

OTU Medical Inc.

**WiScope® Digital Endoscope System**

**WiScope® Single-Use Digital Flexible Ureteroscope**

*OTU-100SR, OTU-100SL, OTU-100RR, OTU-100RL*

**User's Manual**

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# FOREWORD

This User's Manual contains the recommended procedures for preparing and using WiScope® Single-Use Digital Flexible Ureteroscope. It is intended for physicians and other healthcare professionals who will be in contact with the device before, during, and after any procedures. This user manual also contains pertinent information on the handling of the device. Please read and become familiar with this entire manual before using the device.

**NOTE:** Definitions of **WARNING**, **CAUTION**, and **NOTE** are as follow:

- 1) **WARNING:** Alerts possible personal injury, death or other serious adverse reactions associated with the use or misuse of the system.
- 2) **CAUTION:** Alerts potential system problems when being misused, such as system malfunction, system failure, damage to the system or to other properties.
- 3) **NOTE:** Highlights important information on the use of the system.

**CAUTION:** To ensure that the best and latest information is communicated to you, the information in this User's Manual may be updated periodically. If you have any queries regarding the content provided or wish to confirm that this is the most comprehensive information available for this product, please contact your local distributor or OTU Medical Customer Service Department.

**CAUTION:** <sup>Rx</sup> Only Federal law restricts this device to sale by or on the order of a licensed physician.

**WARNING:** Contents supplied has been STERILED using an ethylene oxide (EO) process. Do not use the device if the sterile barrier is damaged.

**WARNING:** Always wear appropriate protective equipment when using the ureteroscope, such as gowns, gloves, surgical masks, and goggles.

**WARNING:** WiScope® Single-Use Digital Flexible Ureteroscope is designed for single use only. Do not reuse, reprocess or re-sterilize the device. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury or illness. Reuse, reprocessing or re-sterilization also create 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 of the patient.

**WARNING:** The Image System should be placed in a non-sterile area away from the sterile field. The physician who is working in the sterile field should not handle the Image System. A professional healthcare assistant, who is not working in the sterile field, should handle the non-sterile Image System.

**NOTE:** During procedure preparation or device setup, packaging can be disposed of in accordance with hospital,

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administrative and/or local government policy. After use, dispose of product and/or packaging in accordance with hospital, administrative and/or local government policy.

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# 1 INTENDED USE

WiScope® Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

# 2 CONTRAINDICATIONS

Diagnostic or therapeutic ureteroscopy is contraindicated in people with an untreated urinary tract infection.

Other contraindications to therapeutic ureteroscopy (e.g. lithotripsy, endopyelotomy, tumor therapy) are more numerous and can mirror those associated with the corresponding open surgical interventions. Patients on anticoagulants or with coagulopathies should be managed appropriately.

# 3 WARNINGS

- DO NOT use electromedical energy sources in the presence of flammable detergents, anesthetics, nitrous oxide (N<sub>2</sub>O), or oxygen.
- Consult the user manuals of all electromedical energy sources used with endoscopic instruments for appropriate instruments, warnings, and cautions prior to use. Such sources of energy include electrical, electrohydraulic, electrosurgical, heat hydraulic, laser, light, pressure, sound, ultrasound, and vacuum.
- DO NOT insert or advance the ureteroscope unless there is a clear live endoscopic view of the lumen through which the scope is being advanced (or confirm with visualization by other imaging modalities).
- During the procedure, if the live endoscopic image is lost, DO NOT advance or insert the ureteroscope and DO NOT insert, advance or actuate accessories.
- DO NOT use excessive force while advancing or withdrawing the scope. If resistance is felt during advancement or withdrawal of the scope, investigate the source of resistance and/or take remedial action if necessary.
- DO NOT force the distal tip of the ureteroscope against the sidewall of the ureter or renal pelvis.
- DO NOT use excessive force when advancing or withdrawing an accessory within the ureteroscope.
- When inserting or using accessories, maintain continuous visualization of the distal tip. Ensure that the distance between the distal tip of the ureteroscope and the object in view is greater than the ureteroscope's minimum visible distance. Failure to do so may result in the accessories causing patient injury.
- DO NOT withdraw a laser fiber back into the ureteroscope while the laser is firing. Doing so may cause patient

