ThruPort systems
ProPlege peripheral retrograde cardioplegia device
Training Module Lessons

- Lesson 1: ProPlege device
- Lesson 2: Preparing for the case
- Lesson 3: Utilizing the device
- Lesson 4: Troubleshooting
Lesson 1: ProPlege device
ProPlege device

Lesson 1 topics:
- Global myocardial protection strategy
- Indications and procedural applications
- Components
- Additional package contents
Global myocardial protection

- Global myocardial protection
  - The combined use of antegrade and retrograde cardioplegia
  - Aims to achieve homogenous protection of the myocardium
Indications and procedural applications

- Indication
  - Used during cardiopulmonary bypass to:
    - Deliver retrograde cardioplegia
    - Provide occlusion of the coronary sinus
    - Allow monitoring of coronary sinus pressure
- Potential minimal incision procedural applications
  - Aortic valve replacement
  - Mitral valve repair or replacement
  - Myxoma resection
  - Maze procedure
  - Reoperation
  - Totally endoscopic coronary artery bypass
Global myocardial protection

- Used for patients with the following:
  - Concomitant procedure
  - Coronary artery disease
  - Re-operation
  - Greater than mild aortic insufficiency
  - Mitral valve surgery where the atrial retractor distorts the aortic valve

Both antegrade and retrograde cardioplegia
Components

- Triple-lumen, 9 Fr shaft which is 59 cm in length
- Elastomeric balloon near distal tip to occlude a range of coronary sinus diameters
- Distal connector with locking mechanism
- Clear contamination guard protects shaft of device
- Positioning dial which articulates the curvature of the distal tip
Components – stopcocks and lumens

- Color coded stopcocks and labeled lumens
  - Blue stopcock
    - Balloon inflation and deflation access
  - Green stopcock
    - Retrograde cardioplegia delivery access
    - Contrast injection access
    - Guidewire access via the rotating hemostasis valve adapter, if needed
  - White stopcock
    - Coronary sinus pressure access
Components – device markers

- Printed longitudinal orientation line
  - Serves as reference for device orientation during insertion and placement
- Depth markers
  - In 5 cm increments beginning at 15 cm from the tip to 45 cm
Components – positioning dial tip articulation

- Introduction position
  - Dial is all the way forward
  - Used when advancing through introducer to right atrium

- Optimal engagement position
  - Dial is in the center
  - Curve of shaft designed to match most patient anatomies

- Articulation position
  - Dial is pulled back and held in place
  - For patients with a sharp coronary sinus angle
Components – how to manipulate the device

- Do not rapidly move the positioning dial
- Do not manually reshape or bend the shaft
- Torquing the device
  - Ensure shaft is not curled or bent
  - Use 2-handed method to torque
    - Hand on shaft near introducer
    - Hand on trifurcation hub
Additional package contents

- 11 Fr introducer sheath kit
- Hemostasis valve
  - For guidewire placement
- 2 mL volume syringe
  - For balloon inflation and deflation
- 30 mL syringe
  - For flushing / priming device and for contrast injection
Lesson 2: Preparing for the case
Preparing for the case

Lesson 2 topics:
- Anatomy
- Equipment for monitoring device location
- Transesophageal echo imaging
- Fluoroscopic imaging
- Perfusion preparation
Anatomy

- Coronary sinus
  - Diameter ranges from 3 - 15 mm in size (8 mm on average)
  - Length is 4.5 - 5.5 cm
  - Shapes are tubular, funnel or windsock shaped and can be visualized using fluoroscopy with contrast
  - The opening of the coronary sinus (ostium) is located in the right atrium
  - ProPlege device is placed in the coronary sinus with the tip of the device proximal to posterior ventricular branch
Anatomy

- Eustachian valve or ridge
  - Lies between the openings of the inferior vena cava and the coronary sinus
- Tricuspid valve septal leaflet (posterior)
  - The coronary sinus lies between the insertion of this leaflet and the Eustachian valve
- Thebesian valve
  - Located at the ostium of the coronary sinus
  - Present in approximately 90% of patients
Equipment for monitoring device location

- Position all monitors for simultaneous viewing
  - Transesophageal echo (4 views)
    - Modified bicaval
    - Deep 4-chamber
    - 2-chamber
    - Left tangential
  - Fluoroscopy
  - Hemodynamic monitor
Transesophageal echo imaging

