Pre-operative set up and exam

1. Operating room set up:

- Hemodynamic monitor (transducer):
  - Right arm radial or brachial arterial pressure (when using the IntraClude intra-aortic occlusion device)
  - Left arterial pressure
  - Aortic root pressure (when using the IntraClude device)
  - Pulmonary arterial pressure
  - Coronary sinus pressure
  - Monitor labeled with respective pressures

- Transesophageal echo machine

- Fluoroscopy/C-arm and monitor/OR table positioned to confirm placement of ProPlege peripheral retrograde cardioplegia device

- Ideal placement of all equipment and monitors to ensure optimal visualization for clinical team members

- Flexible bronchoscope if a double lumen tube is selected

- Separate instrument table for ProPlege device and EndoVent pulmonary catheter preparation

2. Pre-op transesophageal echo exam:

- Baseline cardiac exam:
  - Evaluate cardiac valve pathology and severity of disease state
  - Evaluate for atrial septal defect, patent foramen ovale, ventricular septal defect
  - Evaluate ventricular function
  - Evaluate all TEE accessible areas of the ascending and descending aorta for presence of atherosclerosis/plaque

- IntraClude device placement exam:
  - Determine diameter of ascending aorta and absence of aneurysm
  - Determine degree of aortic insufficiency as the presence of significant aortic valve insufficiency may preclude the use of the IntraClude device
  - Determine any presence of atherosclerosis
3. **ProPlege device and EndoVent catheter preparation:**

- Prepare ProPlege device and EndoVent catheter (anesthesia or nursing) per the IFUs

**Product placement and procedure**

1. **ProPlege device and EndoVent catheter placement:**

- Place introducers and catheters per the IFUs:
  - Place introducers
  - Administer anticoagulants per hospital protocol
  - Confirm position via transesophageal echo guidance and hemodynamic monitoring (per IFUs)
  - Confirm position via fluoroscopy per IFUs
  - Perform venogram to confirm final placement of the ProPlege device
  - Secure catheters
  - Connect catheters to perfusion circuit flush and de-air as needed

2. **QuickDraw venous cannula placement:**

- Cannula placed per the IFU:
  - Prior to cannula insertion administer anticoagulants per hospital protocol
  - Via transesophageal echo guidance, confirm guidewire position in superior vena cava by ensuring the end of the guidewire (the “crook” of the “J-curve”) is observed in real time as it passes into the superior vena cava
  - Inflate the balloon of the ProPlege device prior to the advancement of the QuickDraw cannula
  - Via transesophageal echo guidance, confirm QuickDraw cannula position at superior vena cava/right atrial junction (2-3 cm into superior vena cava)
  - After final positioning of the QuickDraw cannula, verify the continued presence of a “ventricularization” waveform of the ProPlege device, followed by balloon deflation

3. **EndoReturn arterial cannula placement:**

- Cannula placed per the IFU:
  - Via transesophageal echo guidance, confirm guidewire position in descending aorta with the short axis view
  - Perfusion performs a “test dose” of the perfusate to confirm intraluminal placement and no evidence of dissection via TEE view of the descending aorta

4. **IntraClude device placement:**

- IntraClude device placed per the IFU:
  - Via transesophageal echo guidance, confirm guidewire placement in descending aorta with the short axis view
  - Confirm placement of IntraClude device over guidewire with final placement 2-3 cm above the sinotubular junction
5. Procedure set up:
   - IntraClude device:
     - Connect aortic root pressure tubing (red) to hemodynamic monitor (Ao), flush and zero
     - Remind surgeon of ascending aorta diameter
     - Verify ProPlege device has maintained position in the coronary sinus

6. Procedure:
   - Cardio-pulmonary bypass:
     - Perfusion performs a second “test dose” of perfusate before initiating full bypass to confirm there is no evidence of dissection via TEE view of the descending aorta
     - Open EndoVent catheter (to perfusion) once full bypass has been achieved
   - IntraClude device balloon inflation:
     - Via transesophageal echo guidance, confirm IntraClude device balloon position within ascending aorta 2-3 cm above the sinotubular junction and proximal to the brachiocephalic artery during inflation process
     - As balloon is inflated keep aortic valve and balloon in echo view
     - Confirm via the hemodynamic monitor right arterial and left arterial waveforms remain equal during balloon inflation
     - Monitor aortic root pressure during balloon inflation (should fall to 0 with complete occlusion)
   - Antegrade cardioplegia:
     - Via transesophageal echo guidance, confirm IntraClude device balloon position during antegrade cardioplegia delivery
     - Check for aortic insufficiency/left ventricular distension during antegrade cardioplegia delivery
     - Monitor antegrade cardioplegia delivery via color Doppler on the aortic root.
   - Retrograde cardioplegia:
     - Confirm ProPlege device green stopcock is open to deliver cardioplegia
     - Commence retrograde cardioplegia delivery slowly (50 ml/min)
     - Inflate ProPlege device balloon to volume noted to achieve ventricularization
     - Continue to increase cardioplegia delivery to flows and pressures per hospital protocol

7. Coming off bypass
   - Transesophageal echo monitoring for de-airing:
     - Close EndoVent catheter (open to pulmonary arterial pressure)
     - De-air according to hospital protocol
     - Via transesophageal echo guidance, check for residual intracardiac air
     - Verify EndoVent catheter and ProPlege device can move freely
IntraClude device balloon deflation:
- Monitor aortic root pressure during balloon deflation (should rise to match the systemic blood pressure)
- Via transesophageal echo guidance, confirm position of IntraClude device balloon
- Via transesophageal echo guidance, check for residual intracardiac air

Post cardio-pulmonary bypass reminders:
- ProPlege device (green) stopcock turned off to patient after last dose of retrograde cardioplegia
- ProPlege device and EndoVent catheter removed once protamine administration is complete

ThruPort systems product codes:

EndoReturn cannula: ER21B, ER23B
EndoVent catheter: EV
IntraClude device: ICF100
Introducer sheath: IS19A
ProPlege device: PR9
QuickDraw cannula: QD22, QD25

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.