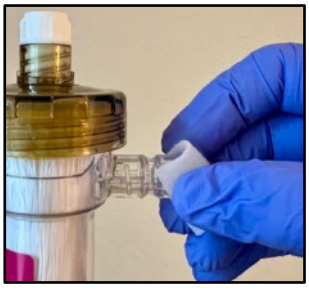


Figure 11: With the cap removed from blood outlet port of the SCD-PED Cartridge, swab the outside of the port with a sterile alcohol wipe to lubricate the plastic to ease attachment of the SCD to Venous Return Line to the SCD-PED Cartridge.

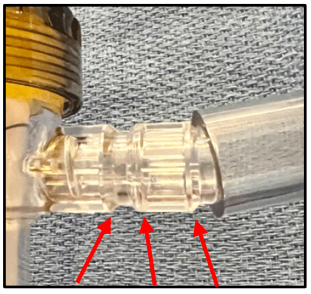


Figure 12: With a "back and forth" motion, firmly push the SCD to Venous Return Line slip-fit segment over the outside of the port, until the tubing passes ridges 1, 2, & 3.

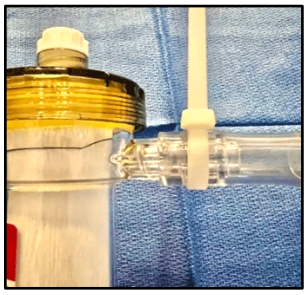


Figure 13: Using a zip-tie that is included in the SCD Blood Tubing Set packaging, tighten the zip-tie around the tubing between ridge 1 & 2.

8. Place the SCD-PED Cartridge with attached SCD to Venous Return Line back onto the sterile blue towel (Figure 14).

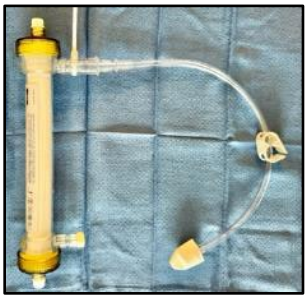


Figure 14

9. Hang and spike a one-liter bag of 0.9% Normal Saline solution with the free flow gravity IV Tubing set. For best results, use an IV pole for priming.
   - Slide the roller clamp to the bottom of the IV tubing closest to the needleless port.

10. Using aseptic technique, connect the spiked bag of Normal Saline and the IV tubing set to the Luer Adapter. Remove small white cap from the end of the Hemofilter to SCD Line, then connect to the Luer Adapter.

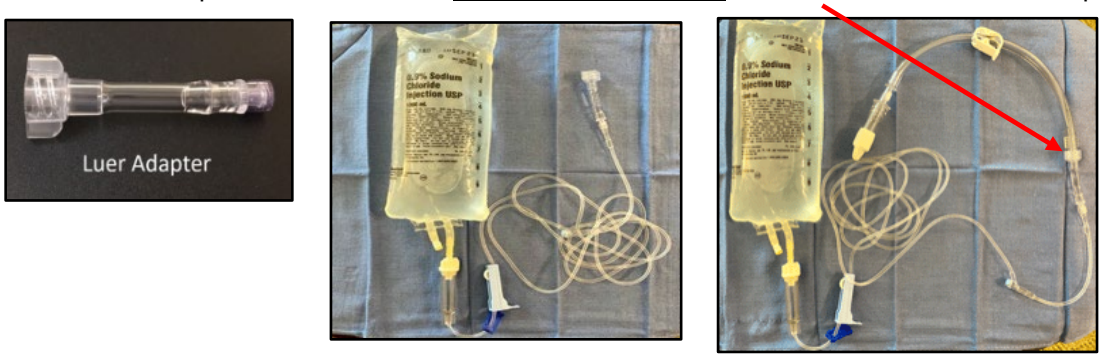


Figure 15 (A): Luer Adapter, (B): NS and IV Tubing, (C): NS and IV Tubing with Hemofilter to SCD Line attached

11. Slowly open the IV tubing clamp to gravity prime the three connected pieces (IV tubing set, Luer Adapter, and the Hemofilter to SCD Line) with Normal Saline, remembering to keep the white slip-on end cap in place during the prime.

12. Once the saline has filled all lines, clamp the IV tubing as well as the Hemofilter to SCD Line.

13. Remove cap from the blood inlet port of the SCD-PED Cartridge located on the lower side of the SCD-PED Cartridge.

14. Connect the slip-fit section of the Hemofilter to SCD Line to the blood inlet port of the SCD-PED Cartridge, including swabbing the outside of the port with a sterile alcohol wipe, pushing the tubing over the port until it passes ridges 1, 2, and 3, and attaching and tightening the zip-tie.

15. Place Normal Saline in Pressure Bag and inflate. See images on pressure bag for reference.

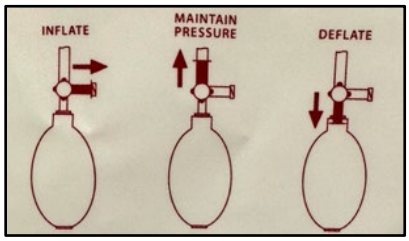


Figure 16: Example Pressure Bag Instructions

16. While holding the ends of the SCD Blood Tubing Set so the SCD-PED Cartridge is horizontal, with the blood inlet/outlet ports pointing up, unclamp the Hemofilter to SCD Line and slowly open the IV tubing set clamp to prime the SCD-PED Cartridge with Normal Saline.

Figure 17: Holding SCD-PED Cartridge Horizontal

17. As the SCD-PED Cartridge completes its prime, ensure that all air is removed from the cartridge. A small amount of air will typically travel back up the Hemofilter to SCD Line.

18. Clamp the IV tubing line but keep the white pinch clamps open on the SCD blood tubing lines.

19. Remove any remaining air using a 20 mL syringe attached to the free flow gravity IV tubing set, then aspirate.
    - Depending on the amount of air that was aspirated from the Hemofilter to SCD Line, you may need to open the priming line to refill the SCD to Venous Return Line.

20. Once the SCD-PED Cartridge and attached tubing lines are fully primed, slide the white pinch clamps of the SCD blood tubing lines close to the open connectors at the end of the tubing, then tightly clamp both SCD blood tubing lines and the IV prime line.

Figure 18: Hemofilter to SCD Line

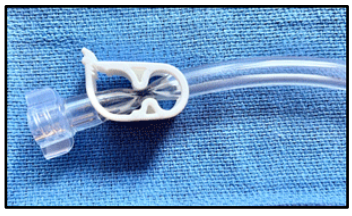


Figure 19: SCD to Venous Return Line

21. Disconnect the IV prime setup (saline bag, tubing, and Luer Adapter) from the Hemofilter to SCD Line.

22. Immediately connect both ends of the SCD blood tubing lines together to prevent air from entering the SCD-PED Cartridge (Figure 20).

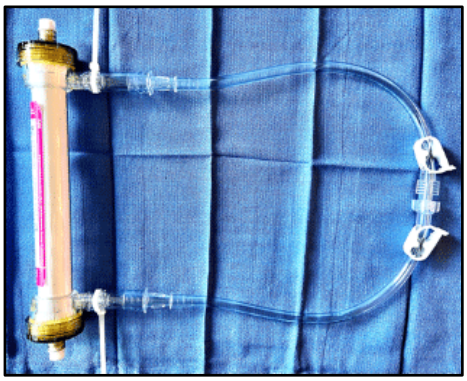


Figure 20:

A small amount of air may remain in the SCD-PED Cartridge and/or tubing set. The air will flow to the deaeration chamber.

23. The SCD-PED Cartridge and SCD Blood Tubing Set are now ready for connection to a fully primed CKRT circuit.

C. PRIMING THE CKRT CIRCUIT

1. Load the Prismaflex/PrisMax HF20/HF1000/HF1400 tubing set as directed by the manufacturer in the Prismaflex/PrisMax *Instructions for Use*.
   - As a reminder, the SCD-PED Cartridge and SCD Blood Tubing Set should be primed separately (see Section B above) prior to the priming of the Prismaflex/PrisMax HF20/HF1000/HF1400 tubing set.

2. Perform the automatic priming sequence as directed by the manufacturer in the Prismaflex/PrisMax *Instructions for Use*.
   - Prismaflex: Select the “Prime” option (not the “Prime + Test” option) as the testing step is done after the SCD-PED is integrated.

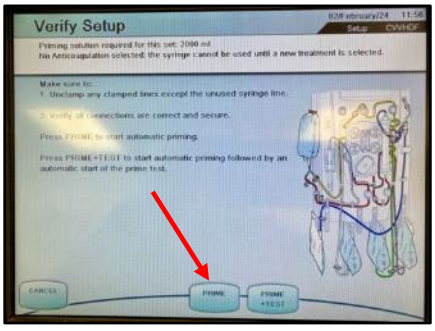


Figure 21: “Prime” Option

   - PrisMax: Select the “Prime” option.
   - Reminder: If using the Pre-Blood Pump (PBP) for citrate infusion, connect the PBP citrate infusion line to the CKRT circuit during this step.

