

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 1/2" perfusion connector for 1/2" 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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