UroGen Pharma

URINARY CATHETER 12 Fr/16 Fr 40 cm

INSTRUCTIONS FOR USE

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

Glossary of Symbols

REF	Catalogue number
LOT	Lot number
	Use by
	Manufacturer
	Manufacturing date
	Single sterile barrier system
	Single use only
STERILIZE	Do not re-sterilize
Rx Only	Federal U.S. law restricts this device to sale by or on the order of a physician
	Caution, consult accompanying documents
	Do not use if package is damaged
	Consult instructions for use
	Protect against moisture
	Protect against direct sunlight
15 °C 59 °F / 25 °C 77 °F	Temperature limitation: Store at 15°C to 25°C (59°F to 77°F)
STERILE EO	Sterilized by means of EO
UDI	Unique device identifier

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

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

Indications

The Urinary Catheter is indicated for use to facilitate access to the urinary tract through a retrograde route for the delivery of gels or fluids into the urinary tract.

Duration of use: up to one hour.

Contraindications

This device is contraindicated for use in patients who are unsuitable for urethral catheterization, such as:

- Insurmountable urethral obstructions
- Urethral injuries
- Urethral inflammation

Warnings and Precautions

- Do not use if the package is open or damaged. If there is any breach to the package seal or if the device appears damaged, **DO NOT USE**.
- 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 prior to placement.
- 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.
- The safety and effectiveness of using this catheter for instillation of drugs unapproved for intravesical use has not been established.

Catheter Description

The Urinary Catheter is a single use 12 Fr or 16 Fr Urethral Catheter with a fixed female Luer lock hub. The catheter is 40 cm long, made of biocompatible soft PVC, is uncoated and available in two tip configurations: Straight and Coudé (Tiemann) tip.

The catheter tube is not made with phthalates, including Di(2-ethylhexyl)phthalate (DEHP).

How Supplied

Sterile.

Storage

The Urinary Catheter should be stored in a cool, dry place and protected from direct sunlight.

Operating Procedure

- Using a sterile technique, insert the catheter fully into the urethra ensuring the tip is beyond the bladder neck.
- If necessary, a lubricant, with or without added local anesthetic, can be applied to the catheter, or instilled in the urethra.
- If a Luer lock syringe cannot be attached to the catheter's Luer lock hub, replace the catheter.
- Gel viscosity of up to 1,500 cP while administering a volume of 20 mL in 30 seconds was tested in-vitro. For lower volumes, instillation duration should be done proportionally to the duration stated for 20 mL.

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

Adverse events or complications can occur, depending on the patient's medical condition and on the frequency of use. The following have been reported after the use of similar catheters: urinary tract infection (UTI), urethral trauma/pain, bleeding, urethritis, stricture, epididymitis, prostatitis, and bladder stones.

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 of infection.

UUC12/16-IFU-005
IFU-Phy-0015721/Ver. 5

Date:	**31-AUG-2023**		
Title	577028 UroGen Urinary Catheter 12 Fr16 Fr IFU-Phy-0015721Ver. 5		
Component Type	Leaflet		
Proof Nº	v11	**Perigord Nº**	577028
Item Nº	IFU-Phy-0015721/Ver. 5	**Barcode Nº**	N/A
Country	N/A	**Size (mm)**	177.8 x 215.9 mm
Client	Urogen	**Min point size**	9 pt
Printing Colours (3)	Pro. Black  Pro. Cyan  Pro Magenta 		
Technical colors			