CentriMag

Magnetically Levitated Circulatory Support System

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103718A

CentriMag

Overview

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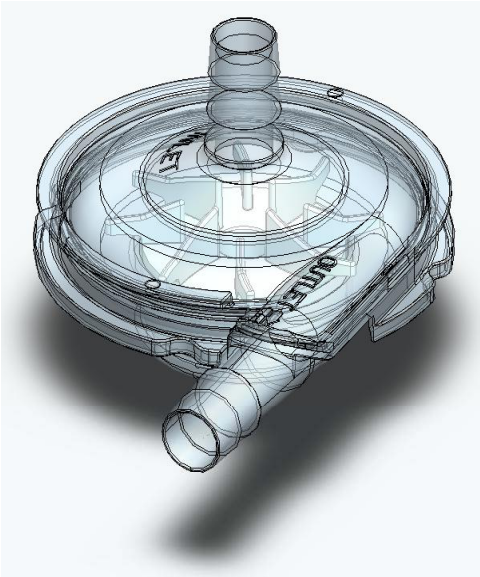
System Components



Pump **Motor** **Console**

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CENTRIMAG PUMP

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CENTRIMAG PUMP & MOTOR

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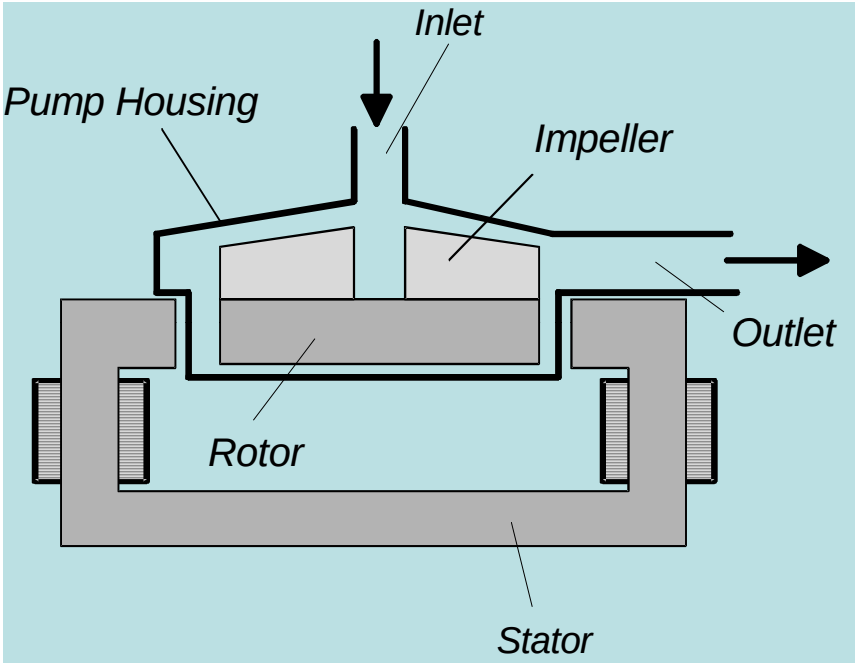
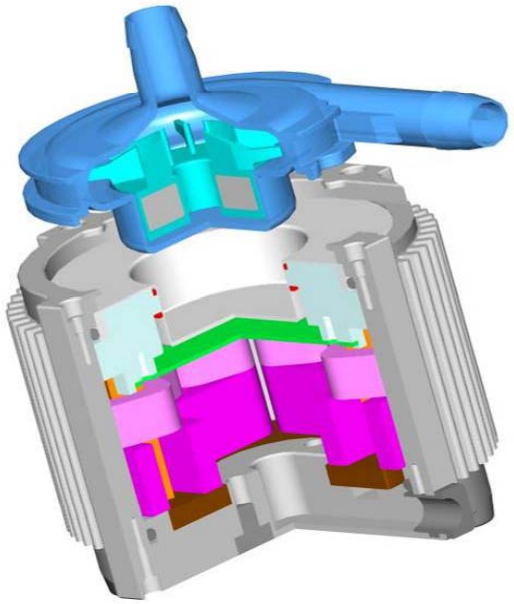
Bearingless Pump & Motor





- Active control of position and speed
- No bearing and seals
- Disposable pump head
- 31 cc priming volume
- 3/8 inch barbed inlet and outlet ports

- Max. pump speed: 5500 RPM
- Max. flow: 9.9 LM
- Medical grade polycarbonate
- Rotor has magnetic core

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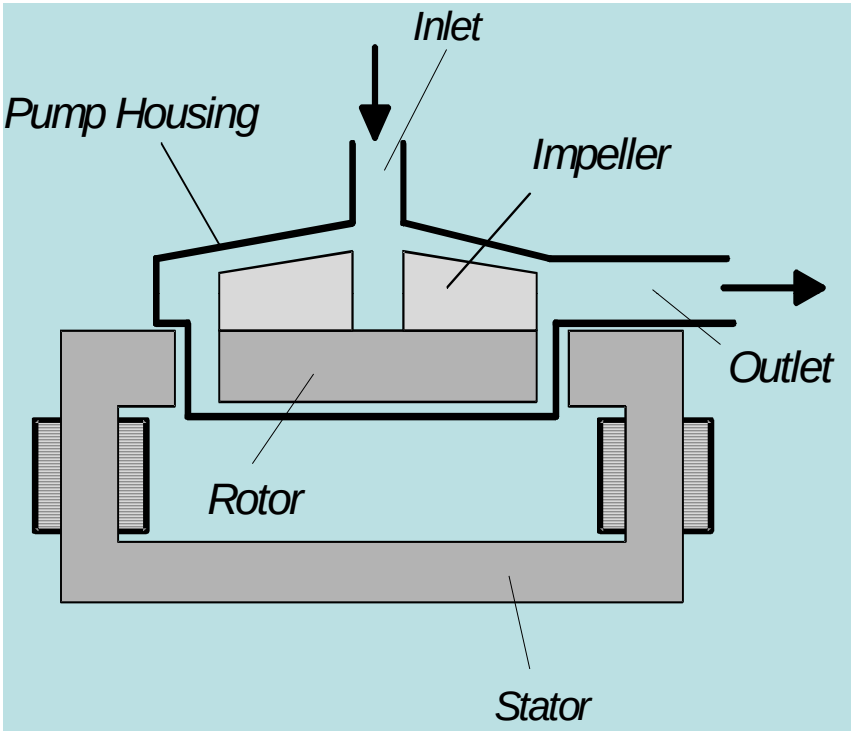
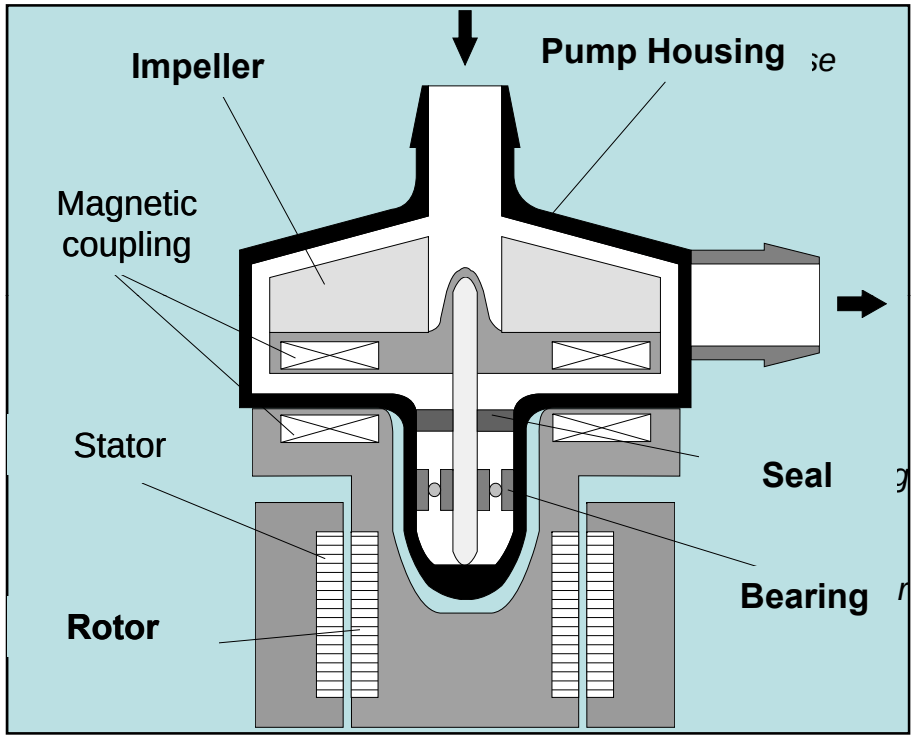
Magnetically Levitated Pump versus Magnetically Driven Pump





