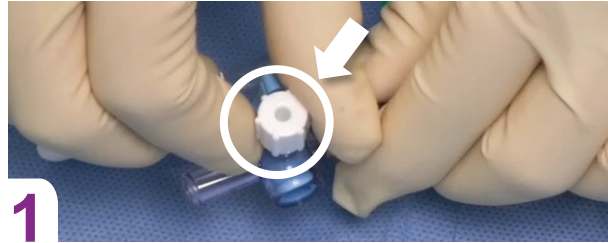


## BALLOON INFLATION LUMEN PREP (de-airing and checking balloon integrity) with the blue stopcock

The ProPlege device is designed for use during cardiopulmonary bypass to provide occlusion of the coronary sinus, to deliver retrograde cardioplegic solution to the myocardium via the coronary sinus, and to monitor the coronary sinus pressure.



- 3**
- Draw back syringe plunger to remove air in balloon and lumen.
  - While syringe plunger is retracted, turn blue stopcock off to device.



- 1**
- Remove white cap from blue stopcock. Verify blue stopcock is turned off to side port.



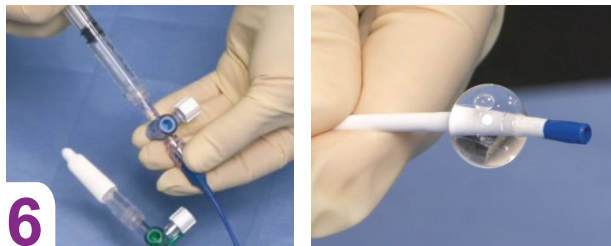
- 2**
- Attach 3 mL syringe to end port on blue stopcock.



- 4**
- Remove and fill 3 mL syringe with heparinized saline and reattach it to end port on blue stopcock.
  - While pointing open side port upwards to facilitate air evacuation, slowly inject up to 0.5 mL of fluid through port until it is de-aired.



- 5**
- Reattach white cap and turn stopcock off to side port.



- 6**
- Flip device over so that positioning dial is downwards facing table. Hold attached syringe vertically, with syringe tip pointing down.
  - In slow and controlled manner, depress syringe plunger to inject no more than 1.4 mL of heparinized saline into balloon.



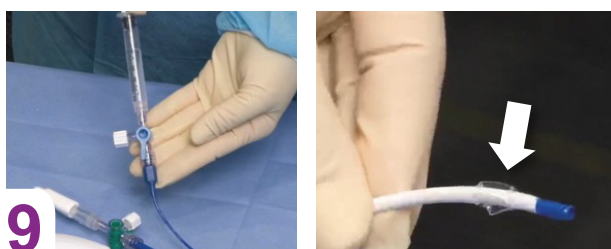
- 7**
- While keeping syringe connected and vertical, slowly pull back syringe plunger to remove air from balloon.
  - Ensure tip of device is pointed upwards to facilitate air removal through distal de-airing hole of balloon.
- Do not flick or apply external pressure to balloon as a means of de-airing as this may damage integrity of balloon.**



- 8**
- In same position, inflate balloon with fluid by depressing syringe plunger, in slow and controlled manner, taking care to not inject air into balloon.
  - Inspect balloon for air.
- If air remains in the balloon, repeat previous balloon deflation and inflation steps until air has been removed.**

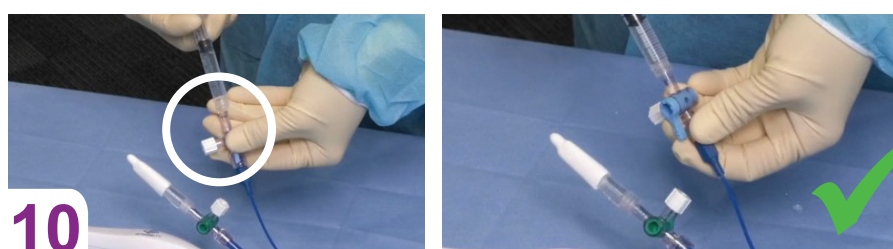
**WARNING: Do not exceed maximum inflation volume of 1.4 mL. Balloon burst and/or coronary sinus injury may occur.**

- Verify balloon integrity and proper inflation.



- 9**
- Once all air removal has been confirmed, draw back syringe plunger to fully deflate balloon.
  - While syringe plunger is retracted, turn blue stopcock off to device, thus creating a vacuum in balloon.

**This step is important to ensure that tip of device passes smoothly through introducer sheath.**



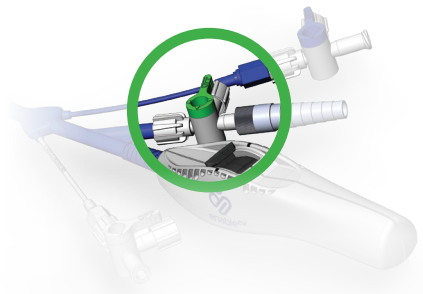
- 10**
- Remove syringe from blue stopcock and wet fill open port.
  - Fill syringe per hospital protocol. Reattach syringe to open wet-filled port.
- Balloon and lumen are now primed.**

**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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**CARDIOPLEGIA LUMEN PREP**

The **green stopcock** provides luminal access for retrograde cardioplegia delivery and, if needed, guidewire access through the included rotating hemostasis valve adapter attachment.