- Modified bicaval view
  - Displays the superior vena cava and the coronary sinus
  - Used to engage the device in the coronary sinus ostium
  - Acquired from
    - The standard bicaval view
    - The long axis view
  - Final probe placement is mid-esophageal depth with an angle of 110-130 degrees
Transesophageal echo imaging

- Deep 4-chamber view
  - Displays the coronary sinus ostium, inferior vena cava, Eustachian valve
  - Used when there is difficulty acquiring the modified bicaval view
  - Acquired from standard 4-chamber view by slightly advancing the probe followed by anteflex or retroflex
  - Final probe placement is mid-esophageal depth with an angle of approximately 0 degrees
Transesophageal echo imaging

- 2-chamber view
  - Displays the left ventricle, atrium and atrial appendage, the mitral valve leaflets, the coronary sinus
  - Used to confirm placement of the ProPlege device within the coronary sinus
  - Acquired from the 4-chamber view by rotating the multi-plane angle forward to 80-100 degrees and retroflexing probe
  - Final probe placement is mid-esophageal depth with an angle of 80-100 degrees
Transesophageal echo imaging

- Left tangential view
  - Used to confirm device depth and cardioplegia flow using color flow doppler mapping
  - Acquired from a 2-chamber view by turning the probe left and adjusting the multiplane angle as needed
  - The two arrows point to segments of the great cardiac vein
Transesophageal echo imaging

- Validate the four standard echo views discussed
- Evaluate patient’s anatomy while validating views
  - Determine presence of an atrial septal defect or patent foramen ovale as presence may impact decision of device use
  - Measure and note diameter of coronary sinus for balloon inflation volume purposes
  - Identify the angle and shape of the coronary sinus noting any anatomical irregularities
Fluoroscopic imaging

- Used with transesophageal echo to provide complete picture
- Use transesophageal echo with pressure monitoring and fluoroscopy
- Benefit of fluoroscopy is a detailed visual image
  - Non-occlusive venogram shows device position, coronary sinus shape and diameter
  - Occlusive venogram provides visual confirmation of final position and shows distribution of contrast throughout the coronary vessels to ensure effective delivery of retrograde cardioplegia
- Position fluoroscope in straight anteroposterior (AP) view
Perfusion preparation

- Pressures
  - Smaller ProPlege device lumen results in higher line pressures
  - Line pressures between 250-300 mmHg (less than 400 mmHg)
  - Coronary sinus pressure of 20-40 mmHg during retrograde cardioplegia
Perfusion preparation (continued)

- Control options for cardioplegia lines
  - Perfusionist controls at heart lung machine
    - Retrograde cardioplegia line to ProPlege device at anesthesia
    - Antegrade cardioplegia line to surgical field
  - Surgeon manually controls on operative field
    - Line connected from perfusion to alternating control on operative field
    - Retrograde cardioplegia line from ProPlege device at anesthesia to operative field
    - Antegrade cardioplegia line to operative field
Lesson 3: Utilizing the device
Utilizing the device

Lesson 3 topics:
- Preparation prior to device insertion
- Inserting and advancing the device
- Engaging the coronary sinus ostium
- Fluoroscopy, venograms and device advancement
- Confirming placement and balloon inflation
- Retrograde cardioplegia
- Deflating balloon and removing device
Preparation prior to device insertion

- Insert introducer sheath in right internal jugular vein
  - If not accessible, consider the left subclavian vein
- Administer anticoagulants per hospital protocol
- Attach coronary sinus pressure line
- Flush line and zero transducer
- Open white stopcock to device
- Verify tight connections to blue stopcock
- Ensure balloon is fully deflated and vacuum has been maintained
- Engage positioning dial and note orientation of curve
Inserting and advancing the device

- Set positioning dial to introduction position
- Insert device tip at 7 o’clock position in introducer
- Insert device through introducer sheath
- Retract the contamination guard to expose the shaft of the device.
Inserting and advancing the device (continued)

- Acquire optimal transesophageal echo view
  - Modified bicaval view
  - Deep 4-chamber view
- Verify positioning dial is in the introduction position
- Advance to superior vena cava / right atrial junction
  - Device depth approximately 25 - 30 cm
- Visualize device tip on transesophageal echo, then torque device counterclockwise while gently advancing tip near coronary sinus ostium
  - Device depth approximately 30 - 35 cm
Engaging the coronary sinus ostium

