

LithoVue™ Single-Use Digital Ureteroscope System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

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

Contraindications

- Contraindications for this device are those specific to urinary tract endoscopy.
- 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.

Warnings

- Do not use electromedical energy sources in the presence of flammable detergents, anesthetics, nitrous oxide (N₂O), or oxygen.
- Consult the operating manuals of all electromedical energy sources used with endoscopic instruments for appropriate instructions, 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). Doing so can cause patient injury such as perforation, avulsion, hemorrhage, or urothelial damage.
- In the event that the live endoscopic image is lost, do not advance or insert the ureteroscope and do not insert, advance or actuate accessories. Doing so can cause patient injury such as perforation, avulsion, hemorrhage or urothelial damage.
- Do not use excessive force while advancing or withdrawing the scope. Doing so can cause patient injury such as perforation, hemorrhage or urothelial damage or damage to the ureteroscope. If resistance is felt during advancement or withdrawal of the scope, investigate the source of resistance and take remedial action (e.g., fluoroscopy, contrast injection).

- Do not force the distal tip of the ureteroscope against the sidewall of the ureter or renal pelvis. Doing so can cause patient injury such as perforation, avulsion, hemorrhage or urothelial damage.
- Do not use excessive force when advancing or withdrawing an accessory within the ureteroscope. Doing so can cause patient injury such as perforation, avulsion, hemorrhage, urothelial damage or damage to 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 such as perforation, hemorrhage or urothelial damage.
- Do not withdraw a laser fiber back into the ureteroscope while the laser is firing. Doing so may cause patient injury and/or scope damage.
- Do not look directly into the light emitted from the ureteroscope. Doing so can result in eye injury.
- Verify ground isolation when setting up and using accessories from different manufacturers. Failure to do so can result in shocks and accessory malfunction leading to patient injury.
- Do not open the handle of the ureteroscope. Doing so can damage the waterproof seals and result in risk of electric shock.
- 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 as this may break or kink the shaft.
- If damage to the ureteroscope occurs or it stops functioning during a procedure, stop using the ureteroscope immediately. Continue the procedure with a new ureteroscope, as appropriate.
- Prior to use of a cardiac defibrillator, remove the ureteroscope from the patient. Failure to remove the ureteroscope from a patient during use of a cardiac defibrillator could result in patient injury or damage to the system due to the discharge of the cardiac defibrillator

This is not a complete list of warnings. All warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

Possible complications include, but may not be limited to:

- Bleeding
- Avulsion
- Stenosis / Stricture
- Inflammation
- Laceration
- Fever
- Sepsis
- Renal failure
- Perforation (ureter, renal pelvis or bladder)
- Hematuria

- Pain
- Discomfort
- Urinoma
- Infection
- Ureteral Reflux
- Hematoma
- Urothelial damage

Precautions

- Only use the LithoVue™ Single-Use Digital Flexible Ureteroscope in conjunction with the LithoVue System Workstation. Connection to other devices may cause device or property damage or operator injury.
- Only physicians with adequate ureteroscopic training should perform procedures with the ureteroscope. Consult the medical literature regarding techniques, complications, and hazards prior to any procedure.
- Use the ureteroscope with caution in patients who have undergone previous urinary tract reconstructive surgery or with known strictures. These conditions may prevent passage of the flexible scope shaft.
- The LithoVue™ System has been tested and shown to be compatible with laser lithotripsy devices. The use of other energized procedural devices may cause loss of image, device damage, or patient injury.
- To ensure satisfactory performance, perform the prescribed inspections and operational checks described in the device preparation section before use.
- The distal tip of the ureteroscope should be straight when inserting and withdrawing accessories. Follow the accessory directions for use regarding inserting the accessory into a flexible ureteroscope. Failure to follow the accessory directions for use may result in patient injury, or accessory and ureteroscope damage or malfunction.
- 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 damage to the shaft and/or light fiber, do not bend the shaft sharply.
- Use only those fluids/lubricants recommended in the ureteroscope
- compatibility section.
- Do not use accessories that fail to meet the compatibility requirements of the ureteroscope as stated on the ureteroscope labeling. Doing so may cause damage to the ureteroscope and/or accessory.
- Failure to thoroughly understand and follow all instructions, cautions and warnings provided in this DFU and the LithoVue System Workstation User's Manual may result in injury to the patient and/or user; and/or may result in damage to, or malfunction of, this equipment. Additionally, damage to other equipment or property may result. Follow all instructions, cautions and warnings provided with all products and equipment to be used in conjunction with the LithoVue System to avoid any possible hazards due to device incompatibility.
- Placing the LithoVue System Workstation near other medical electrical equipment may result in electromagnetic interference (EMI) which may degrade the video image. Additionally, EMI from the LithoVue System Workstation may interfere with other equipment in the operating room. Verify that all electrical equipment is working properly before starting the

procedure. Failure to do so may result in equipment not working, possibly resulting in either a delay of the procedure or an adverse event.

- Do not insert a wet, contaminated, or damaged connector cable plug into the LithoVue System Workstation as poor video performance or damage to the system may result.
- Do not remove the connector cable from the LithoVue System Workstation by pulling on the cable as poor video performance or damage to the system may result. Slide the locking collar on the cable plug toward the cable and pull the plug out to remove the cable.

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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