

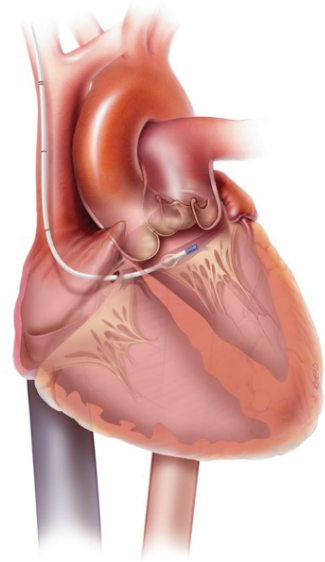


Placement Troubleshooting

ProPlege Peripheral Retrograde
Cardioplegia Device

Troubleshooting Contents

1. Difficulty advancing or torquing
2. Difficulty advancing to final position
3. Challenge locating tip on TEE
 - Right atrial appendage
 - Inferior vena cava
 - Right ventricle/RVOT
 - Side branches
4. Shaft bows in right atrium
5. Using a guidewire for advancement
 - Introduction
 - Placement
 - Removal
6. Inability to inflate balloon
7. Low coronary sinus pressure observed during cardioplegia delivery
 - Ventricularization is not observed
9. Difficulty infusing retrograde cardioplegia
10. Challenge removing catheter through introducer sheath



ProPlege peripheral retrograde cardioplegia device

ProPlege Device Placement

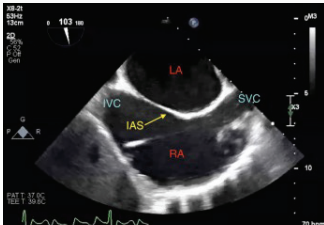
Difficulty Advancing or Torquing

- Do not apply excessive force to the device
- Visualize the device on TEE and / or fluoroscopy

Do you see an obstruction?

Yes, there is an obstruction

- Pull back the catheter to the 20 cm mark
- Go back to the bicaval view
- Re-advance catheter into the right atrium
- Look for tip of catheter



No, I do not see an obstruction

- Ensure distal connector locking mechanism is not engaged
- Make sure device is handled properly for best torque transmission:
 - Straight shaft
 - Two-handed torquing: one hand on distal shaft near introducer and one on trifurcation hub

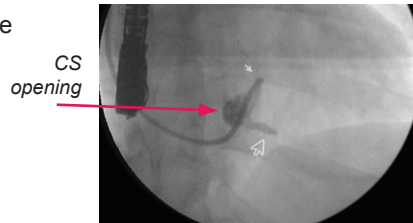


ProPlege Device Placement

Difficulty Advancing to Final Position

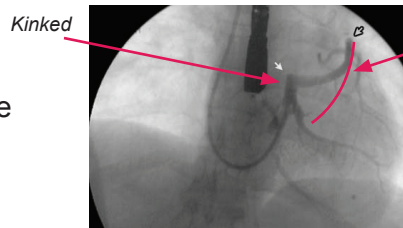
- Possibilities:
 - Tip pushes against CS Thebesian valve and may perforate it
 - Kinked CS because of tip
- To correct this:
 - Slightly withdraw catheter
 - Torque shaft while re-attempting advancement
 - Use articulation position to correct Thebesian valve issue
 - Use the introduction position to correct kinking
- If unsuccessful, consider guidewire

Tip pushes against Thebesian valve



Use advanced position

CS is kinked due to catheter tip



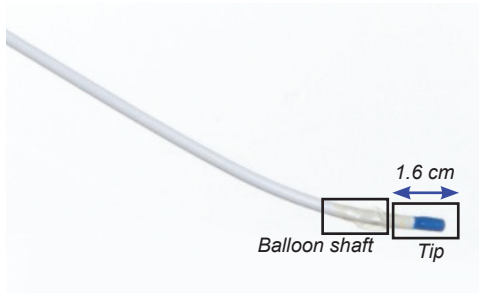
Use introduction position

Images by Dr. Greg Miller

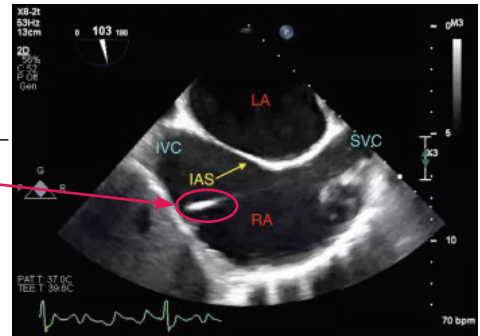
ProPlege Device Placement

Challenge Locating Tip on TEE

- Shaft where balloon sits may be mistaken for catheter tip
- Tip is always 1.6 cm ahead of the balloon
- Check pressure trace on the hemodynamic monitor
- Fluoroscopy straight posterior-anterior (PA view) can confirm tip location