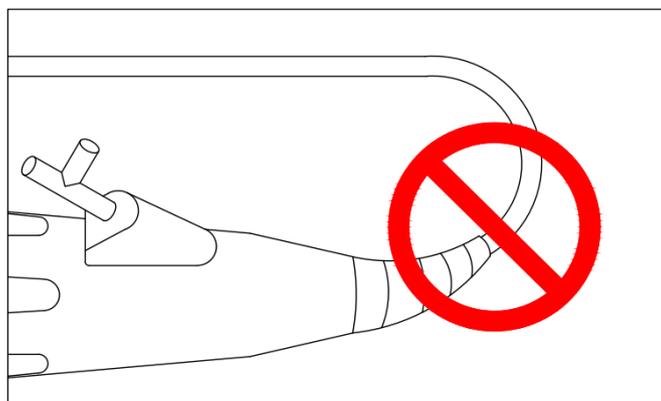
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injury and/or scope damage.

- DO NOT look directly into the light emitted from the ureteroscope.
- Verify ground isolation when setting up and using accessories from different manufacturers prior to procedure.
- DO NOT open the handle of the ureteroscope.
- The ureteroscope is a single-use device and there are no serviceable parts. DO NOT repair damaged or non-operating ureteroscopes. DO NOT use the ureteroscope if damage is discovered or suspected.
- DO NOT excessively bend the flexible shaft or the articulating section of the ureteroscope.
- If damage to the ureteroscope occurs or it stops functioning during a procedure, stop using the ureteroscope immediately. See troubleshooting section for more information. Continue the procedure with a new ureteroscope, as appropriate.

## 4 PRECAUTIONS

- WiScope® Single-Use Digital Flexible Ureteroscope can only be used in conjunction with WiScope® Image System. Connection to other 3rd party devices may cause device damage or operator injury.
- Only physicians with adequate ureteroscopic training should perform procedures with the ureteroscope.
- Use the ureteroscope with caution on patients who have undergone previous urinary tract reconstructive surgery or with known strictures. These conditions may prevent passage of the flexible scope shaft.
- The distal tip of the ureteroscope should be straight when inserting and withdrawing accessories. Follow the accessory user manual for use regarding inserting the accessory into a flexible ureteroscope.
- The ureteroscope features a strain relief at the transition from the handle to the shaft. The strain relief protects the device during use. To prevent shaft damage, do not bend the shaft sharply (Figure 1).



**Figure 1. DO NOT BEND SHARPLY**

- OTU Medical recommends a 200-micron laser fiber for maximum deflection and access to the kidney. A larger fiber may break and be accidentally fired inside the working channel, damaging the endoscope.
- Do not remove the cable plug from the Image System by pulling on cable as poor video performance or damage to the system may occur. Slide the locking collar on the cable plug toward the cable and pull the plug out to remove the cable.

## 5 PRODUCT DESCRIPTION

WiScope® Single-Use Digital Flexible Ureteroscope is a sterile, single-use device comprised of two main components: a control body with articulation controls, accessory access ports and cable, and a flexible insertion tube.

WiScope® Single-Use Digital Flexible Ureteroscope is also referred to as Ureteroscope, Endoscope or Videoscope in these instructions.

The Ureteroscope is used by physicians to access, visualize, and perform procedures in the urinary tract. The ureteroscope enables delivery and use of accessories such as biopsy forceps, laser fibers, guidewires, graspers and retrieval baskets at a surgical site. The distal tip of the ureteroscope articulates to 275 degrees in two directions, and the distal tip can be rotated a total of 360 degrees by rotating the handle.

The flexible insertion tube of the ureteroscope includes one working channel. The working channel enables the delivery of surgical accessories and irrigation solutions to the distal tip and surgical field.

The handle includes an articulation lever that controls the articulation of the distal tip. The handle also includes two access ports. One port accepts surgical accessories and one port provides a connection point for irrigation solution.

## 6 URETEROSCOPE MODELS

There are four models of WiScope® Single-Use Digital Flexible Ureteroscope: Standard Deflection Model for the right-handed (OTU-100SR), Standard Deflection Model for the left-handed (OTU-100SL), Reverse Deflection Model for the right-handed (OTU-100RR), and Reverse Deflection Model for the left-handed (OTU-100RL).

