ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Screw Dilator

Device Description

These are the dilators used for one step dilation, which helps surgeon to do the procedure with minimum blood loss & minimum time.

- One step dilation-Time saving.
- Smooth surface for ease of introduction

Family	Size(Fr)	Length (Cm)	Colour
Screw Dilator (SD)	12 14 16 18 24 30	25 30	Blue

Intended purpose

These are the dilators used for one step dilation & it can be used instead of sequential dilation or fascial 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 strictures – gradual dilation of narrowed urethra to restore urinary flow.
- Meatal stenosis – widening of the narrowed urethral opening.
- Bladder outlet obstruction due to urethral narrowing.
- Preparation for catheter or stent placement in patients with difficult urethral access.
- Post-surgical urethral narrowing – to maintain patency following urological reconstruction.

Performance Characteristics of the Device

The **Screw Dilator** is designed to provide controlled and progressive dilation of the urethra in cases of stricture or stenosis. It is made of medical-grade, biocompatible material with a smooth surface to minimize trauma during insertion. The device is sterile, single-use, and ergonomically shaped for safe handling and effective clinical performance.

Indications

To treat strictures or narrowing in the urethra, facilitating the passage of urine.

Contraindications

No Specific Contraindications

Precautions

- Use only by trained healthcare professionals familiar with urethral dilation techniques.
- Select the correct size and advance gradually to minimize trauma.
- Strict aseptic technique must be followed to reduce the risk of infection.
- Monitor patient for pain, bleeding, or resistance during dilation.
- Device is sterile and intended for single-use only; do not reuse or resterilize.

Warnings

- Do not use if sterile packaging is opened or damaged.
- Forceful or rapid dilation may cause urethral perforation or creation of a false passage.
- Use is contraindicated in patients with active urinary tract infection or acute urethral injury.
- Prolonged or repeated use may increase risk of urethral trauma, bleeding, or scarring.
- Incorrect handling can 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 Screw Dilator is 3 years (Indicated on product label with the use-by symbol and date). Store the Screw Dilator at dry, cool place. Avoid extended exposure to light.

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

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

Directions for Use

- Screw dilator is lubricated and passed through the urethra, until the passage is determined to be open enough to easily pass the urinary stream.
- Local anesthesia may be used. Each physician/surgeon is responsible for the proper procedure and techniques used with this device

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://emedicine.medscape.com/article/83002-overview
- 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