Onset
Medical Corporation

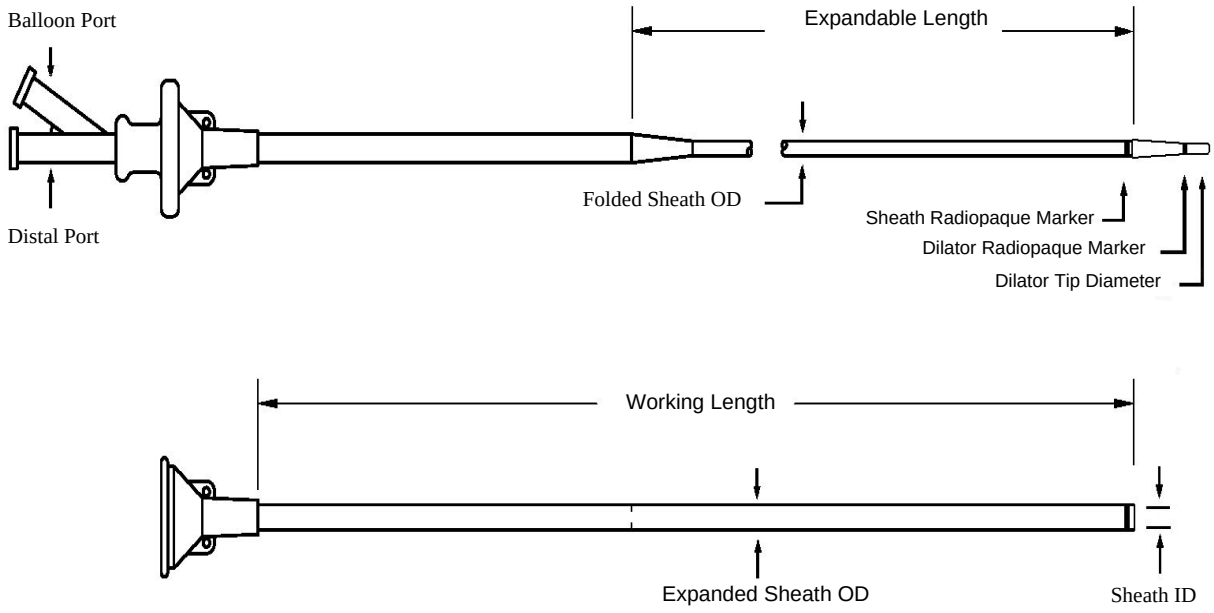
Pathway™ Balloon Expandable Ureteral Access Sheath
INSTRUCTIONS FOR USE

Description

The *Pathway*™ Balloon Expandable Ureteral Access Sheath (the Sheath) consists of a specially folded flexible, hydrophilic coated, reinforced polymer Sheath pre-mounted over a central balloon Dilator (the Dilator). The folded distal region of the Sheath is small in diameter, to facilitate passage, over a guidewire, through the urethra and ureter.

The assembled device is inserted transurethrally into the ureter, over a guidewire, with the deflated balloon Dilator in place. The balloon, when inflated with liquid, exerts controlled radial pressure, enlarging the folded distal region of the Sheath. The Dilator is deflated and removed leaving a large central lumen extending from the proximal end to the distal end of the Sheath. The Sheath is designed for lining the urethra and ureteral tracts, to facilitate instrumentation during ureteroscopy procedures.

Figure 1 – Pathway™ Balloon Expandable Ureteral Sheath



Product Specifications

The *Pathway*™ Balloon Expandable Ureteral Access Sheath is available in three (3) internal diameters (11, 12 and 13-French) and three (3) working lengths (28, 36, and 46-cm). Refer to Table 1.

Table 1 – *Pathway*™ Balloon Expandable Ureteral Access Sheath

Model Number	Sheath I.D.	Expanded Sheath O.D.	Folded Sheath O.D.	Expandable Length	Dilator Tip Diameter	Working Length	Rated Inflation Pressure
	French	French	French	CM	French	CM	ATM/bar
255100	11	14	9.5	20	4.4	28	25
255101	11	14	9.5	25	4.4	36	25
255102	11	14	9.5	25	4.4	46	25
255106	12	15	9.75	20	4.4	28	25
255107	12	15	9.75	25	4.4	36	25
255108	12	15	9.75	25	4.4	46	25

Warning: The *Pathway*™ Balloon Expandable Ureteral Access Sheath 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
Sterilized with ethylene oxide gas.

Single Use Only

Device Construction

- Designed to travel over a 0.038", or smaller, guidewire.
- A flexible, hydrophilic coated Sheath composed of reinforced polymer is compressed, folded and wrapped around a central, removable balloon Dilator.
- A radiopaque marker is located within the Sheath to identify the most distal portion of the access Sheath. A second radiopaque marker is located approximately 1cm proximal from the distal tip to facilitate Sheath placement within the ureter.
- The Dilator balloon is non-compliant and size limited. The balloon Dilator has both an inflation lumen and a guidewire lumen with separate access ports as illustrated in Figure 1.
- A hemostasis valve "Y" connector (not supplied) may be placed on the Distal port so that dilute contrast media may be injected through the guidewire lumen with the guidewire in place.
- The balloon Dilator is configured to be used with standard inflation devices having an appropriate pressure rating for the device selected for use (see Table 1, Rated Inflation Pressure), a male luer lock coupler and capacities of 10 to 30 cc.

