

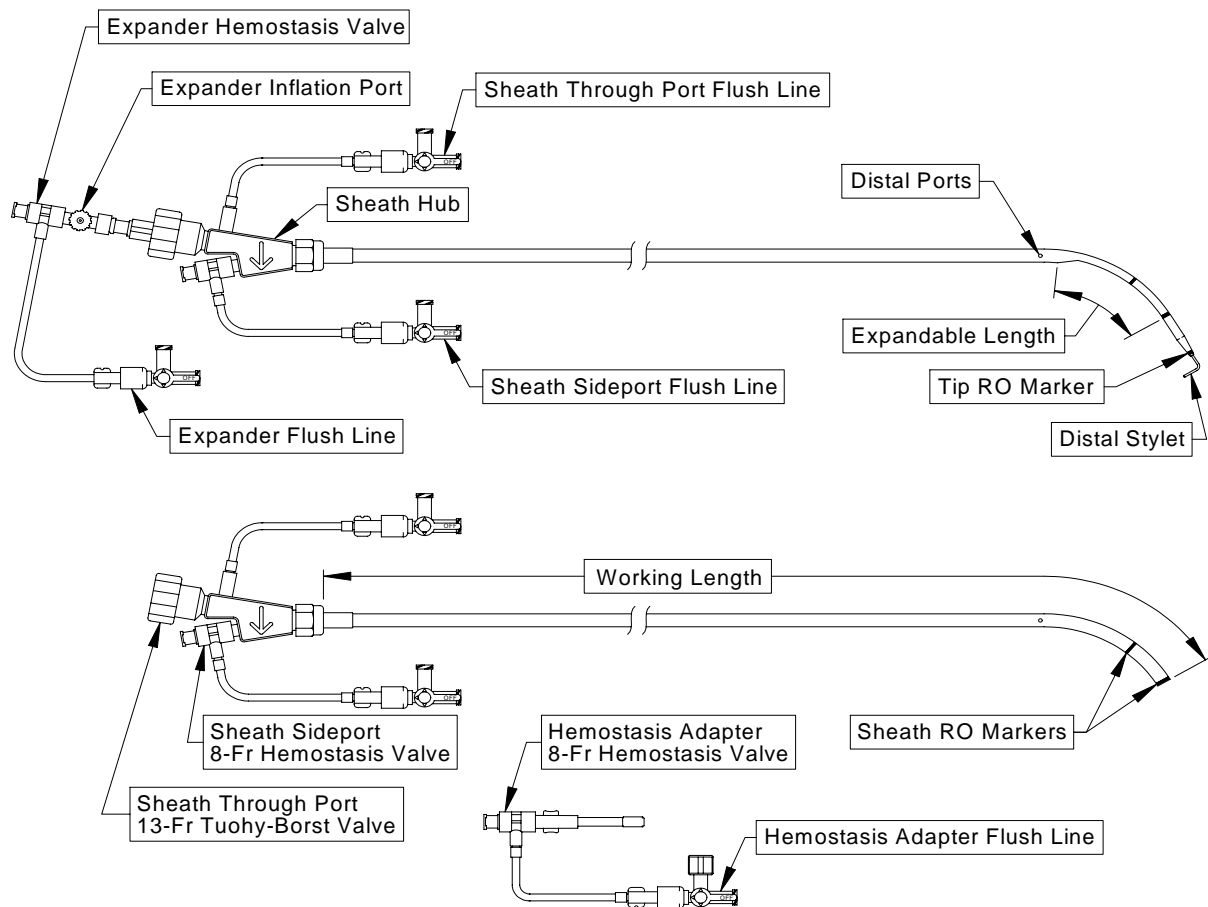


SoloPath™ Balloon Expandable Transseptal Introducer INSTRUCTIONS FOR USE

Description

The Onset Medical Corporation's *SoloPath* Balloon Expandable Transseptal Introducer consists of a flexible, reinforced polymer sheath with a specially folded distal end (the Sheath) pre-mounted over a central balloon dilatation catheter (the Expander). The folded distal region of the Sheath is small in diameter, thus facilitating passage through the atrial septum. The *SoloPath* Assembly is inserted percutaneously into the femoral vein, over a guidewire, with the deflated Expander in place. The *SoloPath* is routed to the right atrium and, following septal puncture with a Brockenbrough-type needle, is advanced across the atrial septum into the left atrium. The Expander balloon, when inflated with liquid, exerts controlled radial force, enlarging the folded distal region of the Sheath and dilating the fossa ovalis of the atrial septum. The Expander balloon is deflated and the Expander is removed leaving a large central lumen extending from the proximal end to the distal end of the Sheath. The Sheath is designed as a guide for catheters introduced into the left atrium of the heart.

