ThruPort systems
Perfusionist checklist

Pre-operative set up and supplies

1. Operating room set up:
   - Hemodynamic monitor (transducer):
     - Right arm radial or brachial arterial pressure (IntraClude intra-aortic occlusion device)
     - Left arm radial or brachial arterial pressure (IntraClude device)
     - Aortic root pressure (IntraClude device)
     - Pulmonary arterial pressure (EndoVent pulmonary catheter)
     - Coronary sinus pressure (ProPlege peripheral retrograde cardioplegia device)
     - Monitor labeled with respective pressures

2. Heart-lung machine set up:
   - Standard heart-lung machine set up
   - Minimal incision valve surgery (MIVS) heart-lung machine additions:
     - Augmented venous return (vacuum or kinetic)
     - Pressure monitor for vacuum regulation (negative pressure readings; inlet), if chosen and according to hospital/procedural protocol
     - Monitor for kinetic assist flow, if chosen and according to hospital/procedural protocol
     - Additional console for kinetic assist applications (centrifugal blood pump), if chosen and according to hospital/procedural protocol
     - Roller-head capabilities for separate aortic root vent line, EndoVent catheter vent line and additional intra-cardiac sucker lines
     - Pressure monitor for IntraClude device balloon pressure capable of reading up to 500 mm/Hg
     - One-way vent valve for IntraClude device aortic root vent line and EndoVent catheter line

3. ThruPort systems supplies:
   - ThruPort systems disposable products (aortic valve procedures):
     - ProPlege device
     - EndoVent catheter
     - Arterial cannula (size as needed, select for direct aortic or femoral cannulation)
     - QuickDraw femoral venous cannula (size as needed)
ThruPort systems disposable products (mitral valve procedures):
- ProPlege device
- EndoVent catheter
- EndoReturn arterial cannula (size as needed)
- QuickDraw cannula (size as needed)
- IntraClude device
- Other supplies as per hospital/procedural protocol

4. Set up: ProPlege device and EndoVent catheter:
- Anesthesia or nursing prepare the ProPlege device and EndoVent catheter according to the IFUs
- Catheter placement:
  - After introducer insertion administer anticoagulants per hospital protocol
  - Anesthesia place catheters per the IFUs
  - Connect EndoVent catheter to ¼” suction line from heart-lung machine
  - Connect ProPlege device to retrograde cardioplegia line from heart-lung machine (flush and de-air)
- Perfusion circuit modifications:
  - ProPlege device retrograde cardioplegia line and EndoVent catheter perfusion line to anesthesia (from heart-lung machine or from sterile field)

5. Set up: QuickDraw venous cannula:
- Nursing prepare QuickDraw cannula according to the IFU
  - 22 Fr QuickDraw cannula (weight and femoral vessel considerations)
  - 25 Fr QuickDraw cannula (weight and femoral vessel considerations)
- Perfusion circuit modifications:
  - Short piece of 3/8” tubing, 3/8” x ½” perfusion connector for ½” venous line connection to QuickDraw cannula
  - Venous perfusion line to heart-lung machine from groin
  - Hard-shell cardiotomy system if using vacuum assist
  - Kinetic pump inserted into venous line (pre-venous reservoir) if used

6. Set up: Arterial cannula preparation:
- Nursing prepare arterial cannula per the IFU:
  - Arterial cannula used in conjunction with IntraClude device:
    - 21 Fr EndoReturn cannula (calculated flow and femoral vessel considerations)
    - 23 Fr EndoReturn cannula (calculated flow and femoral vessel considerations)
    - 19 Fr introducer sheath (femoral vessel considerations)
  - Arterial cannula for contralateral groin if using bi-femoral cannulation
- Perfusion circuit modifications
  - Arterial perfusion lines to heart-lung machine from groin
7. **Set up: IntraClude device preparation:**

- Nursing prepare IntraClude device per the IFU
- Perfusion circuit modifications
  - IntraClude device antegrade cardioplegia line from heart-lung machine
  - IntraClude device aortic root vent line from heart-lung machine (with one way vent valve inserted per IFU)

