

iVAC 2L PROCEDURAL STEPS

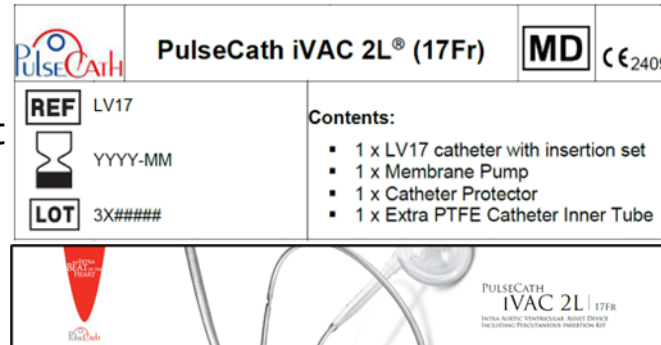


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Materials required

PulseCath iVAC 2L box:

- iVAC 2L catheter with insertion set
- Membrane pump
- Catheter protector
- Extra PTFE Catheter Inner Tube



Accessories Kit:

- 18Fr Introducer sheath
- 50cc Syringe
- 16cm Metal clamp



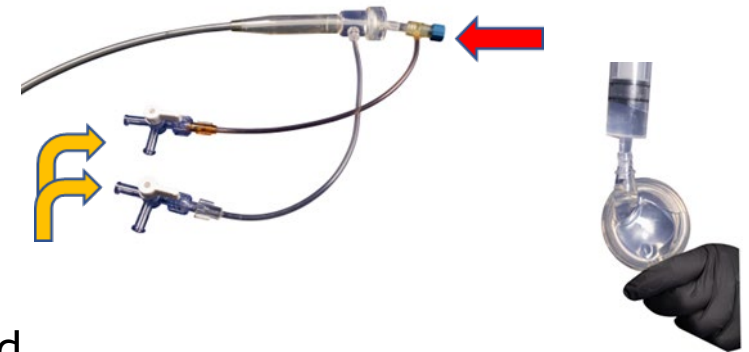
Other items* – provided by hospital

- IABP console* (When using Arrow IABP driver: Arrow Pump adapter for 50cc IABs (Datascope, ref. 0684-00-0501-02) – Orange color. Clinical Specialist to provide)
- 0.035" or 0.038" guidewire, length 260cm (super stiff)*
- Heparinized saline (2500 IU heparin in 500ml saline)*
- Closure device for large bore*

Device preparation

STEP 1

- Preparation of the patient and IABP console.
- IABP console: setup as indicated in the IFU.
 - Turn on the IABP console and open helium gas bottle
- Patient: minimum ACT 200 seconds, femoral artery control, ECG signal and arterial pressure to IABP driver.
 - Oxygen saturation of the leg is monitored as a control on peripheral perfusion
- Replace the inner tube with PTFE inner tube provided.
WARNING: don't damage the bidirectional valve.
- Flush the lines with heparinized saline and make sure all stopcocks are in the OPEN position.
- De-air the membrane pump filling completely with heparinized saline - the flexible membrane must move entirely to the opposite site of the membrane pump.



Insertion

STEP 2

- Prepare the entrance site in the femoral artery according to the hospital standard procedure to manage large bore sheaths.
- Prepare and implant a closure device for large bore access.
- Prepare and insert the 18Fr Introducer sheath following its Instructions for Use.
- Position the guidewire in the left ventricle.
- Insert the iVAC 2L catheter over wire through sheath, de-air the catheter and close the stopcocks.
- Position carefully the iVAC 2L tip 2-3 cm inside the left ventricle.
- When positioning is correct, remove the guidewire.



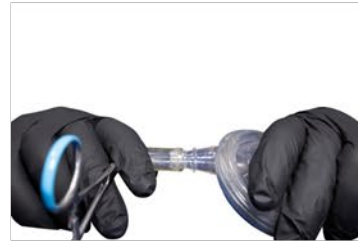
Insertion & Activation

STEP 3

- Pull back the PTFE inner tube until the tip of the tube is in the plug at the proximal end of the iVAC 2L catheter
- Place a tube clamp in the middle of the iVAC 2L catheter connector and disconnect the plug with the iVAC 2L catheter inner tube.
- Never reintroduce the PTFE inner tube when the catheter is inside the body



Insertion & Activation



- Connect the membrane pump to the catheter using a wet-to-wet connection technique. If no air is visible remove the clamp.
- Connect the membrane pump to the IABP driver. If using an Arrow IABP console, connect Arrow Pump adapter for 50 cc IABs to the membrane pump. Connect the Pump adapter to the IABP driver.
- Start pumping @ 1:1 with maximal augmentation, adjust timing (see "operating the IABP driver" in iVAC 2L IFU).

Weaning & Removal

STEP 4

- Weaning is similar to IABP, but do not decrease augmentation (decreases stroke volume and may induce thrombus formation).
- Wean the patient setting support @ 1:2, if tolerated well - STOP pumping.
- Place a tube clamp on the iVAC 2L catheter connector, using a syringe connected to the gas line of the membrane give the blood volume in the membrane pump back to the patient.
- Disconnect the membrane pump.
- Under fluoroscopic guidance slowly remove the iVAC 2L.
- Pull catheter out of the sheath, without any force.
- Cover iVAC 2L valve opening: blood will come out.
- Sheath can be left in patient until the ACT is lower again.
- Remove the 18Fr sheath and close insertion site following its Instructions for Use.
- Close the artery. After hemostasis is obtained close the wound.
- Do NOT use any alcohol containing fluids when disinfecting the device, as this will induce cracks in the membrane pump.

Thank you for listening

