Thoratec® CentriMag® SURGICAL TRAINING CHECKLIST
Abbreviated and Abstracted from the CentriMag Instructions for Use and other CentriMag Educational Materials

(Note: All items to be sterile unless otherwise noted. Inspect all components prior to use)

Circuit Preparation/Primerel:

Method A (back page)
- Qty 2 – 4 ft. 3/8” x 3/32” CPB tubing (Medtronic® Interscept® tubing)
- Sterile basin
- 3L warm .9NS saline for injection with optional 10,000 U/L heparin
- Qty 4 sterile tubing clamps

Method B (back page)
- Medtronic custom tubing pack P/N SG91R2
- 1L warm .9NS saline for injection with optional 10,000 U/L heparin
- Qty 4 – non-sterile tubing clamps
- Qty 4 – sterile tubing clamps
- Tubing scissors

CANNULAE

**Variety of cannulae may be used. Considerations: wire reinforced, single stage, lighthouse tip, malleable**

Suggested trans-thoracic cannulae:
Venous: Edwards TFM036L (36FR single stage, malleable, 12mm, 40cm)
Venous: Edwards TFM036L (36FR single stage, malleable, 12mm, 40cm)
Venous: Edwards TFM040L (40FR single stage, malleable, 13.3 mm, 40cm)
Arterial: Medtronic EOPA™ 22FR (77722 – dilator tip, introducer, guidewire, 30.5cm) or
Arterial: Medtronic EOPA™ 22FR (77522 – blunt tip, introducer, no guidewire, 30.5cm)
Venous (inflow) Medtronic BioMedicus 96670-019 or 96670-021
Suggested percutaneous cannulae:
Venous (inflow) Medtronic BioMedicus 96670-019 or 96670-021
Arterial (outflow) Medtronic BioMedicus 96570-019 or 96570-021

Thoratec Equipment Required for Patient Support:
- CentriMag Blood pump
- CentriMag Flow probe
- CentriMag Motor
- CentriMag Primary Console
- CentriMag Back-Up Console
- Back-up Motor
- 45° Motor Bracket
- Cart (Optional)

Initiation of Patient Support Notes

1. Determine cannulation approach and desired placement of cannulae, avoiding risk of cannulae kinking or torque.
2. If applicable plan for placement of longer term MCS device.
3. Select the inflow and outflow cannulae.
4. Insert cannulae utilizing standard technique.
5. Pass primed and de-airred CentriMag circuit to sterile field and, if not already attached to the cannulae, connect 3/8” connector to each piece of tubing.
6. Utilizing a fluid to fluid connection, attach the inflow cannulae to the 3/8” connector on the venous (inflow) tubing.
7. Tubing connections must be beyond the second barb and secured with 2 tie bands – 6” length, placed at each connection.
8. Clamp inflow cannulae, and attach outflow cannulae to 3/8” connector on arterial (outflow) tubing. Remove clamp from inflow cannulae.
9. Place patient in Trendelenburg position and decrease bypass flow to allow filling of the heart and blood pump(s) by diverting at least 2 liters of blood per minute to the ventricle.
10. Ensure adequate blood volume in heart with Transesophageal ECHO and hemodynamic monitoring to reduce the risk of a suction event and air entrainment.
11. If bi-lateral configuration is used, initiate support of the systemic side followed by the pulmonary side to avoid pulmonary overload.
12. Initiate patient support by increasing RPM on primary console to ±1000 RPM.
13. Release clamp on outflow tubing once speed of pump is ≥ 1000 RPM or greater (to avoid retrograde flow). Continue slowly increasing RPM.
14. Use TEE to check for air and desired unloading/loading of ventricle. Slowly increase RPM on primary console to achieve desired effect.
15. Continue to wean patient off CPB, while ensuring adequate flow to CentriMag pump(s) - treating patient with medications and fluids as necessary.
16. Reverse heparin with administration of protamine per CV Surgery protocol.
17. Dress thoracic incision per standard CV protocol and affix cannulae/tubing to skin for immobilization.