Indications for Use

The *Pathway*™ Balloon Expandable Ureteral Access Sheath is intended to establish a conduit, during endoscopic urological procedures, facilitating the passage of endoscopes and other instruments into the ureter by way of the urethra and bladder.

Contraindications

The *Pathway*™ Balloon Expandable Ureteral Access Sheath is contraindicated when conditions exist which create unacceptable risk during ureteral or urethral access.

Potential Complications

Complications associated with the use of the *Pathway*™ Balloon Expandable Ureteral Access Sheath include but are not limited to, ureteral, urethral, or bladder perforation, infection, post-procedural discomfort, tissue trauma, ureteral tears, hematuria, residual calculi, ureteral or urethral strictures, pyelonephritis, acute bleeding, and injury to the kidney and surrounding structures.

Suggested Procedure

Preparation

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

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

Cystoscopy

With irrigation and endoscopy equipment enabled, a cystoscope is prepared and inserted into the urethra to the bladder, using standard hospital procedure. The entrance to the ureter should be located visually.

A 0.038" stiff guidewire is advanced through the cystoscope and inserted under visual guidance into the selected ureter. The guidewire should be advanced into the ureter and beyond the treatment site under fluoroscopic guidance.

Device Inspection

Using aseptic technique, remove the Sheath from its sterile pouch. Remove the protective cover from the distal end of the Sheath. Visually inspect the Sheath to make sure there is no distortion or kinking in the folded distal end and that a smooth taper exists between the distal end of the Sheath and the balloon Dilator. Make sure the balloon Dilator hub is firmly snapped onto the Sheath hub.

Device Preparation

Liberally apply sterile saline to the hydrophilic coated Sheath before insertion. Keep the surface of the Sheath wet with saline while inserting.

Device Insertion

Sterile lubricating jelly may be applied to the Sheath prior to insertion. The Balloon Expandable Ureteral Access Sheath with its balloon Dilator is advanced as a single unit, under fluoroscopic control, over the guidewire until its radiopaque tip marker is positioned within the ureter at the desired location.

Caution: The *Pathway*™ Balloon Expandable Ureteral Access Sheath is to be advanced over the guidewire as a single unit. Do not separate the central balloon Dilator from the unexpanded Ureteral Access Sheath prior to full insertion. DO NOT use if the Dilator is removed from the Sheath prior to insertion. Do not attempt to reassemble if the Dilator is removed from the Sheath prior to insertion. If components are separated prior to insertion, the device should be discarded.

Caution: The hydrophilic coated sheath must be moistened with sterile saline before insertion and kept wet while maneuvering.

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

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

Sheath Expansion

A dilute 50% solution of Renografin® 60, or other contrast media, and sterile saline is prepared and approximately 10 to 30 cc are drawn up into a high-pressure balloon inflation syringe equipped with a pressure gauge (not supplied). Prior to use, care should be taken to remove all air from the syringe, the Dilator, and associated tubing.

Once the Sheath is properly positioned, the inflation syringe is attached to the Luer inflation port of the balloon Dilator shaft. Under fluoroscopic control, the dilute contrast media is injected into the balloon dilator to an optimum inflation pressure of 20atms. It is normal to observe a drop in pressure as the Dilator progressively expands the folded distal section of the Sheath. The rated inflation pressure should be maintained to fully expand the Sheath or for a minimum of 60 seconds to remove any “waist” segments that may remain along the length of the expanded Sheath. If full Sheath dilation is not achieved, deflate balloon, slightly reposition Sheath and re-inflate at rated inflation pressure and maintain to fully expand the Sheath. If optimum Sheath dilation is not achieved, the device may be held under pressure for a longer period of time and/or the pressure may be increased in 1atm increments until full dilation is achieved, not to exceed the maximum Rated Inflation Pressure per Table 1.

Warning: Only use liquid to inflate the balloon Dilator. NEVER use gas, such as air, to inflate the balloon Dilator or tissue damage could occur.

Deflated Balloon Dilator Removal

Prior to removal of the balloon Dilator, suction is applied with the high-pressure syringe to the inflation/deflation port in order to deflate the balloon. Unsnap the Dilator hub from the Sheath hub. Remove the deflated balloon Dilator from the expanded Sheath. Introduce the ureteroscope or other instrumentation through the central working channel of the expanded Sheath.

Caution: Care should be taken to maintain the position of the expanded Sheath within the ureter during the procedure. Advancement of the expanded Sheath without removing the inflated balloon may potentially result in damage to the ureteral tissue.

Caution: If there is resistance encountered when removing the Dilator, make sure the balloon has been completely deflated before continuing to withdraw the Dilator. If withdrawal resistance persists with the deflated Dilator, remove the Sheath and deflated Dilator together and replace device.

Sheath Removal

Gently withdraw and remove the expanded Sheath from the urinary tract when the procedure has been completed.

How Supplied

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

STERILE EO
Sterilized with ethylene oxide gas.

Single Use Only

CE 0297

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

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 label, provided that the original packaging remains intact, and is not compromised in any manner. The 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 each 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 warranty 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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U.S. and International Patents Pending

UPN Product No. 製品番号

This Product Contains No Detectable Latex.
本製品は検出可能なラテックスを含有しない。

Contents
内容物

Maximum Inflation Pressure

Distributed By:
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