**Ureteroscope Models**

Standard Deflection Models	Pushing the deflection lever upwards articulates the distal tip “up”, and pushing the lever downwards articulates the distal tip “down”.
Reverse Deflection	Pushing the deflection lever upward articulates the

Models	distal tip “down”, and pushing the lever downwards articulates the distal tip “up”.
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Except that a right-handed handle’s accessory/irrigation port is positioned reversely to the left-handed handle’s, their structural design, function, and other parts are identical.

**WARNING:** Never bend the deflection section of the shaft by fingers as this may result in damage to the endoscope.

## 7 TECHNICAL SPECIFICATIONS

### 7.1 Specifications

Field of view	100°
Direction of view	Forward
Depth of field	2 – 50 mm
Distal tip diameter	7.4 Fr (2.47 mm)
Maximum outer diameter of insertion portion	9.5 Fr (3.25 mm)
Insertion tube outer diameter	8.6 Fr
Working channel diameter	3.6 Fr (1.10 mm)
Angulation range	275° Up / 275° Down
Working length of shaft	670 mm
Total length	905 mm
Cable length	2800 mm

### 7.2 Handling, Storage and Transportation

#### 1) Operating Environment

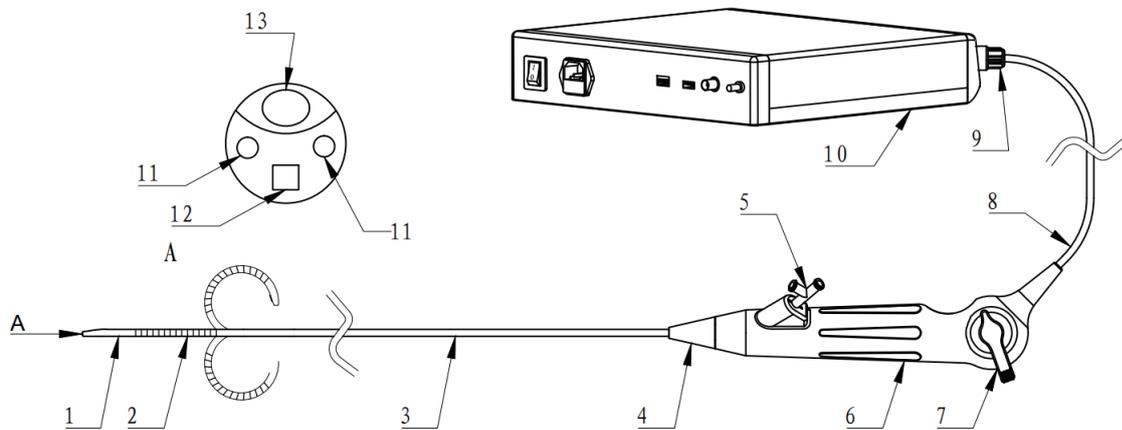
Temperature	10°C to 40°C
Relative Humidity	30% to 85% RH
Air Pressure	700 hPa to 1060 hPa

#### 2) Storage and Transportation Environment

Temperature	0°C to 60°C
Relative Humidity	10% to 95% RH
Air Pressure	700 hPa to 1060 hPa

# 8 INSTRUMENT COMPONENTS

## 8.1 System Diagram



**Figure 2 System Diagram**

- |                                |                                   |                  |
|--------------------------------|-----------------------------------|------------------|
| 1- Rigid distal tip            | 2- Deflection section             | 3- Shaft         |
| 4- Strain relief               | 5- Accessory and irrigation ports | 6- Handle        |
| 7- Articulation lever          | 8- Cable                          | 9- Cable plug    |
| 10- Image system               | 11- Lighting source               | 12- Video camera |
| 13- Opening of working channel |                                   |                  |

## 8.2 Description of Components

WiScope® Single-Use Digital Flexible Ureteroscope is comprised of two main components: Control Body and Insertion Tube.

### A Control Body

This component enables physicians to control over endoscopic functions. It includes an Articulation Lever<sup>7</sup>, Accessory and Irrigation Ports<sup>5</sup>, and a Cable<sup>8</sup>, as shown in Figure 2.

