ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Urethral Dilator Set

Device Description

The Urethral Dilator Sets are provided for use in Urology procedures. The configurations available include:

Family	Size(Fr)	Length (Cm)	color
UTHDS	8	40	Blue
	10		
	12		
	14		
	16		
	18		
	20		
	22		

Intended purpose

Urethral Dilator Sets are used for urethral dilation.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Urethral stricture disease – gradual dilation to restore urethral patency.
- Bladder outlet obstruction due to narrowing of the urethra.
- Meatal stenosis or narrowing at the urethral opening.
- Preparation for catheterization or cystoscopic procedures in patients with narrowed urethra.
- Post-surgical urethral narrowing management to maintain lumen patency.

Performance Characteristics of the Device

The Urethral Dilator Set is designed in graduated sizes to provide controlled and atraumatic dilation of the urethra. It is made of smooth, biocompatible medical-grade material, ensuring safety and patient comfort. The device is sterile, single-use, and ergonomically shaped for ease of handling by clinicians.

Indications

- Indicated for the dilation of urethral strictures or stenosis to restore urinary flow.
- Used to facilitate catheter or instrument placement in patients with narrowed urethral passages.
- Indicated in post-surgical or post-traumatic urethral narrowing management to maintain urethral patency.

Contraindications

- Not to be used in patients with active urinary tract infection or severe urethritis.
- Contraindicated in cases of acute prostatitis or significant genitourinary trauma.
- Should not be used where there is a false urethral passage or suspected urethral perforation.
- Avoid use in patients with known hypersensitivity to device material.

Precautions, Warnings& Complications

Carefully read all instructions for use and product labelling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions

- Use only by trained healthcare professionals with knowledge of urethral dilation techniques.
- Select the appropriate dilator size and progress gradually to minimize risk of trauma.
- Employ aseptic technique during handling and insertion to prevent infection.
- Monitor patient for pain, bleeding, or resistance during the procedure.
- Device is sterile and **single-use only**; do not resterilize or reuse.

Warnings

- Do not use if the sterile packaging is damaged or opened.
- Excessive force or rapid dilation may cause urethral perforation or false passage.
- Prolonged or repeated use increases risk of urethral trauma and scarring.
- Use is contraindicated in active infection or acute trauma (refer to contraindications).
- Incorrect use may lead to serious complications, including urinary retention or hematuria.

Intended Patient Population

- The device is intended for use in adult male patients having the above-mentioned conditions.

Shelf-life of the Product

The shelf life of the Urethral Dilator Set is 3 years (Indicated on product label with the use-by symbol and date). Store the Urethral Dilator Set at dry, cool place. Avoid extended exposure to light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Urethral Dilator set have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- If the sterile package is damaged or possibly opened, do not use. Contact "Distributor" and replace the product.
- The Urethral Dilator Set are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

Suggested instructions for using Urethral Dilator Sets:

- Advance the Guide Wire directly from the enclosed holder.
- Introduce the flexible tip of the Guide Wire in to the urethral meatus and gently manipulate it beyond the obstruction and into the bladder. (The safety index mark, 39cm from the Guide Wire's flexible tip will be externally visible under normal circumstances)
- Note:- The Guide Wire can also be placed through a cystoscope and maintained in position as the scope is removed.
- Progressing from the smallest to the largest appropriate size , pass the radiopaque dilators over the Guide Wire while maintaining the Guide Wire's position.
- Caution :- Do not advance dilators beyond the 39cm safety index mark. When the end of the dilator is at the mark , a 2 cm length of wire protrudes from the tip. Further advancement of the dilator will override the Guide Wire.

Removal Instructions

Retrieve cystoscopically by gently pulling on dilator or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the dilator, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
REF	Catalogue Number	UDI	Unique Device Identifier	2 STERILIZE	Do not re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	75% 30%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35 °C 12 °C	Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- Indications: https://dreminozbek.com/en/ureteral-double-j-cathether/#:~:text=patient's%20urological%20condition.-,Indications%20of%20Double%20J%20ureteral%20cathether%20insertion,the%20kidney%20and%20the%20bladder.
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
  EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer