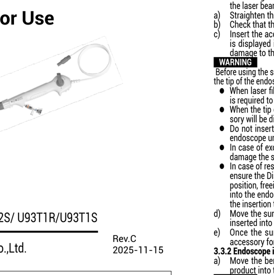
EZISURG MEDICAL

enScope™

Instructions for Use



U75T1R/U75T1S/ U75T2R/U75T2S/ U93T1R/U93T1S

CE 0197

Ezisurg Medical Co.,Ltd.

Rev.C
2025-11-15

Illustration

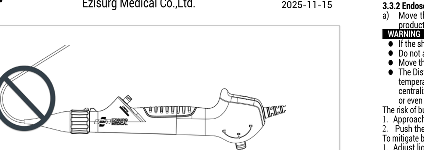


Figure 1

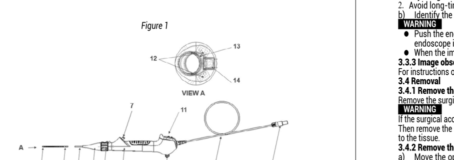


Figure 2

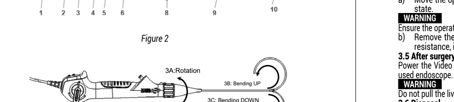


Figure 3

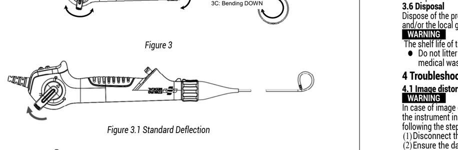


Figure 3.1 Standard Deflection

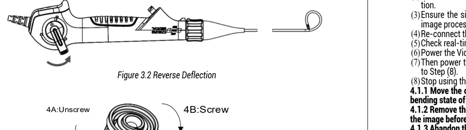


Figure 3.2 Reverse Deflection

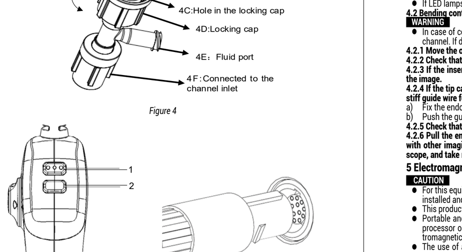


Figure 4

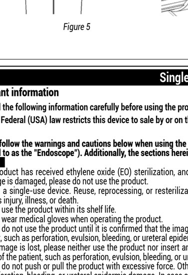


Figure 5

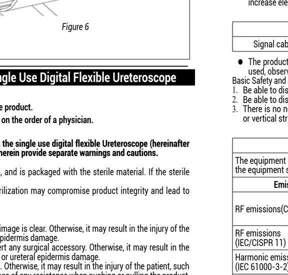


Figure 6

en — Single Use Digital Flexible Ureteroscope

1 Important information

Please read the following information carefully before using the product.

Rx Only **Federal (USA) law restricts this device to sale by or on the order of a physician.**

Notice!

1.1 Please follow the warnings and cautions below when using the single use digital flexible Ureteroscope (hereinafter referred to as the "Endoscope"). Additionally, the sections herein provide separate warnings and cautions.

