

## Instruction for Use

### Metal Dilator

#### Device Description

The Metal Dilator are Used for dilation of urethral in cases of Stricture, or narrowing of the tube which inhibits the flow of urine and cause serious health problems. Metal Dilator also is used in the treatment of urge incontinence and meatal stenosis, or narrowing of the bladder opening. The configurations available include:

Family	Size(Fr)	Length (Cm)	Colour
Metal Dilator (UMD)	6/10	30	Sliver
	8/12		
	10/14		
	12/16		
	14/18		
	16/20		
	18/22		
	20/24		
	22/26		
	24/28		
	26/30		
	28/32		

#### Intended purpose

Metal Dilator are Intended for dilation or stretching of Urethra

#### 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 strictures – for progressive dilation of narrowed urethral segments to restore urinary flow.
- Meatal stenosis – to enlarge the narrowed urethral opening.
- Bladder outlet obstruction – secondary to urethral narrowing or stricture.
- Preparation for catheterization or endoscopic procedures in patients with narrowed urethra.
- Post-surgical urethral narrowing – to maintain patency after urological reconstruction.

#### Performance Characteristics of the Device

The **Metal Dilator** is designed to provide progressive and controlled dilation of the urethra in cases of stricture or stenosis. Manufactured from medical-grade stainless steel, it ensures durability, strength, and smooth passage to minimize trauma. The device is sterile, reusable after proper sterilization, and ergonomically shaped for precise handling by clinicians.

#### indications

To dilate strictures in the urethra or renal pelvis.

#### Contraindications

No Specific Contraindications.

#### 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 urologists experienced in urethral dilation techniques.
- Ensure proper sterilization before each use to prevent infection.
- Select the appropriate dilator size and progress gradually to avoid trauma.
- Employ strict aseptic technique during handling and insertion.
- Monitor patient for pain, bleeding, or resistance while advancing the dilator.
- Avoid excessive force to reduce risk of urethral perforation or false passage.

#### Warnings

- Do not use if the device is damaged, bent, or has surface irregularities that may cause tissue trauma.
- Forceful or improper insertion may lead to urethral perforation, false passage, or bleeding.
- Use is contraindicated in patients with active urinary tract infection, acute urethral injury, or severe inflammation.
- Prolonged or repeated use without clinical indication may increase the risk of scarring or stricture recurrence.
- Incorrect handling may result in serious complications such as urinary retention, infection, or hematuria.

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#### Shelf-life of the Product

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

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

- The Metal Dilator 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 Metal Dilator are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

#### Intended patient population

The device is intended for use in adult patients requiring urethral or ureteral dilation as part of diagnostic or therapeutic urological procedures.

#### Directions for Use

Suggested instructions for using Metal Dilator:

- 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.
- Pass the dilators over the previously placed guide wire while maintaining the guide wire 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
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		



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**Instruction for Use****Metal Dilator****Bibliography**

- Indications: [sciencedirect.com/science/article/abs/pii/S0090429507019760](https://www.sciencedirect.com/science/article/abs/pii/S0090429507019760).
- 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