Magnetically levitated pumps

a) avoid seals

b) avoid bearings

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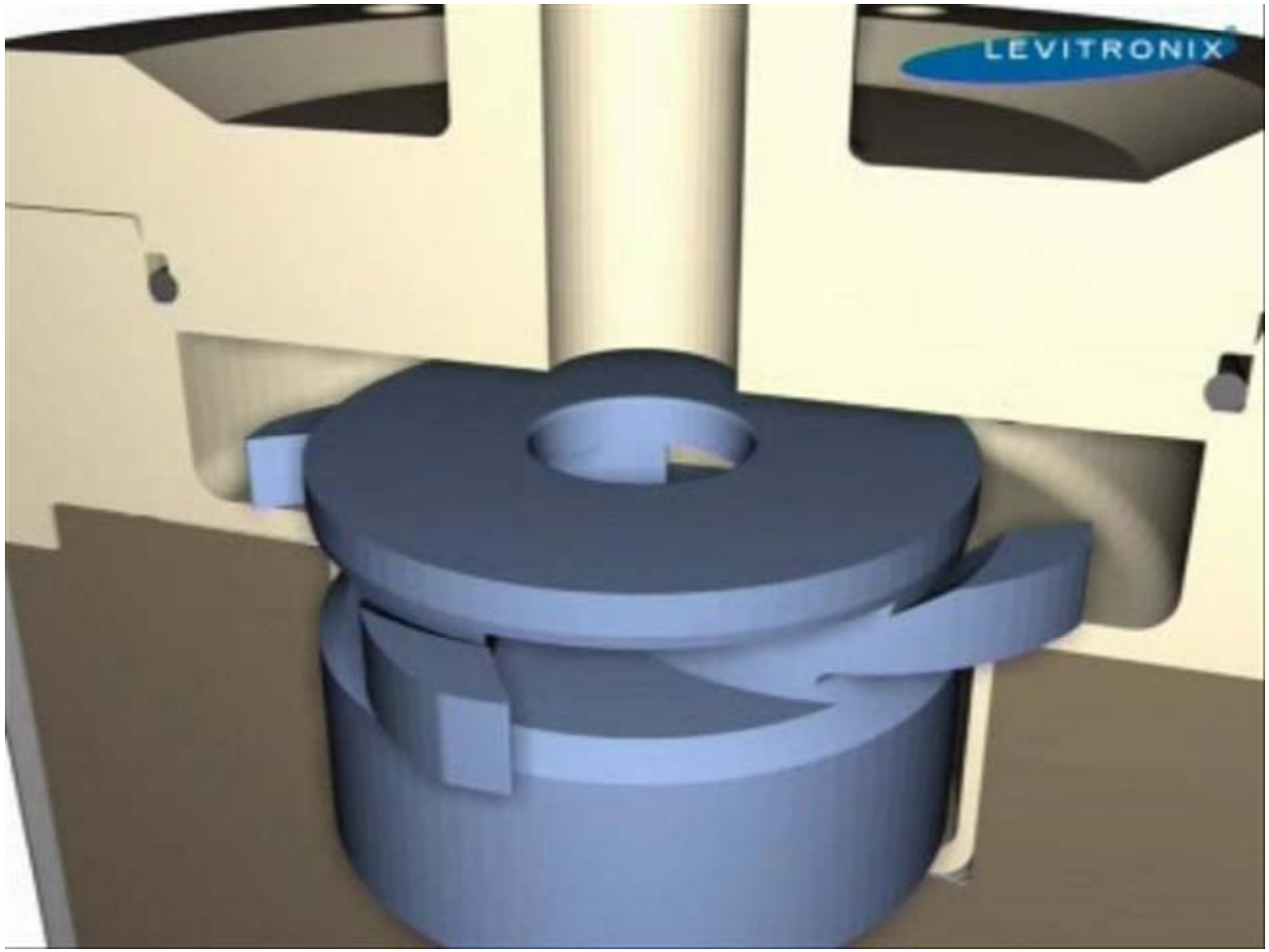
Flow Dynamics in a Magnetically Levitated Pump



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CentriMag Support

Primary Console in use and second Console as back up system

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Thoratec CentriMag® Extracorporeal Blood Pumping System

INDICATIONS FOR USE

- **Indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours).**

- **Also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass**

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Components & Operation

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Primary and Back-Up Consoles

Univentricular Support Configuration on Cart or Stand

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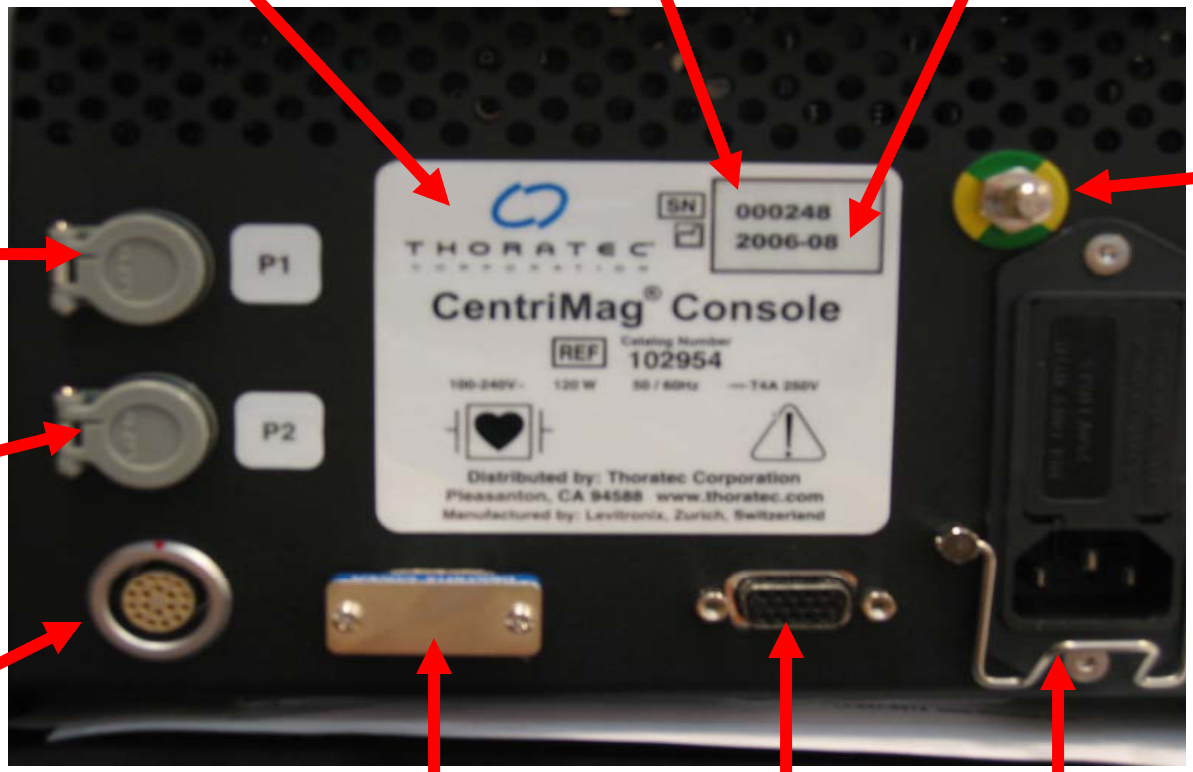
Primary Console Back Panel



Thoratec CentriMag Console Label

Console Serial Number

Date of Manufacture

P1 Pressure Connector

P2 Pressure Connector

Motor Connector

Equipotential Bonding Post

RS-232 Connector (Thoratec Use Only

Flow Probe Connector

AC Power Connector

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Flow Probe

- Reusable, non-patient contacting ultrasonic Flow Probe
- Can detect flows from 0-9.9 LPM
- Can detect retrograde flow of >40 cc/min which is displayed as dashes "----" instead of LPM on the console
- A disconnected or malfunctioning probe will display blank spaces " " instead of LPM on the console
- Compatible with 3/8" ID by 3/32" wall tubing
- Molded clip-on design
- Not necessary to calibrate or zero the probe

Primary Console Control Panel

ROW 1

ROW 2

ROW 3

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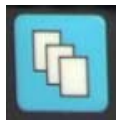
Primary Control Panel

Alarm Acknowledge - Depressing will silence audio alarm. Message remains displayed. Alarm messages will be displayed in order of priority.



Menu – Allows user to select system settings to view or modify – MINIMUM FLOW ALERT, MAXIMUM FLOW ALERT, FLOW LIMIT SENSITIVITY, PRESSURE DISPLAY, SELECT PRESSUE CALIBRATION, SPEED STEP RESOLUTION, LANGUAGE.

Set Pump RPM – When 'SET RPM' is displayed depress for speed adjustment. If 'EXIT' is displayed depress to store value. RPM will remain at set rate.

Decrease - Allows user to decrease selected parameter.

Increase - Allows user to increase selected parameter.

Emergency Stop – Depressing for 2 seconds will cause the pump to STOP.

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Alerts and Alarms

No.	Alarm/ Alert	Description	System Response	Operator Response
1	Alarm	POWER ON TEST FAIL	Blood Pump will not start	Attempt Console re-boot; switch to Back-Up Console if error repeats.
2	Alarm	SYSTEM FAULT (Run-Time System Failure)	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor.
3	Alarm	BATTERY BELOW MINIMUM	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor. Recharge primary Console.
4	Alarm	MOTOR DRIVE FAIL	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor.
5	Alarm	MOTOR FAIL	Console stops Blood Pump	Switch to Back-Up Console and back-up Motor.
6	Alarm	MOTOR DISCONNECTED	No Blood Pump operation	Reconnect Motor and re-start. Switch to Back-Up Console and back-up Motor if alarm repeats.
7	Alarm	PUMP NOT INSERTED	No Blood Pump operation	Reconnect Blood Pump to Motor and re-start. Switch to Back-Up Console and back-up Motor if alarm repeats.
8	Alert	SET PUMP SPEED NOT REACHED	Pumping operation continues	Reduce Pump speed.
9	Alert	FLOW PROBE DISCONNECTED	Pumping operation continues	Manually connect the flow probe. Switch to back-up flow probe if alert repeats.
10	Alert	SELF TEST FAIL (Run-Time Diagnostics)	Pumping operation continues	Switch to Back-Up Console and back-up Motor.
11	Alert	FLOW SIGNAL FAIL (Flow rate sensor error)	Pumping operation continues	Switch to back-up flow probe.
12	Alert	FLOW BELOW MINIMUM (Low Flow)	Pumping operation continues	Check for physiologic cause or circuit obstruction. Check minimum flow set point. Do not increase RPM without confirming adequate blood volume. *See Warning Below.
13	Alert	FLOW ABOVE MAXIMUM	Pumping operation continues	Reduce Pump speed and check for cause.
14	Alert	MOTOR OVER TEMP	Pumping operation continues	Switch to Back-Up Console and back-up Motor.
15	Alert	BATTERY CHARGE FAIL	Pumping operation continues	Switch to Back-Up Console and back-up Motor. Return Console to Levitronix for service or repair.
16	Alert	BATTERY MAINTENANCE REQUIRED	Pumping operation continues	Console does not need to be changed out. Perform Battery Maintenance as detailed in Table 11 after support has been discontinued.
17	Alert	LOW BATTERY	Pumping operation continues	Plug into AC outlet to charge battery.
18	Alert	ON BATTERY	Pumping operation continues	Verify user wants to be on battery. If not, switch to AC power.

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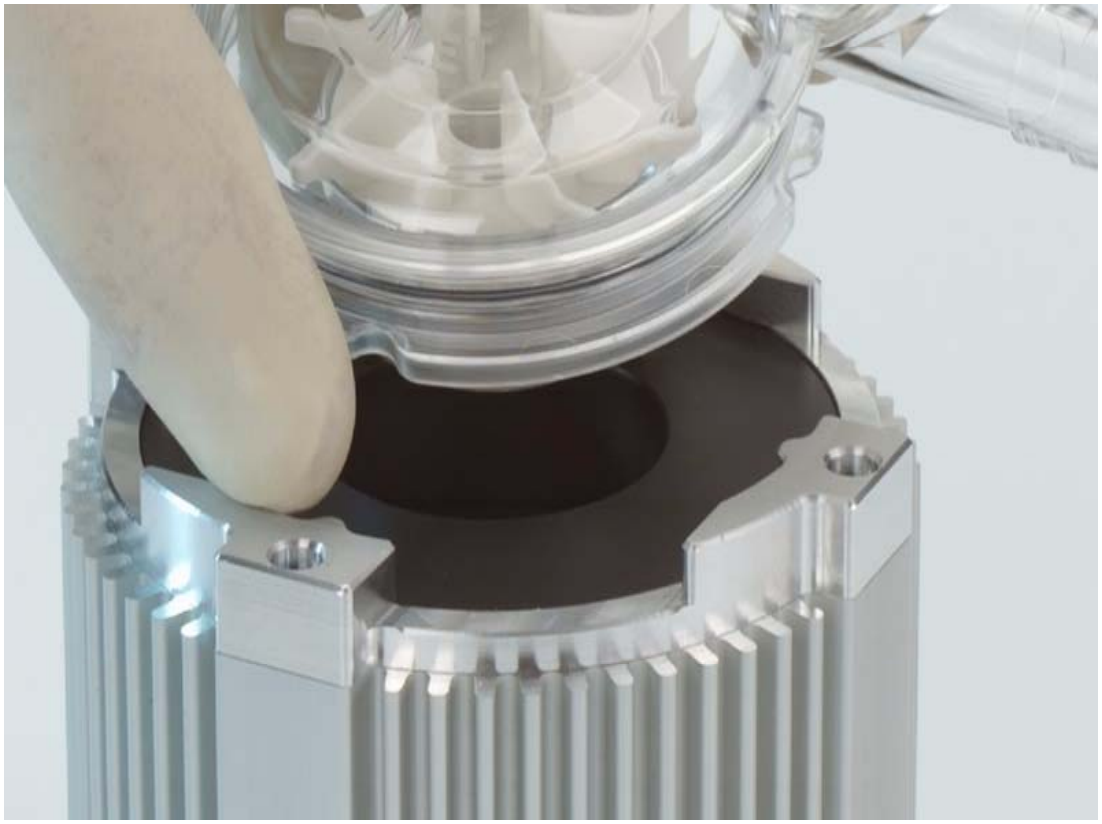
Inserting the Blood Pump

Once the pump is primed and ready to use insert the pump into the motor



Match the grooves on the Pump with those on the motor.
Rotate counterclockwise until the Pump locks into place.
Thread the retaining screw clockwise to secure in place.

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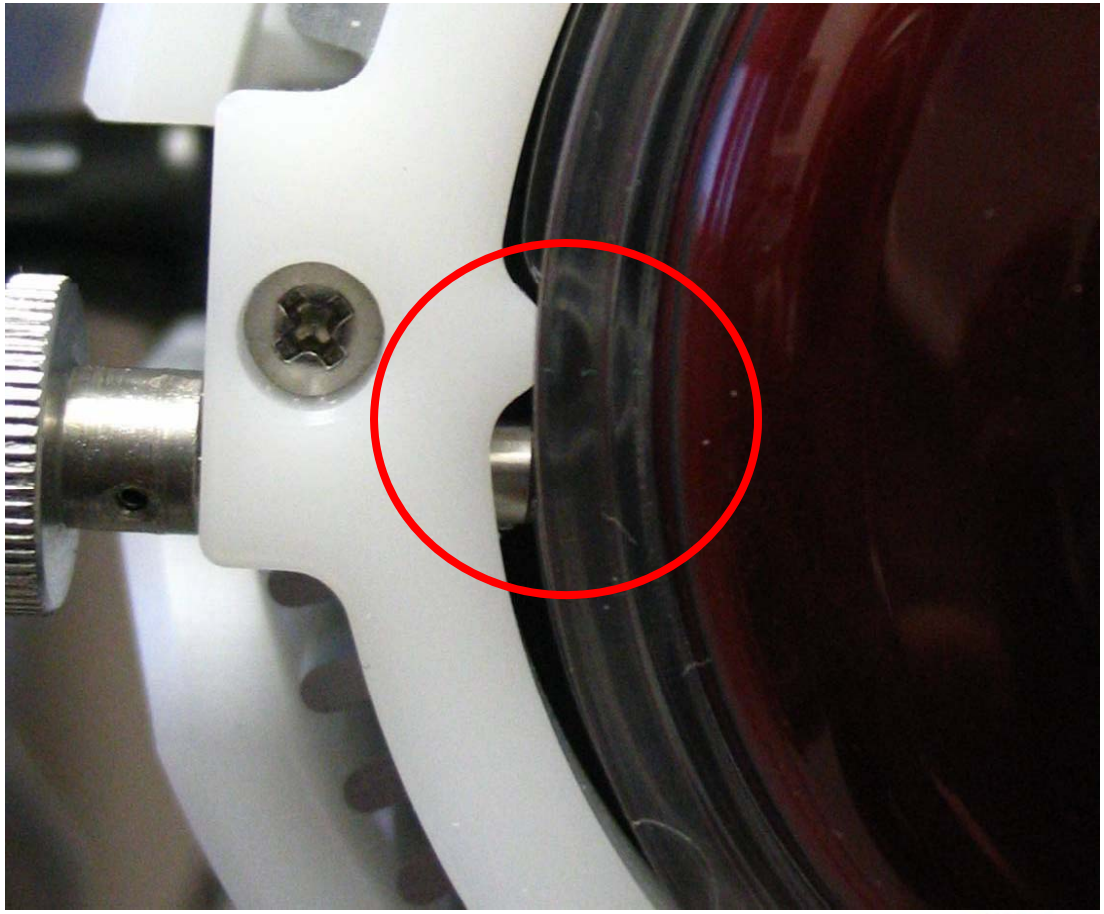
Incorrectly Mounted Blood Pump

Problem: Pump was <u>not</u> rotated counter-clockwise and the retaining screw was advanced into the side of the pump.

The screw should have been advanced into one of the four notches on the pump.