*Tip of the catheter –
bicaaval TEE view*



Tip Location (TEE)

ProPlege Device Placement

Challenge Locating Tip on TEE

Right Atrial Appendage

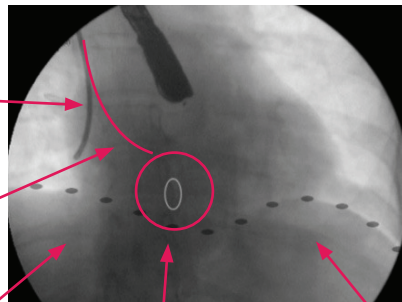
- Verify dial is in introduction position
- Retract device to 20 cm marker
- Note tip at 7:00 position (optimal for normal CS anatomy)
- Re-attempt advancement

Fluoroscopy view

The approx. location of the CS ostium should be 2 cm above the dip between the right and left hemi diaphragm

Wrong direction: Tip is in the right atrial appendage

Ideal positioning of tip so it can enter the CS



Right hemi diaphragm

CS ostium

Left hemi diaphragm

Image by Dr. Greg Miller

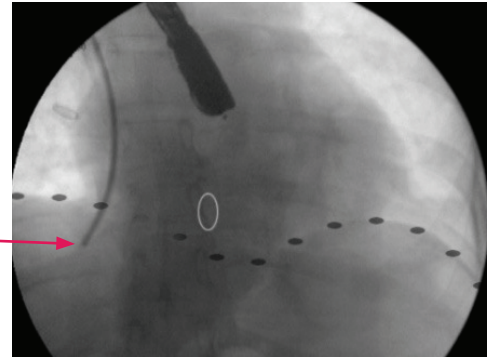
ProPlege Device Placement

Challenge Locating Tip on TEE

Inferior Vena Cava

- Ensure dial is in introduction position
- Simultaneously withdraw and torque clockwise until tip clears right atrium / IVC junction
- Position tip near CS ostium
- Engage CS ostium

Fluoroscopy view



*Wrong direction:
Tip is in the IVC*

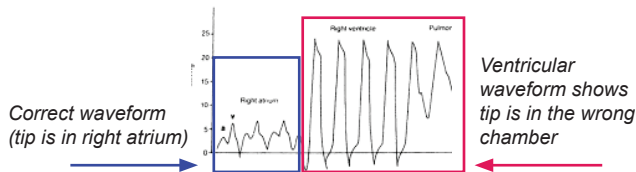
Image by Dr. Greg Miller

ProPleg Device Placement

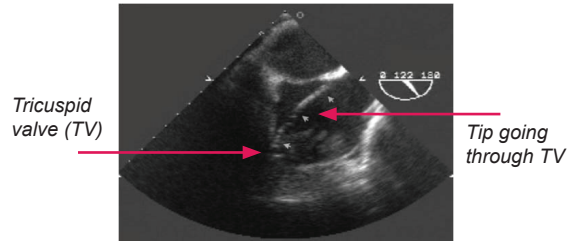
Challenge Locating Tip on TEE

Right Ventricle or RVOT

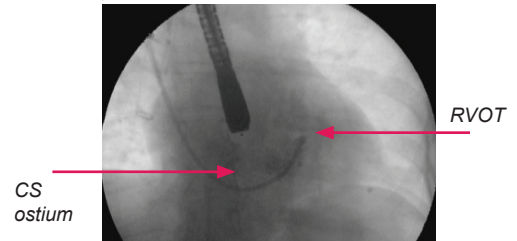
- Note waveform showing ventricular spikes on hemodynamic monitor
- Ensure dial is in introduction position
- Simultaneously withdraw and torque counterclockwise until waveform changes back to atrial waveform
- Position tip near CS ostium and re-engage