- Pull positioning dial to the optimal engagement position

- Use small, slow, deliberate movements to engage the ostium
- Advance device tip through the coronary sinus ostium
- If needed, torque the device and / or use the additional articulation position
Fluoroscopy, venograms & device advancement

- Prepare for Venograms
  - Fluoroscopy
    - Standard AP view
    - 30 ml syringe
      - Do not dilute contrast beyond 50 - 50 ratio
    - Attach syringe
    - Open cardioplegia stopcock
Fluoroscopy, venograms & device advancement (continued)

- Conduct a non-occlusive venogram
  - Rapidly inject contrast while the balloon is deflated
    - For non-diluted contrast, inject 3 - 5 mL
    - For diluted contrast, inject 5 - 10 mL
  - Venogram shows:
    - ProPlege device position
    - Coronary sinus diameter
      - Used to estimate balloon inflation volume
    - Coronary sinus shape
    - Device depth
Fluoroscopy, venograms & device advancement (continued)

- Continue to advance the device within the coronary sinus
  - Past middle cardiac vein
  - Place device tip proximal to posterior ventricular branch
Confirming placement and balloon inflation

- Acquire 2-chamber transesophageal echo view to verify placement within coronary sinus
  - However, precise location of device tip cannot be confirmed with transesophageal echo, therefore fluoroscopy is recommended.
Confirming placement and balloon inflation (continued)

- If using fluoroscopy, fill the 2 mL syringe with diluted contrast
  - 6 parts sterile physiologic solution to 1 part contrast medium
- Attach 2 mL syringe to blue stopcock and open stopcock to syringe
- Slowly inflate balloon while watching pressure trace
- Stop inflating balloon at first sign of ventricularization
  - Do not exceed maximum inflation volume of 1.4 mL
- Turn blue stopcock off to device to maintain balloon volume
Confirming placement and balloon inflation (continued)

- Conduct an occlusive venogram to verify placement
  - Tip proximal to posterior ventricular branch
  - Contrast throughout coronary vessels
  - If not optimal, deflate balloon, reposition and repeat inflation and confirmation steps
Confirming placement and balloon inflation (continued)

- Note balloon volume and device depth
- Attach and secure distal connector to introducer sheath
- Secure locking mechanism
- Place positioning dial in introduction position
- Completely deflate balloon
- Turn stopcock off to the device to ensure balloon remains deflated
Retrograde cardioplegia

- Flush cardioplegia lumen
  - Remove 30 mL contrast filled syringe
  - Attach a syringe filled with heparinized saline (per hospital protocol) to green stopcock
  - Flush cardioplegia lumen with 5 - 10 mL of heparinized solution
  - Turn green stopcock off to the cardioplegia lumen
  - Remove syringe and cap port
Retrograde cardioplegia

- Prepare for delivering retrograde cardioplegia
  - Verify green stopcock off to the patient
  - Connect the retrograde cardioplegia line to the ProPlege device:
    - Remove cap from hose barb adapter and attach tubing
    - Or remove hose barb and connect male luer
  - Remove white cap on side port of green stopcock
  - Flush line with cardioplegic solution until all air is removed
  - Replace white cap on side port
Retrograde cardioplegia

- Deliver retrograde cardioplegia
  - Turn green stopcock off to side port (opens cardioplegia line)
  - Start retrograde perfusion at a low flow rate (<50/mL/min) while inflating balloon
  - Stop inflating balloon once an increase in coronary sinus pressure is visualized
  - Increase flow while observing coronary sinus pressure (pressure not to exceed 40 mmHg)
  - Can visualize retrograde distribution via left tangential view on transesophageal echo
  - Ensure effectiveness of cardioplegia
  - Repeat infusions of cardioplegia as needed
    - Deflate balloon and close infusion line stopcock between retrograde infusions
Deflating balloon and removing device

- Removal of device should occur prior to or at the same time as reversal of anticoagulation therapy to avoid thrombus and thrombo-embolism
- Turn the blue stopcock off to the side port
- Fully deflate balloon by drawing back on the 2 mL syringe plunger twice
- While syringe plunger is retracted, turn blue stopcock off to device
- Disengage distal connector locking mechanism
Deflating balloon and removing device (continued)