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Console Set Up

- **Ensure Console is connected to AC power. (Console should be stored with AC power attached)**
- **Turn on power to console (switch on side panel)**
- **Check Power Status – verify green AC power on indicator is illuminated**
- **Connect Motor drive and Flow probe to back of console**

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Console Power Up Self Tests

- **When Power is turned ON the Self-Test procedure will initiate automatically**
- **If 'POWER ON TEST FAIL' is displayed – Immediately turn OFF the console and then turn back on. If the console does not pass the second self test REPLACE CONSOLE.**
- **When all Self-tests are completed successfully the INITIALIZATION COMPLETE message will appear. MENU and SET RPM are displayed – indicating the console is ready for use.**

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Console Start Up

- Ensure that circuit is primed & de-aired, and that Heart is full prior to initiating support
- Connect Flow Probe to Blood Pump Outlet tubing - ensure arrow is aligned in direction of flow.
- Start the blood pump by depressing the SET RPM keypad. Remove clamp when RPM above 1000. Observe circuit to insure forward flow.
- Depress the INCREASE arrow until the flow rate is at the required level.
- The flow is adjusted by depressing the SET RPM keypad and then using the INC/DEC arrows to increase or decrease flow.

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Back Up Console

- **To provide temporary basic life-support during a Primary Console malfunction**
  - The Primary Console should be replaced with another Primary Console when available
  - The Back-Up Console does not have flow and pressure sensing capability

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Back Up Console

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Back Up Console
Front Panel Symbols

	**Alarm Acknowledge**	**The user is aware of an alarm or alert. Will silence the audio for a fixed period.**
	**Set Pump Speed**	**Allows for adjustment of blood pump speed.**
	**Decrease**	**Decreases the pump speed.**
	**Increase**	**Increases the pump speed.**
	**Emergency Pump Stop**	**Depress for 2 seconds to stop pump.**

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Back-up Console Battery Module

Chemistry	Alkaline Manganese
Voltage	31.5 Volts
Available time	2 hours at 5500 RPM, 3 LPM
Dimensions	Ht: 8 cm , Width: 17 cm , Depth: 16 cm
Operating temp	-20°C to 54°C or -4°F to 130°F
Storage temp	-30°C to 35°C or -22°F to 95°F
Shelf life	24 months
Rechargeable	No, Non-rechargeable
Disposal	Return to Thoratec or dispose in compliance with local laws

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Estimated Battery Time Available

If operating on AC power – Estimate based on use at 5.5 LPM, 3500 RPM or the last condition while the system was operational on battery power.

If operating on Battery power – Estimate based on actual battery usage. Will vary with pump speed and changes in blood pressure and flow.

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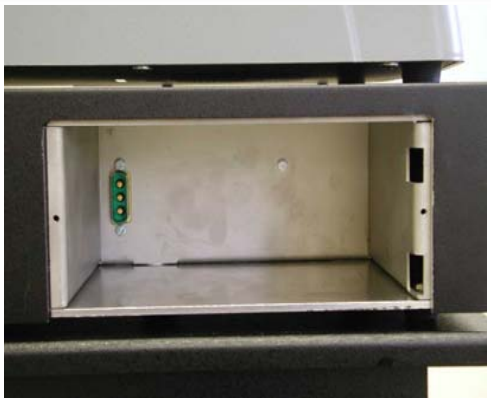
Inserting Battery Module



Insert one of the Battery Modules into the Battery Module compartment.

Secure the Module by tightening the two retaining screws clockwise.

Verify the Battery Module is fully seated by attempting to pull the module outward.

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Back-Up Console Battery

WARNING

The Back-Up Console battery is not rechargeable, and will deplete its charge if the Back-Up Console is not operated with AC power. Always check the remaining battery time available upon powering-up the Back-Up Console.

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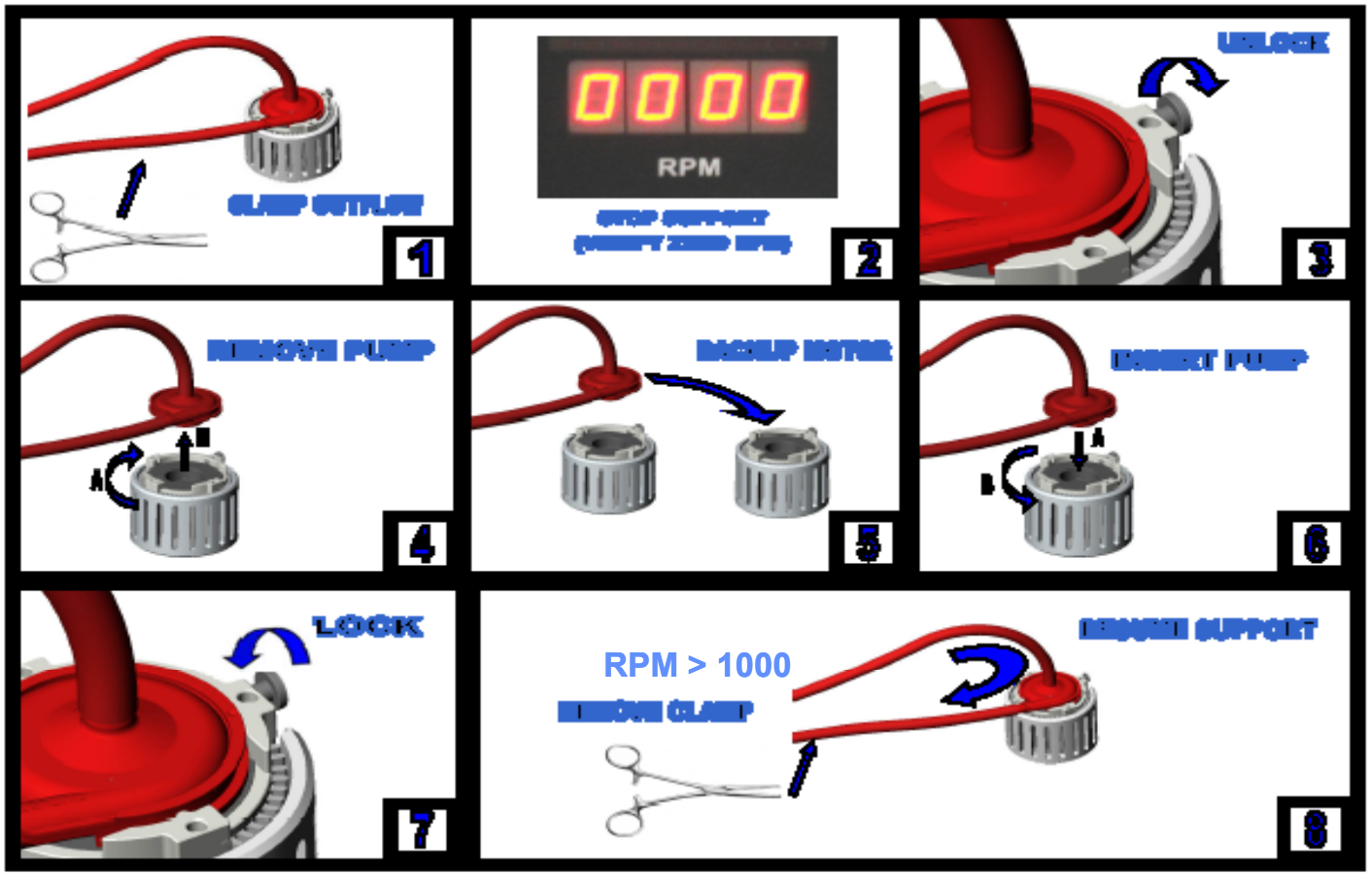
EMERGENCY SWITCH TO BACKUP SYSTEM



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Circuit Preparation & Surgical Implantation

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Equipment for OR Set Up

- **Primary Console with Motor**
- **Back-up Console with Motor**
- **Flow Probe**
- **2 Complete systems (equipment and disposables) and 2 tubing clamp should always be available and in the direct vicinity of the patient during support.**
- **The spare console should be plugged in to maintain battery charge and powered ON ready for use**

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O.R. Supplies - Single Pump Implant

- (1) Blood pump plus (1) spare
- (2) Tubing, 3/8 in ID x 3/32 in wall, 4 foot length
- (1) Inlet cannula
- (1) Outlet cannulae
- (2) Connectors, 3/8 in straight
- Sterile tubing clamps and scissors
- Heparin (10,000 u/L soln) and normal saline or pump prime
- Bulb syringe
- Pledgets and sutures for atria or ventricle.
- Possible 8mm preclotted Dacron graft for return cannulation

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Recommended Cannulae

Trans Thoracic Cannulae	Venous Cannulae	Edwards TFM032L	Single stage malleable venous cannula, 32 Fr. (10.7mm), 40 cm (16”)
		Edwards TFM036L	Single stage malleable venous cannula, 36 Fr. (12mm), 40 cm (16”)
	Arterial Cannulae	Medtronic EOPA 77522	EOPA Arterial cannula, blunt tip introducer without guidewire, 22 Fr, 30.5cm
		Meditronic EOPA 77722	Same as 77522 but with dilator tip introducer and guidewire

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Cannulae Selection

- IDE VAD Kit cannulae are good cannulae
- Both cannulae in kit are wire reinforced
- Single stage lighthouse tip inflow cannula
- Low resistance, versatile outflow cannula
- Malleable inflow cannulae is desirable
- Inflow circuit resistance should be much less than outflow circuit resistance