3. Open the Gambro Accessory 'Y' Connector Packaging.
   - Skip steps 3-5 if infusing calcium chloride through a separate central line.
   - IMPORTANT: Please follow your hospital's standard operating procedure regarding where to infuse calcium chloride if the venous return line of the patient's vascular access catheter is not recommended.

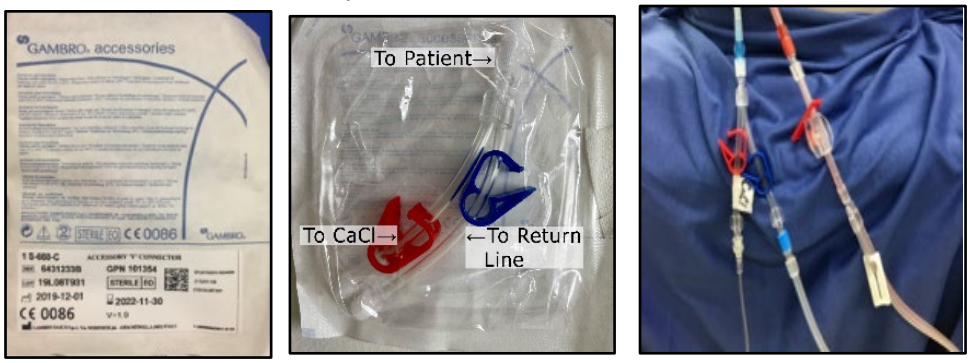


Figure 22 (A): 'Y' Connector package example, (B): 'Y' Connector labeled, (C): 'Y' Connector attached and primed

4. Prime the 'Y' Connector with a 10 mL Normal Saline flush before making any connections.
   - To maintain sterility of the CKRT circuit, leave Normal Saline flush attached to the 'Y' Connector on the side with the red pinch clamp (labeled CaCl in Figure 22 (B and C)).

5. To minimize confusion regarding the red and blue clamps that are already on the 'Y' Connector, it is recommended to label the tubing with the following:
   - 'CaCl'/calcium chloride on the 'Y' Connector tubing with the red clamp (see Figure 22 (B and C)).

6. If using a separate IV infusion pump (not the CKRT's PBP) for citrate infusion, repeat steps 2-4 and label the tubing with the following:
   - 'Citrate' on the 'Y' Connector tubing with the blue clamp.
   - To maintain sterility of the CKRT circuit, leave Normal Saline flush attached on the tubing side with the blue pinch clamp.

   NOTE: If the prescribed blood flow is less than 100 mL/min (typically ordered under the shock citrate protocol), to avoid low return pressures, please attach the MX560 tubing adapter to the venous return line which will then attach to the Gambro 'Y' Connector (see Figure 23 and Figure 24).

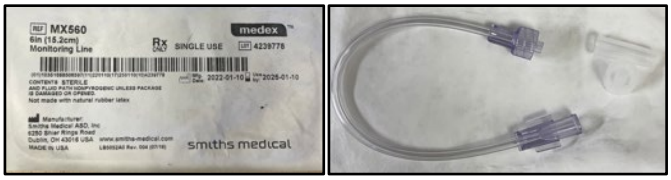


Figure 23: Example MX560 tubing adapter package (A) and adapter (B)

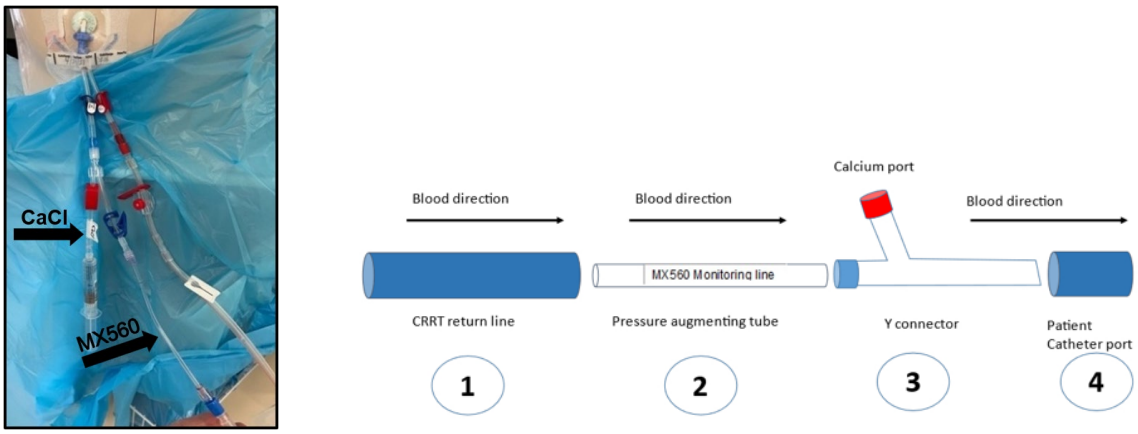


Figure 24: Connection location of MX560 (a) and diagram of connections (B)

D. FOR PRISMAFLEX ONLY: CONNECTING THE SCD-PED TO THE PRISMAFLEX CKRT CIRCUIT

1. Secure the SCD-PED Cartridge to the SCD Securing Bracket (previously attached to the side of the CKRT machine) using the provided releasable zip-ties (see Figure 25 and Figure 26).

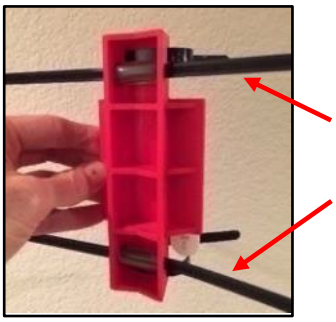


Figure 25: The pre-attached zip-ties are used for securing the SCD-PED Cartridge to the front of the bracket after the SCD Securing Bracket has been previously mounted to the side of the CKRT machine (refer to Section B, Step 1 for bracket mounting).

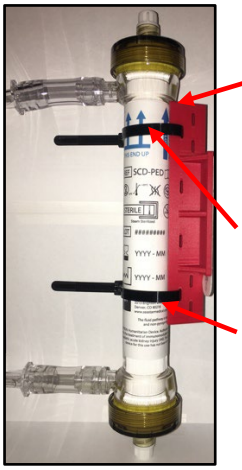


Figure 26: When properly positioned, the upper lip of the SCD-PED Cartridge will rest against the top edge of the SCD Securing Bracket.

Place the SCD-PED Cartridge (with arrows pointing up) against the SCD Securing Bracket and attach with two zip-ties as shown. Do not overly tighten. When properly tightened, there should be resistance against the housing of the SCD-PED Cartridge, but the SCD-PED Cartridge should be able to be rotated.

2. The SCD-PED Cartridge and SCD Blood Tubing Set will be connected to the CKRT circuit after the first bag of Normal Saline is complete during the automatic priming sequence at the following times:
   - For HF20/HF1000 tubing sets, at the *Priming 1 of 1 Cycles Complete* screen.
   - For HF1400 tubing sets, at the *Priming 1 of 2 Cycles Complete* screen.

3. When *Priming Cycle 1* is complete, use plastic hemostats to clamp the access/arterial line below the blood inlet port of the HF20/HF1000/HF1400 hemofilter, then clamp the venous return line above the blood outlet port of the HF20/HF1000/HF1400 hemofilter (see Figure 27).

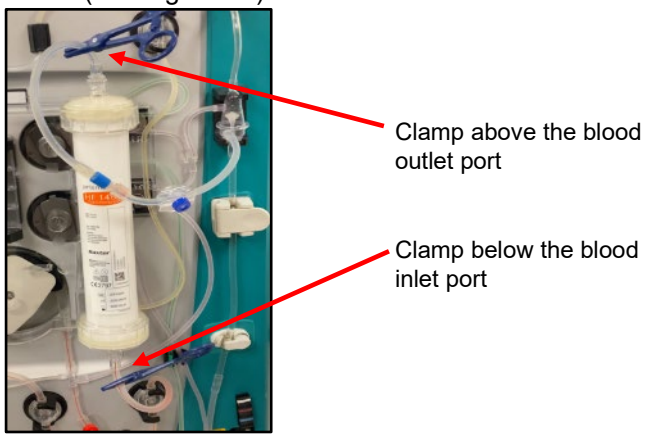


Figure 27

NOTE: If infusing CaCl through a separate central line, skip steps 4-6.

4. Disconnect the venous return line from the collection bag (see Figure 28).

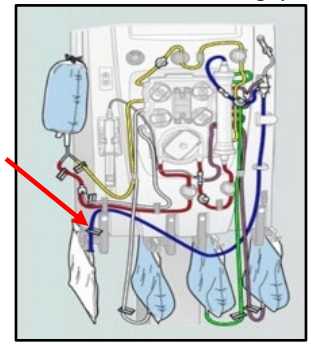


Figure 28: Disconnect venous return line from collection bag.