Figure 1 – *SoloPath* With and Without Expander



Product Specifications

The *SoloPath*[™] Balloon Expandable Transseptal Introducer is available with an 18 French or 16 French internal diameter and a working length of 70-cm. Refer to Table 1.

Model Number	Expanded Sheath I.D.	Expanded Sheath O.D.	Expandable Length	Dilator Tip Diameter	Working Length	Rated Inflation Pressure
	French	French	CM	French	CM	ATM/bar
SoloPath-1870	18	21	8.5	5.3	70	16
SoloPath-1670	16	19	8.5	5.3	70	16

An 8 French Hemostasis Adapter is provided to facilitate the insertion of devices up to 8 French O.D. through the Touhy-Borst valve located at the proximal end of the sheath.

Warning: The *SoloPath* Balloon Expandable Transseptal Introducer is supplied sterile and is intended for single use only. Do not reuse, resterilize or reprocess this device. Do not use this device if product or sterile packaging is damaged.

STERILE EO

② Single Use Only

Device Construction

Intended for travel over a 0.048” Brockenbrough needle or 0.038” or smaller guidewire.

A flexible Sheath composed of reinforced polymer is compressed, folded and wrapped around a central, removable balloon dilatation catheter (the Expander).

Two radiopaque markers are located on the Sheath to indicate optimal positioning of the device prior to expansion. One radiopaque marker is located at the distal end of the Expander to designate the most distal extent of the device.

Multiple distal ports are located near the distal end of the Sheath.

The Expander balloon is non-compliant and size limited. The Expander has both an inflation lumen and a guidewire lumen.

The Expander is configured to be used with standard inflation devices having an appropriate pressure rating, a male Luer lock coupler, and a capacity of 20-CC.

The Sheath is terminated, at its proximal end, by a hub having an angled through-port and a fully-closing Tuohy-Borst valve capable of accepting up to 13-French catheters. The Sheath hub further has an angled sideport terminated with a fully-closing hemostasis valve which is capable of accepting up to 8-French catheters.

Aspiration and infusion ports, terminated with 3-way stopcocks, permit infusion of heparinized saline into both the through-port and the sideport of the Sheath hub, prior to and during the procedure. The Expander incorporates a T-connector, the through lumen port being terminated with a hemostasis valve, for guidewire and Brockenbrough needle introduction, while the right angle port is for inflation of the Expander balloon. A separate aspiration and infusion side port, terminated with a 3-way stopcock, is also provided which permits fluid transfer into or from the guidewire lumen of the Expander.

Indications for Use

The *SoloPath*[™] Balloon Expandable Transseptal Introducer is intended to establish a conduit, into the left side of the heart, through the inter-atrial septum, for the introduction of various cardiovascular catheters.

Caution: A thorough understanding of the technical principles, clinical applications and risks associated with cardiac transvenous, transseptal atrial access is required before attempting to use this device.

Contraindications

The *SoloPath* Balloon Expandable Transseptal Introducer is contraindicated in the following circumstances:

- Previous intra-atrial septal patch or implanted septal closure devices.
- Previous systemic embolization from the left side of the heart.
- Known or suspected left atrial myxoma.
- Known or suspected myocardial infarct (MI) within the last two weeks.
- Unstable angina.
- Recent cerebral vascular accident (CVA).
- Patients who do not tolerate anticoagulation therapy.
- Patients with active infections.

Precautions

- Inspect all components before use.
- Carefully read the instructions for use (IFU) before using this device to help reduce the potential dangers associated with the transseptal technique such as air emboli and/or perforation of the aorta or left atrium.
- Prior to inserting the device into the patient, insert the Brockenbrough needle through the balloon Expander central lumen, checking and correcting for excessive resistance as the tip of the needle advances through the curvature of the Sheath/Expander assembly.
- During insertion of the Brockenbrough needle, use caution not to create new bends or kinks in the Sheath/Expander assembly, which may inhibit advancement of the Brockenbrough needle and may result in inadvertent needle puncture of the Sheath/Expander assembly.
- Use only a Brockenbrough-type needle having an 89-cm working length.
- Frequently aspirate and flush, with heparinized saline, the Sheath, the Expander, the Hemostasis Adapter, and any catheters to minimize the potential for air emboli and/or clot formation.
- Rapid withdrawal of catheter or dilator through the hemostasis valves may cause misalignment of the valve gasket assembly causing bleed-back through the valve. Do not remove the balloon Expander or catheter from the Sheath rapidly or damage to the Tuohy-Borst or hemostasis valves may occur, causing blood leakage out through the valve.

