

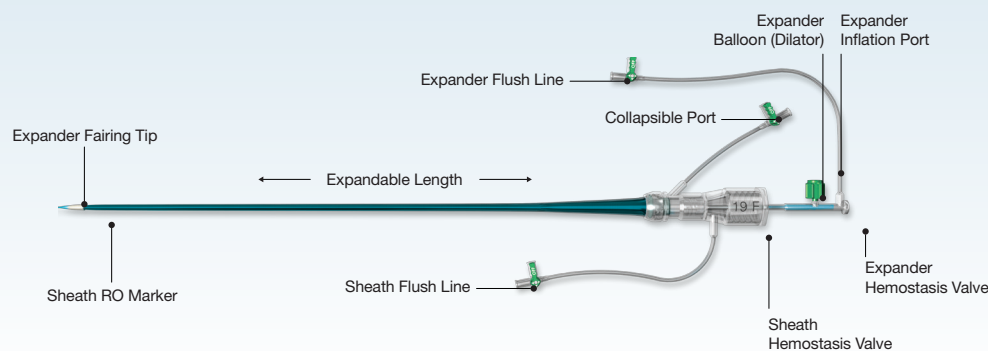


DO NOT PUSH OR PULL THE EXPANDER BALLOON (DILATOR) WITHIN THE SYSTEM PRIOR TO EXPANSION OF THE SHEATH

SoloPath™ RE-COLLAPSIBLE

Re-collapsible Balloon Access System

Components of SoloPath™ Re-collapsible System



Step 1: Insertion



- Flush the **Expander** and **Sheath Flush Lines** with heparinized saline.
- Wipe down the shaft of the sheath with saline prior to insertion to activate hydrophilic coating.
- Apply firm pressure over the access site to prevent excessive bleeding. Using the **Sheath Radiopaque Marker** to visualize tip location, advance the SoloPath over a guidewire using fluoroscopic guidance.

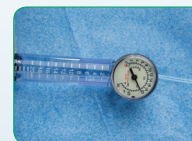
CAUTION: If you encounter resistance, stop advancing SoloPath until the problem has been determined and corrected.

Step 2: Balloon expander preparation

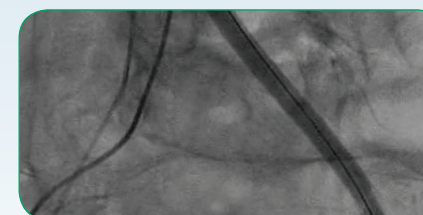


- Utilizing a 25cc inflation device, draw up 20cc of 50% contrast media and sterile saline preparation. Attach to the **Expander Inflation Port**.

NOTE: 20 atmospheres (ATM) may take a bit longer than anticipated due to the volume of fluid that will need to be injected into the balloon to fully inflate.



Step 3: Sheath expansion



- Under fluoroscopic guidance, slowly inflate **Expander Balloon (Dilator)** TO 20 ATM AND HOLD PRESSURE FOR AT LEAST 60 SECONDS.

NOTE: It is common for the pressure measurement to hover around 6 ATM for 20-30 seconds as you turn the inflater during the inflation process until the sheath is fully expanded.

CAUTION: Verify that the sheath is fully expanded under fluoroscopic visualization. Maintain inflation pressure of 20 ATM for AT LEAST 60 SECONDS.

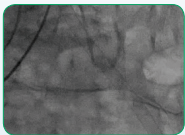
CAUTION: Only inflate the Expander after the Sheath has reached its final target location.

WARNING: NEVER use gas such as air to inflate the Expander.

Step 4: Expander withdrawal

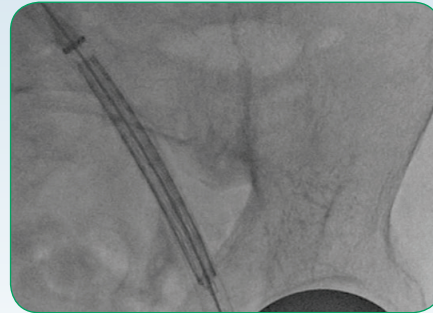


- Pull negative pressure on the indeflator and apply suction to the inflation port of the **Expander Balloon (Dilator)** to deflate the balloon completely. Remove the deflated **Expander Balloon (Dilator)** from the expanded sheath slowly.



CAUTION: Do not remove the Expander from the Sheath while the Expander is still under pressure.

Step 5: Therapeutic device insertion



- Introduce the appropriate therapeutic device or catheter through the **Sheath Hemostasis Valve** of the expanded sheath.

CAUTION: Maintain position of the expanded sheath within the vasculature during the procedure. Do NOT advance the expanded sheath.

CAUTION: If resistance is encountered during therapeutic device insertion, stop immediately, remove the device from the sheath and reinsert the **Expander Balloon (dilator)** over the guidewire.

REPEAT STEPS 3 AND 4 AND REINTRODUCE DEVICE. IF RESISTANCE PERSISTS, STOP AND REMOVE THE SHEATH FROM THE PATIENT.

WARNING: Do NOT attempt to force anything through a partially expanded sheath.

Step 6: Sheath collapse



- Remove all instrumentation from the sheath slowly through the **Sheath Hemostasis Valve** while visualizing on fluoroscopy.
- A diluted 50% solution of radiopaque contrast media and sterile saline is prepared and approximately 20cc are drawn up into an inflation syringe.
- Attach the inflation device to the **Collapsible Port** stopcock on the proximal sheath hub. Verify that the stopcock is in the open position between the collapsible port and inflation syringe.
- Pull a slight negative pressure on the syringe to remove any excess air from the system and inject the diluted contrast solution up to 6 ATM.

Step 7: Sheath withdrawal



- Apply negative pressure on the syringe to remove fluid from the jacket and reduce sheath profile. Prior to removing the sheath, apply slight pressure with the syringe by hand to gently fill the jacket and obstruct blood flow during the removal process.
- Slowly withdraw the sheath from the vascular system while holding pressure at the access site and visualizing on fluoroscopy.

CAUTION: If resistance is encountered or if arterial complication is visualized on fluoroscopy, stop withdrawing the sheath until cause can be determined and corrected.

WARNING: NEVER use gas such as air to collapse the sheath.

Solopath™ is a trademark of Onset Medical Corporation