WARNING

- The product has received ethylene oxide (EO) sterilization, and is packaged with the sterile material. If the sterile package is damaged, please do not use the product.
- This is a single-use device. Reuse, reprocessing, or resterilization may compromise product integrity and lead to serious injury, illness, or death.
- Please use the product within its shelf life.
- Please wear medical gloves when operating the product.
- Please do not use the product until it is confirmed that the image is clear. Otherwise, it may result in the injury of the patient, such as perforation, evulsion, bleeding, or ureteral epidermis damage.
- If the image is lost, please neither use the product nor insert any surgical accessory. Otherwise, it may result in the injury of the patient, such as perforation, evulsion, bleeding, or ureteral epidermis damage.
- Please do not push or pull the product with excessive force. Otherwise, it may result in the injury of the patient, such as perforation, evulsion, bleeding, or ureteral epidermis damage. In case of any resistance when pushing or pulling the product, please identify the resistance source and take remedial measures (such as fluoroscopic examination and contrast agent injection).
- Please do not poke the side wall of the ureter or the pelvis with the tip of the product by force. Otherwise, it may result in the injury of the patient, such as perforation, evulsion, bleeding, or ureteral epidermis damage.
- Please do not push or pull the surgical accessory with excessive force. Otherwise, it may result in the injury of the patient, such as perforation, evulsion, bleeding, or ureteral epidermis damage.
- Please keep normal imaging when pushing or operating the surgical accessory. Otherwise, it may result in the injury of the patient, such as perforation, evulsion, bleeding, or ureteral epidermis damage.
- Do not pull the laser fiber into the body of the product when the laser emission. Otherwise, it may cause the injury of the patient or damage the product. Please read the laser emitter manual carefully to have a good understanding of laser emission parameters. Protect eyes by wearing proper goggles.
- Patient leakage current may increase when powered accessories are used with the product.
- Do not look straight at light emitted from the product. Otherwise, it may damage eyes.
- The single-use product has no serviceable components. Please do not attempt to repair the damaged or failed product. If the product is found or suspected damaged, please do not use it any more.
- Please do not bend the insert portion of the product excessively. Otherwise, it may break or deform the insert portion.
- If the product gets damaged or fails to work during the surgery, please stop using it immediately. For more information, please refer to the section of "fault identification and troubleshooting". Where appropriate, it is allowed to use a new product.
- Before using the cardiac defibrillator, please take the product out of the patient's body. Otherwise, the current of the defibrillator may hurt the patient and damage the product.
- Please do not use the product together with any high-frequency surgical device.
- Please do not use the product when it is placed close to, or stacked with, another device, as it may result in improper operation. If the product has to be used, please observe it and other device to check that it works normally.
- The use of any accessory, sensor and cable other than those specified or provided by the product manufacturer may cause increased electromagnetic radiation or reduced electromagnetic immunity, and may result in improper operation.
- The portable radio frequency communication device (including antenna cable, external antenna and other peripheral components) should be located at least 30 cm (12 in) from the video image processor (including cable designated by the manufacturer). Otherwise, it may impair product performance.
- The manufacturer will not assume liability for any interference or response due to the use of cable other than recommended one or the unauthorized change or modification of the product. The unauthorized change or modification of the product may disable the access of the user to operate the product.
- It is not advisable to use devices emitting radio waves other than those provided by the Company nearby the product, such as mobile phones, radio transceivers, mobile radio transmitters, radio-controlled toys.
- As the product emits some radio frequency energy, it may generate radio frequency interference with other medical, non-medical and radio communication devices. In order to prevent such interference effectively, the product meets radio frequency emission limits under Class A, Group 1 as specified in IEC 60601-1-2. However, the Company will not guarantee that it is free from interference generation in a specific installation environment.
- Type F applied components should be used for the other medical electric devices used together with the product. (But please note that the leakage current of the CF device may exceed specified limits.)
- Excessive intake air or laser auxiliary gas may cause gas embolism.
- Before each use or change of view mode/setting, the operator should check to ensure real-time images (instead of stored images) with correct image directions are viewed via the product.
- Medical devices used together with the product should meet applicable requirements in IEC60601-1.

CAUTION

- The product should only be used together with ESM Video image processor. Its connection with other device may damage the product or the operator. It is allowed to use the general medical monitor meeting corresponding grade.
- Only trained surgeons are allowed to operate the product. Before use, please consult relevant technical data, and medical literature related to complications and adverse events.
- Please DO NOT use this product on the aircraft.
- Please inspect whether such parts of the product and its accessories as are inserted into the human body have rough surfaces, sharp edges and protrusions that may result in safety hazard before use.
- Please use the product WITH CAUTION for the patient who has received the urinary reconstructive surgery or has known narrow ureter carefully in order to prevent the insert portion from failing to pass through the urinary system.
- Please keep the tip of the product straight when pushing or pulling the surgical accessory. Please refer to the surgical accessory manual. If the operator does not follow the manual during operation, it may result in the injury of the patient, or the damage or fault of the surgical accessory and the product.
- Please do not bend the tube by force to prevent damage to the flexible insertion tube (Figure 1).

Figure 1 Please do not bend the tube by force

- Please only use fluid/lubricant intended for the product in the insertion tube. Please do not use any accessory that does not meet the product compatibility requirements. Otherwise, it may damage the product and/or its accessory.
- Please do not pull the data cable by force. Otherwise, it may deteriorate system performance or damage the product.
- To prevent any safety hazard due to device failure, it is required to prepare an endoscope and a Video image processor on standby so that surgery can proceed in case of device failure.
- Please dispose of the product and its package according to the regulations of the hospital, the administration and/or the local government after use.
- Before use, please inspect the compatibility between the endoscope system and any accessory and/or treatment devices.
- Please note that the bending directions are different for the standard and reverse models! For the standard deflection model, the symbol "U" should be positioned on the top and "D" on the bottom; for the reverse deflection model, the symbol "U" should be positioned on the bottom and "D" on the top.