- If resistance is met when advancing or withdrawing the guidewire, Brockenbrough needle or Sheath, determine the cause by fluoroscopy and correct before continuing with the procedure.
- Inject or provide saline flush only through the Expander, the Hemostasis Adapter, or the Sheath Flush Lines.
- Aspirate **only** from the Expander guidewire/needle lumen or Sheath Flush Lines.
- Certain conditions may require special consideration when using the *SoloPath*TM. These conditions may include enlarged aortic root, small left atrium, marked right atrial enlargement, marked distortion of the thorax such as that resulting from excessive kyphosis or scoliosis.

Potential Complications

Complications associated with the use of the *SoloPath* Balloon Expandable Transseptal Introducer include but are not limited to, cardiac perforation, aortic perforation, infection, post-procedural discomfort, air embolism, tissue trauma, hemorrhage, thromboembolism, thrombosis, injury to the vascular introduction site, and death.

WARNINGS

- Do not alter the device in any way.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- Do not reuse this device. Thorough cleaning of biological and foreign material from the device is not possible. Adverse patient reactions may result from reuse of this device.
- Only those physicians who are specially trained in transseptal procedures should use this device.
- Maintain continuous patient blood pressure monitoring throughout the procedure.
- Immediate availability of anterior-posterior and lateral fluoroscopy is required throughout the procedure.
- Always observe acceptable pressure tracings prior to advancing the dilator or any other component.
- Do not permit air to enter the Sheath. Remove components and make catheter exchanges slowly.
- Using the flushing lines, purge all air from the device prior to infusion.
- Provide a continuous drip of heparinized saline, under pressure, through the device while the Sheath remains within the vessel or cardiac structures.
- Fibrin may accumulate in or on the Sheath tip during the procedure. Aspirate following removing the Expander, Brockenbrough needle, or catheters.
- The device is intended for procedures only within the venous circulation or left atrium. Do not introduce the device into the systemic (arterial) circulation.

Suggested Procedure

Preparation

A standard cardiac, transseptal preparation should be completed per hospital protocol. Standard fluoroscopic equipment should be available for use during the procedure. Proper radiological protection should be provided for all attending personnel.

Device Inspection

Using aseptic technique, remove the *SoloPath™* and Hemostasis Adapter from its sterile pouch. Visually inspect the *SoloPath* to make sure there is no distortion or kinking in the shaft of the sheath or in the folded distal end and that a smooth taper exists between the distal end of the Sheath and the balloon Expander. The balloon Expander shaft is clamped into position within the Sheath by the closed Tuohy-Borst valve on the proximal end of the Sheath.

Caution: Do NOT attempt to unlock or separate the Sheath from the balloon Expander by loosening the Tuohy-Borst valve at any time prior to expansion of the Sheath within the atrial septum.

SoloPath Device Preparation

Use aseptic technique for all steps of the procedure. Remove the Distal Stylet from the *SoloPath*. Open the 3-way stopcock on the Through Port Flush Line of the Sheath and flush with sterile, heparinized saline. Close the stopcock. Open the 3-way stopcock on the Sheath Sideport Flush Line and flush with sterile, heparinized saline to ensure that all air is removed from the Sheath. Verify saline flow from the Distal Ports on the Sheath. Close the stopcocks to prevent saline loss or air embolism during the procedure.

Brockenbrough Needle Preparation

Remove a Brockenbrough Needle from its package and remove the stylet from the Needle. With the stopcock in the open position, flush the Brockenbrough needle with heparinized saline. Reinsert the stylet and lock it onto the hub.

Open the 3-way stopcock on the Expander Flush Line and flush with sterile, heparinized saline to ensure that all air is removed from the Expander guidewire lumen. Close the stopcock.

Fully insert the Brockenbrough needle into the hemostasis valve on the Expander. Advance the needle until it extends beyond the distal tip of the Expander. Withdraw the Brockenbrough needle until its tip is just within the distal end of the Expander. Measure the distance between the pointer flange on the proximal end of the Brockenbrough needle and the proximal end of the hemostasis valve on the Expander.

Fully remove the Brockenbrough needle from the *SoloPath*, open the 3-way stopcock, and again flush through the Expander Flush Line, using heparinized saline, making sure fluid flows from the distal end of the Expander.

Attach the through lumen of a high pressure stopcock to a high pressure line attached to a pressure transducer for later connection to the Brockenbrough needle for intra-atrial blood pressure measurements.

Percutaneous Access

A Seldinger preparation and access are completed into the femoral vein using, for example, an 18-gauge thin wall access hollow needle. A 0.038" stiff guidewire with a floppy tip is advanced through the access needle and into the femoral vein. Route the 0.038" guidewire

into the venous system, through the inferior vena cava, and into the superior vena cava under fluoroscopic guidance.