**1) Articulation Lever:** Located on the Control Body, this component controls the articulation of Deflection Section<sup>2</sup>. The only difference between Standard Deflection Models and Reverse Deflection Models is that the Up and Down conventions are reversed in the Articulation Lever<sup>7</sup>, causing an opposite articulation/deflection.

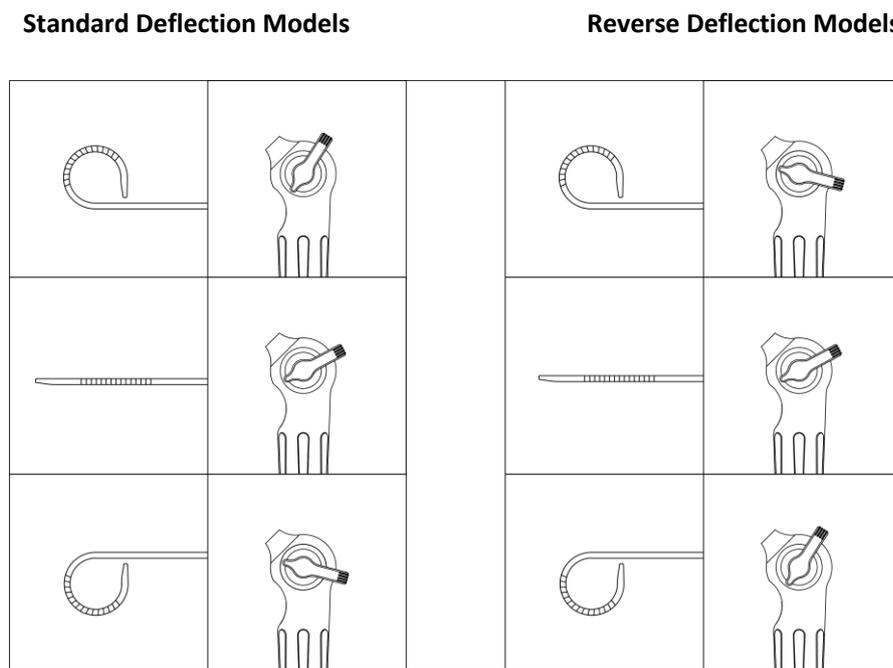
#### Standard Deflection Models:

The Articulation Lever<sup>7</sup> on Standard Deflection Models provides control of the bending section in an

“intuitive” direction. It indicates that when the Articulation Lever<sup>7</sup> is moved towards the “top” of the Control Body, the Deflection Section<sup>2</sup> will articulate in the visually “up” direction. When the Articulation Lever<sup>7</sup> is moved towards the Insertion Tube, the Deflection Section<sup>2</sup> will articulate towards the visually “down” direction.

**Reverse Deflection Models:**

The Articulation Lever<sup>7</sup> on the Reverse Deflection Models provides control of the bending section in a “traditional” direction. It indicates that when the Articulation Lever<sup>7</sup> is moved towards the “top” of the Control Body, the Deflection Section<sup>2</sup> will articulate in the visually “down” direction. When the Articulation Lever<sup>7</sup> is moved towards the Insertion Tube, the Deflection Section<sup>2</sup> will articulate in the visually “up” direction.



**Figure 3 Standard Deflection Models and Reverse Deflection Models**

- 2) **Accessory and irrigation ports:** Allow rapid fluid injection and access of surgical accessories during procedures.

**CAUTION:** There is no guarantee that instruments selected solely using the minimum instrument channel width will be compatible with WiScope® Single-Use Digital Flexible Ureteroscope.

- 3) **Cable:** The Cable Plug<sup>9</sup> at the end of the cable connects to the Image System.

**B Insertion Tube**

This segment, along with the Distal Tip<sup>1</sup>, constitutes the part of the endoscope to be inserted into the patient. This component contains a Video Camera<sup>12</sup> that transmits real-time images/videos, Lighting Source<sup>11</sup>, and Working Channel<sup>13</sup> for accessories and irrigation.

**CAUTION:** There is no guarantee that instruments selected solely using the maximum insertion portion

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width and working length will be compatible with WiScope® Single-Use Digital Flexible Ureteroscope.