Echo: Tip is wrongly positioned in right ventricle



Fluoroscopy: Tip is wrongly positioned in RVOT



Images by Dr. Greg Miller

ProPlege Device Placement

Challenge Locating Tip on TEE

Side Branches

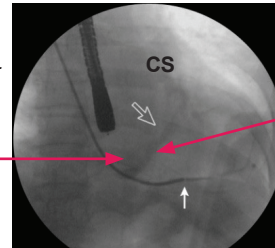
If device is in middle cardiac vein or shallow posterior ventricular branch:

- Do not inflate balloon
- Do not advance
- Withdraw device
- Simultaneously torque and retract lever on in third (advanced) position
- Re-attempt advancement
- Consider guidewire if needed

Tip is in middle cardiac vein

Tip looks like L vs. reverse lazy J

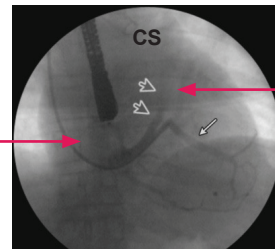
CS ostium



Middle cardiac vein/ branch tip slipped into

Tip is in shallow posterior ventricular branch

CS ostium



Images by Dr. Greg Miller

ProPlege Device Placement

Shaft Bows in Right Atrium

- Verify balloon is deflated
- Try to locate tip on TEE (modified bicaval or 4-chamber view)
- Pan echo probe as catheter tip is micro-turned and retracted slightly

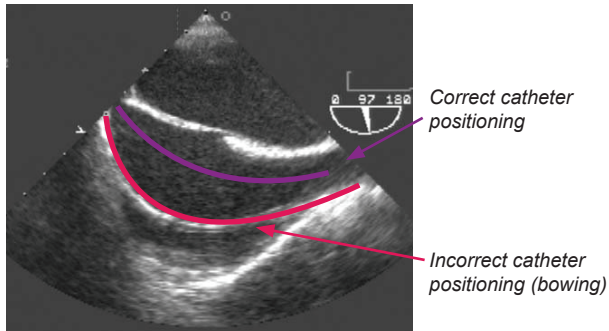


Image by Dr. Greg Miller

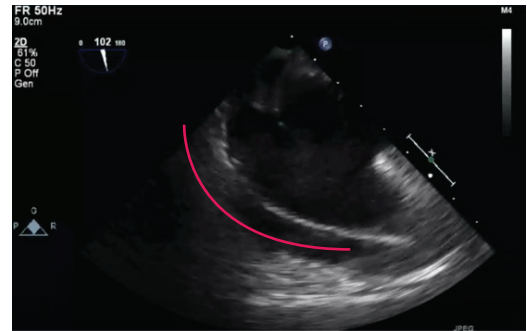


Image by Dr. Alina Nicoara

ProPlege Device Placement

Using a Guidewire for Advancement

- Ensure device tip is engaged in CS ostium and not forcefully contacting a wall
- Careful utilization is essential to prevent perforating CS
- Select a .035" guidewire with soft J tip; at least 100 cm long

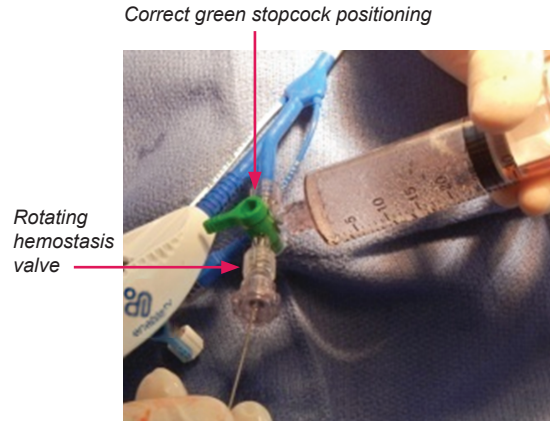


ProPlege Device Placement

Using a Guidewire for Advancement

Introduction

1. Withdraw the catheter slightly
2. Remove hose barb from green stopcock
3. Attach rotating hemostasis valve to green stopcock end port
4. Attach contrast-filled 30 mL syringe to side port
5. Open green stopcock to opposite side of side port
6. Open hemostasis valve by rotating it
7. Verify blood flows through hemostasis valve
8. Introduce guidewire through the hemostasis valve