CentriMag Console Set-Up

1. All consoles should be stored with AC power connected.
2. Connect Motor and Flow probe to Primary console.
3. Connect Motor to Back-Up Console (Back-Up equipment must be present in case the primary console or motor fails).
4. Turn on power to both consoles (switch on side panel).
5. Console power up self-tests:
   a. When power is turned ON the self-test procedure will begin automatically.
   b. If “POWER ON TEST FAIL” is displayed – immediately turn OFF the console and re-power. If the console does not pass the second self-test, REPLACE CONSOLE and MOTOR.
   c. When all self-tests are completed successfully the INITIALIZATION COMPLETE message will appear. MENU and SET RPM are displayed – console is connected to AC power.
   d. If time permits, test console and motor operation with the Training Loop (Optional).
6. Console is ready for use.

Note: A complete Back-Up system (Equipment & Disposable) and 2 tubing clamps per pump should always be available and in direct vicinity of the patient during support. Except during transport, both the Primary and Back-Up consoles should be plugged in at all times to maintain the charge on their batteries.
### Method A: Submerision Circuit Preparation Technique (Sterile techniques)

1. Sterile technique utilized (cap, gown, gloves, mask, field, etc.)
2. Fill large sterile basin with 3L warm injectable .9NS
3. Slowly submerge one end of 4 ft. tubing into basin and gradually submerge entire piece in circular motion creating a siphon allowing tubing to fill completely with injectate gradually from one end to the other. Clamp both ends of tubing upon completion of priming and de-airing.
4. Repeat step 3 for 2nd piece of 4 ft. tubing
5. Open and inspect CentriMag pump prior to use
6. Submerge CentriMag pump in sterile basin, rotate side to side, and ensure complete removal of all air and air bubbles.
7. To remove small bubbles on inner surface, rotate pump using a large bubble to sweep-up and collect smaller bubbles.
8. With pump and tubing completely submerged, release one tubing clamp and connect tubing to the inlet barb of pump.
9. Repeat step 8 with 2nd piece of tubing, attaching it to outflow barb of pump. After completing this connection, reposition the tubing clamp approximately 3” from the pump outflow. This tubing clamp will remain in place until initiation of patient support.
10. Visually inspect pump and tubing to ensure complete de-airing.
11. Circuit should still have three tubing clamps at this time; one near each end where the tubing will be connected to the cannulae and one approximately 3” from the pump outlet.
12. Remove the assembled circuit from the basin and wipe dry.
13. Straighten tubing to remove twists.
14. Return open ends to basin and ensure complete submersion of ends in prime fluid.
15. Pass the pump to the CentriMag operator taking care to insure sterility of the cannulae ends of the tubing and sterile field.
16. Follow Console Set Up procedure on opposite page
17. Secure CentriMag pump in motor mount after first unscrewing the motor retaining screw & aligning groove with retaining screw
18. Connect the flow probe to the arterial outflow tubing approximately six inches from the outlet of the pump
19. To re-circulate the prime remove all tubing clamps while maintaining submersion of open tubing ends in the basin.
20. Initiate flow by increasing RPM on the console to > 500 RPM to allow for continuous re-circulation of priming fluid to remove any micro-bubbles from the circuit
21. When ready to initiate patient support, stop the console by depressing and holding the console STOP button.
22. Replace clamps on cannulae ends of the circuit.
23. Place a tubing clamp ~ 3 inches from the pump outlet. This clamp will remain in place until support initiation.
24. Visually inspect pump and tubing to ensure complete de-airing.
25. Pass cannulae ends of the tubing circuit to the surgeon for connection to cannulae.