1.2 Signal words

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

1.3 Intended use/Indications for use

The Single Use Digital Flexible Ureteroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

1.4 Clinical benefit

1. Provide clear images for visualization.
2. Provide working channel for diagnostic and therapeutic accessories.
3. Single-use avoiding cross-contamination and reduce cost.

1.5 Intended use population

Adults only.

1.6 Product structure and composition

The product is composed of a Distal end, a bend portion, an insert portion, an operating portion and a connecting portion.

Distal end (1- Distal tip, 12- LED, 13- Working channel, and 14– Camera module); Bending portion (2– Bending rubber); Insert portion (3- Insertion tube, 4 - Insert protective jacket); Operating portion (5- Thumbwheel (only for the U75T1R/U75T1S & U75T2R/U75T2S), 6- Operating handle, 7- Channel inlet, 8- Operating lever, 11- Keys (only for the U75T1R/U75T1S)); Connecting portion (9- Signal cable, 10- Signal plug).

Figure 2 Schematic Diagram of the Product

Accessories: Irrigation and locking valve.

1.7 Product description & specification

Table 1. Product Description

Product name	Catalogue number	Description	Note
Single Use Digital Flexible Ureteroscope	U75T1R	With Customized Keys, Insertion Tube Outer Diameter 7.5Fr, Reverse Deflection	Length of insert portion: 680 mm, inner diameter of channel: 3.6 Fr, camera: 160,000 px, lighting: LED
	U75T1S	With Customized Keys, Insertion Tube Outer Diameter 7.5Fr, Standard Deflection	
	U75T2R	Without Customized Key, Insertion Tube Outer Diameter 7.5Fr, Reverse Deflection	
	U75T2S	Without Customized Key, Insertion Tube Outer Diameter 7.5Fr, Standard Deflection	
	U93T1R	Without Customized Key, Insertion Tube Outer Diameter 8.7Fr, Reverse Deflection	Length of insert portion: 680 mm, inner diameter of channel: 3.6 Fr, camera: 160,000 px, lighting: LED, no thumbwheel (5), without rotation function
	U93T1S	Without Customized Key, Insertion Tube Outer Diameter 8.7Fr, Standard Deflection	

Table 2. U75T1R/U75T1S /U75T2R/U75T2S Product Specification

Item		Index
Basic parameters	Outer diameter of distal end	2.5mm (7.5 Fr)
	Insertion tube outer diameter	2.5mm (7.5 Fr)
	Inner diameter of channel	≥ 1.2mm (3.6Fr)
	Working length	680mm
	Field of view (diagonal)	130°
	Depth of field observed	2mm ~ 100mm
	Center resolution	≥ 7.87lp/mm
	Angle of bend	Upper/lower bend: 275° (lower limit: -10%, no upper limit)
General specifications	Shock-proof type	N/A
	Shock-proof degree	Type BF applied part (insert portion) when connected to the Video image processor
	Safety degree when used with flammable anesthetic mixture with air or flammable anesthetic mixture with oxygen or nitrous oxide	A device that should not be used with flammable anesthetic mixture with air or flammable anesthetic mixture with oxygen or nitrous oxide
	Ingress protection against fluid	IPX7 for insert portion; Other parts IPX2
	Shelf life	3 years

Table 3. U93T1R/U93T1S Product Specification

Item		Index
Basic parameters	Outer diameter of distal end	3.1mm (9.3 Fr)
	Insertion tube outer diameter	2.9mm (8.7 Fr)
	Inner diameter of channel	≥ 1.2mm (3.6Fr)
	Working length	680mm
	Field of view (diagonal)	130°
	Depth of field observed	2mm ~ 100mm
	Center resolution	≥ 7.87lp/mm
	Angle of bend	Upper/lower bend: 275°, tolerance: -10%; no upper limit
General specifications	Shock-proof type	N/A
	Shock-proof degree	Type BF applied part (insert portion) when connected to the Video image processor
	Safety degree when used with flammable anesthetic mixture with air or flammable anesthetic mixture with oxygen or nitrous oxide	A device that should not be used with flammable anesthetic mixture with air or flammable anesthetic mixture with oxygen or nitrous oxide
	Ingress protection against fluid	IPX7 for insert portion; Other parts IPX2
	Shelf life	3 years

