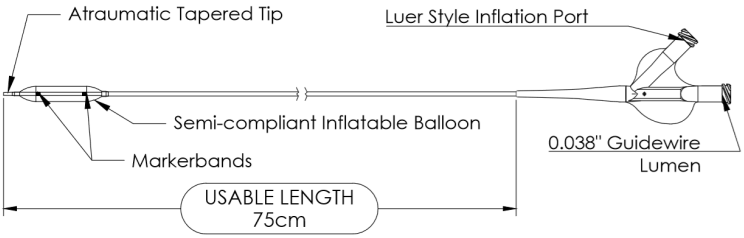
Instructions for Use

Optilume Basic Urological Balloon Dilation Catheter

1. DEVICE DESCRIPTION

1.1 Balloon Catheter

The Optilume Basic Urological Balloon Dilation Catheter is a 0.038" (0.97 mm) guidewire and flexible cystoscope compatible over-the-wire (OTW) catheter with a dual lumen design and a tapered atraumatic tip. The Optilume Basic Catheters are recommended for dilatation of the ureteral sections. The distal end of the catheter has a semi-compliant inflatable balloon. The device has two radiopaque marker bands that indicate the working length of the balloon.



The device is sterilized using ethylene oxide (EO) in a Tyvek pouch. Post sterilization the pouched catheter is sealed in a foil pouch with desiccant and contained within a single unit carton.

Each Dilation Catheter is supplied with a protective sheath that covers the balloon portion of the catheter. A balloon compliance chart is located on the Tyvek pouch label.

2. INTENDED USE

The Optilume Basic Urological Balloon Dilation Catheter is intended to dilate the urinary tract

3. INDICATIONS FOR USE

The Optilume Basic Urological Balloon Dilation Catheter is indicated for dilation of the urethral strictures.

4. CONTRAINDICATIONS

None known.

5. WARNINGS

- The Optilume Basic Dilation Catheter is supplied using ethylene oxide (EO) process. The Balloon is STERILE for single use only. Do not reprocess or resterilize. Reprocessing and re-sterilization could increase the risk of patient infection and risk of compromised device performance.

- The foil pouch and the outer surface of the inner pouch are NON-STERILE. The CONTENTS of the inner pouch are STERILE. Use Immediately once the foil pouch has been opened.
- Do not use this device if there is infection in the Urethra (UTI) or Bladder. Infection must be cleared before treating with Dilation Catheter.
- Do not use after the "Use By" date.
- Never use air or any gaseous medium to inflate the Balloon.
- Do not manipulate the balloon in an inflated state.

6. **PRECAUTIONS**

- The Optilume Basic Dilation Catheter are intended for use by physicians trained and experienced in techniques, clinical applications and balloon catheter dilation.
- Prior to use, physicians should read and understand the instructions for use. Failure to follow the indications, warnings and precautions may result in complications.

7. POTENTIAL COMPLICATIONS

Possible complications associated with the use of the Balloon Catheter may include, but are not limited to:

- Pain and tenderness
- Tissue Trauma in surrounding structures, including urethral damage
- Tissue perforation

8. HOW SUPPLIED

The Optilume Basic Dilation Catheter is supplied STERILE for single use only. The Dilation Catheter is in a double pouch packaging system (foil and Tyvek pouches) contained within a single unit box. Do not use if the package is damaged or opened.

9. STORAGE

The Optilume Basic Dilation Catheter should be stored at room temperature in a dry location in its original packaging.

10. DIRECTIONS FOR USE

It is required that physicians follow the AUA guidelines for pre-procedure medications and preparation for an endoscopic procedure.

Prior to use, verify that the balloon catheter or sterile package has not been damaged. Do not use damaged product and contact Urotronic.

10.1. PURGE AIR FROM BALLOON CATHETER

10.1.1. Attach an inflation device to stopcock with plunger depressed.
10.1.2. Draw back plunger to full volume of inflation device and hold. Close stopcock
10.1.3. Open stopcock and repeat step 9.1.2
10.1.4. Leave stopcock closed to maintain vacuum in balloon and remove inflation device.

10.2. BALLOON CATHETER INSERTION

10.2.1. Position a 0.038" guidewire past the stricture; with the aid of an endoscope.
10.2.2. Leave the stopcock in the closed position.
10.2.3. Remove the Balloon Protector from the tip of the Balloon Catheter.
10.2.4. Advance the Balloon Catheter over the guidewire
10.2.5. Use the endoscope to guide the placement of the Balloon. Alternatively position the Balloon with Fluoroscopy by using the radiopaque markets located under the balloon body/cone transition.

Caution: *Do not advance the guidewire or the balloon dilation catheter if resistance is met without first determining the cause of resistance and taking remedial action.*

10.3. OPTILUME BASIC DILATION CATHETER INFLATION

Caution: *Inflation devices can attain very high pressures with minimal effort. The use of an inflation device with a high-pressure gauge is strongly recommended.*

10.3.1. Fill the inflation device with 1:1 ratio of saline: contrast
10.3.2. Inflate the Balloon using the inflation device.
Note: Do not exceed rated burst pressure (RBP) of the balloon.
10.3.3. Open stopcock and begin inflation of balloon

Caution: *If resistance is encountered when removing a guidewire through a catheter through a cystoscope, STOP and remove them together at the same time as a complete unit to prevent damage to the guidewire, catheter or patient anatomy.*

10.4. OPTILUME BASIC DILATION CATHETER WITHDRAWAL

10.4.1. Apply suction to deflate balloon using inflation device.
10.4.2. Withdrawal balloon slowly after balloon is deflated.

Caution: *The rated burst pressure should not be exceeded. Refer to product label for rated burst pressures. Inflation beyond the rated burst pressure may cause the balloon to rupture. If loss of pressure within the balloon occurs during inflation or if balloon ruptures during dilation, immediately discontinue the procedure. Deflate the balloon carefully and remove from urethra. Do not re-inflate.*

11. WARRANTY

Urotronic warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Urotronic's control directly affect the device and the results obtained from its use. Urotronic's obligation under this warranty is limited to the repair or replacement of this device and Urotronic shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. Urotronic assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, express or implied, including but not limited for a particular purpose, with respect to such devices.

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12. Symbols Used in the Device Labels

	Quantity of 1 per box
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Indicates the date when the medical device was manufactured.
	Do not resterilize
	Do not re-use
	Do not use if package is damaged
	Fragile
	Use-by date
	Keep away from sunlight
	Keep Dry
	Manufacturer
	Does not contain latex
	Temperature limit 15°C - 30°C
	Caution: Consult instructions for use
	Sterilized using ethylene oxide
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Medical Device
	Unique Device Identifier
PREDIL	Pre-Dilation

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