- Withdraw device until contamination guard is fully extended
- Disconnect device’s distal connector from introducer sheath
- Remove device from the introducer
- Dispose of device per hospital protocols for biohazards
- Introducer sheath may be left in place for venous access
Lesson 4: Troubleshooting
Troubleshooting

Lesson 4 topics:

- Difficulty advancing or torquing the device
- Challenge locating the tip of the device on transesophageal echo
- Difficulty advancing device to final position within coronary sinus
- Use of guidewire to advance device
- Shaft of device buckles in right atrium
- Unable to inflate the balloon
- Ventricularization waveform not observed
- Difficulty infusing retrograde cardioplegia while observing high retrograde cardioplegia line pressure and high coronary sinus pressure
- Low coronary sinus pressure
- Challenge removing device through introducer
Difficulty advancing or torquing the device

- Do not apply excessive force to the device
- Visualize the device on transesophageal echo and/or fluoroscopy
  - Obstruction:
    - Refer to troubleshooting techniques in this lesson
  - No obstruction:
    - Ensure distal connector locking mechanism is not engaged
    - Properly handle device to ensure best torque transmission
      - Shaft is straight
      - 2-handed method: one hand on distal shaft near introducer and one hand on trifurcation hub
Challenge locating the tip of the device on transesophageal echo

- Proximal segment of shaft may be mistaken for the tip
  - Check pressure trace
  - Consider using fluoroscopy to confirm tip location
    - Inject contrast through cardioplegia channel
- Straight AP view
- Capture quick image on fluoro
- Evaluate both fluoroscopy and the hemodynamic monitor
- Possible locations of the device:
  - Right atrial appendage
  - Inferior vena cava
  - Right ventricle
  - Right ventricular outflow tract
Challenge locating the tip of the device on transesophageal echo (continued)

- If device tip is in the right atrial appendage
  - Verify positioning dial is in introduction position
  - Retract device to 20 cm marker
  - Tip at 7 o’clock position
  - Re-attempt advancement

- If device tip is in the inferior vena cava
  - Ensure positioning dial is in introduction position
  - Simultaneously withdraw and torque clockwise until tip clears right atrium / inferior vena cava junction
  - Position tip near coronary sinus ostium
  - Engage coronary sinus ostium
Challenge locating the tip of the device on transesophageal echo (continued)

- If device tip is in the right ventricle
  - Waveform verifies location
  - Ensure positioning dial is in introduction position
  - Simultaneously withdraw and torque counterclockwise until waveform changes to a venous pattern
  - Position tip near coronary sinus ostium
  - Engage coronary sinus ostium

- If device tip is in the right ventricular outflow tract
  - Ensure positioning dial is in introduction position
  - Simultaneously withdraw and torque counterclockwise until waveform changes to a venous pattern
  - Position tip near coronary sinus ostium
  - Engage coronary sinus ostium
Difficulty advancing device to final position within coronary sinus

- Side branch cannulation
  - If device is in the middle cardiac vein
    - Do not inflate balloon
    - Do not advance
    - Withdraw device
    - Simultaneously torque and reattempt advancement
    - Consider guidewire if needed
  - If device is in a shallow posterior ventricular branch
    - Withdraw device
    - Simultaneously torque and reattempt advancement
    - Consider guidewire if needed

![Image of device advancement](image-url)
Difficulty advancing device to final position within coronary sinus (continued)

- Presence of a coronary sinus valve
  - Potential challenges:
    - Obstruct retrograde cardioplegia flow
    - Device can become dislodged
  - To bypass the valve:
    - Slightly withdraw
    - Torque shaft while reattempting advancement
    - If efforts are futile, consider guidewire

- Kinked coronary sinus
  - If deep, withdraw device to desired position
  - To bypass a shallow kink:
    - Slightly withdraw
    - Torque shaft while reattempting advancement
    - If unsuccessful, consider guidewire
Use of guidewire to advance device

- Must use fluoroscopy
- Ensure device tip is engaged in coronary sinus and not forcefully contacting wall before advancing a guidewire
  - Withdrawing the catheter slightly and verifying free flow of blood via green stopcock decreases the likelihood that the device is in forceful contact with the vessel wall
- Select a hydrophilic coated, soft tip .035” or .89 mm, minimum 100 cm long guidewire
- Verify green stopcock is off to device
- Attach contrast filled 30 mL syringe to side port
- Remove hose barb from green stopcock
- Attach hemostasis valve adapter to end port on green stopcock
- Open the hemostasis valve
Use of guidewire to advance device (continued)

