Suction Evacuation Access Sheath

MODEL
Ureteral Access Sheath
Cystoscope Sheath

Type
ClearPetra Ureteral Access Sheath
ClearPetra Ureteral Access Sheath Duo
ClearPetra Flexi Ureteral Access Sheath
ClearPetra Flexi Ureteral Access Sheath Duo
ClearPetra 2.0 Ureteral Access Sheath
ClearPetra 2.0 Ureteral Access Sheath Duo
ClearPetra Drive Ureteral Access Sheath
ClearPetra Drive Ureteral Access Sheath Duo
ClearPetra Cystoscope Sheath

DESCRIPTION
The Suction Evacuation Access Sheath consists of a straight distal tube and a proximal bifurcated tube. The distal straight tube of the ureteral access sheath is reinforced with metal wires for torque resistance. The oblique tube is to be connected onto a negative pressure aspiration device. 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 twisting locking mechanism. A silicone cap with central aperture is provided to be placed at the proximal end of the straight tube after the removal of the obturator.

FEATURES
- The sheath features a pressure vent that can be used for adjustment of negative aspiration pressure.
- The proximal end of the sheath features a red band mark that serves as the limit for endoscope withdrawal.
- The Ureteral Access Sheath has hydrophilic coating on the outer surface for smooth placement.
- The Cystoscope Sheath has an obturator with blunt tip for atraumatic insertion into the bladder.

INTENDED PURPOSE
The Suction Evacuation Access Sheath is used to establish an access during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. The oblique channel can be attached to the suction system for the evacuation of intracavity fluid, stone fragments, dust and other foreign body .

CLINICAL BENEFITS
- Increase stone free rate by evacuating stone dust and/or fragments via suction.
- Reduce the intra-renal pressure and temperature during lithotripsy by actively evacuating the intracavity fluid, thus reducing post-operative complications (sepsis, infections etc).
- Provide a good vision field by removing the dust and bleeding via suction.

PATIENT TARGET GROUP
Adult, Child.

INTENDED USER
This device can only be used by trained professionals.

INDICATIONS

The product can be used on patient who need endoscopic urological procedures for removal of stone(s), tumors, or other foreign bodies from the urinary system .

CONTRAINDICATIONS

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

ADVERSE REACTIONS

- Tissue Trauma
- Tissue perforation
- Bleeding
- Infection

DIRECTIONS FOR USE

1.ClearPetra Ureteral Access Sheath/ClearPetra Ureteral Access Sheath Duo

(1) Pre-operative Preparation

- Selection: Select the appropriate device model and size based on the surgical procedure, patient anatomy, and device specifications.
- Inspection: Inspect packaging integrity and the device for defects. Verify that the model and size on the product label match the surgical requirements.
- Aseptic Technique: Remove the device from the sterile packaging and place it in the sterile field.

(2) Primary Access

- Initial Access: Under endoscopic visualization, place a primary guidewire (OD < 1.0 mm) into the urinary tract. Remove the endoscope while maintaining wire position.

(3) Safety Guidewire Placement with dual lumen obturator of ClearPetra Ureteral Access Sheath Duo,

- Activation: Remove the dual-lumen obturator from the sheath and immerse it in sterile water to activate the hydrophilic coating.
- Obturator Insertion: Advance the obturator over the primary guidewire to the target position.
- Safety Wire Insertion: Insert a secondary urological guidewire through the secondary lumen (marked "Y"; see Figure 1).
- Withdrawal: Maintain both guidewire positions and withdraw the obturator.

Figure 1

(4) Sheath Placement

- Assembly: Lock the obturator and the access sheath as an assembly, or reinsert the dual lumen obturator (for the ClearPetra Ureteral Access Sheath Duo,) into the access sheath and lock the connector. Activate the hydrophilic coating of the assembly with sterile water.
- Insertion: Advance the assembly over the primary guidewire to the desired position. Confirm placement via fluoroscopy.
- Deployment: Secure the sheath, unlock the obturator, and remove both the obturator and the primary guidewire. Attach the sealing cap to the distal port.

