

Urethral Self Dilator

Size (Fr)

6, 8, 10, 12, 14,
& 16

Length (cm)

20 & 30

Models

Straight with hole & without hole
Curved with hole & without hole

Intended Purpose, Duration & Population

Intended to be used by males for self-dilation of urethra for a up to a period of up to 04 hours.

Indications For Use & Contraindications

Indicated to be used to dilation of urethra. No known contraindications.

Potential Complications

Potential complications include but not limited to UTI and Pain.

Warnings And Precautions

- The device should be used only by male patients with not less than 15 years of age, those who are physically and mentally capable to use it after getting necessary training from physician.
- The device shall be used only and only after it has been recommended by the treating doctor/nurse and patient or her attendant has received appropriate training for using it.
- If the patient uses it for any purpose other than described here, he uses it on her own risk.
- Upon completion of usage, dispose of the device and its components if any as per local regulatory guidelines for bio-hazardous medical waste or as informed by physician during training.
- Do not use if package is opened or damaged or expired. Do not use the product if there is suspect that the device is not sterile. Device is not intended for permanent use.

Instructions For Use

IMPORTANT NOTE: Self-Dilation means the patient can dilate the urethra by themselves at home in aseptic conditions as mentioned in the procedure below and on prescription of a qualified physician. The user has to undergo training with a qualified physician.

CHOOSING THE RIGHT DILATOR TYPE: Consult your physician to choose the right type of dilator, curved dilators are chosen to navigate specific strictures in the urethra.

1. **Cleaning of genitalis:** Clean the genitals thoroughly with antiseptic soap and water. Once cleaned, genitals should be mopped dry by a clean piece of towel. Then, pull back the foreskin (if any) and clean the genitalia by Povidone iodine solution-soaked gauze piece.
2. **Instill xylocaine jelly in urethra:** Thoroughly clean the nozzle of xylocaine gel by soap and water, decontaminate it with Povidone iodine solution and then introduce the tip of nozzle into urethral orifice and apply some jelly along the tip and shaft of the dilator [medications will be provided by physician only]
3. **Inserting:** After instilling some xylocaine jelly in urethra, with the foreskin (if any) pulled back, gently insert the Dilator. Hold through the rear end. Do not touch the tip or shaft of the dilator.
4. **Advancing:** As you advance the dilator inside the urethra, be gentle, slow and follow the direction of urethra. The direction of urethra may vary in different patients and can learn during the training session.
5. **Enter the bladder lumen and Removal (DILATOR WITH HOLE)** - As the dilator enters the bladder lumen urine starts flowing out of the rear end hole of the dilator. Do not over insert the dilator. Take instruction from your doctor/nurse/trainer about how much dilator you should insert in urethra. Wait for some time to let the bladder completely empty as the speed of flow of urine is rather slow. The patient is advised to have patience at this stage. Once the urine stop flowing, you may apply some Suprapubic pressure by her hand to facilitate emptying. Withdraw the dilator slowly and incrementally. Avoid removing the dilator with jerks.
6. **Enter the bladder lumen and removal (DILATOR WITHOUT HOLE)** Once the prescribed length of dilator is inserted you will reach the bladder lumen. Wait for some time to let the urethra to dilate, the dilator should not be withdrawn with a jerk, Instead, with drawn it slowly and incrementally. Withdraw it by half centimeter increments. Once the dilator is withdrawn urine starts flowing out, he may apply some Suprapubic pressure by his or her hand to facilitate emptying.

Supply and Storage

The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight.

Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossary And Definitions

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barrier system with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



Authorized Representative in the European Community
Arazy Group (Ireland) Ltd
19 Baggot Street Lower, Dublin
2, D02 X658, Ireland
E-mail: Ireland@arazygroup.com



Manufacturer
Blue Neem Medical Devices Pvt Ltd
Plot Nos 270 & 271, Road No 5, Harohalli Industrial Area
II Phase, Kanakapura Taluk, Ramanagara
Karnataka - 562112, India.
Phone: +91 80 29761336
E-Mail: contact@blueneem.com
Website: www.blueneem.com