1.8 Compatible accessory specification

Specification of surgical compatible accessories

1. Core diameter of laser fiber: ≤ 365 um;
2. Outer diameter of stone retrieval basket: ≤ 2.2 Fr;
3. Outer diameter of biopsy forceps: ≤ 1 mm;
4. Video image processor (ESM: ESP20 or ESP30);
5. Irrigation and locking valve;

Please note that in addition to complying with the above size requirements, compatible accessory also need to hold a CE certificate to ensure its compliance of launched on the EU market

1.9 Working principle

Working principle: Two small-sized LED lamps and one CMOS image sensor powered by the Video image processor are installed on the Distal end of the product. LED lamps illuminate the cavity of the human body. The CMOS image sensor converts the reflected light signal received into electrical signal, and transmits electrical signal to the Video image processor via CMOS cable, the signal converter board and signal cable.

1.10 Contraindications

Contraindications of the product only refer to observation and diagnosis applications with the product. Please do not use the product to diagnose or treat the patient with urinary tract infection.

For the contraindications of the product in other treatment applications (such as lithotripsy, endoscopic incision, and oncotherapy), please refer to corresponding open surgeries.

1.11 Adverse events

Possible complications include but are not limited to: Bleeding, Fever, Pain, Avulsion, Sepsis, Stenosis/Stricture, Renal failure, Inflammation, (ureter, renal pelvis or bladder) Perforation, Laceration, Hematuria, Urinoma, Discomfort, Hematoma, Urothelial damage and Infection.

1.12 Qualification to use

The product should be used only by professional endoscope physicians or medical staff under their supervision. The operators should receive sufficient clinical skill training. But this document does not cover any explanation of or discussion over clinical skills.

1.13 Sterilization/ validity period

The product has received ethylene oxide sterilization, with its production date and shelf life indicated on the label.

1.14 Transportation conditions & storage conditions:

Temperature: -20°C ~ 55°C; relative humidity: 10% RH ~ 80% RH; atmospheric pressure: 700 hPa ~ 1,060 hPa.

1.15 Working conditions:

Temperature: 10°C ~ 40°C; relative humidity: 30% RH ~ 75% RH; atmospheric pressure: 700 hPa ~ 1,060 hPa.

2 Check & inspection

2.1 Unpacking and check

Check whether the transport carton and sterile package delivered are free from damage. Check that the sterile package is intact and inspect the shelf life. Do not use an endoscope with a damaged package or expired shelf life.

Inspect product components per the packing list (Table 4). Please do not use the product delivered in case of shortage or damage, and contact the manufacturer immediately. Please keep all the packing materials that may be required when claiming from the carrier.

Table 4. Product Packing List

No.	Name	Quantity
1	Endoscope	1
2	Instructions for Use	1
3	irrigation and locking valve	1

2.2 Description of structure and composition

The main components of the product are shown in the figure 2.

Portion	No.	Name	Description
Distal end portion	1	Distal end	Camera, LED lamps and channel outlet are on the Distal end
	12	LED	Illuminator
	13	Channel outlet	It is allowed that the surgical accessory stretches out of the channel or fluid flows out of the channel.
	14	Camera module	Convert light signal into electrical signal
Bend portion	2	Bend portion	The bend portion works to move the Distal end by moving the operating lever.
Insert portion	3	Insertion tube	Connect the handle and the bend portion.
Operating portion	4	Insert protective jacket	Prevent the joint between the insertion tube and the handle from being bent excessively.
	5	Thumbwheel	Rotating component of Distal end (not for U93T1R/U93T1S)
	6	Operating handle	The surgeon holds the handle to operate the product.
	7	Channel inlet	It allows surgical accessory or fluid.
	8	Operating lever	When the operating lever rotates towards the "U" direction, the bend portion moves upward. When the operating lever rotates towards the "D" direction, the bend portion moves downward.
	11	Key	It serves as Customized keys. (only for the U75T1R/U75T1S)
Connecting portion	9	Signal cable	It supplies power to the camera and LED lamps, and transmits the electronic signal of the image from the camera to the Video image processor.
	10	Signal plug	It connects the product and the Video image processor.

2.3 Inspection before use

2.3.1 Visual inspection and internal connection inspection

WARNING

- If inspection before use is absent, it may hurt the patient, or damage the product and its accessories.