(5) Suction and Lithotripsy

- Connection: Connect the oblique side-port to a negative pressure aspirator or a stone collection bottle.
- Irrigation: Insert the selected ureteroscope, with an outer diameter not exceeding 75% of the inner diameter of the sheath, into the sheath as required. Apply continuous pressurized irrigation through the endoscope at a flow rate of 50–100 mL/min.
- Positioning: Under direct visualization, align the tip of the ureteroscope with the tip of the sheath and advance both together as a single unit..
- Aspiration: Activate continuous suction at 150–200 mmHg (20–27 kPa). Adjust suction using the pressure vent or regulating slider (if supplied).
- Fragment Removal: During lithotripsy, withdraw the scope proximal to the bifurcation (red band) to allow large fragments to pass through the sheath when indicated.

(6) Post-Procedure

- Stop the irrigation and negative pressure aspiration. Slowly withdraw the sheath from the patient. Submit the stone collection bottle for laboratory analysis.

2. ClearPetra Flexi Ureteral Access Sheath/ClearPetra Flexi Ureteral Access Sheath Duo &ClearPetra 2.0 Ureteral Access Sheath/ ClearPetra 2.0 Ureteral Access Sheath Duo

(1) Pre-operative Preparation

- Selection: Select the appropriate device model and size based on the surgical procedure, patient anatomy, and device specifications.
- Inspection: Inspect packaging integrity and the device for defects. Verify that the model and size on the product label match the surgical requirements.
- Aseptic Technique: Remove the device from the sterile packaging and place it in the sterile field.

(2) Primary Access and Dilation

- Initial Access: Under endoscopic visualization, place a primary guidewire (OD < 1.0 mm) into the urinary tract. Remove the endoscope while maintaining wire position.
- Sequential Dilation if indicated: If sequential dilation is anticipated such as a tight ureter, perform pre-dilation using the provided additional dilators. Activate the coating on the dilators with sterile water. Advance the smallest diameter dilator over the guidewire and exchange progressively for larger sizes until the desired tract diameter is achieved.

(3) Safety Guidewire Placement with dual lumen obturator or ClearPetra Flexi Ureteral Access Sheath Duo or ClearPetra 2.0 Ureteral Access Sheath Duo if needed:

- Activation: Remove the dual-lumen obturator and immerse it in sterile water to activate the hydrophilic coating.
- Obturator Insertion: Advance the obturator over the primary guidewire to the target position.

- Safety Wire Insertion: Insert a secondary urological guidewire through the secondary lumen (marked "Y"; see Figure 2).

  8.5 Fr Obturator: Accepts up to 0.028" guidewire.

  9.5 Fr Obturator: Accepts up to 0.032" guidewire.

  Other Sizes: Accept guidewires with OD < 1.0 mm.
- Withdrawal: Maintain both guidewire positions and withdraw the obturator.

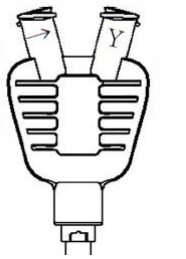

Figure 2

(4) Sheath Placement

- Assembly: Lock the obturator and the access sheath as an assembly, or reinsert the dual lumen obturator (for the ClearPetra Duo or ClearPetra 2.0 Duo) into the access sheath and lock the connector. Activate the hydrophilic coating of the assembly with sterile water.
- Insertion: Advance the assembly over the primary guidewire to the desired position. Confirm placement via fluoroscopy.
- Troubleshooting: If resistance prevents placement, perform further pre-dilation using the additional dilators provided.
- Deployment: Secure the sheath, unlock the obturator, and remove both the obturator and the primary guidewire. Attach the sealing cap to the distal port.

(5) Suction and Lithotripsy

- Connection: Connect the oblique side-port to a negative pressure aspirator or a stone collection bottle.
- Irrigation: Insert the selected ureteroscope, with an outer diameter not exceeding 75% of the inner diameter of the sheath, into the sheath as required. Apply continuous pressurized irrigation through the endoscope at a flow rate of 50–100 mL/min.
- Positioning: under direct visualization, align the tip of the ureteroscope with the tip of the sheath and advance both together as a single unit. Alternatively, advance the ureteroscope to the desired position first, and then advance the sheath over the shaft of the ureteroscope to the desired position Aspiration: Activate continuous suction at 150–200 mmHg (20–27 kPa). Adjust suction using the pressure vent or regulating slider (if supplied).
- Fragment Removal: During lithotripsy, withdraw the scope proximal to the bifurcation (red band) to allow large fragments to pass through the sheath when indicated.