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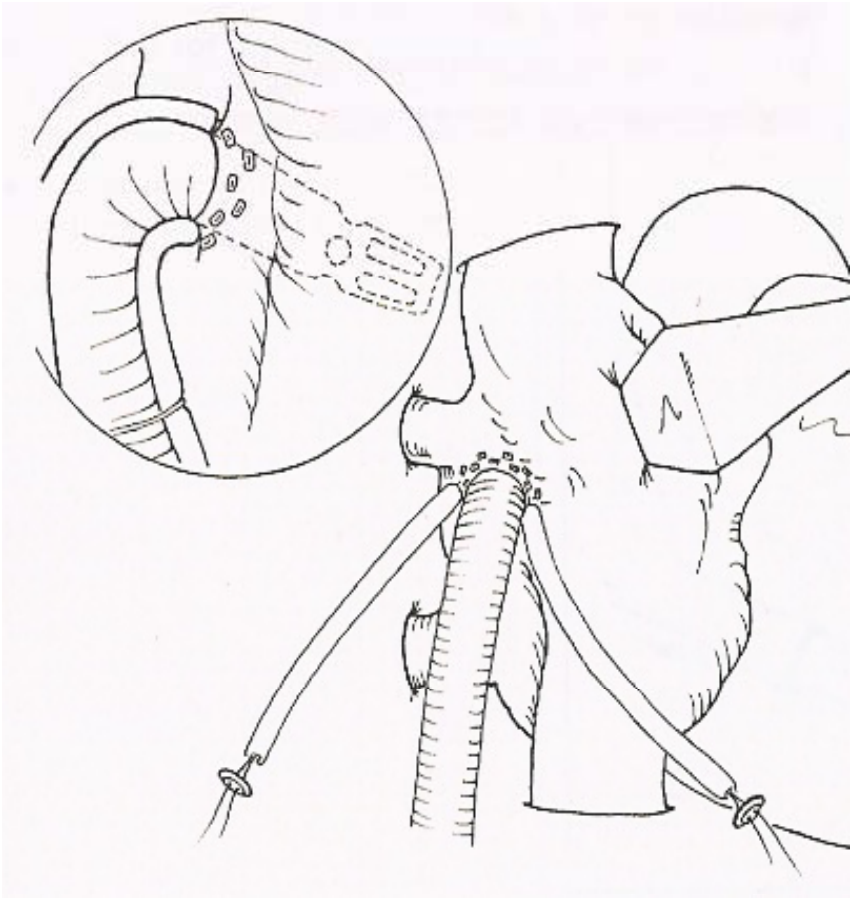
Left Atrial Cannulation



- Cannulate wall of Left Atrium
- Cannulate between RSPV & RIPV
- Use two buttressed concentric purse-string sutures

Adapted from Richenbacher W: Mechanical Circulatory Support, 1999

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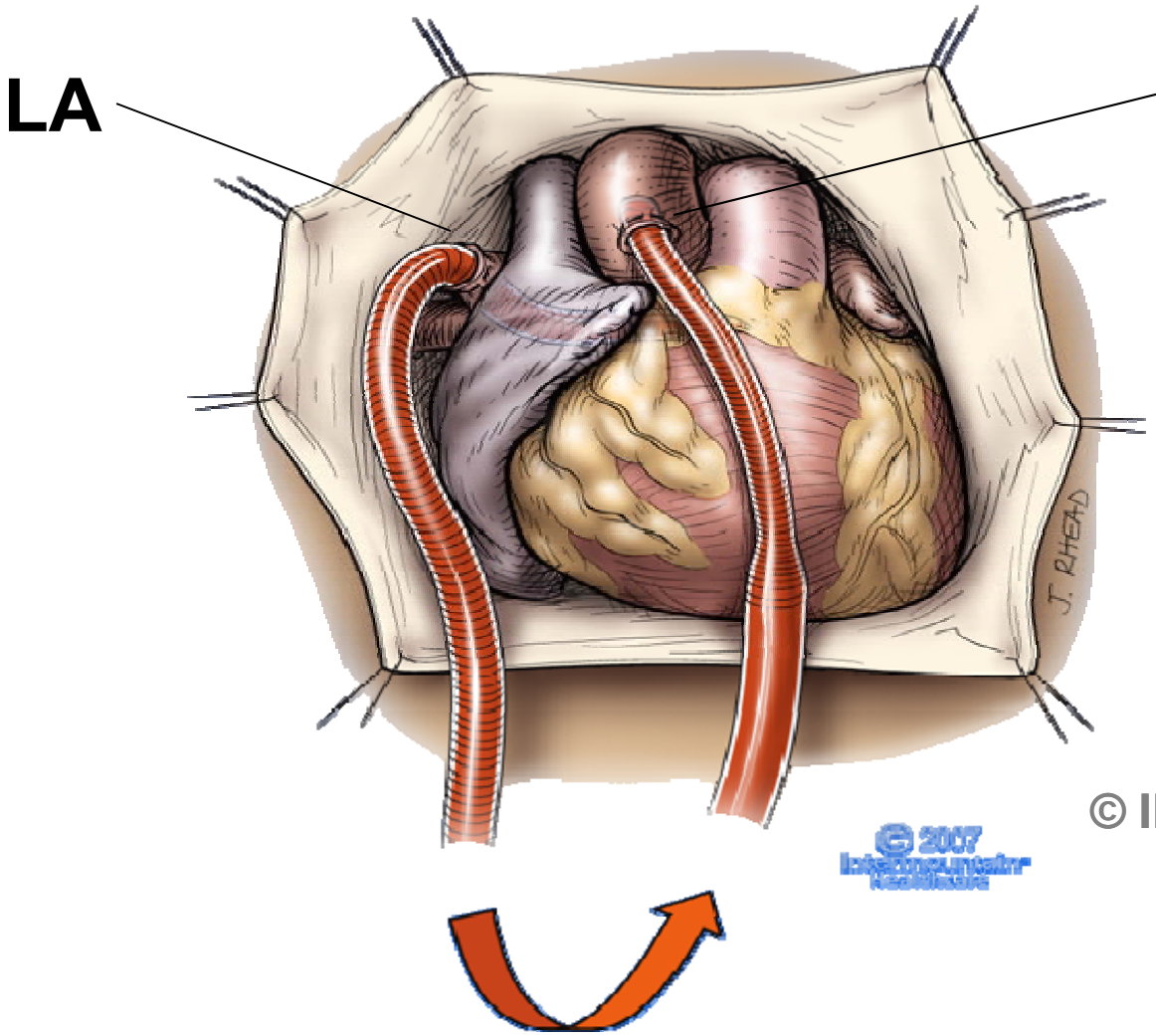
Left Heart Cannulation