## 9 OPERATION AND USE

**WARNING:** DO NOT use if the package is open or damaged. DO NOT use if labeling is incomplete or illegible.

**WARNING:** Place WiScope® Single-Use Digital Flexible Ureteroscope and Image System away from radios, televisions, cell phones, or any other devices that emit electromagnetic energy. These may interfere with proper operations. Avoid stacking the Ureteroscope or Image System on other equipment to avoid possible electromagnetic interference.

**WARNING:** DO NOT use this device in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide (N<sub>2</sub>O). There is a possibility of fire or explosion.

### 9.1 User Qualifications

This device should only be used in a medical facility by or under the supervision of a physician trained in ureteroscopy. The operator should have complete familiarity with the operation of the entire system prior to clinical use.

Only healthcare professional with adequate training in ureteroscopy should perform ureteroscopy procedures. OTU Medical strongly recommends a thorough review of all relevant medical literature relative to techniques, complications, and hazards prior to undertaking any ureteroscopy procedure.

For the preparation of the endoscope before use, disassembly and dispose of after use, users should be thoroughly trained. Failure to completely understand these details may pose an infection risk and/or cause device damage and/or patient injury.

If training assistance is required from either the manufacturer or local distributor, please contact your local distributor or OTU Medical Customer Service Department.

### 9.2 Unpacking

Upon receipt, examine the shipping carton and its contents for signs of damage. Confirm that the sterile barrier is intact and check the expiration date. DO NOT use a damaged or expired ureteroscopy. DO NOT attempt to repair the ureteroscopy.

Inside the shipping carton, the ureteroscopy is packaged in a tray which is sealed by a sterile barrier. Open the

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packaging by peeling off the sterile barrier from the corner. Take out the ureteroscope from the tray by holding the handle and connector cable, lifting the ureteroscope out of the tray, perform the following operational checks.

### 9.3 Inspection and Operational Checks

Inspect the entire surface of the flexible shaft visually by feeling the shaft with your fingertips with gloves on. Examine the handle, articulation lever, and accessory and irrigation ports to ensure no components are loose, bent, broken or having sharp edges.

Visually inspect the distal tip for any flaw including dents, protrusions, tears and holes.

Examine the ureteroscope in up, down, and straight articulated modes. Confirm the plane of articulation. Confirm that the scope tip articulates smoothly in both directions.

**WARNING:** DO NOT force the flexible tip into a straight or flexed position while holding the articulation lever. Doing so can damage the control mechanism.

**WARNING:** Failure to perform inspection and operational checks may result in patient injury and/or damage to the device and accessories.

### 9.4 Setup

- 1) Setup Image System according to WiScope® Digital Endoscope System User's Manual.
- 2) Insert the cable plug of the ureteroscope into the receptacle on the front panel of Image System until the cable plug is fully inserted.

**CAUTION:** Line up the convex on the ureteroscope Cable Plug with the groove on the cable receptacle, when connecting the Ureteroscope to the Image System.

- 3) Power up the Image System by following WiScope® Digital Endoscope System User's Manual.
- 4) Move the distal tip of the ureteroscope close to an object (until their distance is approximately the same as the width of the shaft) and ensure the video monitor displays a clear, sharply-focused, and high-quality image.
- 5) Adjust the brightness and white balance, as necessary. (See WiScope® Digital Endoscope System User's Manual.)
- 6) Connect a Luer-type cap or Luer-type sealing device to the accessory and irrigation ports on the handle to prevent fluid leakage from the port during the procedure. If necessary, connect the irrigation supply tube from a compatible irrigation source to the irrigation port on the handle of the ureteroscope.

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## 9.5 Articulate the Distal Tip

To articulate the distal tip, move the articulation lever on the handle with your thumb.

**NOTE:** For standard-type ureteroscopes, the up-and-down motion of the distal end goes with the moving direction of the articulation lever. For reverse-type ureteroscopes, the up-and-down motion of the distal end is opposite to the moving direction of the articulation lever.

**WARNING:** DO NOT apply excessive force to the articulation lever when the distal tip is hindered by obstacles. Doing so may damage the control mechanism or cause injury to the patient.

## 9.6 Connect Irrigation Source

Connect the irrigation supply tube of a compatible irrigation source (syringe, gravity-fed bag, or pump) to the irrigation port on the ureteroscope using a Luer-type fitting (Figure 2).