**Product placement and procedure**

1. **EndoReturn arterial cannula placement:**

- After correct placement of the EndoReturn cannula is confirmed
  - Connect cannula to perfusion circuit and de-air per protocol
  - Give a ‘test dose’ to verify intraluminal insertion and appropriate system line pressure

2. **IntraClude device placement:**

- Prior to IntraClude device insertion:
  - Flush and de-air IntraClude device cardioplegia/aortic vent line “Y” by advancing the antegrade cardioplegia with the aortic root vent on. Blue and red thumb clamps open, white thumb clamp closed
  - IntraClude device blue-stripe balloon pressure line to heart-lung machine pressure monitor device (flush and zero)

- After correct placement of the IntraClude device is confirmed:
  - Repeat ‘test dose’ to verify intraluminal insertion and appropriate system line pressure once IntraClude device is in place

3. **Going on bypass:**

- Initiation of cardiopulmonary bypass:
  - Confirm that right radial, left radial and aortic root mean pressures are equal
  - Commence venous return, via gravity drainage and eventual augmented venous return techniques to completely drain the right heart
  - Turn on roller pump to initiate EndoVent catheter return and open stopcock on EndoVent catheter to venting position
  - Commence arterial blood flow slowly, monitoring system line pressures and all mean arterial pressures
  - Stop all ejection of blood from the heart as evidenced by non-pulsatile arterial wave forms
  - Begin aortic root venting with a flow of approximately 100 ml/min
- **IntraClude device balloon inflation:**
  - Confirm via transesophageal echo IntraClude device position within ascending aorta
  - 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 zero or negative with complete occlusion)
  - Confirm via transesophageal echo guidance position of IntraClude device balloon in aorta during inflation process
  - Inflated balloon pressures monitored at the heart-lung machine; initial balloon pressure should be 300-400 mm/Hg

- **Antegrade cardioplegia (IntraClude device):**
  - Confirm via transesophageal echo guidance balloon position during antegrade cardioplegia delivery
  - Turn off aortic root vent
  - Open appropriate red or blue thumb-clamp where antegrade cardioplegia line is attached
  - Begin antegrade cardioplegia delivery slowly, monitoring the rise in the aortic root pressure
  - Continuously monitor right radial and left radial pressure during antegrade administration
  - Deliver antegrade cardioplegia per hospital protocol
  - Once delivered, open appropriate blue or red thumb-clamp on cardioplegia “Y” to open aortic root vent
  - Turn on aortic root vent until root pressure falls to zero or negative and then turn off the aortic root vent
  - Aortic root vent should be used intermittently to keep the root pressure at or below zero

- **Retrograde cardioplegia (ProPlege device):**
  - Commence cardioplegia delivery slowly (50 ml/min)
  - Anesthesia inflate balloon to observe response in coronary sinus pressure
  - Deliver retrograde cardioplegia as per protocol

- Repeat cardioplegia doses as needed

4. **Coming off bypass:**

- **De-airing process:**
  - Discontinue use of the EndoVent catheter
  - Commence the use of the aortic root vent on the IntraClude device
  - De-air according to hospital protocol
□ IntraClude device balloon deflation:
□ Continue the use of the aortic root vent during balloon deflation
□ Monitor aortic root pressure during balloon deflation (should rise to match the mean of the right arterial pressure and left arterial pressure)
□ Pull back appropriate amount of volume from balloon syringe and open stopcock to read balloon pressure; it should read zero or negative pressure
□ Confirm via transesophageal echo guidance deflation of balloon on IntraClude device
□ Via transesophageal echo guidance check for residual intracardiac air
□ Aortic root vent should remain on until de-airing is complete
□ EndoVent catheter stopcock positioned to read pulmonary arterial pressure
□ Remove IntraClude device after patient is weaned from bypass

□ Post cardio-pulmonary bypass reminders:
□ 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.

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