(6) Post-Procedure

- Stop the irrigation and negative pressure aspiration. Slowly withdraw the sheath from the patient. Submit the stone collection bottle for laboratory analysis.

3. ClearPetra Drive Ureteral Access Sheath/ClearPetra Drive Ureteral Access Sheath Duo

(1) Pre-operative Preparation

- Selection: Select the appropriate device model and size based on the surgical procedure, patient anatomy, and device specifications.
- Inspection: Inspect packaging integrity and the device for defects. Verify that the model and size on the product label match the surgical requirements.
- Aseptic Technique: Remove the device from the sterile packaging and place it in the sterile field.

(2) Primary Access and Dilation

- Initial Access: Under endoscopic visualization, place a primary guidewire (OD < 1.0 mm) into the urinary tract. Remove the endoscope while maintaining wire position.
- Sequential Dilation if indicated: If sequential dilation is anticipated such as a tight ureter, perform pre-dilation using the provided additional dilators. Activate the coating on the dilators with sterile water. Advance the smallest diameter dilator over the guidewire and exchange progressively for larger sizes until the desired tract diameter is achieved.

(3) Safety Guidewire Placement with dual lumen obturator if ClearPetra Drive Ureteral Access Sheath Duo needed:

- Activation: Remove the dual-lumen obturator and immerse it in sterile water to activate the hydrophilic coating.
- Obturator Insertion: Advance the obturator over the primary guidewire to the target position.
- Safety Wire Insertion: Insert a secondary urological guidewire through the secondary lumen (marked "Y"; see Figure 3).

  8.5 Fr Obturator: Accepts up to 0.028" guidewire.

  9.5 Fr Obturator: Accepts up to 0.032" guidewire.

  Other Sizes: Accept guidewires with OD < 1.0 mm.
- Withdrawal: Maintain both guidewire positions and withdraw the obturator.

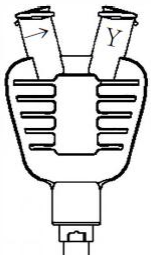

Figure 3

(4) Sheath Placement

- Assembly: Lock the obturator and the access sheath as an assembly, or reinsert the dual lumen obturator (for the ClearPetra Drive Ureteral Access Sheath Duo) into the access sheath and lock the connector. Activate the hydrophilic coating of the assembly with sterile water.
- Insertion: Advance the assembly over the primary guidewire to the desired position. Confirm placement via fluoroscopy.
- Troubleshooting: If resistance prevents placement, perform further pre-dilation using the additional dilators provided.
- Deployment: Secure the sheath, unlock the obturator, and remove both the obturator and the primary guidewire. Attach the sealing cap to the distal port.

(5) Suction and Lithotripsy

- Connection: Connect the oblique side-port to a negative pressure aspirator or a stone collection bottle.
- Irrigation: Insert the selected ureteroscope, with an outer diameter not exceeding 75% of the inner diameter of the sheath, into the sheath as required. Apply continuous pressurized irrigation through the endoscope at a flow rate of 50–100 mL/min.
- Positioning: Under direct visualization, align the tip of the ureteroscope with the tip of the sheath and advance both together as a single unit. Alternatively, advance the ureteroscope to the desired position first, and then advance the sheath over the shaft of the ureteroscope to the desired position Manipulate the control mechanism of the sheath to secure the angulation of the sheath if needed.
- Aspiration: Activate continuous suction at 150–200 mmHg (20–27 kPa). Adjust suction using the pressure vent or regulating slider (if supplied).
- Fragment Removal: During lithotripsy, withdraw the scope proximal to the bifurcation (red band) to allow large fragments to pass through the sheath when indicated.

(6) Post-Procedure

- Stop the irrigation and negative pressure aspiration. Straighten the sheath，slowly withdraw the sheath from the patient. Submit the stone collection bottle for laboratory analysis.