- 1**
- Turn green stopcock off to device.
  - Remove white cap from side port and contamination cap from hose barb connector.



- 2**
- Fill 30 mL syringe with heparinized saline; attach to open side port of green stopcock.
  - With hose barb adapter pointing up, inject fluid until a continuous flow exits hose barb adapter. Recap it. Turn stopcock off to hose barb adapter.



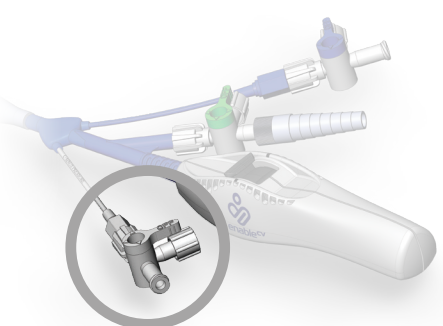
- 3**
- Depress syringe plunger to flush cardioplegia infusion lumen until fluid comes out of tip and all air is removed.



- 4**
- Turn green stopcock off to device.
  - Remove syringe, wet fill side port, and reattach white cap.



- 4**
- Turn green stopcock off to device.
  - Remove syringe, wet fill side port, and reattach white cap.
- Cardioplegia lumen is now primed.**

**CORONARY SINUS PRESSURE LUMEN PREP**

The **white stopcock** is attached to the coronary sinus pressure lumen.



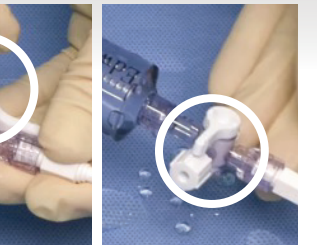
- 1**
- Remove two white caps on white stopcock and turn stopcock off to device.



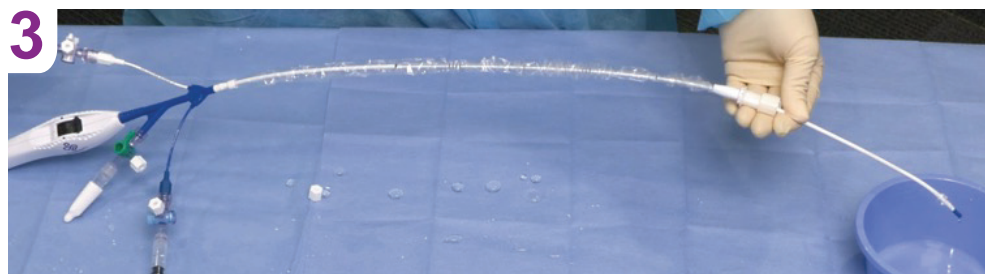
- 2**
- Attach 30 mL syringe with heparinized saline to end port.
  - Point open side port upwards to facilitate air evacuation.
  - Slowly inject fluid through side port until it is deaired.
  - Reattach white cap and turn stopcock off to side port.



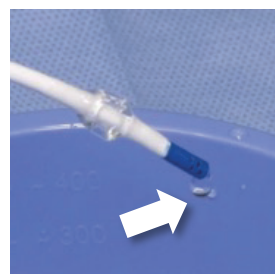
- 3**
- While pointing tip of device downwards, flush heparinized saline through coronary sinus pressure monitoring lumen until all air is removed.
  - Visually verify that fluid is dripping from one or more of holes at distal tip of device.



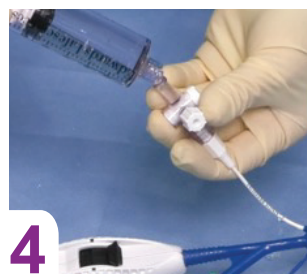
- 4**
- Turn white stopcock off to device
  - Remove syringe, wet fill end port, and reattach white cap.



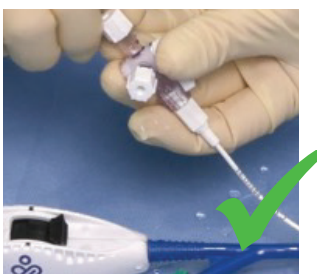
- 3**
- While pointing tip of device downwards, flush heparinized saline through coronary sinus pressure monitoring lumen until all air is removed.
  - Visually verify that fluid is dripping from one or more of holes at distal tip of device.



- 4**
- Turn white stopcock off to device
  - Remove syringe, wet fill end port, and reattach white cap.



- 4**
- Turn white stopcock off to device
  - Remove syringe, wet fill end port, and reattach white cap.
- Coronary sinus pressure lumen is now primed.**



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