Remove the protective tube of the insert portion, and take out the Endoscope:

a. Inspect the surface of the flexible insertion tube by feeling the tube with fingers to ensure the surface is free from burr.
b. Inspect whether the bend portion has extruded metal parts.
c. Inspect whether the Distal end has contamination and damage traces such as dent, hump, crack or hole visually.
d. Inspect the handle, the operating lever and the channel inlet. Check that parts are free from looseness, bending or damage.
e. Inspect whether the signal cable and the signal plug have damage or contamination visually and whether the electric contact in the signal plug has corrosion traces.
f. Hold the bend portion with one hand gently, and push, pull and rotate the Distal end with the other hand slowly to ensure the connection between the bend portion and the Distal end does not become loose.
g. Hold the insertion tube with one hand gently, and push, pull and rotate the bend portion with the other hand slowly to ensure the connection between the insertion tube and the bend portion does not become loose.

2.3.2 Inspection of bending and rotating operations

WARNING

- If the operating lever becomes loose and/or moves unstably, or if the bend portion rotates unstably, the bending mechanism may be abnormal. In this case, do not use the product because the bend portion cannot be straightened, and it may result in injury, bleeding and/or perforation of the patient.

CAUTION

- Do not straighten or bend the bend portion by force when operating the operating lever. Otherwise, it may damage the direction control mechanism.

1. Hold the product (holding area as shown in Figure 3) with one hand, and operate the operating lever up and down slowly until it stops. Check that the bend portion rotates smoothly and correctly, and that it can rotate to the maximum angle. The "UP" (Marked as "U")and "DOWN" (Marked as "D")side show in the figure 3.

Figure 3. Schematic Diagram of Operation
Figure 3.1 Standard Deflection; Figure 3.2 Reverse Deflection;

2. Operate the operating lever slowly until it moves to the straight (neutral) position. Check that the bend portion restores to the approximate straight position stably.
3. Rotate the thumbwheel slowly to the "0" point until a "tick" sound.

2.3.3 Channel inspection

CAUTION

- The irrigation and locking valve, a single-use part, is sterile in the inner package of the product.
- The product is known to resist the following fluid types: blood, urine, normal saline, contrast agent and water-based lubricant.

1. Align the Lure fitting at the bottom of the irrigation and locking valve as shown in the following figure to the channel inlet of the product, and screw the fitting clockwise.
2. Screw the locking cap of the irrigation and locking valve clockwise. Inject 2 ml sterile water into the fluid port of the valve with an injector to check that there is no fluid leak and water flows out of the channel outlet.
3. Unscrew the locking cap of the irrigation and locking valve anticlockwise (figure 4). Insert the properly-sized accessory (for specific size, refer to the " Compatible Accessory Specification" in the "Basic Product Information") into the channel via the hole in the locking cap, and check that the accessory passes through the channel without any resistance.

Figure 4. Schematic Diagram of the Irrigation and locking valve

2.3.4 Inspection of endoscope image

1. Ensure the Video image processor is powered off. Then connect the product and the Video image processor, and power the processor on.

NOTE: For detailed connection information, please refer to the "Connection" in the "Operation and Application".

2. Check that LED lamps light up, and that the camera works normally.
3. Check that LED lamps have effective light intensity control function.

NOTE: For detailed light intensity control information, please refer to the "Unpacking Inspection, Appearance and Functions" in the "Instructions for Use of the Video Image Processor".

4. Confirm that the endoscope image is clear, the product light is normal, the image is displayed in real time and the change without affecting observation are the basic performance of the endoscope.
5. Check that customized keys function normally.(only for U75T1R/U75T1S)

Key 1: zoom (Figure 5);
Key 2: photo;

The functions of key 1 and key 2 can be customized as follows: "zoom", "photo", "freeze" and "video". The key functions may be customized via the host computer. For details, please refer to the «Instructions for Use of the Video Image Processor - Menu Item #13».

The "ZOOM" function has a total of 4 levels: 0X, 1X, 2X and 3X. Each level corresponds to an increased magnification multiple; they cycle through in this order.

Figure 5 Schematic Diagram of Keys

3 Operation & use

3.1 Connection

WARNING

- If inspection before use is absent, it may hurt the patient, or damage the product and its accessories.

3.1.1 Connect the product and the Video image processor.

Ensure the Video image processor is powered off. Then connect the product and the Video image processor, and power the processor on. Align the convex of the signal plug to the concave of the processor signal socket, and insert to connect the endoscope to the processor.