5. Connect primed calcium chloride/CaCl labeled 'Y' Connector to the venous return line where it was disconnected from the collection bag.

6. After connecting the primed 'Y' Connector to the venous return line, reconnect the 'Y' Connector to the collection bag.

7. Disconnect the CKRT venous return line from the HF20/HF1000/HF1400 hemofilter's blood outlet port (located on the top of the hemofilter – see Figure 29 [next page]).
   - It may be necessary to use a tool (plastic or metal hemostat) to unscrew the CKRT venous return line located on the top of the HF20/HF1000/HF1400 hemofilter's blood outlet port.
   - If a hemostat is used to unscrew the line, do not twist the port sideways or port breakage may occur.

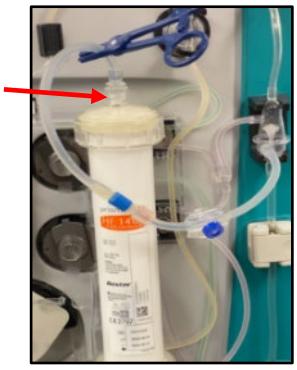


Figure 29: CKRT Venous Return Line example

8. Connect the Hemofilter to SCD Line (Figure 65, item B) to the HF20/HF1000/HF1400 hemofilter's blood outlet port (Figure 30, item A).

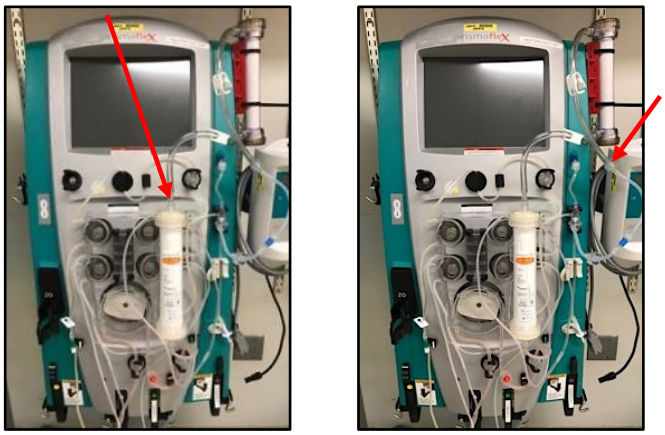


Figure 30 (A) blood outlet port and (B) CKRT venous return line

9. Connect the SCD to Venous Return Line (Figure 65 item C) to the CKRT venous return line that was disconnected from the HF20/HF1000/HF1400 hemofilter's blood outlet port (Figure 65, item A; also noted in Figure 30, item B).
    - CAUTION: Once secured, verify the SCD-PED Cartridge is positioned so that when connected, the blood exiting the HF20/HF1000/HF1400 hemofilter is going into the blood inlet port of the SCD-PED Cartridge (lower side of SCD-PED Cartridge) and flowing up against gravity through the SCD-PED Cartridge (see Figure 31).

Figure 31: Red arrows showing direction of blood flow exiting from the top of the HF20/HF1000/HF1400 hemofilter and going into the blood inlet port located at the lower side of the SCD-PED Cartridge.

10. Disconnect the plastic hemostats from above and below the HF20/HF1000/HF1400 hemofilter and unclamp the white pinch clamps on the SCD Blood Tubing Set.

11. As a reminder, refer to step 2 of this section for continuing the priming process after connecting the pre-primed SCD-PED Cartridge and SCD Blood Tubing Set.
    - For HF20/HF1000 tubing sets, at the *Priming 1 of 1 Cycles Complete* screen, hang additional one-liter Normal Saline bag and repeat the priming sequence by pressing REPRIME.
    - For the HF1400 tubing sets, at the *Priming 1 of 2 Cycles Complete* screen, hang additional one-liter Normal Saline bag and press CONTINUE.

12. Once the Priming Cycles are complete, check the fluid level in the deaeration chamber prior to starting the Prime Test and adjust accordingly (see Figure 32).

Figure 32: Deaeration Chamber

13. Press the PRIME TEST button on the screen to initiate the prime test.

14. Due to the amount of air being purged, the Prismaflex occlusivity test sequence may fail one or two times before succeeding; press RETEST when the “Malfunction: Prime Self-Test” (code 20) screen is displayed to repeat the test and pass the prime tests (see Figure 33).

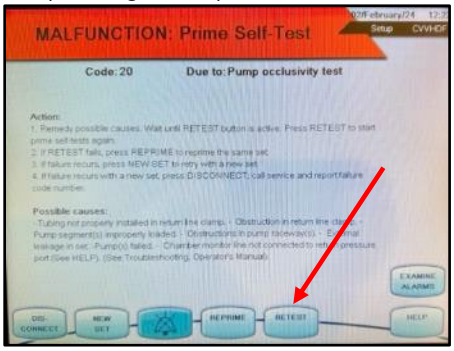


Figure 33

- If the occlusivity test fails three times in a row, carefully inspect the Prismaflex tubing set and SCD-PED Cartridge for external leakage. Inspect the HF20/HF1000/HF1400 hemofilter for proper loading. Refer to Prismaflex *Instructions for Use* for troubleshooting.

15. Once the prime test sequence is passed, follow the manufacturer’s Prismaflex *Instructions for Use* to continue with patient connection and the start of treatment.
    Reminder: During the prime and operation procedures, observe closely for blood/fluid leakage at all circuit connections. If tightening the connections does not stop leakage, replace the SCD-PED Cartridge and the SCD Blood Tubing Set. Leakage can cause blood loss or air entry/air embolism.

E. FOR PRISMAX ONLY: CONNECTING THE SCD-PED TO THE PRISMAX CKRT CIRCUIT

1. Secure the pre-primed SCD-PED Cartridge and SCD Blood Tubing Set to the SCD Holder on the back of the PrisMax monitor, positioned so the Hemofilter to SCD Line is located at the bottom and the label arrows are at the top and pointing up (see red arrow in Figure 34).

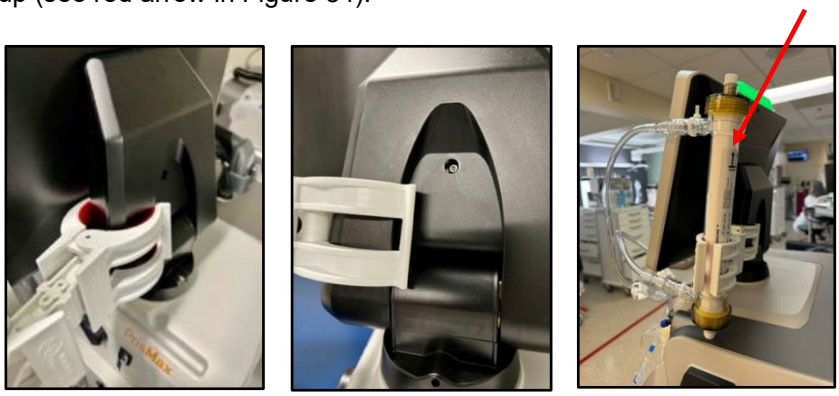


Figure 34: The SCD Holder has two identical clamps (one that clamps to the side of the monitor's base, and the other clamp for holding the SCD-PED Cartridge).

2. The SCD-PED Cartridge and SCD Blood Tubing Set will be connected to the PrisMax CKRT circuit after the priming cycle(s) is(are) complete during the automatic priming sequence.
   - For HF20/HF1000 tubing sets, the priming cycle is complete after the first bag of normal saline is used.
   - For HF1400 tubing sets, the priming cycles are complete after the second bag of normal saline is used.
   - Reminder: do not attempt to integrate the SCD-PED Cartridge and SCD Blood Tubing Set before the priming cycle(s) is(are) complete, or between *Priming Cycle 1* and *Priming Cycle 2* of the HF1400 tubing set (integration of the SCD-PED between *Priming Cycle 1* and *2* only occurs when using the Prismaflex machine, not the PrisMax machine).

3. When the priming cycle(s) is(are) complete, use plastic hemostats to clamp the access/arterial line below the blood inlet port of the HF20/HF1000/HF1400 hemofilter, then clamp the venous return line above the blood outlet port of the HF20/HF1000/HF1400 hemofilter.

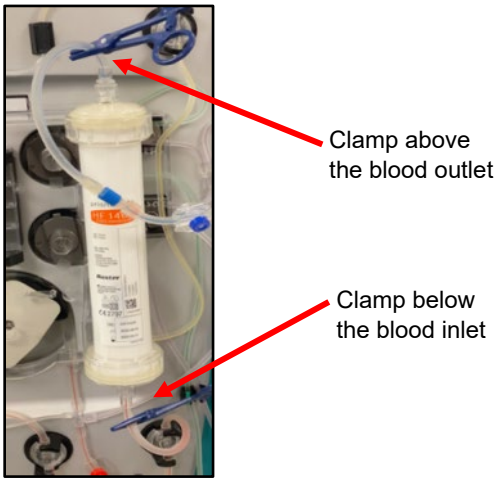


Figure 35: Location of clamps for Step 3

NOTE: If infusing CaCl through a separate central line, skip steps 4-6.