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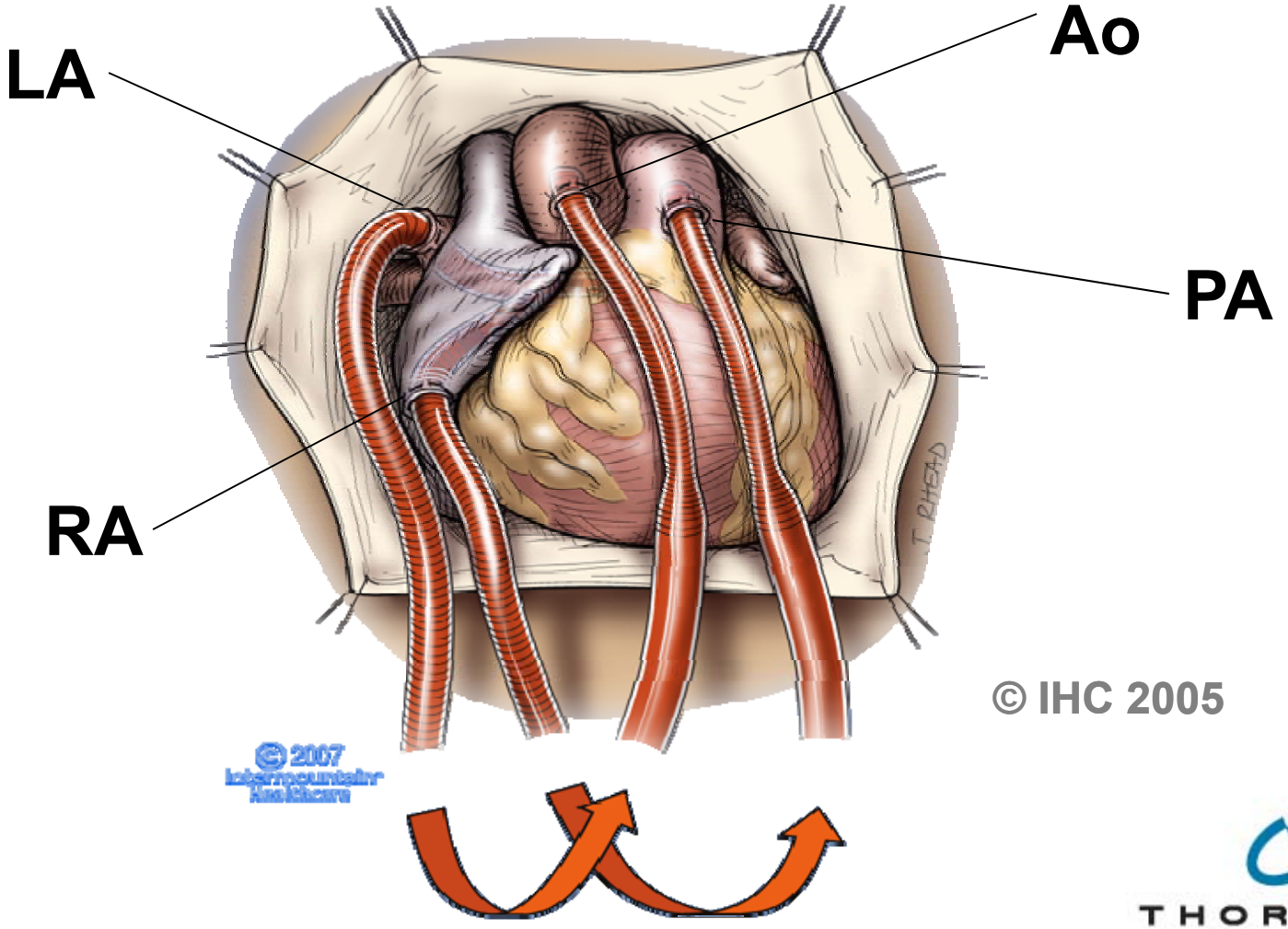
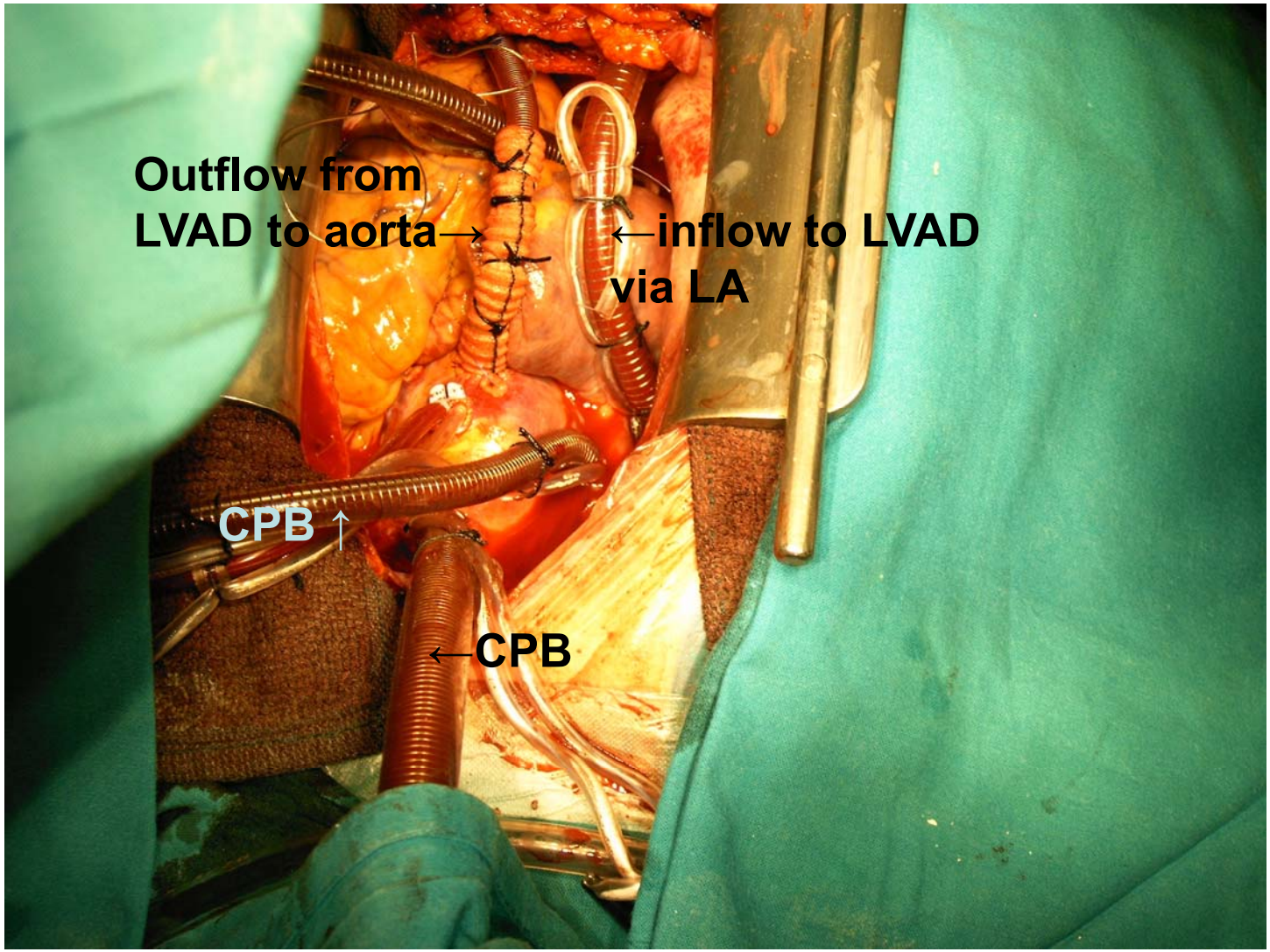
Bilateral Support



Surgical Cannulation



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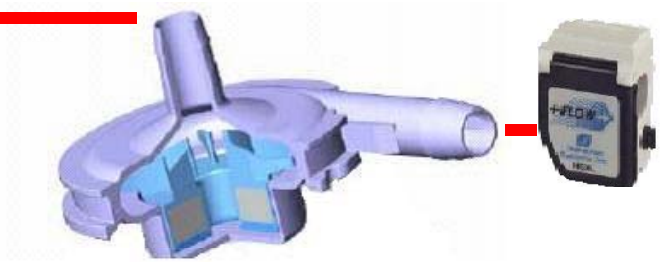
Pump Circuit

Drainage (Inflow) cannula

Flow Probe



Return (Outflow) Cannula

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Circuit Priming

Circuit Priming

What works for your hospital?

On the field or off the field?

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Priming & Deairing

- Two recommended techniques
  - Closed Bag System for Centrifugal Pump
    - Pre-assembled circuit (Medtronic)
    - Ability to recirculate
  - Submersion technique
    - Unassembled tubing
    - Must assemble within sterile field

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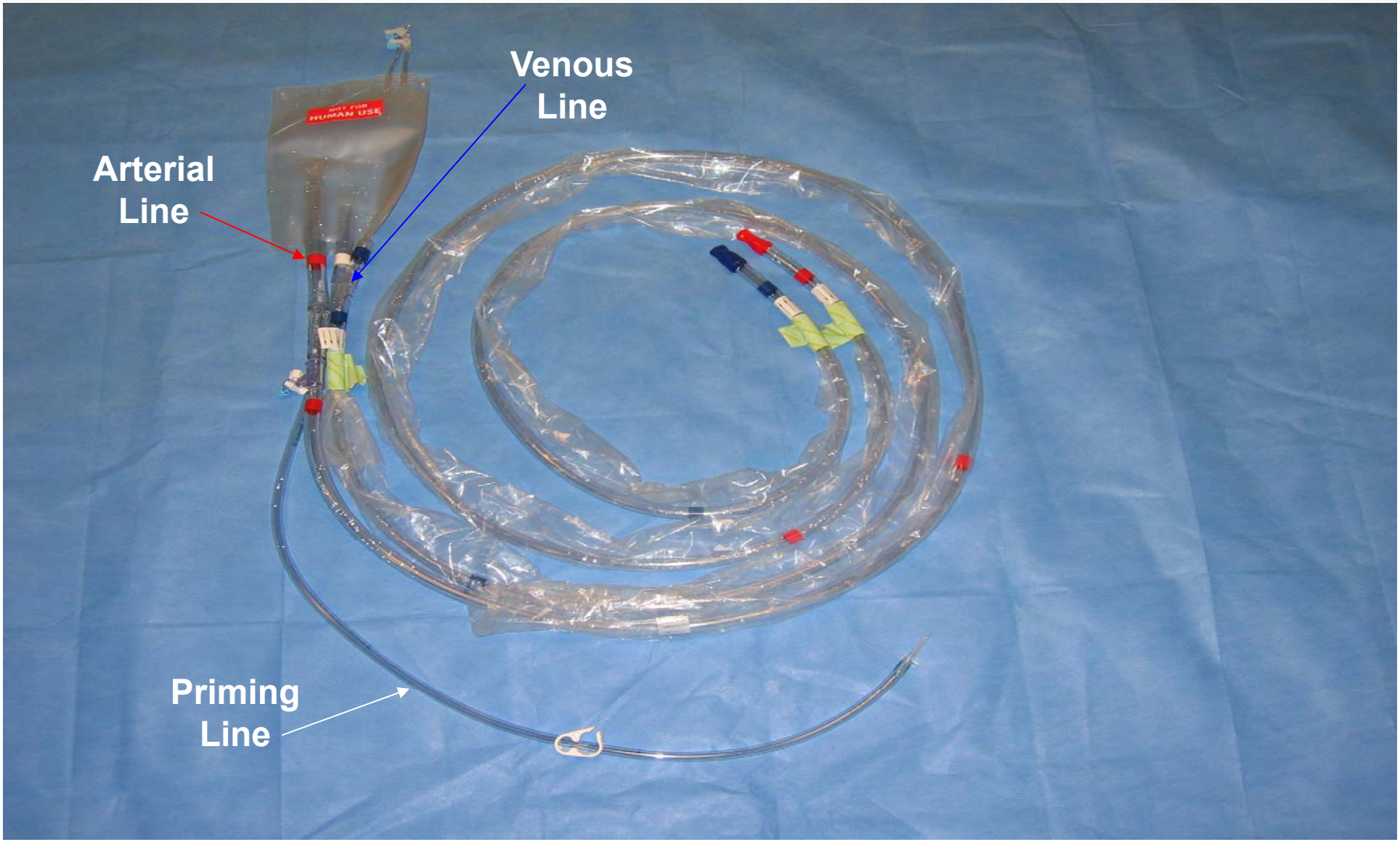
Priming Pack for Closed Bag System