Figure 6 Connect the signal plug to the Video image processor

WARNING

- The convex cannot be inserted into the concave if they are not aligned(figure 6). Insertion by force may damage the endoscope or the processor.
- Please use the Video image processor of the specified model. Otherwise, it may damage the product.

3.1.2 Connect the product to the rinse source

Connect one end of the rinse pipe to the injector, or the gravity feeding bag, or the discharge port of the pump, and connect the other end of the pipe to the channel inlet of the product (or the fluid port of the irrigation and locking valve).

3.2 How to bend the Distal end and rotate the Distal end properly

WARNING

- Do not straighten or bend the bend portion by force when operating the operating lever or rotating the thumbwheel. Otherwise, it may damage the direction control mechanism.

3.2.1 Rotate the operating lever on the handle with the thumb to bend the Distal end.

3.2.2 When the operating lever rotates towards the "U" direction, the Distal end and the bend portion move upward. When the operating lever rotates towards the "D" direction, the bend portion moves downward (Figure 3).

3.2.3 When the operating lever is in the straight (neutral) position, the bend portion moves back to the approximate straight position.

3.2.4 Using fingers to rotate the Thumbwheel clockwise or counterclockwise allows the distal end to rotate in the corresponding direction (Figure 3). The Thumbwheel can rotate within a range of ±60°

3.3 Insertion and observation

3.3.1 Surgical accessory insertion

CAUTION

- If the laser lithotripsy system is used, please select a system with adjustable intensity or pulse options. Adjust laser intensity or pulse until the target of lithotripsy is displayed clearly in real time. Do not start any surgical accessories and devices, including laser lithotripsy device if no image is displayed clearly. Stop the surgery if the image is clear but laser is not adjusted in place.
- Neither start the tip of the surgical accessory nor stretch this tip out of the sheath when inserting the surgical accessory. Otherwise, it may damage the product and/or its surgical accessory.
- In the laser lithotripsy, laser fiber must stretch out of the channel outlet by 8-10 mm before the surgery. Otherwise, it may hit the front lens accidentally, damaging the product.
- The heat generated by the laser beam due to high temperature will weaken the intensity of components. Do not leave the laser beam to directly point at components, especially plastic components.

a) Straighten the bend portion of the product before inserting the accessory.
b) Check that the tip of the surgical accessory has been stopped or retracted into the sheath (if any).
c) Insert the accessory tip into the channel inlet. Push the accessory slowly to insert it into the channel until the tip is displayed in the image. During this operation, do not shake the handle to ensure stable image and avoid any damage to the patient or the product.

WARNING

Before using the surgical accessory, ensure the tip of the endoscope does not contact the body wall. If no gap is left between the tip of the endoscope and the body wall, perforation may be caused when the device stretches its tip.

- When laser fiber is used, mucosa burn or perforation may be caused due to heat generated by laser beam. Hence, it is required to keep proper distance between the laser fiber outlet and the mucosa.
- When the tip of the surgical accessory stretches out of the Distal end of the endoscope by about 2.5 mm, the accessory will be displayed in the image.
- Do not insert the surgical accessory by force or suddenly. The accessory may stretch out of the Distal end of the endoscope unexpectedly, which may result in injury, bleeding and/or perforation of the patient.
- In case of excessive resistance during insertion, stop insertion. Excessive force of insertion may hurt the patient, or damage the sheath, the endoscope and/or the accessory.
- In case of resistance when the surgical accessory is pushed into or pulled out of the endoscope, check image first to ensure the Distal end of the endoscope does not contact any tissue. Then ensure the operating lever is in the neutral position, freeing the bend portion of the endoscope from bending. Besides, ensure the surgical accessory is inserted into the endoscope under a proper state. That is, the stone retrieval basket of the accessory should keep closed and the insertion tube is not knotted.

d) Move the surgical accessory slowly and pay close attention to the video image in real time from the accessory is inserted into the endoscope until it is just displayed in the image.
e) Once the surgical accessory is displayed in the image, operate the operating lever to bend the tip and the accessory for surgery.

3.3.2 Endoscope insertion

a) Move the bend portion or the insertion tube to approach the patient and push the product slowly to insert the product into the patient's body properly.