4. Disconnect the CKRT venous return line from the collection bag/Auto Effluent set (Figure 36).

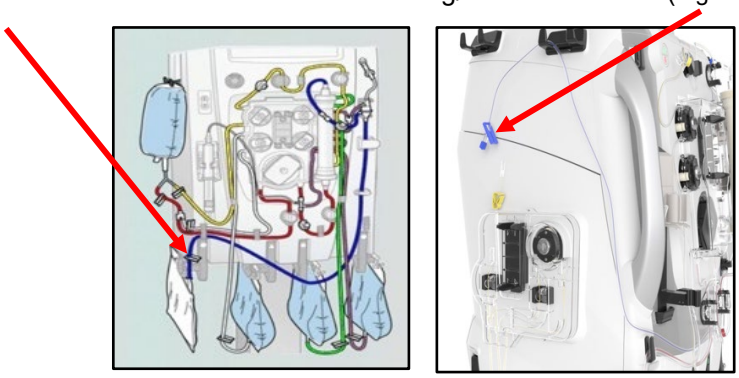


Figure 36

5. Connect primed calcium chloride/CaCl labeled 'Y' Connector to the venous return line where it was disconnected from the collection bag.

6. After connecting the primed 'Y' Connector to the venous return line, reconnect the 'Y' Connector to the collection bag.

7. Disconnect the CKRT venous return line from the HF20/HF1000/HF1400 hemofilter's blood outlet port (located on the top of the hemofilter – see arrow on Figure 37).

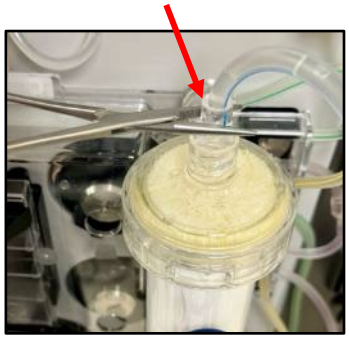


Figure 37

- It may be necessary to use a tool (plastic or metal hemostat) to unscrew the CKRT venous return line located on the top of the HF20/HF1000/HF1400 hemofilter's blood outlet port.
- If a hemostat is used to unscrew the line, do not twist the port sideways or port breakage may occur.

8. Connect the Hemofilter to SCD Line to the HF20/HF1000/HF1400 hemofilter's blood outlet port (Figure 38 (A)).

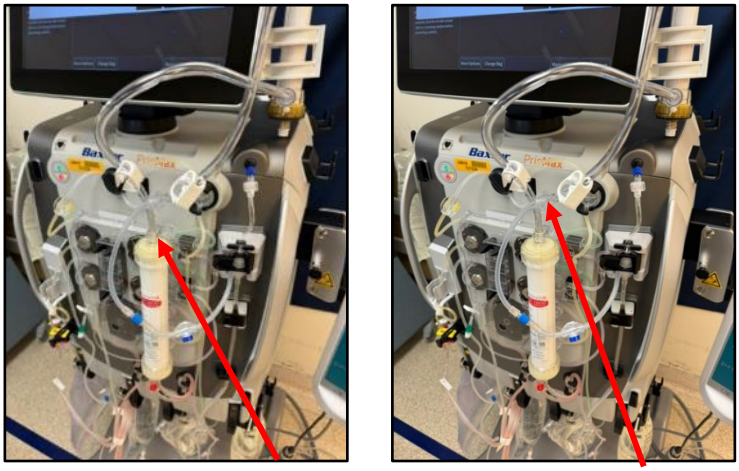


Figure 38 (A) arrow indicating hemofilter blood outlet port; (B) arrow indicating CKRT venous return line

9. Connect the SCD to Venous Return Line to the CKRT venous return line that was disconnected from the HF20/HF1000/HF1400 hemofilter's blood outlet port (Figure 38 (B)).

- CAUTION – Once secured, verify the SCD-PED Cartridge is positioned so that when connected, the blood exiting the HF20/HF1000/HF1400 hemofilter is going into the blood inlet port of the SCD-PED Cartridge (lower side of SCD-PED Cartridge) and flowing up against gravity through the SCD-PED Cartridge.

Figure 39: Red arrows showing direction of blood flow exiting from the top of the HF20/HF1000/HF1400 hemofilter and going into the blood inlet port located at the lower side of the SCD-PED Cartridge.

10. As a reminder, refer to step 2 of this section for continuing the priming process after connecting the pre-primed SCD-PED Cartridge and SCD Blood Tubing Set.

11. At the Prime Completed screen, hang additional 1-liter Normal Saline bag and press the More Options button (see Figure 40 [next page]).

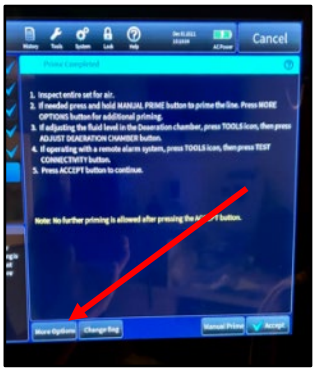


Figure 40: Location of the More Options button.

12. After pressing the More Options button, press the Flush button (see Figure 41).

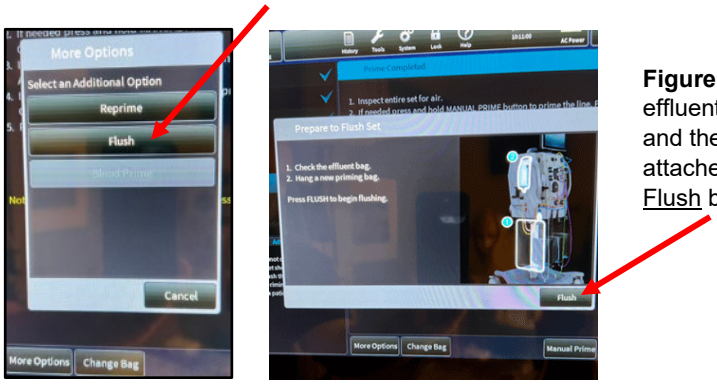


Figure 41: Make sure the effluent bag has enough room and the saline priming bag is attached before pressing the Flush button to continue.

13. Due to the amount of air being purged during the flush, it is important to monitor the deaeration chamber and adjust accordingly by selecting the Tools icon at the top of the screen then pressing the Adjust Deaeration Chamber button.

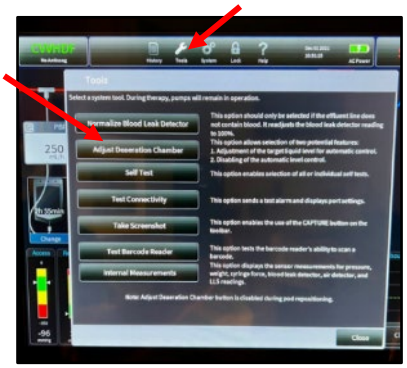


Figure 42: Location of 'Tools' button and 'Adjust Deaeration Chamber' button

14. Once the flush has completed, follow the manufacturer's PrisMax *Instructions for Use* to continue with patient connection and the start of treatment.

F. CITRATE & CALCIUM INFUSION SET UP (Prismaflex and PrisMax)

NOTE 1: Regional Citrate Anticoagulation protocol is ordered by a physician or provider according to the hospital's current citrate protocol.

NOTE 2: Post-SCD circuit ionized calcium level must be maintained at less than 0.40 mmol/L for at least 90% of the therapy duration.

NOTE 3: The blood sample for the post-SCD ionized calcium level is obtained from the CKRT circuit's blue sample port/line after the hemofilter.

1. Connection of the citrate infusion is done per the hospital's current citrate protocol. The connection can be made using either of the following methods:
   - Connect the citrate infusion to the access/arterial line port of the CKRT blood circuit closest to the patient's vascular access catheter using the Gambro 'Y' line connector.
   - Connect the citrate infusion via the PBP bag on the Prismaflex machine.
     Reminder: connection of the citrate infusion to the CKRT circuit is performed during the automatic priming sequence (see Section C, Step 1 above).

2. Connect the calcium chloride infusion to the venous return line of the CKRT blood circuit using the Gambro 'Y' line connector to the patient's vascular access catheter (not applicable if infusing calcium chloride through a separate central line on the patient).

G. CONFIRM THAT THE SYSTEM IS READY (Prismaflex and PrisMax)

1. Visually inspect the joints and connections of the SCD-PED Cartridge, SCD Blood Tubing Set, and the CKRT circuit for leakage or air bubbles.

2. Blood lines are connected to the patient's vascular access and all clamps are open.

3. Calcium chloride infusion is properly connected to the Venous Return Line of the CKRT blood circuit via the 'Y' Connector.
   - IMPORTANT: Please follow your hospital's standard operating procedure regarding where to infuse calcium chloride if the venous return line of the patient's vascular access catheter is not recommended.