**NOTE:** Connect a Luer-type cap or Luer-type sealing device to the accessory and irrigation ports on the handle to prevent fluid leakage from the port prior to beginning flow of irrigation into the ureteroscope.

## 9.7 Access, Visualization and Application of Therapy

1) Gently advance the scope as per standard practice to the desired treatment area.

**CAUTION:** If using an access sheath, do not articulate the distal tip inside the access sheath.

**CAUTION:** Do not apply excessive force to the articulation lever.

**CAUTION:** Grasp the ureteroscope shaft close to the urethral meatus and advance with short strokes to prevent buckling of the shaft. If passing the scope through a nephrostomy cannula, grasp the ureteroscope shaft close to the cannula and advance with short strokes.

2) Utilize imaging to confirm position and articulation of the distal tip of the ureteroscope.

**CAUTION:** Confirm via the live endoscopic video image or other imaging modality that the distal tip of ureteroscope is advancing when the ureteroscope shaft being guided through the anatomy.

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## 9.8 Inserting and Removing an Accessory and Application of Therapy

**WARNING:** Before inserting an accessory, please check the appearance of the accessory, especially its end, to make sure there is no burrs, broken or other sharp edges, otherwise the accessory will puncture working channel of ureteroscope and then results in device damage.

**WARNING:** Not all accessories will be compatible with WiScope® Single-Use Digital Flexible Ureteroscope. Some accessories may not pass through the proximal section or the distal end of the working channel due to the larger size or stiffness. For example, Amplatz 0.035”(0.89 mm) or larger super stiff guidewire, Cook Medical 3.2Fr biopsy brush set are not compatible with WiScope® Single-Use Digital Flexible Ureteroscope.

**NOTE:** If an accessory cannot pass through the distal end of working channel even when it is in the neutral position, please slightly articulate the distal tip of the ureteroscope and then try to advance again, meanwhile twisting the accessory, if necessary.

**NOTE:** If using a laser lithotripsy system, select a system that features an aiming beam with adjustable intensity or pulse option. Adjust aiming beam intensity or pulsation to allow clear live video image of the lithotripsy target. DO NOT actuate any accessory device, including laser lithotripsy devices, without a clear endoscopic live video image. If the laser aiming beam cannot be adjusted to provide a satisfactory image, abort the procedure.

- 1) Prior to advancing an accessory, ensure that the tip of the scope is not in contact with the sidewall of the collecting system. Failure to leave a space between the tip of the scope and the sidewall may result in an unintended perforation when the instrument is advanced.
- 2) Insert the desired accessory device into the ureteroscope using the accessory and irrigation ports (Figure 2). While doing this, be sure that the scope is stabilized to prevent inadvertent movement which might cause injury to the patient or ureteroscope.
- 3) Advance the accessory slowly while observing the live video image for the initial entry of the accessory into the field of view.
- 4) Once the accessory is in the field of view, use the articulation lever to articulate the tip and accessory to achieve treatment objective.

**WARNING:** If you encounter resistance when advancing or withdrawing an accessory through the ureteroscope, visually confirm that the tip of the ureteroscope is not in contact with tissue. Then, ensure the articulation lever is in the Neutral position so that the distal tip of the ureteroscope is in its straight, non-articulated position. Also, ensure the accessory is in the proper configuration for passage through the ureteroscope. For example, confirm that the stone basket is in a closed configuration, the shaft is not kinked, etc. If you still encounter resistance, carefully withdraw the accessory, inspect it for any defects and if none are found, reintroduce it.

- 5) Before withdrawing an accessory, visually confirm that it is in the proper configuration (without deflection)

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for passage through the ureteroscope before pulling it back.

## 9.9 Removing the Ureteroscope from the Patient

1. Return the articulation lever to the Neutral position to allow the ureteroscope distal tip to relax into its straight, non-articulated position.

**CAUTION:** Ensure the articulation lever is in the **Neutral** position when removing the ureteroscope from the patient.

2. Under direct visualization, slowly withdraw the ureteroscope from the patient. If you feel resistance, investigate the source of the resistance using another imaging modality before continuing to withdraw the ureteroscope.