WARNING

- If the sheath is used, prevent bending in the sheath.
- Do not apply excessive force to the operating lever.
- Move the insertion tube of the endoscope to approach the urethral orifice and push it slowly to prevent tube bending.
- The Distal end of the electronic endoscope has strong illumination capacity, which may cause temperature rise. If the temperature of the Distal end exceeds 41°C, and the Distal end keeps quite close to the mucosa, intense light will be centralized in a small area, and the tissue in the area involved will be heated due to long illumination on the surface or even be burned.

The risk of burns may increase under the following conditions:

1. Approach the mucosa normally or at a fixed point and observe it for a long time;
2. Push the electronic endoscope in a narrow lumen.

To mitigate burn risk, take the following measures:

1. Adjust light intensity manually to the minimum as required to make observation clear.
2. Avoid long-time observation at a fixed point as far as possible.

b) Identify the position of the endoscope and the bending angle of the Distal end in the image.

WARNING

- Push the endoscope following the principles of anatomy. Ensure the image processor displays the video image of the endoscope in real time while the Distal end of the endoscope is pushed. Otherwise, it may hurt the patient.
- When the image is frozen, neither push nor bend the endoscope.

3.3.3 Image observation

For instructions of adjusting the endoscope image, please refer to the Instructions for Use of the Video Image Processor.

3.4 Removal

3.4.1 Remove the surgical accessory

Remove the surgical accessory slowly when the tip of the accessory is switched off and/or is retracted into the sheath.

WARNING

If the surgical accessory cannot be removed from the endoscope, please switch off the accessory or retract it into the sheath. Then remove the surgical accessory and the endoscope simultaneously while observing the endoscope. Prevent any damage to the tissue.

3.4.2 Remove the endoscope

a) Move the operating lever to the neutral position, leaving the Distal end of the endoscope to restore to the straight state

WARNING

Ensure the operating lever keeps in the neutral position when the endoscope is removed from the patient's body.

b) Remove the endoscope from the patient's body slowly while paying close attention to the image. In case of any resistance, identify the resistance source with another imaging means before the endoscope is removed.

3.5 After surgery

Power the Video image processor off; remove the signal plug of the endoscope from the image processor; dispose of the used endoscope.

WARNING

Do not pull the live signal plug. Otherwise, it may damage the device.

3.6 Disposal

Dispose of the product, its accessory and packaging material according to the regulations of the hospital, the administration and/or the local government.

WARNING

The shelf life of the product is 3 year. Do not use the product if it is expired.

- Do not litter the abandoned endoscope and its accessory as they will pollute the environment. Instead, hand over the medical waste to the agency designated by the local environmental protection administration for proper disposal.

4 Troubleshooting

4.1 Image distortion or no image

WARNING

In case of image distortion or no image during surgery, stop pushing the endoscope and stop inserting, pushing or operating the instrument in the channel. Otherwise, improper operations may hurt the patient or damage the endoscope. Troubleshoot following the steps below:

(1) Disconnect the endoscope and the Video image processor.
(2) Ensure the data cable and the connectors of both the endoscope and the Video image processor are in good condition.
(3) Ensure the signal cable and the connector of the endoscope, and the data cable and the connector of the Video image processor are clean and dry.
(4) Re-connect the product and the Video image processor securely.
(5) Check real-time image. If no image is displayed, proceed to Step (6).
(6) Power the Video image processor off.
(7) Then power the Video image processor on, and check real-time image again. If no image is displayed still, proceed to Step (8).
(8) Stop using the endoscope and pull it out following the steps below:

4.1.1 Move the operating lever back to the neutral position, leaving the Distal end to restore straight state. Check the bending state of the endoscope in the image.

4.1.2 Remove the endoscope from the patient's body slowly. In case of any resistance, identify the resistance source in the image before continuing to remove the endoscope.

4.1.3 Abandon the endoscope and use a new one to complete the surgery.

- If LED lamps on the Distal end are damaged, abandon the endoscope and use a new one to complete the surgery.

4.2 Bending control failure

WARNING

- In case of control failure, stop pushing the endoscope, and stop inserting, pushing or operating the accessory in the channel. If direction control fails, stop using the endoscope following the steps below:

4.2.1 Move the operating lever back to the neutral position.

4.2.2 Check that the insertion tube is in straight state in the image.

4.2.3 If the insertion tube is still bent, straighten the tube tip with the operating lever while paying close attention to the image.

4.2.4 If the tip cannot be straightened with the operating lever, it is recommended to use 0.035 in (0.89 mm) or thicker stiff guide wire for tip straightening following the steps below.

a) Fix the endoscope handle and insert the guide wire into the port of the device.
b) Push the guide wire slowly until its tip is observed in the real-time image. Then, stop pushing the wire.