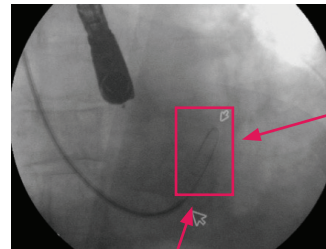
ProPlege Device Placement

Using a Guidewire for Advancement

Placement

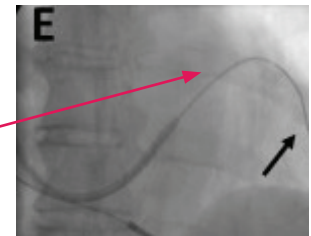
Use fluoroscopy to visualize--but first, verify hemostasis valve seal is completely closed

1. Insert guidewire
2. Tighten hemostasis valve until bleeding stops
3. Gently advance guidewire past catheter tip as much as possible
4. Slightly retract catheter to straighten shaft
5. Re-advance catheter into desired position
6. Confirm catheter location



*Incorrect positioning:
Guidewire is not advanced enough and turning back on itself*

Catheter tip



*Correct positioning:
Guidewire is advanced well beyond catheter tip*

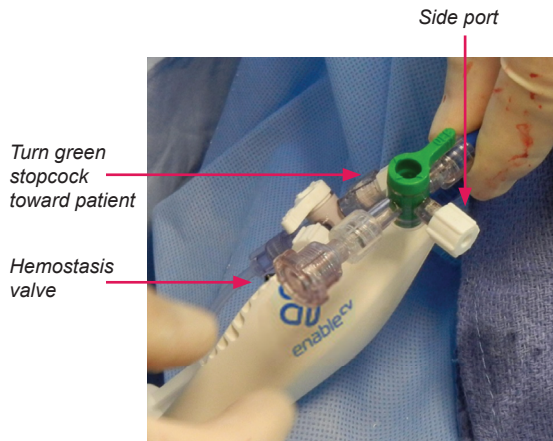
Images by Dr. Greg Miller

ProPlege Device Placement

Using a Guidewire for Advancement

Removal

1. Remove guidewire
2. Turn green stopcock toward patient
3. Remove hemostasis valve
4. Remove contrast filled syringe
5. Attach syringe with sterile heparinized physiologic solution to green stopcock side port
6. Flush contrast
7. Remove syringe from side port and re-cap to close off
8. Reconnect hose barb adapter to keep catheter sterile



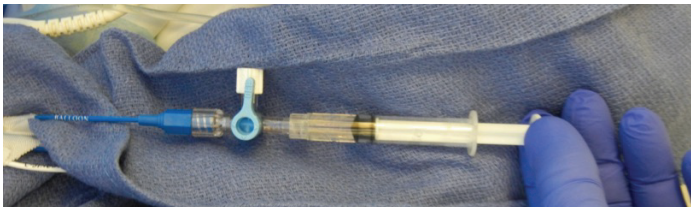
ProPlege Device Placement

Inability to Inflate Balloon

Verify:

- Luer connection on blue stopcock is secure
- 3 mL syringe is secure on blue stopcock
- Stopcock turned off to side port
- Device is not kinked
- Contrast was not mixed incorrectly (mixture ratio)

WARNING: Do not exceed maximum inflation volume of 1.4 mL. Balloon burst and/or coronary sinus injury may occur.



ProPlege Device Placement

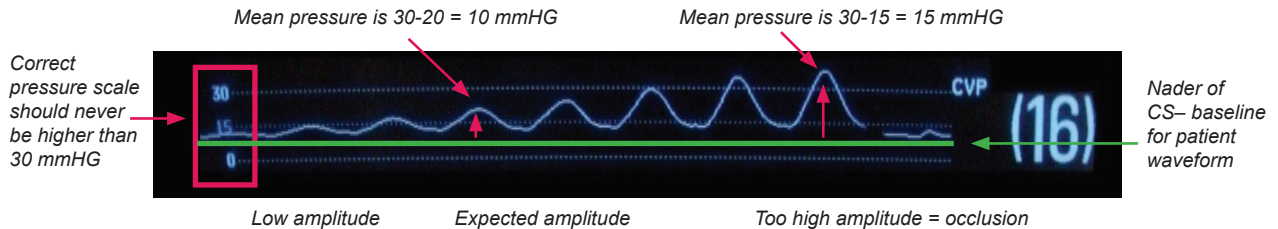
Ventricularization is Not Observed

Catheter is not in the CS, so:

- Use transesophageal echo and/or fluoroscopy to locate catheter
- Verify scale is adjusted to read 30 mmHg
- Consider patient may keep low amplitude ventricularization waveform
- Re-inflate balloon and evaluate change in waveform amplitude before and after

WARNING: Do not exceed maximum inflation volume of 1.4 mL.