**Warning:** If the articulation lever cannot be used to straighten the distal tip, a 0.035" (0.89 mm) or larger super stiff guidewire may be passed, floppy end first, through the working channel to aid in straightening the distal tip using the following steps:

- a. Stabilize the handle of the ureteroscope and insert the guidewire into the ureteroscope using the accessory and irrigation ports (Figure 2).
- b. Advance the guidewire slowly, observing the live video image for initial entry of the guidewire into the field of view.
- c. Stop advancing the guidewire when the stiff portion of the guidewire emerges from the distal tip and is visible on the live video image.
- d. Use fluoroscopy or other imaging modality to confirm that the ureteroscope shaft has straightened.
- e. Slowly withdraw the ureteroscope from the patient. Monitor the withdrawal using spot fluoroscopic imaging or other imaging modality. If you feel resistance, investigate the source of resistance and take remedial action before continuing to withdraw the ureteroscope.

If the above method of using stiff guidewire doesn't work, cut the insertion tube of ureteroscope by surgical scissors to allow the ureteroscope distal tip to relax into its straight, non-articulated position automatically.

## 9.10 Post Procedure

Unplug the ureteroscope from Image System by grasping the grey collar on the cable plug and pulling it backwards towards the user.

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## 9.11 Disposal of the Ureteroscope and Packing Materials

After use, dispose of ureteroscope and packaging in accordance with hospital, administrative and /or local government policy.

# 10 ADVERSE EVENTS

Possible complications include, but may not be limited to:

- ◆ Discomfort
- ◆ Bleeding
- ◆ Infection
- ◆ Injury (ureter, renal pelvis or bladder)

# 11 TROUBLESHOOTING

The information in this section is intended to help users diagnose problems that may occur during operation of the endoscope. The followings include some of the problems that could arise during operation, possible causes for those problems, and suggested corrective action.

**CAUTION:** If the problem persists even after the corrective action has been taken, or a problem occurs that is not covered in this section, do not use the endoscope. Contact OTU Medical for counseling and service.

WiScope® Single-Use Digital Flexible Ureteroscope requires WiScope® Image System to process and display images. In order to identify issues related to image problems, you may also have to refer to the Troubleshooting section in WiScope® Digital Endoscope System User's Manual.

Problem	Cause	Solution
Angulation feels stiff	Damaged Deflection section causing impaired angulation	Dispose of the ureteroscope and replace with a new one.
Angulation alignment is no longer up/down	Insertion Tube has become twisted.	Dispose of the ureteroscope and replace with a new one.
Loss of angulation	Angulation wires have been stretched or broken.	Dispose of the ureteroscope and replace with a new one.
Cloudy or foggy images or poor image quality	Material or stain on the Objective Lens	Dispose of the ureteroscope and replace with a new one.
	Damaged optics, sensor or electronics in the ureteroscope	Dispose of the ureteroscope and replace with a new one.

No image	Image System is not powered on.	Check power cord connection and fuses, or connect the Image System to a different power outlet.
	Connection between the ureteroscope and the Image System is lost.	Check the cable connection between the ureteroscope and the Image System.
	No video output signal to a monitor	Check the video output cable connections when using an external monitor. Replace the cable if necessary.
	Damaged optics, sensor or electronics in the ureteroscope	Dispose of the ureteroscope and replace with a new one.
Loss of illumination	Material or stain on the Objective Lens	Dispose of the ureteroscope and replace with a new one.
	Light Intensity is set too low.	Adjust Light Intensity setting.
	Damaged LED Source	Dispose of the ureteroscope and replace with a new one.
The Accessory will not pass through Working Channel	Accessory is too large.	Check the outer diameter of the accessory. Make sure that the Accessory is compatible with the working channel.
	The ureteroscope's deflection section is angulated.	Maneuver the ureteroscope's Distal Tip to an area of the anatomy in which it can be safely straightened out. Insert the Accessory until its tip can be seen on the ureteroscopic image. Now angulated the ureteroscope's deflection section and proceed to the desired area.

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## 12 DESCRIPTION OF SYMBOLS



Batch code



Use-by date (YYYY-MM-DD)



Caution or Warning



Prohibition



Type BF applied part



Follow instructions for use



Do not reuse

**R<sub>x</sub> Only**

Federal law restricts this device to sale by or on the order of a physician



Sterile product. Sterilization by EO.



Do not use if the product sterilization barrier or its packaging is damaged



Manufacturer

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