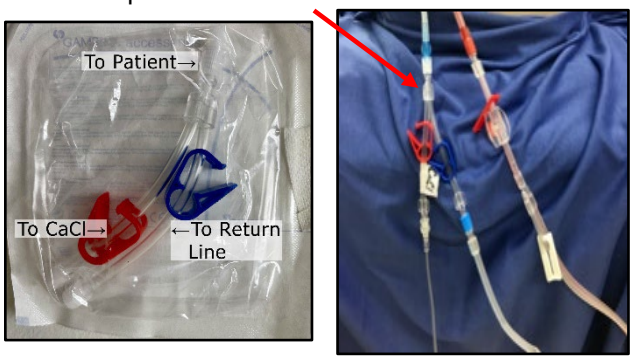


Figure 43 (A): Y Connector Labeled (B): Y Connector Connected

   - Reminder: Start the calcium chloride infusion pump at the same time the SCD-PED therapy is started on the CKRT circuit.

4. If using a separate IV infusion pump (not the CKRT's PBP) for citrate infusion, confirm the citrate infusion is properly connected to the Access/Arterial Line of the CKRT blood circuit via the Gambro 'Y' Connector.
   - Reminder: Start the citrate infusion pump at the same time the SCD-PED therapy is started on the CKRT circuit.

5. Confirm all clamps of the CKRT circuit are open.

6. Confirm all clamps of the SCD Blood Tubing Set are open.

7. Initiate the SCD-PED therapy, including the CKRT machine, the calcium chloride infusion pump, and the regional citrate infusion.

8. PrisMax ONLY**:** After the SCD-PED therapy has started, follow your hospital's standard operation procedure for determining when to perform a Self-Test.

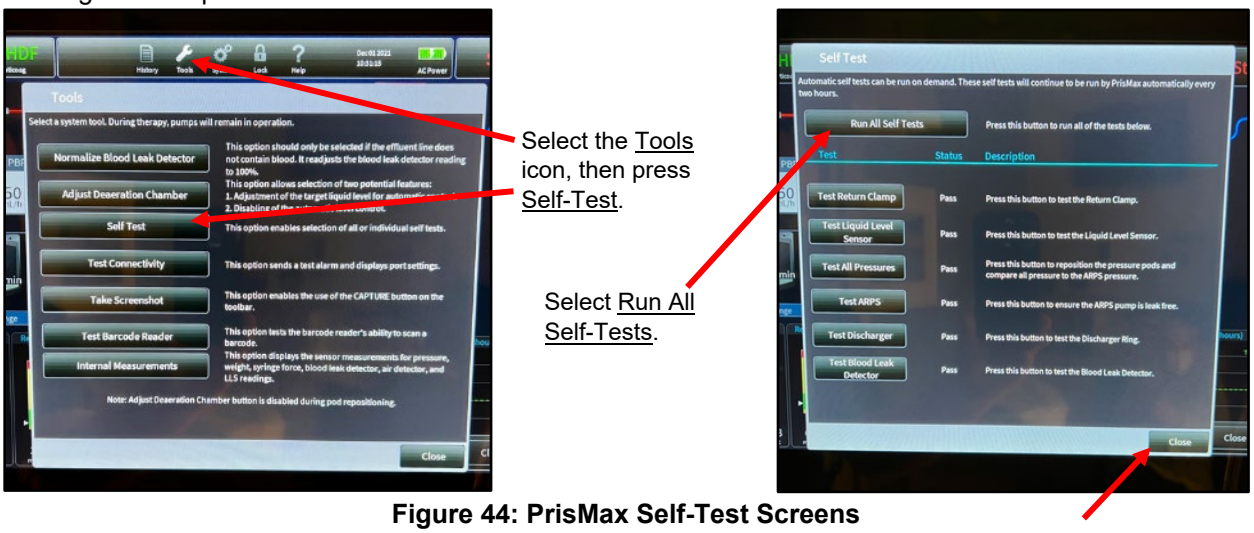


Figure 44: PrisMax Self-Test Screens

9. PrisMax ONLY**:** Press the Close button once all self-tests have passed and continue with SCD-PED therapy.

H. PRISMAFLEX ONLY: SCD-PED CARTRIDGE REPLACEMENT

NOTE 1: Refer to the SCD-PED Cartridge information located on Page 1 of this document describing when the SCD-PED Cartridge and SCD Blood Tubing Set are to be replaced.
NOTE 2: Although not required, a second nurse to assist with SCD-PED changeout is highly recommended.
NOTE 3: Some institutions prefer to replace the entire circuit (HF20/HF1000/HF1400 cartridge, SCD-PED Cartridge and the SCD Blood Tubing Set every 24 hours) instead of incorporating a newly primed SCD-PED Cartridge and SCD Blood Tubing Set into an existing HF20/HF1000/HF1400 cartridge. Please follow your hospital's standard policy/procedure regarding accessing an existing circuit when replacing the SCD-PED Cartridge and SCD Blood Tubing Set every 24 hours.

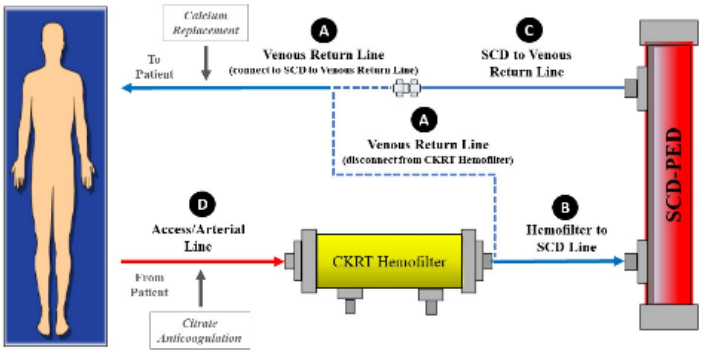


Figure 45: SCD-PED Therapy Set-up with Lines Identified with A-D Lettering

1. Gather Supplies:
   - SCD-PED Cartridge and SCD Blood Tubing Set
   - SeaStar Medical Humanitarian Device Label
   - Free flow gravity IV tubing set
   - 1-liter bag of 0.9% Sterile Normal Saline Solution (2 bags)
   - Pressure bag
   - 20 mL Luer-lock syringe
   - Hemostats (2 plastic, 1 stainless steel)
   - Gambro Accessory 'Y' Connector
   - Sterile Access Spike (2)
   - New effluent collection bag
   - Alcohol wipes (2)
   - Sterile caps
   - Sterile blue disposable towel
   - Red biohazard waste bag
   - Towel or paper chuck – place on floor under hemofilter

2. Verify that the new SCD-PED Cartridge and SCD Blood Tubing Set is primed (see Section B) prior to proceeding with the next steps.

3. Follow the CKRT device manufacturer's *Instructions for Use* for the recirculation procedure and blood return.
   - IMPORTANT: Stop both the Calcium Chloride infusion and the Citrate infusion pumps prior to returning patient's blood.
   - Remember to select "Saline Recirculation" and not "Blood Recirculation" (see Figure 46 [next page]).
     - *NOTE: please follow your hospital's standard operating procedures for blood recirculation and/or blood priming.*

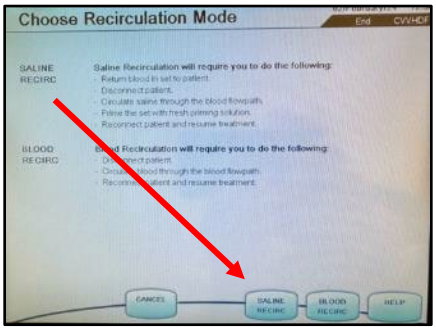


Figure 46

- Use a new Accessory 'Y' Connector and a new sterile access spike for blood return per the manufacturer's instructions.

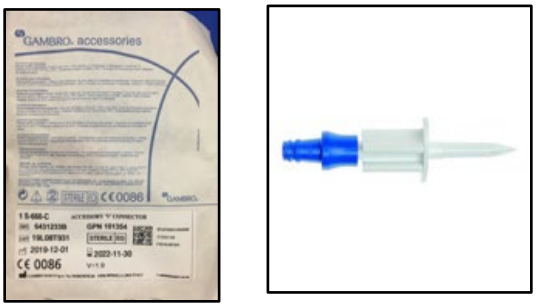


Figure 47 (A) and (B): example Accessory 'Y' connector and sterile access spike

4. When the blood return is complete, confirm that all pumps are stopped, then press "CONTINUE".
   - Reminder: Due to the volume of the SCD-PED Cartridge and SCD Blood Tubing Set (approximately 150 mL), an additional manual return of blood is required.

5. Complete the steps of the "Saline Recirculation" according to the manufacturer's *Instructions for Use* by following the steps on the screen.