### Method B: Closed Bag Circuit Preparation Technique (Perfusion technique)

1. Attach an assembled CentriMag motor and bracket to an IV pole
2. Hang 1L bag of pre-warmed injectate (.9NS) on the IV pole
3. Open sterile tubing pack. Remove accessory packs, hang IV pole tubing on the tubing stand.
4. Open outer CentriMag pump pack. Invert to place sealed inner pump pack with pump into large blue tubing pack tray.
5. Don sterile gloves
6. Open inner pump pack and inspect pump within packaging
7. Secure venous (blue) tubing line onto inlet barb of pump
8. Remove pump from inner packaging
9. Secure arterial (red) tubing line onto outlet barb of pump
10. If time permits, flush reservoir & circuit with CO2 for 2 minutes
11. Place a clamp on each of the three lines below the reservoir
12. Open vent port stopcock on arterial (red) tubing
13. Open vent ports on reservoir bag, invert injectate bag, spike it with priming line, remove all air from injectate bag then remove clamp from line to allow reservoir bag to fill completely, allowing air to vent at top of reservoir bag. Once reservoir bag is full of priming solution and de-aired, close vents at top of bag.
14. Prime circuit by releasing clamp on venous (blue) tubing line, allowing gravity to force injectate through circuit; meticulously monitoring meniscus and movement of priming solution through circuit.
15. When fluid level reaches inlet of pump, manipulate and rotate CentriMag pump to remove all air, ensuring air bubbles move to outlet side of pump and through tubing. Close vent port on stopcock once prime solution reaches this level.
16. Insure CentriMag circuit and pump are completely de-aired.
17. Follow Console Set Up procedure on opposite page
18. Secure CentriMag pump in motor mount after first unscrewing the motor retaining screw & aligning groove with retaining screw
19. Connect the flow probe to the arterial outflow tubing approximately six inches from the outlet of the pump
20. Initiate flow by increasing RPM on console to > 500 RPM to allow for continuous re-circulation of priming fluid to remove any micro-bubble from circuit.
21. When ready to initiate patient support, stop the console by depressing and holding the STOP button until the pump stops.
22. Clamp all three lines below reservoir bag
23. Position a tubing clamp approximately 3 inches from the pump outlet. This tubing clamp will remain in place until initiation of patient support.
24. Peel back tubing sheath to expose sterile portion of tubing. Present a loop of sterile tubing to the surgeon. The surgeon will divide the lines by placing two clamps between the colored bands; cutting each line with a sterile scissors.
25. As surgeon secures the sterile end of each tube, continue to peel back the sheath. Remove sheaths at the end of case.

### Starting the blood pump

1. Confirm with the surgeon that all of the cannulae connections have been made, inspected, direction of flow confirmed, and tubing clamps removed. At this time there should only be one tubing clamp remaining on each circuit; positioned approximately 3” from the outlet of each pump.
2. Start each blood pump by first depressing the SET RPM keypad. SET PUMP SPEED=000 RPM will be displayed. Depress the INCREASE key. When the RPM is > 1,000 RPM, remove the pump outlet tubing clamp. With continuous hemodynamic and TEE monitoring of the heart to insure adequate blood volume, slowly increase the RPM to achieve desired flow.
3. Increase the RPM to desired blood pump flow but not to exceed 4,000 RPM unless the circuit includes an oxygenator or small cannulae.
4. Under perfuse the patient while chest is open and continuously monitor console and pump to prevent suction event and air entrainment.
5. As soon as a stable flow is achieved, set the low flow alarm to approximately 75% of desired flow (eg. For 4 LPM set alarm at 3 LPM).

**CAUTION1:** Massive air entry into the Pump will cause the Pump to deprime and blood flow to stop. Stop the pump and remove air prior to resuming circulation. Note that air can be introduced into the right blood pump circuit when IV tubing or bags are being changed. It is also possible to entrain air into the pump circuit when infusing medication via a vented bottle if the bottle and tubing are allowed to empty.

**CAUTION2:** Always fully unscrew the pump retaining screw before inserting the pump. Rotate Blood Pump counterclockwise until the matching groove on the Blood Pump body is located in front of the locking screw. Failure to do so may inhibit the ability to fully insert the pump resulting in loss of function and a MOTOR FAIL alarm. Should this condition occur, clamp outflow tubing, remove the pump, unscrew the retaining screw, reinset the pump, tighten the retaining screw, turn the Console power OFF and ON, and resume pumping.

**CAUTION3:** Monitor patient’s hemodynamics and the Console Flow display to insure the patient has adequate blood volume, that the inlet cannula is properly positioned, the Blood Pump RPM is appropriate, and desired flow is achieved. Increase Blood Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing inlet cannula obstruction, suction, outgassing, and/or cavitation. In the O.R. volume status of the heart is often monitored with TEE, arterial pressure monitoring, and direct visualization of the heart.

This checklist is not intended to replace medical or clinical care of the patient. Individual patient care is the responsibility of the Cardiac Surgeon and the surgical clinical team. Specifications may change without notice. Therefore, please refer to the Instructions for Use shipped with the CentriMag for the most current information regarding Indications, Contraindications, and Precautions. Thoratec is a registered trademark of Thoratec Corporation. Levitronix and CentriMag are registered trademarks of Levitronix LLC. CentriMag System is manufactured for Thoratec by Levitronix. Medtronic, Intersect and DUP are registered trademarks of Medtronic Corp. EOPA is a trademark of Medtronic Corp. Edwards Lifesciences is a registered trademark of Edwards Lifesciences.

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. © 2007 Thoratec Corporation. 103719A