SoloPath™ Device Insertion

Ensure that the Tuohy-Borst valve is closed and that all ports have been flushed and primed with heparinized saline and are free of air. The *SoloPath* with its integral balloon Expander is advanced as a single unit, under fluoroscopic control, over the 0.038” guidewire until its Tip radiopaque marker is positioned well within the superior vena cava. Inject radiopaque contrast media through the Expander Flush Line, as required, under fluoroscopic visualization to ensure correct placement. Remove the guidewire from the Expander.

Caution: The *SoloPath* is to be advanced over the 0.038” guidewire as a single unit. Do not allow separation or misalignment of the central balloon Expander from the unexpanded Sheath prior to expansion within the atrial septum.

Caution: Should resistance be encountered, cease advancing the *SoloPath* until the cause of the resistance can be determined and corrected.

Caution: The balloon Expander is intended for inflation only after the unexpanded Sheath has been completely advanced to its final target location within the atrial septum.

Caution: Do not attempt to refold an expanded sheath.

Brockenbrough Needle Insertion

Carefully attach a 10-cc syringe filled with 1-cc of sterile heparinized saline to the Expander Flush Line and withdraw until blood is observed. Repeat this procedure to ensure the Expander Flush Line is free of air.

Insert the Brockenbrough needle with stylet into the needle guidewire port of the Expander and route the Brockenbrough needle so that its tip is aligned behind (proximal to) the radiopaque marker located at the distal tip of the *SoloPath* Expander. This is confirmed using the dimensions measured earlier between the pointer flange and the *SoloPath* proximal end. Rotate the Brockenbrough needle and *SoloPath* so that the pointer on the Brockenbrough is aligned with the *SoloPath* Sheath Hub Sideport and that both Brockenbrough pointer and Sheath Hub Sideport are oriented medially. Remove the stylet from the Brockenbrough needle and attach the 3-way, high pressure stopcock with attached pressure transducer to the Luer port of the Brockenbrough needle. Attach a 10-cc syringe filled with 1-cc of heparinized, sterile saline to the side port of the 3-way stopcock. Withdraw blood into the 10-cc syringe. Close the 3-way stopcock and remove and discard the syringe. Repeat the blood withdrawal with another new 10 cc filled with 1 cc of heparin to insure the absence of air.

Atrial Access

The *SoloPath*, with Brockenbrough needle inserted, is withdrawn caudally with the tip of the Brockenbrough needle oriented medially, toward the atrial septum as evidenced by the orientation of the pointer flange being at 3:00 to 5:00 as observed from the patient’s feet. Withdrawal of the *SoloPath* will result in the tip moving medially when it enters the right atrium. When, upon further withdrawal, the tip of the *SoloPath* abruptly moves markedly medially into the fossa ovalis, further withdrawal is discontinued and the atrial septal wall should be engaged. The fossa ovalis is now “tented” toward the left atrium.

Using a 10-cc syringe filled with radiopaque contrast media, inject a small amount of contrast media through the high pressure stopcock attached to the central lumen of the Brockenbrough needle to “Paint” the fossa ovalis with a mark that is visible under fluoroscopy.

Caution: Make sure that the tip of the Brockenbrough needle is withdrawn just inside the RO marker at the distal tip of the Sheath Expander by checking the distance previously measured between the proximal end of the *SoloPath*[™] and the Brockenbrough needle pointer flange.

Carefully monitoring the pressure within the lumen of the Brockenbrough needle, the Brockenbrough needle is next advanced out of the *SoloPath* and through the atrial septum into the left atrium, taking care not to move the *SoloPath*. Continuous fluoroscopic monitoring is essential during this phase.

Warning: Penetration of the wrong structures could lead to aortic puncture, exsanguination, and patient death.

The fossa ovalis will, under mechanical pressure, move laterally over the *SoloPath* so that the distal end of the device now resides within the left atrium as indicated by pressure waveforms consistent with the left atrium and fluoroscopic observation. The proximal and distal Sheath Radiopaque Markers (second and third RO markers from the distal end of the *SoloPath* assembly) should now straddle the position of the fossa ovalis the location of which is evidenced by the “Painted” mark generated in a prior step.

Sheath Expansion

A dilute 50% solution of radiopaque contrast media and sterile saline is prepared and approximately 15-CC are drawn up into a high-pressure balloon inflation syringe equipped with a pressure gauge (not supplied). Care should be taken to remove all air from the syringe, the Expander, and associated tubing. Remove the vented cap from the Expander balloon inflation port and attach to it the 3-way stopcock. Attach the pressure line of the inflation device to the through lumen of the 3-way stopcock attached to the Expander balloon inflation port. Attach a syringe filled with radiopaque contrast media to the other lumen of the 3-way stopcock.

