ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

S Shape Urethral Dilator Set

Device Description

Used for dilation of male urethra in cases of Stricture Urethral dilation. Sterile and intended for single use. Duration of Contact with the body is 1day.The configurations available include:

Family	Size(Fr)	Length (Cm)	Colour
S Shape Urethral Dilator Set	8 10 12 14 16 18 20 22	37	Blue

Intended Purpose

S Shaped Urethral dilator set is intended for dilation of the male 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

- Gradual dilation of urethral strictures to restore normal urine flow
- Relief of urinary obstruction caused by urethral narrowing
- Preparation of the urethra for catheterization or endoscopic procedures
- Post-operative urethral management to prevent stricture recurrence

Performance Characteristics of the Device

S curve dilator design for ease passage and reduce trauma by supporting the natural curvature of the male urethra. Smooth surface for effortless dilator advancement across tight strictures. Embossed sizes allow for quick identification and size selection.

Indications

- Urethral Strictures
- Urine Incontinence
- Metal Stenosis and narrowing of the bladder emptying in men.

Contraindications

- Acute Urethral Infection
- Uncorrected Bleeding Diathesis
- Uncooperative Patients

Precautions & Warnings

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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:

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the Sclerotherapy Needle at a temperature between 12-35^{0}C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- The device is intended for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

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

Shelf-life

The shelf life of the S Shape Urethral Dilator Set is 3 years (Indicated on product label with the following use-by date symbol).

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

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S Shape Urethral Catheter Set

- The S Shape Urethral 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.
- Exposure to high levels of Ethylene Oxide may result in residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- If the sterile package is damaged or possibly opened, do not use.
- The S Shape Urethral Dilator Set is packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

- After urethrography, 0.038-inch guidewire should be inserted through the urethra into the bladder.
- The insertion is to be done under fluoroscopic control or with the help of an endoscope.
- The S-shaped urethral dilator is to be immersed into the normal saline and it is introduced over the guidewire into the urethra.
- The dilators are introduced into the urethra serially by slowly rotating.
- On insertion of the last dilator, it is left in place until the bladder is empty.

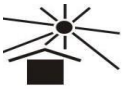
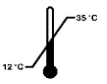
Removal Instructions

- Retrieve by gently pulling on the dilator. If resistance is encountered during removal of the dilator, stop and determine the 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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Bibliography

- Contraindications:https://www.oregonurologyalliance.com/urethra-dilation-urological-surgeon-tualatin-or.html#:~:text=Indications%20and%20Contraindications%20for%20Urethral%20Dilation&text=The%20main%20goal%20of%20the,disease%2C%20bleeding%20and%20untreated%20infection.
- Single Use Medical Device: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- 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.