“Submersion” Helpful Hints

Sterile technique must be observed

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“Submersion” Helpful Hints

Sterile technique must be observed

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Circuit De-Airing Suggestions

- Prime with warm NS, not blood
- Recirculate the prime solution, if possible
- Do not use connectors with Leur ports
- Do not hit or strike blood pump to de-air
- Use large bubble in pump to collect small
- Slowly add fluid while making final connection
- Alternatively, gently squeeze tubing to eject air while making final connection

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Anesthesia Considerations

- **Heart failure patient versus a simple failure to wean from cardiopulmonary bypass**
- **Pharmacologic Considerations – ACE inhibitors and amiodarone, impaired renal or hepatic function**
- **Preop Assessment – assess degree of organ failure**
- **Lining and induction – large bore IV and radial arterial line before induction and after induction TEE, Swan-Ganz and maybe a second central line for rapid volume infusion**

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Separation from CPB

- First check for PFO, aortic insufficiency and left ventricle decompression with TEE

- Inotropes and afterload reduction for right heart

- Prevent air entrainment

  - Balance coming off CPB with going on CentriMag. Keep atria or ventricle full enough to not pull air through suture lines.

  - Avoid air in venous & arterial lines

- Insure adequate blood products

- If surgeon manipulates heart to stop bleeders – COMMUNICATE. Perfusion should slow or stop CentriMag

- Completely reverse Heparin

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Transesophageal Echo

- Pre-bypass – Aortic valve and PFO
- During bypass – Assess inflow cannula placement.
- Initiation of support – Assess volume status & detect air.
- Post-bypass – monitors right ventricular function and left heart decompression. Septum in neutral position.
- Warning - Left atrial or ventricular collapse with resulting inlet cannula occlusion can lead to air entrainment and stop the pump.

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O.R. Potential Complications

- **Right ventricular dysfunction**
- **Low flow/ Inflow obstruction**
- **Air entrainment / embolism**

} Often Related

- **Increased pulmonary vascular resistance**
- **Cannulae selection, position and stability**
- **PFO and systemic desaturation**
- **Bleeding (cannulation & other sites)**
- **Similar to other devices**

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Prevention of Air Entrainment

When *initiating* support:

- **Partially inflate lungs prior to separation from CPB**
- **Place patient in Trendelenburg position**
- **Monitor aorta for air with TEE**
- **Fill chest with warm normal saline or CO_2**
- **Increase RPM very slowly**
- **Insure adequate volume in heart chamber when coming off cardiopulmonary bypass**
- **Watch circuit and use clamp to prevent air from entering blood pump**

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Prevention of Air Entrainment

During **Support**

- **Monitor blood volume with TEE &/or Pressures**
- **Maintain atrial pressures 10–15 mm Hg in the O.R.**
- **Under perfuse while the chest is open**
- **Encourage the use of ventricular cannulation**
- **Encourage the use of biventricular support**
- **Reduce RPM for any indication of inadequate volume**
- **Reduce RPM for manipulation of the heart**
- **Reduce RPM for movement of the patient**
- **Monitor tubing for "chatter" & be prepared to respond**
- **As soon as possible set the low flow alarm**
- **Reduce flow when inflating lungs**

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IABP Considerations

- May provide pulsatile perfusion
- Under inflate balloon to reduce pump afterload
- Pull back sheath to improve distal perfusion
- Monitor distal limb perfusion at least hourly
- If balloon is to be removed:
  - In O.R. with Femstop or cutdown repair
  - In ICU after coagulation parameters have normalized

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CPS

- Oxygenator may be added to circuit
- Provides pulmonary support
- Negates need for sternotomy
- Less cardiac unloading

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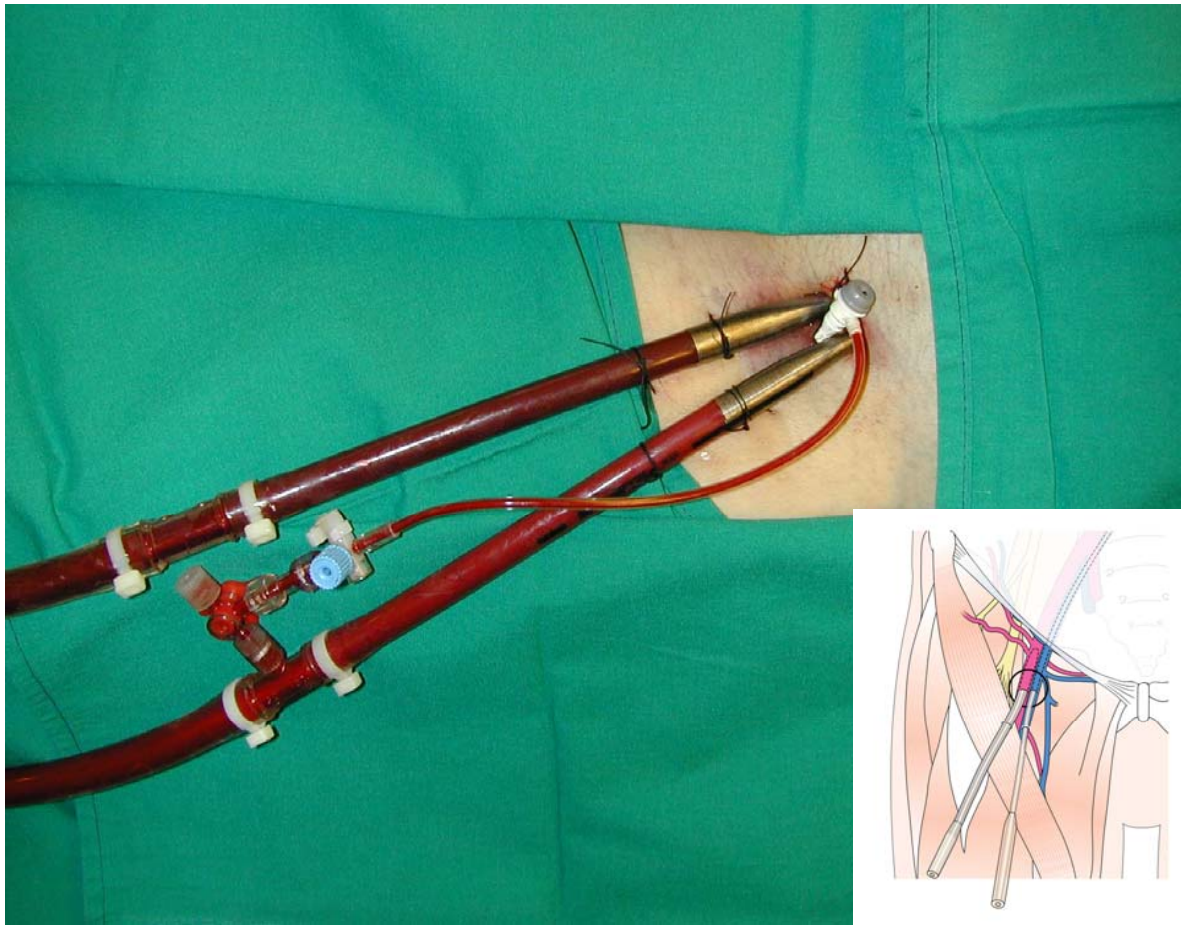
Percutaneous Cannulation

Generally Femoral vein to Femoral artery

In adults 19-21 Fr venous drainage cannula and 19-21 Fr arterial return cannula

5Fr distal arterial cannula



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Recommended Percutaneous Cannulae

- **Venous (Inflow) Cannulae**
  - BioMedicus 96670-019
  - BioMedicus 96670-021
- **Arterial (Outflow) Cannulae**
  - BioMedicus 96570-019
  - BioMedicus 96570-021