4. ClearPetra Cystoscope Sheath

(1) Preparation and Access

- Selection & Inspection: Select the device model and size based on patient anatomy and procedural requirements. Inspect the sterile packaging for integrity. Verify the model and size on the product label.
- Preparation: Aseptically transfer the device to the sterile field.
- Access: Advance the Cystoscope Sheath over a guidewire into the bladder.
- Assembly: Remove the obturator and secure the sealing cap onto the proximal straight port.

(2) System Connection and Calibration

- Aspiration Setup: Connect the oblique side-port to a negative pressure aspirator (or stone collection bottle) using the provided tubing.
- Suction Parameters: Activate continuous suction at 150–200 mmHg (20–27 kPa). Adjust aspiration intensity via the pressure vent on the side port.
- Irrigation Parameters: Introduce the cystoscope through the sealing cap. Initiate continuous pressurized irrigation at a minimum flow of 50–100 mL/min.

(3) Lithotripsy and Evacuation

- Lithotripsy: Advance the cystoscope to the stone and commence lithotripsy (Laser or Pneumatic).
- Note: High-frequency and low-energy laser settings are recommended to produce fine fragments for optimal aspiration.
- Fragment Clearance: Small fragments evacuate through the space between the scope and the sheath.
- Larger fragments: If fragments enter the sheath but are obstructed by the scope, slowly withdraw the scope tip until it is just proximal to the bifurcation (marked by the red band). This creates an unimpeded channel to the oblique tube for evacuation.

(4) Post-Procedure

- Shutdown: Upon completion, turn off the irrigation and suction. Reinsert the obturator and slowly withdraw the sheath and obturator from the patient. Submit the collected stone fragments for laboratory analysis.

PRECAUTIONS / WARNINGS

PRECAUTIONS

- Dispose of product and packaging in accordance with hospital administrative and/or local government policy.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.

WARNINGS

- Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- This device can only be used by trained professionals.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use if it's damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.
- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Use continuous negative pressure aspiration mode at 150 - 200 mmHg (20-27 kPa) pressure setting.
- Use continuous pressurized irrigation with a flow at 50 to 100cc per minute at the least.
- Make sure all connections are secure. Poor connection might affect the negative pressure aspiration.
- Make sure the connecting tubes do not kink.
- Make sure the obturator is properly fixed withthe sheath during the insertion process.
- Advance the sheath to the target as close as possible to achieve the best performance.

STORAGE CONDITIONS

- Store in a cool or ambient temperature, keep away from sunlight.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

APPENDIX A The Key Performance Characteristics of Suction Evacuation Access Sheath

- Airtightness: Apply a 30±1 kPa negative pressure for the sheath system for 15 seconds, make sure the airtightness of the system is qualified.
- Table of the Type of Suction Evacuation Access Sheath

Type	Size
ClearPetra Ureteral Access Sheath	9.5Fr x 13cm, 10Fr x 13cm, 11Fr x 13cm, 12 Fr x 13cm 9.5Fr x 26cm, 10Fr x 26cm, 11Fr x 26cm, 12 Fr x 26cm 9.5Fr x 36cm, 10Fr x 36cm, 11Fr x 36cm, 12 Fr x 36cm 9.5Fr x 40cm, 10Fr x 40cm, 11Fr x 40cm, 12 Fr x 40cm 9.5Fr x 46cm, 10Fr x 46cm, 11Fr x 46cm, 12 Fr x 46cm 9.5Fr x 55cm, 10Fr x 55cm, 11Fr x 55cm, 12 Fr x 55cm

