

EXTRA  
BEAT OF THE  
HEART

## iVAC 2L PROCEDURAL STEPS

PULSE CATH





V112022\_001

# Materials required

## PulseCath iVAC 2L box:

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



	<b>PulseCath iVAC 2L® (17Fr)</b>	<b>MD</b>	CE <sub>2409</sub>
<b>REF</b> LV17	<b>Contents:</b> <ul style="list-style-type: none"><li>▪ 1 x LV17 catheter with insertion set</li><li>▪ 1 x Membrane Pump</li><li>▪ 1 x Catheter Protector</li><li>▪ 1 x Extra PTFE Catheter Inner Tube</li></ul>		
 YYYY-MM			
<b>LOT</b> 3X#####			
		<b>PULSECATH</b> <b>iVAC 2L   17FR</b> <small>INTRAAORTIC-VENTRICULAR ASSIST DEVICE INCLUDING PERCUTANEOUS INSERTION KIT</small>	



## Accessories Kit:

- IABP catheter extender
- 18Fr Introducer sheath
- 50cc Syringe
- 16mm Metal clamp



## Other items\* – provided by hospital

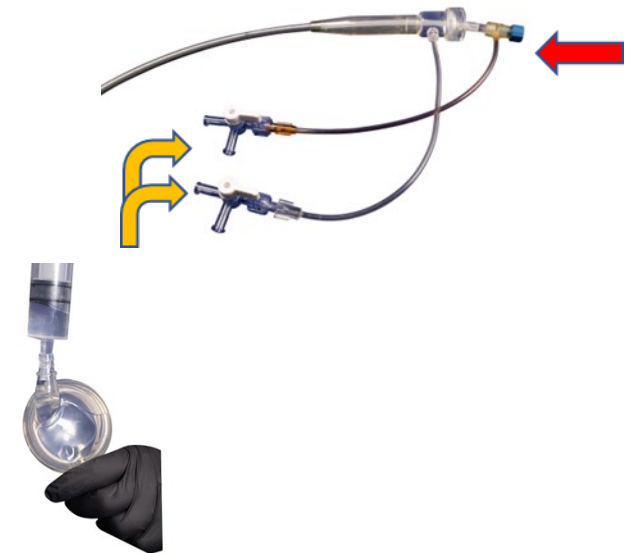
- IABP console\* (When using Arrow IABP driver: Arrow 50cc IAB adapter – Orange color. Clinical Specialist to provide)
- 0.035" or 0.038" guidewire, length 260cm (super stiff)\*
- Heparinized saline (2500 IU heparin in 500ml saline)\*
- Closure device for large bore\*

\* Not supplied

# Device preparation

## STEP 1

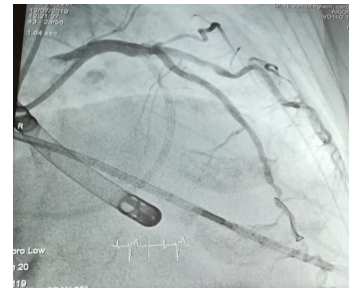
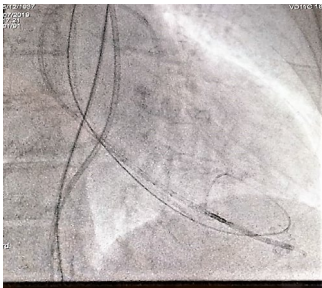
- Preparation of the patient and IABP console IABP console: setup as indicated in the IFU.
  - Turn on the IABP console and open helium gas bottle
- Patient: minimum ACT 200 seconds, femoral artery control, ECG signal and arterial pressure to IABP driver.
  - Oxygen saturation of the leg is monitored 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.
- Using the IABP catheter extender, connect the membrane pump to the IABP driver. If using an Arrow IABP console, replace the male Luer-lock with the Arrow 50cc connector.
- 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.



# iVAC 2L Procedure



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Thank you for Listening

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