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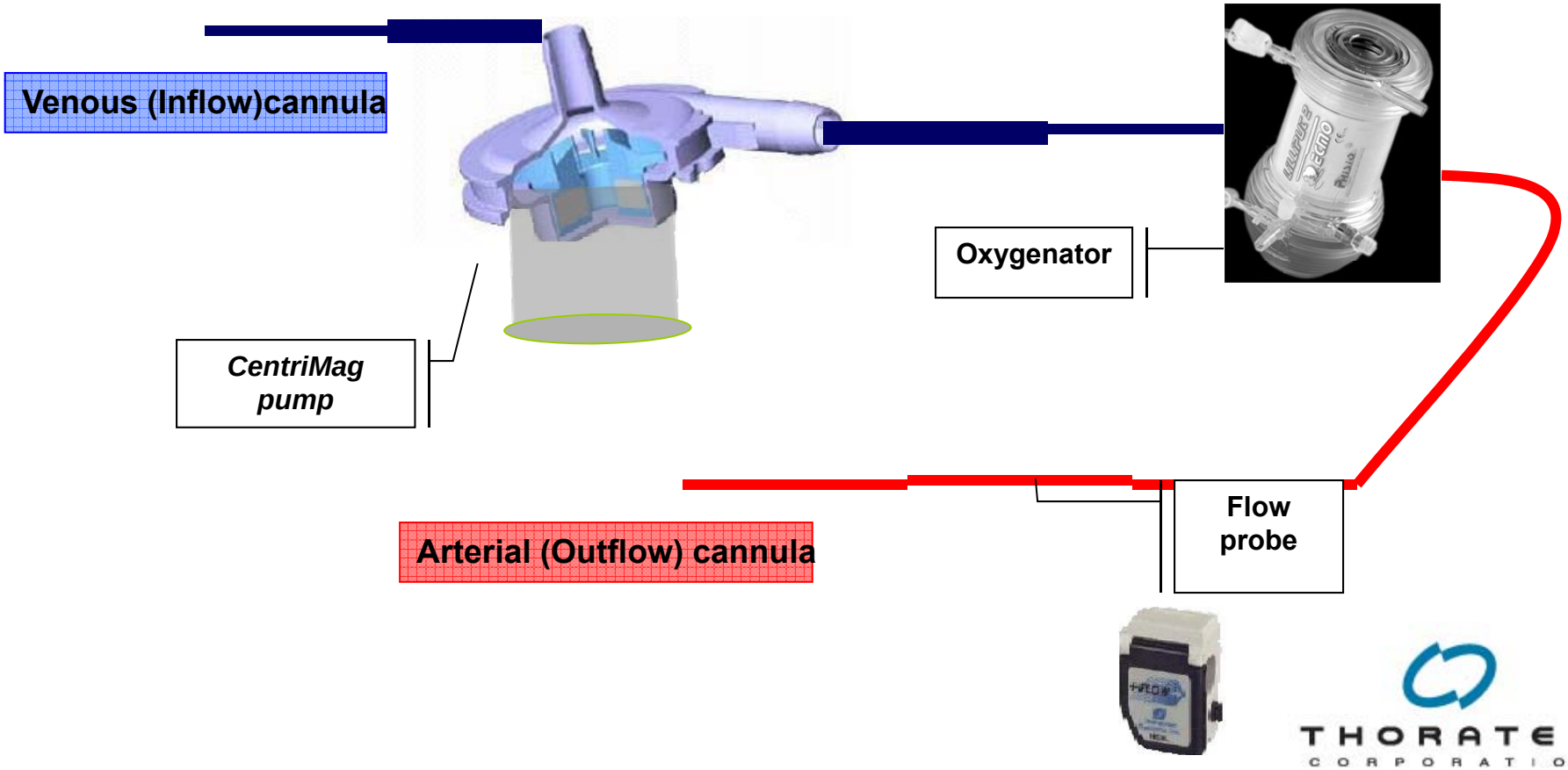
Circuit w/ Oxygenator



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Patient Transport

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Patient Movement & Transport

- Risk of decannulation is greater during transport of the patient
- Continuously monitor patient's hemodynamics and pump flows
- Assign one individual to monitor consoles and blood pumps
- Place blood pump and motor on the bed between the patients legs
- Insure pumps are not covered
- Backup console and clamps must always be with the patient
- The Primary Console has approximately 1 hr of battery power and a Back Up Console has 2 hrs of battery power

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CentriMag® Transport Capabilities

- Air or ground transport
- Left, right, or biventricular
- May include oxygenator
- Pediatric or adult capability
- Three hour total battery capacity
- Transport to CentriMag Hub

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Transport General Concepts

- Identify receiving center in advance (hub)
- Three protocols (spoke, transport, hub)
- Preposition equipment and supplies
- Train and conduct dress rehearsals
- Adapt current transport protocols

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To Include in Transport Protocol

- Equipment and supplies needed
- Individuals and responsibilities
- Primary and backup power sources
- Response to most likely complications
- Securing of equipment during transport

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Transport Tips

- Assign one individual to monitor system
- Decannulation can occur during transport
- Monitor pressures & flow continuously
- Place blood pumps and motors on the bed between the patient's legs if intra-hospital
- Blood pumps secured to stretcher for inter-hospital transport.
- Back-Up Console and clamps must be available
- Primary Console has approximately 1 hr power

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In the air / On the road

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Perioperative Management

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Routine Patient Care

- **Routine patient care for patients on the CentriMag® Blood Pump is similar to that for patients on other type of extracorporeal support.**

- **Many patients are fully sedated and on ventilatory support.**

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Management Points

- CentriMag system has no auto-control
- Adjustments in flow must be gradual
- Avoid conditions that result in line “chatter”
- Avoid flexing of tubing near the connectors
- Balance left & right filling pressures not flows
- Forces are easily transmitted through tubing

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Anticoagulation Guidelines* (If no CPB)

- **Full anticoagulation (ACT ~ 300) is essential prior to cannulae insertion**
- **Maintain heparin infusion if CT drainage < 50 ml/hr**
- **When pump flow is sufficient, target ACT 160 – 180 (PTT 1.5-1.8 times normal)**
- ***Anticoagulation needs vary per patient**

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Anticoagulation Guidelines* (with CPB)

- Achieve optimal CentriMag flow then reverse heparin
- Start heparin infusion when CT < 50 ml/hr for 2-3 hours
- Target ACT 160 - 180
- Target PTT 1.5-1.8 times normal
- *Anticoagulation needs vary per patient

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Fluid Balance

- **It is essential for safe device operation that the LV (or LA if atrial cannulation) is supplied with sufficient volume.**
- **Adequate fluid balance should be checked by monitoring CVP, LA pressure or wedge pressure if available, and careful monitoring of fluid input/output balance**
- **An increase in RPM should always cause an increase in flow – if this does not occur reduce RPM until changes in flow do occur. Leave set approx. 1 LPM lower.**

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Patient Management

- Bleeding
- Perioperative nutrition
- Tamponade
- Arrhythmias
- Variable volume
- Variable device flow
- Pulmonary dysfunction
- Right ventricular failure

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Defibrillation / Cardioversion

- **CentriMag does not need to be stopped.**
- **If CentriMag used as right heart support with long term LVAD, consult LVAD instructions for use.**

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Normal Operating Conditions

- **Pump Speed : 3000 – 4000 RPM**
- **Pump Flow(s): 4 – 5 LPM**
- **RAP / LAP: 10 – 15 mm Hg**
- **Target ACT 160 - 180**

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Perioperative Complications

- **Most common**
  - Low flow
- **Rare but has occurred**
  - High RPM
  - Hemolysis
  - Incorrect pump mount
  - Console or Motor failure
  - Thrombus in atria or ventricle

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Response to Complications

- **Low flow – ↓ RPM, Identify cause.**
- **Thrombus on connectors – Precautions to avoid tubing flex or abrupt flow changes.**
- **High RPM -↓ RPM, Identify cause.**
- **Hemolysis -↓ RPM, Identify cause.**
- **Incorrect mount – Correctly mount.**
- **Console or Motor failure – To Backup.**
- **Thrombus in atria or ventricle – Assess stability, Avoid conditions that will dislodge, ↑ Anticoagulation.**

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Frequent System Checks

- **Activated Clotting Time (ACT) within target range?**
- **Line chattering or shaking?**
- **Record pump flow and RPM with vital signs**

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Periodic System Checks

- Move flow probe ~1 cm
- Tubing secured to patient?
- Tubing bends wide and smooth?
- On AC power and battery fully charged?
- Air circulation around motor & console?
- Two tubing clamps near each blood pump?
- Backup console ready with battery life > 60 min?
- Low flow alarm set 1.0 LPM less than target?
- Review “Emergency Switch to Backup” ref. card
- Practice pump “Switch” with the backup console

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Review Questions

1. Expected battery life for each console?
2. Action to take for low flow or line shaking?
3. Target CVP? Must L. and R. flow be equal?
4. At what value should the flow alarm be set?
5. Indicator that the pump is mounted correctly?
6. Backup items required with patient at all times?

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