ClearPetra Ureteral Access Sheath Duo	10Fr x 13cm, 11Fr x 13cm, 12 Fr x 13cm 10Fr x 26cm, 11Fr x 26cm, 12 Fr x 26cm 10Fr x 36cm, 11Fr x 36cm, 12 Fr x 36cm 10Fr x 40cm, 11Fr x 40cm, 12 Fr x 40cm 10Fr x 46cm, 11Fr x 46cm, 12 Fr x 46cm 10Fr x 50cm, 11Fr x 50cm, 12 Fr x 50cm 10Fr x 55cm, 11Fr x 55cm, 12 Fr x 55cm
ClearPetra Flexi Ureteral Access Sheath	8.5Fr x 26cm, 9.5Fr x 26cm, 10Fr x 26cm, 11Fr x 26cm, 12 Fr x 26cm, 13Fr x 26cm 8.5Fr x 36cm, 9.5Fr x 36cm, 10Fr x 36cm, 11Fr x 36cm, 12 Fr x 36cm, 13Fr x 36cm 8.5Fr x 40cm, 9.5Fr x 40cm, 10Fr x 40cm, 11Fr x 40cm, 12 Fr x 40cm, 13 Fr x 40cm 8.5Fr x 46cm, 9.5Fr x 46cm, 10Fr x 46cm, 11Fr x 46cm, 12 Fr x 46cm, 13Fr x 46cm 8.5Fr x 50cm, 9.5Fr x 50cm, 10Fr x 50cm, 11Fr x 50cm, 12 Fr x 50cm, 13 Fr x 50cm 8.5Fr x 55cm, 9.5Fr x 55cm, 10Fr x 55cm, 11Fr x 55cm, 12 Fr x 55cm, 13 Fr x 55cm
ClearPetra Flexi Ureteral Access Sheath Duo	10Fr x 36cm, 11Fr x 36cm, 12 Fr x 36cm, 10Fr x 40cm, 11Fr x 40cm, 12 Fr x 40cm 10Fr x 46cm, 11Fr x 46cm, 12 Fr x 46cm 10Fr x 50cm, 11Fr x 50cm, 12 Fr x 50cm 10Fr x 55cm, 11Fr x 55cm, 12 Fr x 55cm
ClearPetra 2.0 Ureteral Access Sheath	8.5Fr x 26cm, 9.5Fr x 26cm, 10Fr x 26cm, 11Fr x 26cm, 12 Fr x 26cm, 13Fr x 26cm 8.5Fr x 36cm, 9.5Fr x 36cm, 10Fr x 36cm, 11Fr x 36cm, 12 Fr x 36cm, 13Fr x 36cm 8.5Fr x 40cm, 9.5Fr x 40cm, 10Fr x 40cm, 11Fr x 40cm, 12 Fr x 40cm, 13 Fr x 40cm 8.5Fr x 46cm, 9.5Fr x 46cm, 10Fr x 46cm, 11Fr x 46cm, 12 Fr x 46cm, 13Fr x 46cm 8.5Fr x 50cm, 9.5Fr x 50cm, 10Fr x 50cm, 11Fr x 50cm, 12 Fr x 50cm, 13 Fr x 50cm 8.5Fr x 55cm, 9.5Fr x 55cm, 10Fr x 55cm, 11Fr x 55cm, 12 Fr x 55cm, 13 Fr x 55cm
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ClearPetra Drive	8.5Fr x 40cm, 9.5Fr x 40cm, 10Fr x 40cm, 11Fr x 40cm

Ureteral Access Sheath	8.5Fr x 46cm, 9.5Fr x 46cm, 10Fr x 46cm, 11Fr x 46cm 8.5Fr x 50cm, 9.5Fr x 50cm, 10Fr x 50cm, 11Fr x 50cm
ClearPetra Drive Ureteral Access Sheath Duo	8.5Fr x 40cm, 9.5Fr x 40cm, 10Fr x 40cm, 11Fr x 40cm 8.5Fr x 46cm, 9.5Fr x 46cm, 10Fr x 46cm, 11Fr x 46cm 8.5Fr x 50cm, 9.5Fr x 50cm, 10Fr x 50cm, 11Fr x 50cm
ClearPetra Cystoscope Sheath	18Fr x 21cm, 20Fr x 21cm, 22Fr x 21cm 18Fr x 24cm, 20Fr x 24cm, 22Fr x 24cm

MEANING OF SYMBOLS ON PACKAGE

Date of manufacture

Use-by-date

Batch code

Do not re-use

Consult instructions for use

Do not use if package is damaged

Sterilized using ethylene oxide (for sterile products)

Do not resterilize (for sterile products)

Single sterile barrier system with protective packaging inside

Medical Device

Manufacturer

Keep dry

Keep away from sunlight

Importer

This way up

Catalogue number

Unique Device Identifier

Fragile, handle with care

Does not contain or presence of phthalate

CE Marked Product

Authorized representative in the European Community

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