6. Flush patient's HD catheter per hospital policy to maintain patency.

7. Clamp the patient's HD catheter.

8. Using aseptic technique, place sterile caps on patient's HD access lines.

9. Select the "STOP RECIRC" option (Figure 48).

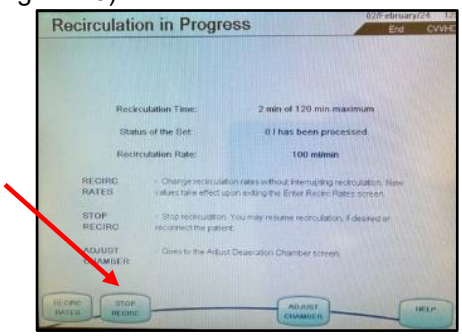


Figure 48

10. Using a plastic hemostat, clamp the blood inlet port tubing at the bottom of the HF20/HF1000/HF1400 hemofilter (See Figure 49, item 1).

11. Using a second plastic hemostat, clamp the venous return line (Figure 45, item A) of the HF20/HF1000/HF1400 closest to the SCD to Venous Return Line (Figure 45, item C) as in Figure 49, item 2.

12. Slide the white pinch clamp of the Hemofilter to SCD Line (Figure 45, item B) as close as possible to the connection at the top of the HF20/HF1000/HF1400 hemofilter, then tightly clamp (see Figure 49, item 3).

13. Slide the white pinch clamp of the SCD to Venous Return Line (Figure 45, item C) as close as possible to the connection at the venous return line of the HF20/HF1000/HF1400 tubing set, then tightly clamp (see Figure 49, item 4).

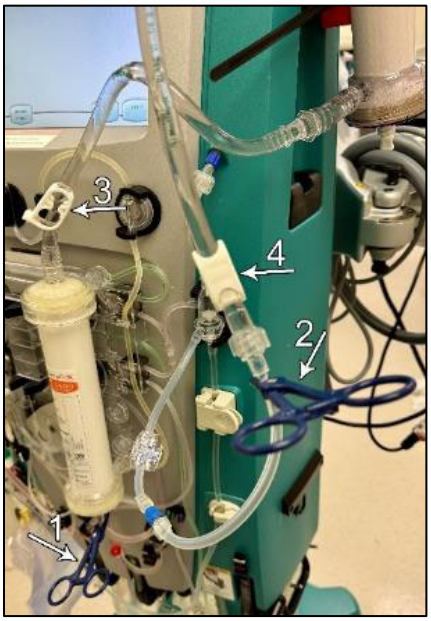


Figure 49

14. Remove the used SCD-PED Cartridge from the SCD Securing Bracket by releasing the zip-ties as shown in *Section B* of this document.
    - It may be helpful to have a second nurse hold the SCD-PED Cartridge that was just removed.
15. Attach the new, pre-primed SCD-PED Cartridge to the SCD Securing Bracket as explained in Section D, Step 1 of this document.

16. Disconnect the used Hemofilter to SCD Line (Figure 45, item B) from the HF20/HF1000/HF1400 hemofilter.

17. Using aseptic technique, clean port at top of HF20/HF1000/HF1400 hemofilter with a sterile alcohol wipe.

18. Connect the new Hemofilter to SCD Line (Figure 45, item B) that is attached to the pre-primed SCD-PED Cartridge.

19. Disconnect the used SCD to Venous Return Line (Figure 45, item C) of the SCD-PED Cartridge to be replaced from the circuit's venous return line (Figure 41, item A).

20. Using aseptic technique, clean connector at the end of the venous return line (Figure 45, item A) with a sterile alcohol wipe prior to connecting the pre-primed SCD to Venous Return Line (Figure 45, item C) of the new SCD-PED Cartridge.

21. Connect the SCD to Venous Return Line (Figure 45, item C) of the new SCD-PED Cartridge to the venous return line (Figure 45, item A).

22. Discard the used SCD-PED Cartridge and associated lines in accordance with hospital procedures for biohazardous waste and applicable local, state, and federal laws and regulations.
    - Connect the ends of the SCD Blood Tubing lines from the used SCD-PED Cartridge prior to placing in an appropriate biohazard bag for disposal.

23. Unclamp the plastic hemostat on the blood inlet port tubing at the bottom of the HF20/HF1000/HF1400 hemofilter.

24. Unclamp the plastic hemostat on the venous return line.

25. Unclamp both the Hemofilter to SCD Line and the SCD to Venous Return Line of the new SCD-PED Blood Tubing Set.

26. Select the “PREPARE TO PRIME” option.

27. Complete the steps of the “PREPARE TO PRIME” screen according to the CKRT machine manufacturer’s *Instructions for Use*.

28. Select the “PRIME + TEST” option.

29. Once the prime test sequence is passed, press “CONTINUE” then follow the CKRT machine manufacturer’s *Instructions for Use* by following the steps on the screen to continue with patient reconnection.

30. Once patient reconnection is complete, press the “START” button to restart CKRT treatment and SCD-PED therapy.

31. Restart the Citrate infusion pump (if using a separate pump) and the Calcium Chloride infusion pump.

I. PRISMAX ONLY: SCD-PED CARTRIDGE REPLACEMENT

NOTE 1: Refer to the SCD-PED Cartridge information located on page 1 of this document describing when the SCD-PED Cartridge and SCD Blood Tubing Set are to be replaced.
NOTE 2: Although not required, a second nurse to assist with the SCD-PED is highly recommended.
NOTE 3: Due to the differences between the Prismaflex and PrisMax machines regarding blood return, it is required to replace the entire circuit (HF20/HF1000/HF1400 cartridge, SCD-PED Cartridge and the SCD Blood Tubing Set) every 24 hours when using a PrisMax machine. Please follow the steps below for returning blood and changing out the entire circuit.

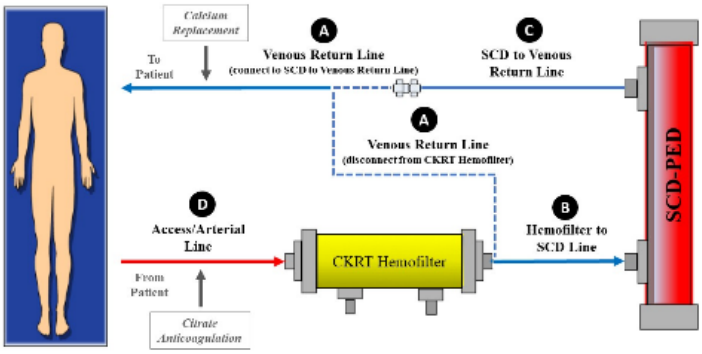


Figure 50: SCD-PED Therapy Set-up with Lines Identified with A-D Lettering

1. Gather Supplies:
   - SCD-PED Cartridge and SCD Blood Tubing Set
   - SeaStar Medical Humanitarian Device Label
   - Free flow gravity IV tubing set
   - 1-liter bag of 0.9% Sterile Normal Saline Solution (2 bags)
   - Pressure bag
   - 20 mL Luer-lock syringe
   - Hemostats (2 plastic, 1 stainless steel)
   - Gambro Accessory 'Y' Connector
   - Sterile Access Spike (2)
   - Alcohol wipes (2)
   - Sterile caps
   - Sterile blue disposable towel
   - Red biohazard waste bag

2. Verify that the new SCD-PED Cartridge and SCD Blood Tubing Set is primed (see Section B) prior to proceeding with the next steps.

3. Follow the CKRT device manufacturer's *Instructions for Use* for the recirculation procedure and blood return.
   - IMPORTANT: Stop both the Calcium Chloride infusion and the Citrate infusion pumps prior to returning patient's blood.
   - Remember to select "Recirculate Saline" and not "Recirculate Blood" (Figure 51).
     - NOTE: please follow your hospital's standard operating procedures for blood recirculation and/or blood priming.

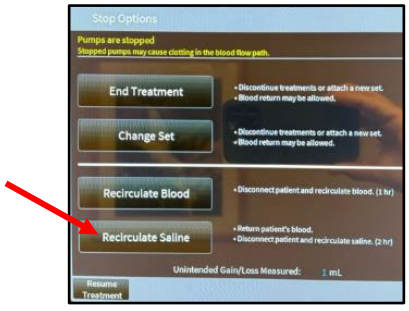


Figure 51

- Use a new Accessory 'Y' Connector and a new sterile access spike for blood return per the manufacturer's instructions.

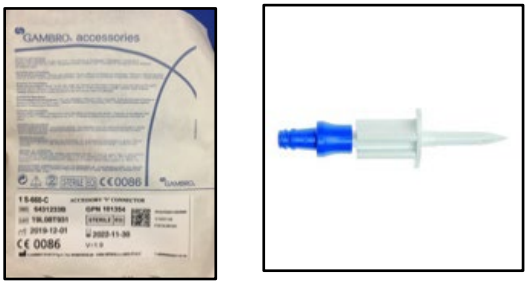


Figure 52 (A) and (B): example Accessory 'Y' connector and sterile access spike

4. Complete the steps of the "Saline Recirculation" according to the manufacturer's *Instructions for Use* by following the steps on the screen.

