

7 Fr URETERAL CATHETER

INSTRUCTIONS FOR USE



READ THE FOLLOWING PRECAUTIONS, WARNINGS AND INSTRUCTIONS FOR USE CAREFULLY.

Indications

The UroGen Ureteral Catheter is indicated for use by physicians for facilitating access to the urinary tract through a retrograde route, and may be used in conjunction with a guidewire or for the injection of gels or fluids into the urinary tract.

Duration of use: up to one hour.

Contraindications

Do not use in patients with a known sensitivity to Thermoplastic Polyurethane (TPU).

Warnings and Precautions

- Do not use if the package is open or damaged.
- Store the catheter in a cool, dry place, protected from light.
- The catheter should be used by trained healthcare professionals.
- Any use other than those stated in the indication is at the discretion of the physician.
- Single use only – do not sterilize! Reprocessing, cleaning, disinfection, and sterilization may compromise the catheter's characteristics. This could create an additional risk of harm or infection to the patient.
- Use aseptic technique when removing the catheter from the package and during use.
- Use before the expiration date.
- Carefully inspect the catheter prior to use to verify that it has not been damaged during shipment.

- Do not advance the catheter if significant resistance is encountered. If significant resistance occurs, determine the cause of the resistance and take remedial action.
- Avoid kinking or severely bending the catheter.
- Dispose of the catheter properly after use.
- There is a Luer lock hub fixed to the catheter. Bench testing has shown it does not separate from the catheter under high pressure. Therefore, it should not be used as a visual indicator of high pressure. Users should inject gels and fluids gradually and use their clinical judgement when applying pressure to the urinary tract.

Catheter Description

The UroGen Ureteral Catheter is a 7 Fr Ureteral Catheter with a fixed female Luer lock hub. The catheter has an open tip, is 70 cm long and made of radiopaque polyurethane (20% BaSO₄). The catheter is to be placed over a guidewire.

How Supplied

Sterile.

Storage

The UroGen Ureteral Catheter should be stored in a cool, dry place and protected from light.

Operating Procedure

- Before introducing the catheter, ensure that it moves freely inside its surrounding sheath.
- The catheter should be introduced into the urinary tract over a guidewire that is not larger than 0.038" in diameter.
- Placement of catheters is typically done under fluoroscopy guidance.
- Catheter graduation marks are provided to facilitate location and should not be used for measurement.
- Following catheter insertion, ensure that it is correctly positioned before removing the guidewire.
- If a Luer lock syringe cannot attach to the catheter's Luer lock hub, replace the catheter. For example, gel on the catheter's Luer lock hub can prevent a Luer lock syringe from attaching to it.

- Gel viscosity of up to 7,000,000 cP while administering a volume of 20 mL in 60 seconds was tested in-vitro. For lower volumes, instillation duration must be done proportionally to the duration stated for 20 mL.

The following are examples of tested viscosities of approved products:

- o BackStop® Gel* at 16 °C (61 °F), which is equivalent to 128 cP.
- o Lidocaine HCl 2% at 25 °C (77 °F), which is equivalent to 1284 cP.
- o BackStop® Gel* at 22 °C (72 °F), which is equivalent to 5,300,000 cP.
- The in-vitro test data did not directly measure applied pressures and focused on the mechanical integrity of the catheter.

Removal

- By simple withdrawal.
- Verify the catheter's integrity after removal.
- If it is difficult to disconnect the syringe from the catheter's Luer lock hub, remove the catheter with the syringe.


















Adverse Events


- The following events have been reported with the use of similar catheters (although their occurrence highly depends on patients' medical conditions): infection, obstruction, migration, urinary tract irritation, and pain.
- Ureteral perforation may be related to the catheter procedure or to guidewire use.
- Catheter complications can include, but may not be limited to: extravasation, hemorrhage, sepsis, edema, peritonitis, loss of renal function, and perforation of kidney, renal pelvis, ureter and bladder.

Follow Up

- Regular monitoring for adverse events should be implemented following catheter placement.
- Catheter should be removed if drainage is obstructed or if there are signs for infection.

Glossary of Symbols

	Catalogue number		Caution, consult accompanying documents
	Lot number		Do not use if package is damaged
	Use by		Consult instructions for use
	Manufacturer		Protect against moisture
	Manufacturing date		Protect against direct sunlight
	Single sterile barrier system		Sterilized by means of EO
	Single use only		Temperature limitation: Store at 15 °C to 25 °C
	Do not re-sterilize		Unique device identifier
	Federal U.S. law restricts this device to sale by or on the order of a physician		

 Manufactured for:
UroGen Pharma Ltd.
9 HaTa'asiya St.
Ra'anana 4365405
Israel

Manufactured by:
MED pro Medical B.V.
Vendelier 45 E
3905PC Veenendaal
The Netherlands

* BackStop® is a registered trademark of the Boston Scientific Corporation.

UUC7-IFU-004

IFU-Phy-0000023/Ver. 5