ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

Ureteral Access Sheath with Suction

Device Description

The Ureteral Access Sheath with suction consists of a straight distal tube and a proximal bifurcated tube. The distal straight tube of the access sheath is reinforced with metal wires for torque resistance. One segment of the proximal bifurcated tube is straight and is contiguous with the distal tube. The other is constructed in an oblique angle with a longitudinal pressure control vent. An obturator is included for the insertion of the sheath. The obturator can be locked to the proximal end of the straight tube using a luer lock mechanism. A rubber cap with central aperture is included as an accessory. It is to be placed at the proximal end of the straight tube after the removal of the obturator. The oblique tube is to be connected directly to a negative pressure aspirator with a clear tube or alternatively, connected to a specimen collector (packed separately) then onto a negative pressure aspirator. The configurations available include:

Family	Size(Fr)		Length (Cm)		Type	Accessories
	Catheter	Sheath	Catheter	Sheath		
Ureteral Access Sheath with Suction	10	12	18	13	Bendable Straight	Connecting Tube, Stone Collection Bottle, Rubber Cap
	11	13	31	26		
	12	14	41	36		
	13	15	45	40		
	14	16	51	46		
			60	55		

Intended Purpose

The Ureteral Access Sheath with suction is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during endoscopic procedures.

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

- Facilitation of ureteroscopic access for the management of ureteral and renal stones
- Removal of stone fragments and debris during endourological procedures
- Reduction of intrarenal pressure during stone management to minimize risk of infection or sepsis
- Enhancement of urinary drainage and visualization during ureteroscopic interventions

Performance Characteristics of the Device

The device provides shorter procedure time by efficiently controlling and removing fragments, the total time is reduced. Provides improved visual field due to the continues irrigation and suction, bleeding and dust storm from stone pulverization no longer obscure the visual field. Improved stone clearance, the device effectively prevents retrograde stone migration with negative pressure aspiration and at the same time remove the stone fragments. A vortex is created by continuous irrigation and suction which reduces the intra-luminal pressure. Under the negative pressure aspiration, the stone fragments are captured and evacuated hence, other devices like stone baskets, forceps and anti-retropulsion devices are no longer necessary.

Indications

- During Flexible Ureteroscopy for Renal Stones by decreasing the risk of Postoperative Systemic Inflammatory Response Syndrome.
- To facilitate passage of endoscopes, urological instruments.

Contraindications

- Coagulation disorders
- Acute urinary tract infection
- Severe cardiopulmonary insufficiency
- Uncorrected diabetes

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 Ureteral Access Sheath with Suction 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.
- The endoscope used should least 3Fr. Smaller and 7cm longer than the sheath.
- The sheath should be placed within 5-10mm from the stone to be effective
- Turn on the continuous negative pressure aspiration before starting the essurized irrigation when use the access sheath for the semi-rigid ureteroscopy and percutaneous nephroscopy. Turn on the irrigation before the negative pressure aspiration when it is sued for the flexible ureteroscopy and cystoscopy.

Intended Patient Population

- The device is intended for use in adult patients having the above-mentioned conditions. The device can be used in both male and female patients.

Shelf-life

The shelf life of the Ureteral Access Sheath with Suction 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

- The Ureteral Access Sheath with Suction 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 Ureteral Access Sheath with Suction is packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

- Advance the ureteral access over the guide wire until it is within 1 cm distance of the stone or steinstrasse. Remove the obturator and place the rubber cap onto the proximal straight end.
- Connect the oblique tube of the access sheath to the negative pressure aspirator or the stone collection bottle (packed separately) with the clear tubing then onto a negative pressure aspirator. Activate the suction at the continuous mode and maintain the pressure at 150 – 200 mm Hg (20-27 kPa)
- Insert the ureteroscope through the centre aperture of the rubber cap and turn on continuous pressurized irrigation at the flow of 50 to 100 CC per minute. Advance the scope to the stone or steinstrasse. Commence lithotripsy using Holmium – YAG laser or pneumatic lithotripter. We recommend using a higher frequency and lower energy setting on the laser for finer stone fragmentation.
- The negative aspiration pressure can be adjusted using the pressure vent on the oblique side port. When using access sheath for the flexible ureteroscope, the negative aspiration pressure can also be adjusted using the pressure control knob located on the egress tube stone collection bottle.
- During the process of lithotripsy, the stone fragments tend to aggregate at the opening of the distal tube. The small stone fragments will exit in the space between the scope and the sheath. When larger fragments that are small enough to come into the sheath but too large to pass in the space between the scope and the sheath, withdraw the scope slowly to just proximal to the bifurcation (the red band) of the sheath. This will open up an unimpeded channel to the oblique tube to allow evacuation of the larger stone fragments
- After the surgery is completed, turn off the perfusion equipment and then the negative pressure aspirator.
- Reinsert the obturator back into the sheath. Guide wire can be inserted at this point if indicated. Slowly withdraw the sheath from the patient. Send the stone collection bottle with the stone fragments to the laboratory for urinary stone analysis.

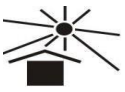
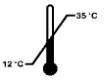
Removal Instructions

- Retrieve by gently pulling on the device. 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

- 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.