



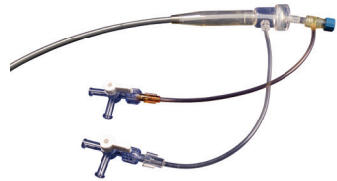
# Overview Procedure IVAC 2L - pVAD

**Percutaneous Ventricular  
Assist Device**



## Step 1

- IABP Console: Setup as indicated in the IFU.
- Patient: Minimum ACT 200 seconds, femoral artery control, ECG signal and arterial pressure to IABP driver.
- Replace the inner tube with PTFE inner tube provided. WARNING: do not 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.



## 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.

## Step 3A

- 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.



### Step 3B

- Connect the membrane pump to the catheter using a wet-to-wet connection technique. If no air is visible remove the clamp.

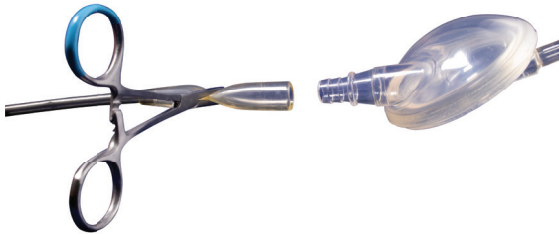


- Connect the membrane pump to the IABP driver.
- Start pumping @ 1:1 with maximal augmentation, adjust timing.

## Step 4

### Removal of iVAC 2L

- 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.



- Under fluoroscopic guidance slowly remove the iVAC 2L.
- Remove the 18Fr sheath following its Instructions for Use.
- Close the artery. After hemostasis is obtained close the wound.

## Material Required

### iVAC 2L content:

- iVAC 2L LV17 catheter with insertion set
- Membrane Pump
- Catheter Protector
- Extra PTFE Catheter Inner Tube

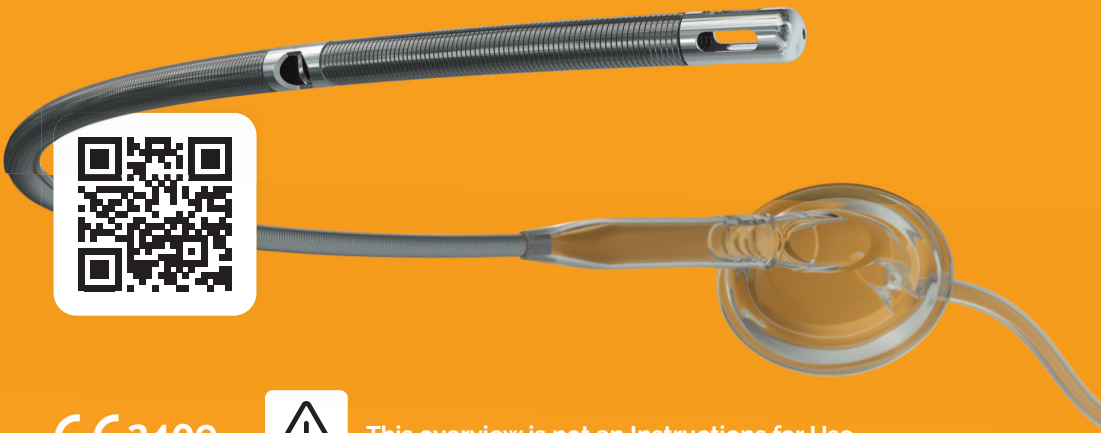
### *Additional items shipped with iVAC 2L:*

- 18Fr introducer sheath
- 16cm metal clamp
- 50cc syringe

### Provided by hospital

- IABP console
- 0.035" or 0.038" guidewire, length 260cm (super stiff)
- Heparinized saline (2500 IU heparin in 500ml saline)
- Closure device for large bore.





CE 2409



This overview is not an Instructions for Use