

Step-by-step Procedure Overview

PulseCath
Engineering the Pulse of Life

Insertion of SheathLess Ready (SLR) Catheter

1. Perform femoral access evaluation (angiography, vascular ultrasound, or computed tomography). If there is no significant vascular disease or tortuosity, the SLR approach may be considered.
2. Introduce a 6 Fr sheath into the common femoral artery.
3. Deploy a large bore access closure device of choice.
4. Introduce a 0.035" or 0.038" super-stiff guidewire into the left ventricle under TEE or X-ray guidance.
5. Progressively dilate the femoral artery to 14 Fr.
6. Insert the heparinized iVAC 2L catheter with PTFE stylet over the super-stiff guide wire and advance carefully. De-air the catheter and close the stopcocks.
7. The distal PTFE stylet forms a conical tip extending beyond the iVAC 2L catheter, acting as a dilator to facilitate femoral artery insertion. Once inserted, carefully advanced the catheter through the aorta, past the aortic arch branches, toward the coronary ostia.

   Before crossing the aortic valve, retract the PTFE stylet until it's tip is positioned inside the iVAC 2L catheter.
8. Carefully guide the tip of the iVAC 2L catheter into the ventricle (approx. 1.5 - 2 cm) and inspect the position by TEE or X-ray. When the position is correct, remove the guide wire.
9. Pull back the PTFE stylet until the tip of the stylet is in the plug at the proximal end of the iVAC 2L catheter. Then, place a tube clamp in the middle of the iVAC 2L catheter connector and disconnect the plug with the PTFE inner stylet.
10. Connect the membrane pump to the iVAC 2L catheter connector using a wet-to-wet connection technique with heparinised saline solution.
11. Remove the tube clamp and make sure (visually) that there are no air bubbles in the membrane pump. When confirmed, connect the driveline of the membrane pump with the IABP driver.
12. Start pumping at 1:2 frequency with maximal augmentation. Observe for any signs of obstruction or indications that the catheter tip has migrated too deeply. If repositioning is required – stop the IABP, reposition and restart the pump.
13. If the membrane inside the pump chamber moves smoothly and the timing is correct, set the frequency to 1:1.

Removal with direct puncture technique

1. Wean the patient by setting the frequency to 1:2 and to 1:4 for a period of time depending on the condition of the patient. Then, **Stop the IABP.**
2. Clamp the iVAC 2L catheter connector (consider returning the blood from the membrane pump back to the patient before clamping) and disconnect the membrane pump.
3. Pull the iVAC 2L catheter backwards gently until the catheter tip reaches the abdominal aorta.
4. Puncture the soft connector chamber with a standard femoral access needle proximal to the metal clamp. Then, introduce a long polymeric and hydrophilic 0.035" wire through a femoral access needle until the guide wire exits through the catheter tip or catheter valve and is visible under fluoroscopy.

   Consider placing a protection wire in the radial artery or contra-lateral superficial femoral artery before removing the iVAC 2L and starting with large bore closure procedure.
5. Once the guidewire is in place, remove the iVAC 2L catheter as per IFU instructions.
6. Proceed with closure as per standard guided practice.
7. Confirm haemostasis.