

Urethral Dilator

Device description

The Urethral Dilators are tube like devices made from medical grade plastic material, with a slender hollow body and a tapered tip at the distal end. They are designed for dilation of the urethra due to urethral obstruction or to facilitate subsequent urological procedure through natural orifice.

The Urethral Dilators are available in following sizes.

Size (Fr)	Length (cm)	Models
8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28 & 30	40	Straight & S-Curved. Urethral Dilator Set 8-24 Fr: 8, 10, 12, 14, 16, 18, 20, 22, 24 Fr Urethral Dilator Set 8-30 Fr: 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28 & 30 Fr

Intended Purpose & Duration

Intended to be used for dilation of urethra and for single time use up to a period of 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 urine leakage and infection.

Warnings And Precautions

- Do not reuse the device. Reuse or resterilization can compromise the structural integrity of the device and may cause serious harm to the patient. It can also cause severe patient infection and harm due to contamination.
- 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.
- Ensure guidewire compatibility before use. The compatible guidewire information is mentioned on the label.
- Use with caution when advancing the dilators to avoid tissues and vessel damages. Advancement of dilator beyond its length may cause override over guidewire.
- Dilation procedure should be performed under fluoroscopic guidance
- Product use should not be carried out by unauthorized or untrained personnel. Product should be used by trained physician with support from qualified technicians using aseptic technique. On completion of the procedure, dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.

Instructions For Use

1. Introduce the flexible tip of the guidewire into the urethral meatus and gently manipulate it beyond the obstruction and into the bladder.
2. Progressing from the smallest to the largest appropriate size, pass the radiopaque dilators over the guidewire while maintaining the Guidewire's position.

Note: Guidewire can also be place through cystoscope and maintained in position as the scope is removed from its position.

Intended population group

All Patient groups with stricture or obstruction in urethra/urethral meatus and limitation of using appropriate size.

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 Glossory And Definations

Standard Reference:

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

Symbol	Symbol Title
	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.



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