- Insert guidewire to device tip
- Tighten hemostasis valve
- Open green stopcock to all 3 side ports
- Gently advance guidewire to past tip of the device
- Slightly retract device to straighten shaft
- Re-advance device into desired position
- Confirm device location
  - Prior to conducting venograms verify seal on hemostasis valve
Use of guidewire to advance device (continued)

- Remove guidewire
- Remove contrast filled syringe
- Attach a syringe filled with sterile heparinized physiologic solution to green stopcock
- Flush cardioplegia lumen with 5 to 10 mL of heparinized solution
- Turn green stopcock off to the device
- Remove syringe and cap side port
- Remove hemostasis valve adapter
- If desired, reconnect hose barb adapter
Shaft of device buckles in right atrium

- Device not tracking properly
- Device tip potentially encountered an impediment
- To troubleshoot:
  - Verify balloon deflated
  - Locate tip of device on transesophageal echo
    - Tip engaged in coronary sinus
      - Review other section in this module
    - Tip not engaged in coronary sinus
      - Position dial in introduction position
      - Retract device to 20 cm marker
      - Tip at 7 o'clock position
      - Reattempt advancement
Unable to inflate the balloon

- Verify the following:
  - Luer connection on blue stopcock is secure
  - 2 mL syringe is secure on blue stopcock
  - Stopcock turned off to side port
  - Device is not kinked
Ventricularization waveform not observed

- Confirm location of device on transesophageal echo and fluoroscopy
- Verify scale is adjusted to read 30 mmHg
- After verifying free flow of blood via green stopcock, consider injection of small amount of contrast to evaluate match of balloon to coronary sinus diameter and leak around balloon
- Consider possibility of low amplitude ventricularization waveform and evaluate change in mean pressure before and after balloon inflation
Ventricularization waveform not observed (continued)

- If challenges visualizing the waveform are still encountered:
  - Ensure lumen was properly prepped
  - Check connections and function of monitoring / transducer system
  - Check coronary sinus pressure stopcock on device
  - Re-zero and flush the coronary sinus pressure lumen
- If efforts are futile, consider repositioning device
  - Retract device into right atrium
  - Reposition device and confirm placement
Difficulty infusing retrograde cardioplegia while observing high line pressure and high coronary sinus pressure

- ProPlege device has more resistance to cardioplegia flow and higher line pressures due to smaller lumen size and length
- Troubleshoot infusion challenges combined with high line pressure
  - Flush retrograde cardioplegia lumen
  - Verify stopcocks and connections properly positioned
  - Ensure lines are not kinked or twisted
Difficulty infusing retrograde cardioplegia while observing high line pressure and high coronary sinus pressure (continued)

- Consider possibility of tip too deep, in a side branch, adjacent to vessel wall or proximal to coronary sinus valve
  - Temporarily discontinue infusion of cardioplegia
  - Deflate balloon
  - Unlock distal connector
  - Retract device no more than 1 cm
  - Reinflate balloon
  - Relock distal connector
  - Reattempt retrograde cardioplegia infusion
  - Repeat steps until successful
- If repositioning does not resolve inability to give retrograde, proceed with antegrade-only cardioplegia strategy
Low coronary sinus pressure

- Confirm the balloon is inflated
- Verify position of device within the coronary sinus
  - Temporarily inflate balloon during patient positioning and venous cannula placement to prevent device dislodgement
  - Windsock shaped coronary sinus may contribute to dislodgement
- Look for persistent left superior vena cava
  - Diagnose with fluoroscopy
  - Determine effectiveness of retrograde cardioplegia
Challenge removing device through introducer

- Resistance felt when attempting removal of device through introducer
  - Do not exert excessive force
  - Ensure balloon completely deflated
  - Confirm blue stopcock is off to the device
  - Gently reattempt removal
  - While using fluoroscopic guidance, remove device and sheath as one unit
Thank You

For further information regarding this device and other products, please visit our website at:

thruportmivs.com
For professional use. 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.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Proper surgical procedures and techniques are the responsibility of the medical profession. Described procedures are provided for informational purposes only. Each physician must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.

Edwards, Edwards Lifesciences, the stylized E logo, ProPlege and ThruPort are trademarks or service marks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

© 2017 Edwards Lifesciences Corporation. All rights reserved. PP-US-1708 v1.0

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com