



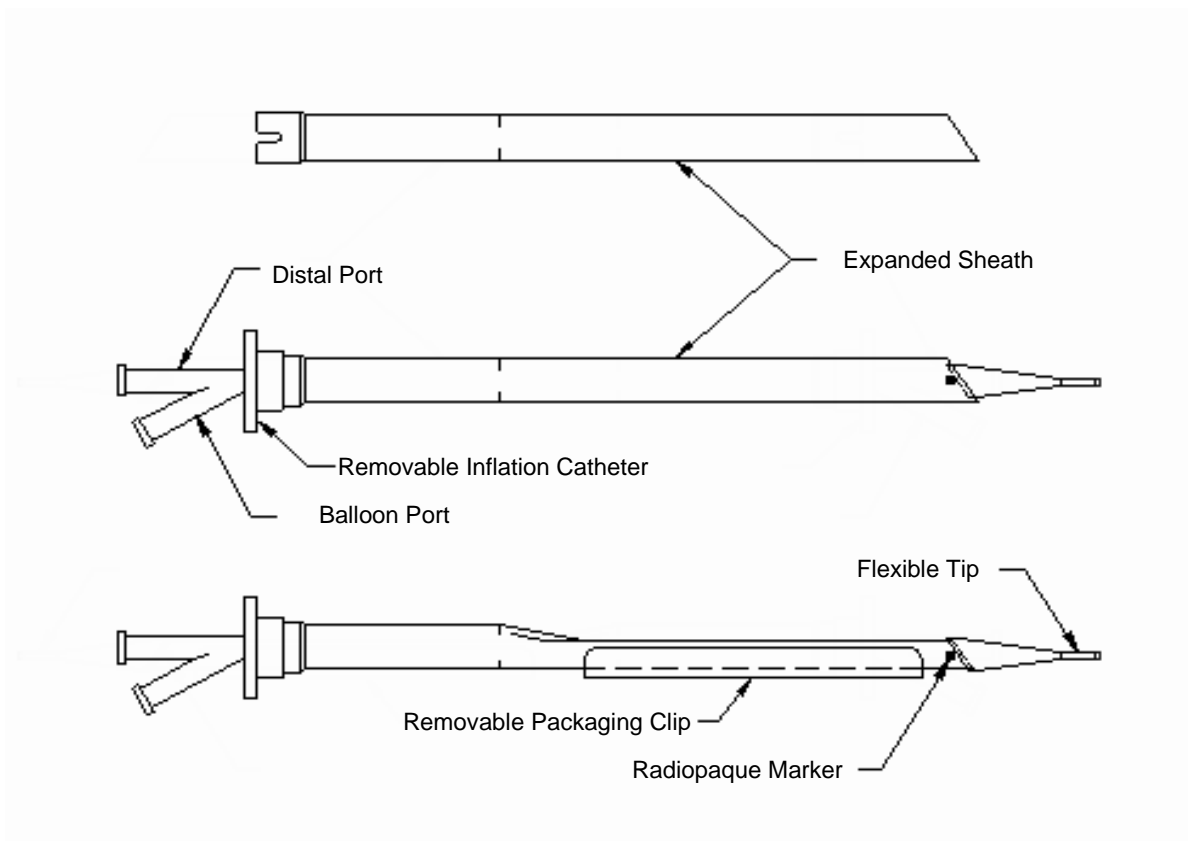
Pathway™ Balloon Expandable PCNL Sheath **INSTRUCTIONS FOR USE**

Rx ONLY Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

1. Description

The *Pathway* Balloon Expandable PCNL Sheath (the Sheath) consists of a specially folded flexible PTFE sheath mounted on a central balloon catheter (the Dilator) with a hydrophilic coated flexible tip. The balloon, when inflated with fluid, exerts controlled radial pressure, enlarging the folded radiopaque sheath. Once the folded sheath is expanded, it exerts controlled radial pressure on the surrounding tissue tract through which it travels. This device is designed for enlargement of percutaneous nephrostomy tracts in procedures for the removal of renal and ureteral calculi.

Figure 1



Product Specifications

The *Pathway*™ Balloon Expandable PCNL Sheath is available in three (3) different sizes (See Table 1).

