ASTER
....Where Research is Routine

ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

CE 2803

Ureteral Balloon Dilation Catheters

Device Description

The Ureteral Balloon Dilation Catheters are provided for use in Urology procedures for dilation of ureteral strictures or ureteral dilation prior to ureteroscopy or stone manipulation. Radiopaque markers indicate the proximal and distal ends of the balloon. Intended for single use. Duration of Contact with the body is 1 day. The configurations available include:

Family	Accessories	Size (Fr.)	Length (cm)	Inflated Balloon Diameter (mm)	Balloon Length (cm)	Rated Burst Pressure (ATS)	Catalogue Number	Color
Ureteral Balloon Dilation Catheter (UBDC)	Three-way stopcock	5 6	70	4	4	14	AMPLCT012	Blue

Intended Purpose

Ureteral Balloon Dilation Catheters are used to provide radial dilation of the urinary tract to facilitate the placement of surgical instruments during endoscopic procedures and in the treatment of ureteral stenosis.

Performance Characteristics of the Device

Ureteral Balloon Dilation Catheter is designed for the radial dilation of the Urinary Tract. It is composed of dual lumen shafts with inflation and guide wire lumens and a dilatation balloon on the distal end. The dilator balloon has two radiopaque bands which define the balloon working length and facilitate radiographic visualization and placement.

Indications

- Ureteropelvic junction obstruction.
- Dilation of ureteral meatus and/or ureteral canal during endoscopic procedures
- Treatment of ureteral stenosis

Contraindications

- Untreated urinary tract Infection
- Uncorrected Bleeding Diathesis
- Uncooperative Patient

Precautions & Warnings

Carefully read all instructions for use and product labeling. 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:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Do not use the device if there is any indication that the sterility of the device has been compromised.
- Balloon dilation catheters are intended for use by Urologist/physicians trained and experienced in techniques for balloon – catheter dilation or treatment of Urinary System disorders and related Urological procedures. Do not exceed the maximum rated burst pressure (listed on label) for this balloon device. Do not pre- inflate the balloon. Refer to product label or the inflation check valve on the balloon device for appropriate balloon volume. The burst pressure was analyzed using factors for a one-sided tolerance to determine with 95% confidence that 99.9% of these balloons would not burst at or below the calculated rated burst pressure.

Warnings:

- All components of the Ureteral Balloon Dilation Catheters are for single use only.
- Always inflate the balloon with a sterile liquid. Never inflate with air, carbon dioxide or nay other gas. Do not over inflate. Using excessive pressure to inflate the balloon on this device can cause the balloon to rupture.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient:
- Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Intended Patient Population

- Ureteral Balloon Dilation Catheter is used prior to endoscopy procedures and treatment of ureteral stenosis
- The device is intended for use in patients above the age of 18 having the above-mentioned conditions.
- The above-mentioned sizes are not intended for use in infants and children.

Shelf-life and storage condition of the Product

- The shelf life of the Ureteral Balloon Dilation Catheters is 3 years (Indicated on product label with the following use-by symbol).
- Store the Ureteral Balloon Dilation Catheters at a temperature between 12°-35°C and a Humidity range of 30%-75%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

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

- The Ureteral Balloon Dilation Catheters have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of 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. Contact “Manufacturer or Distributor” and replace the product.
- The Ureteral Balloon Dilation Catheters are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

ASTER MEDISPRO PRIVATE LIMITED

CE 2803

Instruction for Use

Ureteral Balloon Dilation Catheters

Directions for Use

- Open the package from the Chevron Side ('V' Notch) of the pouch.
- Suggested instructions for using Ureteral Balloon Dilation Catheters:
- BALLOON PREPARATION:
- Upon removal from the package, inspect the balloon catheter to ensure no damage has occurred during shipment.
- Remove the protective sleeve from the balloon and discard. Lock a 10ml syringe filled with 5ml of dilute contrast medium onto the balloon lumen and apply negative pressure for 20 to 30 seconds. Release negative pressure on syringe allowing medium to draw into balloon. Detach the syringe leaving medium in the balloon lumen.

BALLOON CATHETER INTRODUCTION AND INFLATION

- Under fluoroscopic control, cystoscopically pass a guide wire (up to 0.038" in diameter) the desired distance into the ureter beyond the area of planned dilation.
- Carefully advance the balloon catheter over the previously placed guide wire under fluoroscopic guidance utilizing the radiopaque markers to ensure proper positioning. Advance catheter so the entire balloon extends beyond the end of the cystoscope before inflating the balloon
- Prepare the inflation device in standard manner and purge all air from syringe and tubing. To ensure proper regulation of balloon pressure, use of a balloon inflation device and pressure gauge is recommended.
- Attach the prepared inflation device to the catheter, open the stopcock on the inflation device and inflate the balloon.
- Close the stopcock on the inflation device for at least 30 seconds to maintain pressure and allow adequate dilation. Time, rather than excessive pressure, is the key factor in transluminal dilation.
- BALLOON DEFLATION AND WITHDRAWAL
- As pirate the balloon completely.
- When the balloon is completely deflated, remove the device by withdrawing the catheter slowly. Removal of the catheter is facilitated by rotating the shaft counterclockwise during withdrawal. Using excessive force to withdraw the balloon can inflict trauma to tissue and /or damage the cystoscope.
- Duration of contact with the body is 1 day.

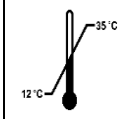
Removal Instructions

- 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		CE Mark		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		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Ureteral Balloon Dilation Catheters

CE 2803

Aster Medispro Pvt. Ltd
S.P.181, 10th Main, 1st Stage,
DR.B.R.Ambedkar Industrial Estate (KSSIDC)
Jigani Industrial area, Jigani,
Bangalore- 560105, Karnataka, India.
Tel: +91 80-42062716
Email: info@astermedispro.net
Web: www.astermedispro.net

EC REP

M/sCMC Medical Devices& Drugs S.L.
located in C/Horacio Lengo N° 18, CP29006,
Málaga, Spain
Tel : +34951214054, Fax: +34952330100
E-mail : mmateos@cmcmedicaldevices.com
Web : www.cmcmedicaldevices.com

Bibliography

- 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 20417:2021 – Medical Devices- Information to be supplied by the manufacturer.