5. Due to the volume of the SCD-PED Cartridge and SCD Blood Tubing Set (approximately 150 mL), an additional manual return of blood is required.
   - Reminder: The volume returned is preprogrammed by the PrisMax machine to coincide with the cartridge being used (HF20/HF1000/HF1400) – approximately 58, 165, or 184 mL respectively.

6. When the set volume of blood return is complete (100% on the Blood Return screen), press and hold the "Manual Return" button until the set volume returned reaches 150% (Figure 53).
   - Reminder: Notate how many total mLs of volume is returned after reaching 150% as that total, along with the approximately 150 mL volume of the SCD-PED Cartridge and SCD Blood Tubing Set, will be used to calculate how many mLs of blood needs to be returned in Step 18 below.

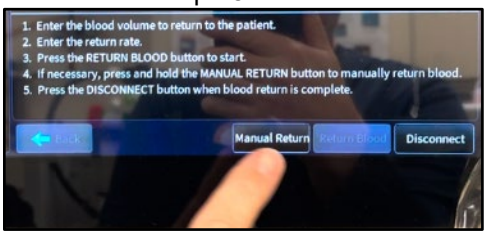


Figure 53

7. Once the set volume returned reaches 150%, press the "Cancel" button in the top right corner of the screen (Figure 54).

Figure 54

8. On the next screen, press the “Cancel Recirculation” button (Figure 55).

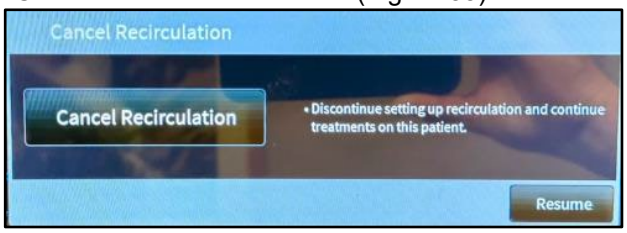


Figure 55

9. On the Reconnect Patient screen, press the “Next” button (Figure 56).

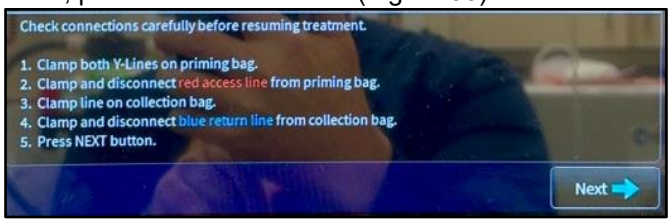


Figure 56

- IMPORTANT: Do not reconnect the red access line to the patient at this time. In order to return the total extracorporeal blood volume (CKRT cartridge set volume + SCD-PED Cartridge and Blood Tubing Set), keep the red access line connected to the saline bag and continue with the steps below prior to reconnecting the patient.

10. Press the “Confirm All” button (Figure 57).

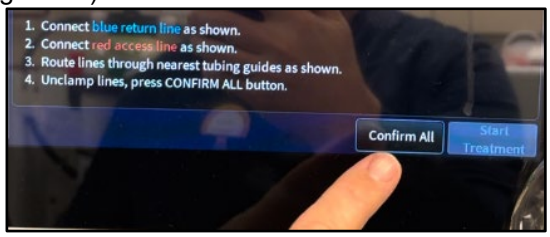


Figure 57

11. Press the “Start Treatment” button. A confirmation screen will appear. Press “Start Treatment” again (Figure 58).

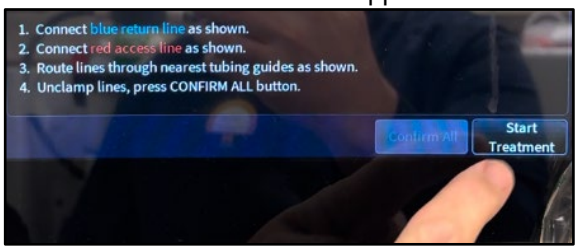


Figure 58

12. Allow the treatment to run for 15-20 seconds.
    - Reminder: the red access line should still be connected to the saline bag, not the patient.

13. Press the “Stop” button (Figure 59).

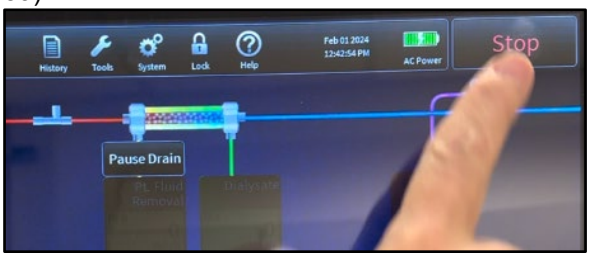


Figure 59

14. Press the “End Treatment” button (Figure 60).

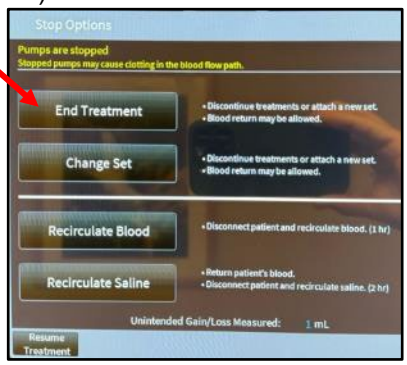


Figure 60

15. On the End Treatment/Discard Set screen, select “Discard All”, Blood Return “Yes”, then “Accept” (Figure 61).

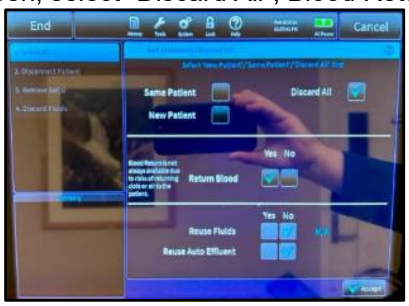


Figure 61

16. On the Prepare for Blood Return screen, select “Next” (Figure 62).

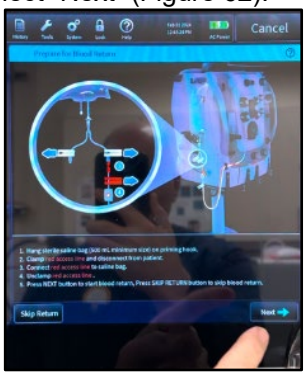


Figure 62

17. On the Return Blood screen, select “Manual Return” (Figure 63).
    - Reminder: The volume returned is preprogrammed by the PrisMax machine to coincide with the cartridge being used (HF20/HF1000/HF1400) – approximately 58, 165, or 184 mL respectively.

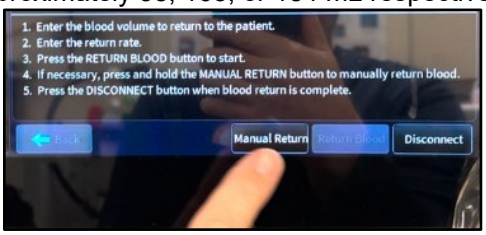


Figure 63

18. Hold the “Manual Return” button down until the desired amount of blood is returned.
    - Reminder: Using the total volume returned in Step 6 above, plus the approximately 150 mL volume in the SCD-PED Cartridge and SCD Blood Tubing Set, the desired amount to be manually returned in this step can be calculated using the total extracorporeal blood volume (HF20/HF1000/HF1400 cartridge volume + SCD-PED Cartridge & SCD Blood Tubing Set) minus the volume returned in Step 6 above.
        - For example: If using an HF1000 cartridge (approximately 165 mL) + the 150 mL in the SCD-PED Cartridge/Tubing Set, the total extracorporeal blood volume is 315 mL. The PrisMax limits the amount originally returned to 150% of the HF1000 cartridge which equals 247 mL (amount returned in Step 6 above). The desired amount of blood to manually return in this step would then be (165 + 150) - 247 = 68 mL.
        - Reminder: visually inspect the lines to assure the fluid is light pink to confirm the correct amount of blood has been returned.

19. Once the blood return is complete, press the “Disconnect” button (Figure 64).

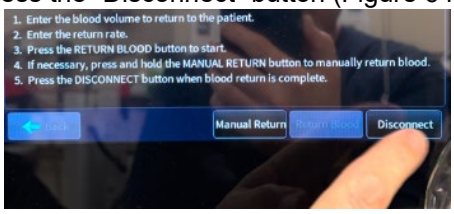


Figure 64

20. Follow the steps on the screen to disconnect the red access line from the saline bag and the blue return line from the patient.

21. Flush the patient’s hemodialysis catheter per hospital policy to maintain patency.

22. Clamp the patient’s hemodialysis catheter.

23. Using aseptic technique, place sterile caps on patient’s hemodialysis access lines.

24. Follow the steps in Section E above to continue with SCD-PED therapy.

J. CKRT DEVICE ALARMS

1. Review the CKRT machine manufacturer's Instructions for Use for resolving any CKRT device alarms that may occur during SCD-PED therapy.