Table 1 <i>Pathway</i> Balloon Expandable PCNL Sheath							
Model Number	Expanded Sheath I.D.		Expanded Sheath O.D.		Working Length	Overall Assembly Length	Rated Burst Pressure
	French	mm	French	mm			
215202	18	6.0	21	7.0	20	26.4	25
215304	30	10.0	33	11.0	17	23.4	25
215306	30	10.0	33	11.0	20	26.4	25

2. Warning

The *Pathway* Balloon Expandable PCNL 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

3. Device Construction

- Designed to travel over a 0.038" guidewire.
- A flexible, radiopaque sheath composed of PTFE is compressed down, folded and wrapped around a central balloon catheter.
- A radiopaque marker is located within the balloon to indicate the proximal edge of the Sheath's distal opening.
- A flexible hydrophilic coated distal tip.
- The central balloon is non-compliant and size limited. The balloon catheter has both an inflation/deflation lumen and a 0.038" guidewire lumen.
- An optional 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 folded PTFE sheath and central balloon have a removable packaging clip that is removed prior to insertion.

4. Indications for Use

The expandable sheath is designed for percutaneous formation of nephrostomy tracts required for removal of renal and ureteral calculi.

5. Caution

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

6. Contraindications

The *Pathway* Balloon Expandable PCNL Sheath is contraindicated when conditions exist which create unacceptable risk during percutaneous nephrostomy access.

7. Potential Complications

Complications associated with the use of the *Pathway* Balloon Expandable PCNL Sheath include but are not limited to, tissue trauma, tissue perforation, acute bleeding and/or injury to the kidney.

8. Recommended Procedure

Preparation

The *Pathway™* Balloon Expandable PCNL Sheath is designed for percutaneous introduction into the nephrostomy path over a 0.038" guidewire. Guidewires should be securely placed into the ureter prior to advancement of the *Pathway* Balloon Expandable PCNL Sheath.

Caution: The *Pathway* Balloon Expandable PCNL Sheath is to be advanced over the guidewire as a single unit. Do not separate the central balloon catheter from the unexpanded access sheath prior to 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.**

Device Insertion

Remove the packaging clip from the device. With a 0.038" stiff guidewire placed beyond the renal pelvis into the ureter, a minimum 1cm incision is made to the skin and fascia at the guidewire skin entry site. Next, liberally apply sterile saline to the hydrophilic coated distal tip and advance the Sheath, avoiding any twisting of the device where possible, under fluoroscopic control and over the guidewire until its radiopaque tip marker is positioned within the collecting system.

Sheath Expansion

A dilute 50% solution of contrast media and sterile saline is prepared and 15 cc are drawn up into a high pressure balloon inflation syringe with a pressure gauge (not supplied). Care is taken to remove all air from the syringe and associated tubing.

Once the *Pathway* Balloon Expandable PCNL Sheath device is properly positioned, the inflation syringe is attached to the Balloon port of the central balloon shaft. Under fluoroscopic control, the dilute contrast media is slowly injected up to the maximum Rated Burst Pressure per Table 1. It is normal to observe a drop in pressure as the Dilator progressively expands the folded distal section of the sheath. As the device is inflated, it is recommended to maintain position by utilizing a 4x4 gauze pad to hold the device in place. Inflation pressure should be maintained for a minimum of 60 seconds or longer to fully expand any "waist" that may remain along the length of the expanded sheath.

Deflated Balloon Removal

Prior to deflation of the balloon Dilator, confirm under fluoroscopy that the Dilator's radiopaque marker indicating the most proximal opening of the Sheath is within the collecting system.

Once proper placement is confirmed, the balloon Dilator may be deflated by applying suction with a high-pressure syringe to the Balloon Port.

Finally, while stabilizing the sheath with a 4x4 gauze pad, remove the deflated balloon Dilator from the expanded sheath by gently pulling back on the inflation catheter hub. The expanded sheath is now ready to accept surgical and/or endoscopic devices.

Note: Care should be taken to maintain the position of the expanded Sheath during the procedure.

Sheath Removal

Gently withdraw and remove the expanded Sheath from the nephrostomy tract after the PCNL procedure has been completed.

9. How Supplied

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

STERILE EO
Sterilized with ethylene oxide gas.

② Single Use Only

C€0297

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

10. Storage

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

11. 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

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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**
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 **Maximum Inflation Pressure**

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