

Brief Summary Document

Overview

Product

LithoVue™ Single-Use Digital Flexible Ureteroscope	IFU 51116905
LithoVue™ System Workstation	IFU 51116907

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Only physicians who have ureteroscopic diagnostic and therapeutic training should use the LithoVue Flexscope. A thorough understanding of the techniques, principles, clinical applications, and risks associated with ureteroscopy is necessary before using the device. This includes but is not limited to: devices used in laser lithotripsy, administration of irrigation/contrast, and use of procedural accessories such as baskets/forceps, access sheaths, renal sheaths, guidewires and antiretropulsion devices.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

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 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.
- Do not open the handle of the ureteroscope. Doing so can damage the waterproof seals and result in risk of electric shock.
- 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.
- Failure to perform inspection and operational checks may result in patient injury and/or damage to the device and accessories.

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

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.
- 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.
- 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.

- 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.

This is not a complete list of precautions. All precautions 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
- Laceration
- Pain
- Discomfort
- Urinoma
- Extravasation
- Fever
- Sepsis
- Inflammation
- Perforation (ureter, renal pelvis or bladder)
- Ureteral Reflux
- Hematoma
- Urothelial damage
- Infection