Under fluoroscopic control, the high-pressure inflation syringe’s dilute contrast media is injected up to the maximum Rated Inflation Pressure per Table 1. It is normal to observe a drop in pressure as the Expander balloon progressively expands the folded distal section of the Sheath. The rated inflation pressure should be maintained for a minimum of 30 seconds to expand any “waist” that may remain along the length of the expanded Sheath.

Warning: Only use liquid to inflate the Expander. NEVER use gas, such as air, to inflate the Expander.

Deflated Expander Removal and Sheath use

Apply suction, using the high-pressure inflation syringe, to the inflation/deflation port attached to the 3-way stopcock on the Expander inflation port in order to deflate the balloon of the Expander. Slightly loosen the Tuohy-Borst valve on the through lumen at the proximal end of the Sheath hub. Remove the deflated Expander from the expanded Sheath being careful to immediately close the Tuohy-Borst valve to prevent blood loss or introduction of air. Introduce the appropriate therapeutic or diagnostic catheter(s) through the central working channel of the expanded Sheath into the left atrium.

An 8 French Hemostasis Adapter (provided) may be inserted and sealed within the Touhy-Borst valve to facilitate introduction and removal of diagnostic or therapeutic devices. This adaptor may be placed after the Expander has been removed from the Touhy-Borst valve. Before placement, flush the adaptor with heparinized saline to remove air. Insert the stem of the Hemostasis Adapter into the Touhy-Borst valve and tighten snugly by hand. When the Hemostasis Adapter is secured, connect a 10 cc syringe filled with 1 cc of heparin to the Hemostasis Adapter Flush Line’s stopcock and withdraw blood to ensure the absence of air in the system. The Hemostasis Adapter is now ready for use.

Caution: Care should be taken to maintain the position of the expanded Sheath within the heart during the procedure. Advancing an already expanded Sheath must be avoided as this movement may not be possible and any attempt will potentially damage cardiac tissue.

Sheath Removal

Remove any instrumentation from the Sheath, being careful to control the Tuohy-Borst or hemostasis valves to prevent blood loss. While maintaining hemostasis and using standard hospital procedure to control a venous percutaneous puncture site, gently withdraw and remove the expanded Sheath from the venous circulation when the procedure has been completed.

How Supplied

Contents of unopened, undamaged package are sterile and non-pyrogenic.

STERILE EO  **Single Use Only**

This device is sterilized with ethylene oxide gas. It is intended for single use only. Do not use if the package is opened or damaged.

Storage

Store in a cool, dry place. Rotate inventory so that products are used prior to the sterilization expiration date on package label.

Warranty

Warranty and Limitations: Onset warrants to Customer that its products are free from defect in design, workmanship and materials. For its sterile products Onset further warrants to Customer that such products will remain sterile to the expiration date specified on the applicable product's label, provided that the original packaging remains intact, and is not compromised in any manner. This warranty shall not apply to any products, which have been re-sterilized, repaired, altered or modified in any manner, or to any products, which have been improperly stored, installed, operated, used or maintained in any manner. In the event of any breach of its warranty set forth above, Onset's sole obligation shall be to repair or replace, at its sole option, any product that Onset determines was defective in workmanship or materials at the time of shipment if notice thereof from Customer is received by Onset within the "use before" or expiration date, as applicable, described on such product's label. Except as expressly provided above, Customer assumes all responsibility and all other liability, whether based upon warranty, contract, negligence, or otherwise, for injury or damages resulting from handling, possession, use or misuse of any Onset product and agrees to defend and indemnify Onset for same. Because Onset has no control over the operation, use, or maintenance of its products, the selection of patients or their condition, and does not warrant the performance of its products, THE WARRANTY SET FORTH ABOVE IS EXPRESSLY ACKNOWLEDGED BY CUSTOMER TO BE IN LIEU OF ANY OTHER EXPRESS WARRANTY AND OF ANY OTHER OBLIGATION ON THE PART OF ONSET. The remedies set forth in this Warranty and Limitations shall be the exclusive remedy available to any person. No officer, employee, representative or any other agent of Onset has any authority to change or otherwise modify in any respect any of the foregoing, or to act in any manner to assume or bind Onset to any additional liability or responsibility in connection to its products. Customer's submission of any orders for any Onset product(s) shall be deemed irrevocable acceptance of all of the terms and conditions of the foregoing Warranty and Limitations.

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