2. Follow the on-screen instructions of the CKRT device for troubleshooting any arterial or venous access pressure alarms that may occur during SCD-PED therapy.

K. DISPOSAL

1. Discard the used, contaminated SCD-PED Cartridge and associated lines in accordance with hospital procedure and applicable local, state, and federal laws and regulations.

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CLINICAL DATA

The safety and feasibility of the SCD has been tested across two pediatric studies.

SCD-PED-01: Pediatric Study in Patients ≥ 15 kg

This study was designed to evaluate the safety and efficacy of the SCD-PED in pediatric patients with AKI due to ATN with at least one additional organ failure who were being treated with CKRT with regional citrate anticoagulation and who weighed ≥ 15 kg. The primary objective was to evaluate the safety of up to seven consecutive 24-hour SCD-PED treatments, and the secondary objective was to evaluate the effectiveness of these treatments on all-cause mortality and dialysis dependency at Day 28 and Day 60.

Patients < 22 years old and weighing ≥ 15 kg with a threshold blood pressure of 80/40 mmHg and platelet count ≥ 15,000/mm^3 at the time of screening who were in the ICU with a clinical diagnosis of AKI requiring CRRT with at least one non-renal organ failure were included in this study. Patients who had been on CKRT longer than 12 hours with irreversible brain damage, advanced chronic renal failure at baseline (with eGFR of < 30 ml/min/1.73 m^2), severe chronic liver failure, metastatic malignancy, and chronic immunosuppression were excluded.

A total of 305 subjects were screened, and 19 subjects were enrolled. Three of these subjects were withdrawn prior to SCD therapy, and 16 subjects (8 female/8male) were ultimately treated. The most common reasons for exclusion were weight < 15 kg (n=124) and presence of chronic kidney disease stage 4 or 5 or ESRD (n=38).

Mean subject age was 12.3 ± 5.1 years (range 4-21 years), weight was 53.8 ± 28.9 kg (range 19.1-111 kg), and median PRISM II score at CKRT initiation was 7 (range 2-19). Two subjects received ECMO. The most common diagnosis leading to ICU admission was septic shock (n=6), followed by pneumonia (n=2) and then n=1 each for rhabdomyolysis, pulmonary hypertension, hemolytic uremic syndrome, encephalomyelitis, disseminated adenoviral infection, cardiac arrest, acute respiratory failure, and acute liver failure.

The median SCD-PED treatment course duration was 6 days (range 1-7 days). Circuit iCa concentrations were < 0.40 mmol/L for 90.2% of the time. Subject systemic iCa concentrations were maintained at > 1.0 mmol/L in 97.5% of measurements, with a lowest value of 0.89 mmol/L. Only one subject required a calcium bolus after initiating SCD therapy. Because maintaining a post-SCD ionized calcium level of < 0.40 mmol/L is critical to the function of the SCD-PED therapy, the per protocol requirements were to maintain a circuit, post-SCD ionized calcium at < 0.40 mmol/L, at least 90% of therapy duration. The requirements for systemic ionized calcium measurements are based off the hospital's current citrate protocol with calcium chloride replacement titrated accordingly, typically every 6 hours.

Fifteen of the 16 subjects (93.75%) survived to the end of SCD-PED treatment. The one subject who did not survive SCD-PED treatment died at seven hours of therapy after developing irreversible ventricular tachycardia, which was not considered to be device related. Twelve (12) of the 16 subjects (75%) survived to hospital discharge. Three (3) subjects who received ECMO therapy died during the study after completion of SCD-PED treatment. Two (2) of them were related to hemorrhage in major organs (cerebral, pulmonary), and the third died of refractory respiratory failure. There were 12 SAEs observed during the study (cardiac arrest with viral myocarditis, vascular graft occlusion, adrenal insufficiency, pneumoperitoneum, Steven Johnson's syndrome, nephrolithiasis, cardiac arrest, cerebral hemorrhage, pulmonary hemorrhage, junctional tachycardia, and two instances of respiratory failure). The causality of these SAEs was undetermined. No device-related infections were observed in the study.

Of the 12 survivors, 10 were dialysis independent at 28 days (83%), and all 12 were dialysis independent and had a normal serum creatinine at 60 days (100%).

SCD-PED-02: Pediatric Study in Patients ≥ 10 kg and ≤ 20 kg

This study was designed to evaluate the safety and efficacy of the SCD-PED in pediatric patients with AKI due to ATN and at least one additional organ failure who were being treated with CKRT with regional citrate anticoagulation and who weighed between ≥ 10 kg to ≤ 20 kg. The primary objective was to evaluate the safety of up to 10 consecutive 24-hour SCD-PED treatments, and the secondary objective was to assess the effect of

SCD-PED treatment on 28- and 60-day all-cause mortality, as well as time to renal recovery and necessity for chronic dialysis up to day 60. Additional endpoints included time to ICU discharge and time to hospital discharge.

Patients < 18 years old and weighing ≥ 10kg with a threshold blood pressure of 80/40 mmHg and platelet count ≥ 15,000/mm^3 at the time of screening who were in the ICU with a clinical diagnosis of AKI requiring CRRT with at least one non-renal organ failure were included in this study. Patients who had been on CKRT longer than 12 hours with irreversible brain damage, advanced chronic renal failure at baseline (with eGFR of < 30ml/min/1.73 m^2), severe chronic liver failure, metastatic malignancy, and chronic immunosuppression were excluded.

Seven (7) subjects were enrolled. One (1) subject was withdrawn prior to receiving SCD-PED therapy due to screening failure. Six (6) subjects received treatment with the SCD-PED.

Mean subject age was 3.0 years (range 1.6-10.4 years), weight was 13.5 kg (range 11.9-16.5 kg). Four (4) subjects were male and 2 were female. Median PRISM II score at CKRT initiation was 17.7 (range 12-27). All 6 subjects were receiving invasive mechanical ventilation at SCD-PED start. Five (5) patients were septic at SCD-PED start and 5 were on vasopressors. One (1) patient was on ECMO.

The median SCD-PED treatment course duration was 4.7 days (range 0.9-8.7 days). Ultimately, 5 subjects survived to Day 28 and Day 60 (5/6; 83%). One (1) subject died on post-SCD-PED Day 1 (withdrawal of care). The 5 surviving subjects were dialysis independent on Days 28 and 60 (100%).

During the study, 6 SAEs were observed (septic shock, pneumothorax, vascular site thrombosis, cardiac arrest, respiratory failure, lactic acidosis). The causality of these SAEs was undetermined.

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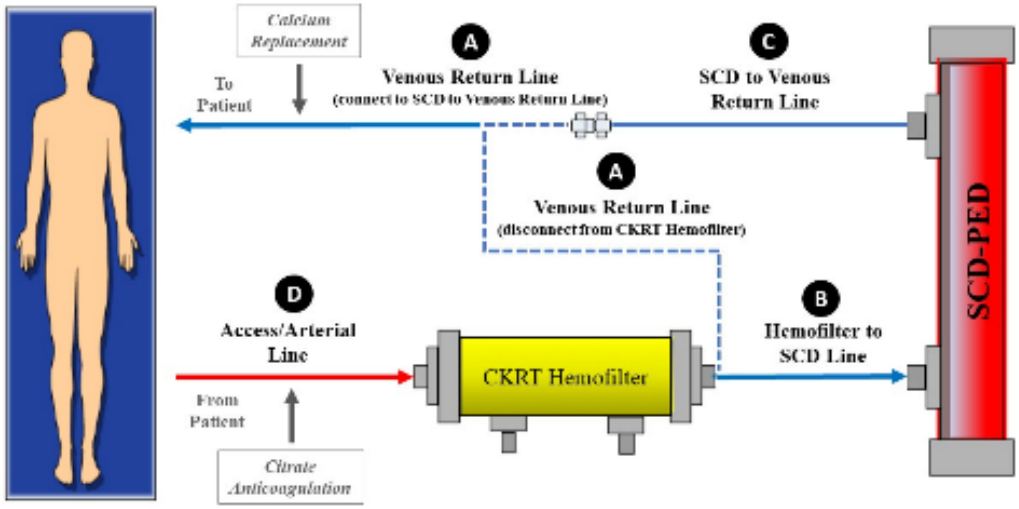

Figure 65: SCD-PED Therapy Set-up with Lines Identified with A-D Lettering

Table 3: Description of Symbols Found in QUELIMMUNE Labeling

Symbol	Description
	Consult instructions for use
	Caution
	Non-pyrogenic
	Manufacturer
	Date of manufacture
	Use-by date
	Do not re-use
	Do not resterilize
	Do not use if package is damaged or if filter is damaged or port caps are loose or missing
	Temperature limit
	Humidity limitation
REF	Catalogue number
LOT	Batch code
UDI	Unique device identifier
MD	Medical device
STERILE EO	Sterilized using Ethylene Oxide
	Non-sterile

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