4.2.5 Please check that the insertion tube is straightened with the fluoroscope or other imaging means.

4.2.6 Pull the endoscope out of the patient's body slowly. Monitor the pulling process in the dot fluorescent image or with other imaging means. In case of resistance, identify the resistance source before continuing to pull the endoscope, and take remedial measures.

5 Electromagnetic compatibility

CAUTION

- For this equipment, special precautions regarding electromagnetic compatibility (EMC) must be taken, and it must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.
- This product conforms to the relevant requirements of IEC 60601-1-2 standard electromagnetic compatibility.
- Portable and mobile radio frequency communication devices may hinder the normal operation of the Video image processor or the electronic endoscope. Please use the processor and the endoscope under the recommended electromagnetic environment.
- The use of accessories and cables (energy converters) other than those sold as spare parts for the product may increase electromagnetic emission or lower electromagnetic immunity. The product contains the cable below:

Table 5 Cable Information

Cable name	Length
Signal cable (a part of the endoscope catheter)	2.8 m

- The product should not be used when it is placed close to, or stacked with, another device. If the product has to be used, observe it to check that it works normally in the given configuration.

Basic Safety and Essential Performance:

1. Be able to display real-time images.
2. Be able to display image with the correct orientation.
3. There is no noise in image which can affect doctor's diagnosis, noise may manifest as grains or specks, horizontal or vertical stripes, flickering, and snowy screen.

Table 6 Declaration of Compliance (Electromagnetic Emission)

Manufacturer's Declaration – Electromagnetic Emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions(CISPR 11)	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions (IEC/CISPR 11)	Class A	The equipment is suitable for use in all establishments, other than non-domestic or domestic establishments directly connected to the public low-voltage power supply network that supplies buildings used.
Harmonic emissions (IEC 61000-3-2) Not Applicable	Not Applicable	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Not Applicable	

Table 7 Declaration of Compliance (Electromagnetic Immunity - High Voltage)

Manufacturer's Declaration – Electromagnetic Immunity		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Immunity test	Compliance Level	Electromagnetic environment-Guidance
Electromagnetic discharge(ESD) (IEC61000-4-2)	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Floors should be made of wood, concrete or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electromagnetic fast transient/ burst (IEC61000-4-4)	± 2 kV for power supply lines ± 1 kV for signal lines	Mains power quality should be of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge (IEC61000-4-5)	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC61000-4-11)	0% U_T, 0.5cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T, 1 cycle 70% U_T, 25/30 cycles Single phase: at 0° 0% U_T, 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment with highly reliable service. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field (IEC61000-4-8)	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields From RF wireless communications equipment (IEC61000-4-3)	Refer to next table	Portable and mobile RF communications equipment should be used no closer to any part of the product
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz, PM, 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 kHz, 7.5 A/m	The sources of proximity magnetic fields should be used no closer than 0.15 m to any part of the product
Conducted RF (IEC 61000-4-6)	3 Vrms, 150 kHz~80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be separated from any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2√P d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.7 GHz
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz ~2.7 GHz	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a), should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE:
1: U_T is the AC mains voltage before application of the test level.
2: At 80 MHz and 800 MHz, the higher frequency range applies.
3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
4: To established the proximity threshold 0.15 m for Proximity magnetic fields, the IEC Subcommittee (SC) 62A has considered the types of proximity magnetic field disturbance sources expected:
– induction cooking appliances and ovens operating at frequencies up to 30 kHz;
– RFID readers operating at both 134.2 kHz and 13.56 MHz;
– electronic article surveillance (EAS) systems;
– sponge detection systems;
– equipment used for position detection (e.g. in catheter labs);
– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.
These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of the collateral standard IEC 60601-1-2:2014+A1:2020 .

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended minimum separation distances:

Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This Systems has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014+A1:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this Systems as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power(W)	Distance (m)	Immunity test level(V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sinue	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

6 After-sales maintenance, service and part replacement

WARNING

- he product does not contain any user serviceable parts. Please do not dismantle, modify or attempt to repair the product as it may hurt the patient or the operator, or damage the product.
- The disassembly, repair, change or modification of the product by personnel other than those of Ezisurg Medical Co., Ltd. (ESM) are beyond the warranty scope of ESM. ESM will not bear any warranty liability for those actions.

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