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Instructions for Use

WortX™ Ureteral Access Sheath with Suction

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Device Description

The WortX™ Ureteral Access Sheath with Suction is a medical device that uses a flexible tip for ureteral access and a unique oblique branch to connect to a suction system for continuous irrigation and aspiration of stone fragments during endoscopic procedures. Its key advantages include improved visualization by removing bleeding and dust, reduced stone retropulsion by aspirating fragments, and increased stone clearance by aggregating them at the distal end for removal. This reduces the need for accessory devices and helps maintain lower intrarenal pressure, leading to fewer complications and potentially better outcomes compared to traditional sheaths.

Size (Fr)	Length (cm)	Component
9, 9.5, 10, 11 & 12	25, 35, 40, 45 & 50	Sheath, Obturator, Luer Connector, Y Connector & Rubber Cap

Intended Purpose

WortX™ Ureteral Access Sheath with Suction facilitates ureteral dilation, ensuring smooth and efficient scope access to the ureter. It enhances safety and effectiveness during RIRS procedures, contributing to an improved stone-free rate (SFR) up to a period of less than 04 hours.

Indications For Use & Contraindications

Device is indicated for: Providing access to the ureter and kidney during endoscopic procedures. Assisting in the removal of stones, foreign bodies, or other obstructions in the urinary tract. Facilitating irrigation and suction during procedures.
Patients who are contraindicated for retrograde urological procedures; presence of tight strictures, which would limit use of the device; presence of large obstructing distal ureteral stone.

Potential Complications

Potential complications Include but not limited to Irritation, inflammation, Urethra perforation, UTI, False route, Bleeding & ureteral avulsion.

Warnings And Precautions

- Do not reuse or resterile the device and do not use if product is damaged or expired.
- Use only components supplied along with device packaging.
- Dispose off the device and its components, if any, as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
- This device is intended for use by physicians trained and experienced in endourological techniques, standard techniques should be employed.
- Ensure that the size of the sheath is appropriate for the patient's anatomy to prevent injury. Monitor the patient for signs of ureteral trauma or perforation during the procedure

Instructions For Use

Note:
- Use endoscopes at least 3 Fr smaller and 7 cm longer than the WortX sheath.
- Make sure the tip of the WortX sheath is within 5-10 mm distance of the stone
- Set the continuous negative aspiration at the 150-200 mm Hg pressure
- Set the continuous pressurized irrigation at 50-100 cc per minute
- Turn on the suction before the pressurized irrigation

Product Recommendations

Size (G)	Accepted Guidewire (inch)
9, 9.5, 10, 11 & 12	0.035

Procedure

1. Advance the WortX sheath over a guidewire until it is within 1 cm of the stone or steinstrasse. Remove the obturator and place the rubber cap onto the proximal straight end.
2. Connect the oblique tube of the WortX sheath to a negative pressure aspirator or to the stone collection bottle with the clear tubing (packed separately) then onto the negative pressure aspirator. Activate the suction at continuous mode and maintain the pressure at 150 – 200 mm Hg.
3. Insert the endoscope through the center aperture of the rubber cap and turn on the continuous pressurized irrigation at a flow of 50 to 100 cc per minute. Advance the scope to the stone or the steinstrasse. Commence the lithotripsy using a Holmium – YAG Laser or pneumatic lithotripter. We recommend using a higher frequency and lower energy setting on the laser for fine stone fragmentation.
4. When using the WortX sheath, the negative aspiration pressure can be adjusted using the pressure vent on the oblique side port of the sheath, or the pressure control knob located on the egress tube of the stone collection bottle.
5. During the process of lithotripsy, the stone fragments tend to aggregate at the distal opening of the WortX sheath. The small stone fragments will exit in the space between the scope and the WortX sheath. With larger fragments that are small enough to come into the WortX sheath but too large to pass in the space between the scope and the WortX sheath, withdraw the scope slowly to just proximal to the bifurcation of the WortX sheath. This will open up an unimpeded channel to the oblique tube allow evacuation of the larger stone fragments.
6. After surgery is completed, turn off the perfusion equipment and the negative pressure aspirator. Send the stone collection bottle with stone fragments to the laboratory for urinary stone analysis.

Supply and Storage

The device is packed in primary pack made of polyethylene and the secondary package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20^{o}C to 40^{o}C and away from direct sunlight.

Target Population Group

Adult male and females who requires treatment for urinary obstruction and urinary stones

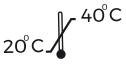
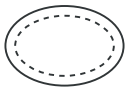
Report Any Serious Incident

If problems occur using this device or any serious incidents or adverse events, please contact our customer relations department or call to the contact provided in our manufacturing address and competent authority of the Member State in which the user and/or patient is established.

Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

Symbol	Symbol Title
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Temperature limit
	Keep away from sunlight
	Do not re-use
	Not made with natural rubber latex
	Sterilized using ethylene oxide
	Non-pyrogenic
	Keep dry
	Medical device
	Single sterile barriersystem with protective packaging inside
	Does not contain DEHP
	Unique device identifier
	Date of Manufacture
	Use-by date
	Batch code

	Catalogue number
	Authorized Representative in the European Community/ European Union
	Manufacturer
	Caution
	Prescription

- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.

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