Balloon burst and/or coronary sinus injury may occur.



No Ventricularization

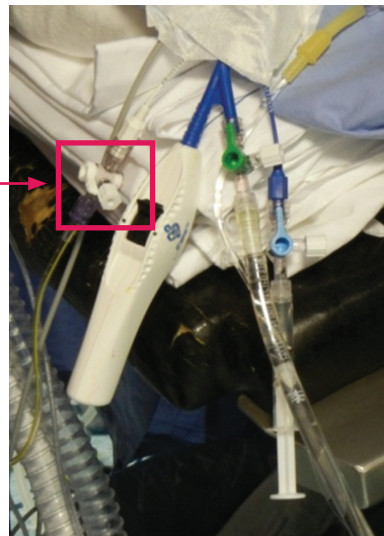
ProPlege Device Placement

Ventricularization is Not Observed

Next steps for troubleshooting:

- Ensure catheter was properly prepped
- Check monitoring/transducer system function
- Ensure all connections are tightened
- Check that white stopcock is turned toward side port
- Flush and re-zero CS pressure lumen
- Consider repositioning device: Retract device into right atrium
 - Reposition it
 - Confirm placement

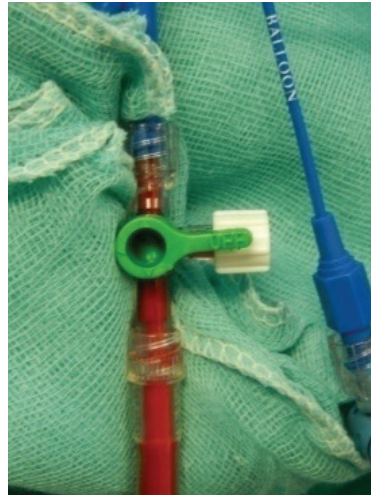
Correct white stopcock position



ProPlege Device Placement

Difficulty Infusing Retrograde Cardioplegia

- Cause: ProPlege device's smaller catheter size and length and smaller lumen can result in more resistance to cardioplegia flow and higher line pressures
- To troubleshoot:
 - Flush residual contrast from catheter
 - Verify green stopcock and connections are properly positioned toward side port
 - Ensure lines are not kinked or twisted



Correct positioning of green stopcock

ProPlege Device Placement

Difficulty Infusing Retrograde Cardioplegia

Next steps for troubleshooting

Consider tip may be too deep, in side branch, adjacent to vessel wall, or proximal to CS valve:

1. Temporarily discontinue cardioplegia infusion
2. Deflate balloon
3. Unlock distal connector
4. Retract catheter no more than 1 cm
5. Re-inflate balloon and re-lock distal connector
WARNING: Do not exceed maximum inflation volume of 1.4 mL. Balloon burst and/or coronary sinus injury may occur.
6. Re-attempt retrograde cardioplegia infusion
7. If unsuccessful, repeat by pulling catheter up to 2 cm
8. If still unsuccessful, try to deliver as much cardioplegia as possible
9. If still unsuccessful, proceed with antegrade-only cardioplegia strategy

Distal connector is unlocked: The two rings are misaligned, meaning disengagement



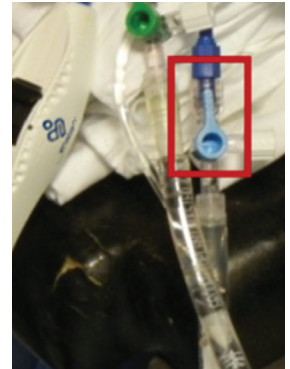
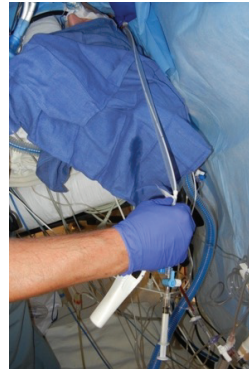
ProPlege Device Placement

Challenge Removing Catheter Through Introducer Sheath

If resistance is felt when attempting device removal through introducer:

- Do not exert excessive force
- Ensure balloon is completely deflated
- Confirm blue stopcock is off to the patient
- Gently re-attempt removal
- If unsuccessful, check whether the catheter was inadvertently sewn in

Still unsuccessful? Remove device and sheath as one unit.



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.

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.

Images courtesy of Dr. Greg Miller and Dr. Alina Nicoara.

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