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# LithoVue Elite with Pressure Monitoring Single-Use Digital Flexible Ureteroscope

## StoneSmart™ Connect Console

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### Prescriptive Information

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

#### INTENDED USE/INDICATION FOR USE

The LithoVue Elite Digital Flexible Ureteroscope 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. Contraindications associated with therapeutic ureteroscopy (e.g., lithotripsy, endopyelotomy, tumor therapy) are more numerous and can mirror those associated with the corresponding open surgical interventions. Consideration should be given to the contraindications for those procedures.

#### WARNINGS - StoneSmart Connect Console

- Do not use the LithoVue Elite System in the presence of flammable fluids and gases such as alcohol or oxygen. Doing so can result in fire and burns to the operator and patient.
- 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 LithoVue Elite Ureteroscope unless there is a clear, live endoscopic view of the lumen through which the ureteroscope 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 LithoVue Elite Ureteroscope and do not insert, advance or actuate accessories. Doing so can cause accessory damage or patient injury such as perforation, avulsion, hemorrhage, or urothelial damage.
- Do not use excessive force when advancing or withdrawing the LithoVue Elite Ureteroscope. Doing so can cause patient injury such as perforation, hemorrhage or urothelial damage, or damage to the LithoVue Elite Ureteroscope. If resistance is felt during advancement or withdrawal of the LithoVue Elite Ureteroscope, investigate the source of resistance and take remedial action (e.g., fluoroscopy, contrast injection).

- Do not force the distal tip of the LithoVue Elite 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 LithoVue Elite Ureteroscope. Doing so can cause patient injury such as perforation, avulsion, hemorrhage, urothelial damage, or damage to the LithoVue Elite Ureteroscope.
- When inserting or using accessories, maintain continuous visualization of the distal tip. Ensure the distance between the distal tip of the LithoVue Elite Ureteroscope and the object in view is greater than the LithoVue Elite Ureteroscope's minimum visible distance. Failure to do so may result in accessory damage or patient injury such as perforation, hemorrhage, or urothelial damage.
- The distal tip of the LithoVue Elite Ureteroscope should be straight when inserting and withdrawing accessories. Follow the accessory instructions for use regarding inserting accessories into a flexible ureteroscope. Some accessories may be inserted or withdrawn in a ureteroscope with a deflected distal tip, some accessories should be inserted or withdrawn in a straightened distal tip. Failure to follow the accessory instructions for use may result in patient injury such as avulsion, perforation, stenosis, additional intervention, and an unretrieved device fragment, or accessory and ureteroscope damage or malfunction.
- The LithoVue Elite System has been tested and shown to be compatible with laser lithotripsy devices. The LithoVue Elite System is not intended to be used with High Frequency Surgical Equipment. The use of other energized procedural devices may cause loss of image, device damage, or patient injury such as burn, erectile dysfunction, hematoma, hemorrhage, nerve injury, perforation, reflux (genitourinary), restenosis, stenosis, and urinary retention.
- Do not initiate laser firing while a laser fiber distal tip is still within the ureteroscope working channel or withdraw a laser fiber's distal tip back into the ureteroscope working channel while the laser is firing. Doing so may cause patient injury such as perforation and stenosis, and/or ureteroscope damage.
- Do not look directly into the light emitted from the LithoVue Elite Ureteroscope. Doing so can result in eye injury.
- Do not open the handle of the LithoVue Elite Ureteroscope. Doing so can damage the waterproof seals and result in risk of electric shock.
- The LithoVue Elite Ureteroscope is a single-use device, and there are no serviceable parts. Do not repair damaged or non-operating LithoVue Elite Ureteroscopes. Do not use the LithoVue Elite Ureteroscope if damage is discovered or suspected.
- Do not excessively bend the flexible shaft or the articulating section of the LithoVue Elite Ureteroscope as this may break or kink the shaft.
- If damage to the LithoVue Elite Ureteroscope occurs or it stops functioning during a procedure, stop using the LithoVue Elite Ureteroscope immediately. See "TROUBLESHOOTING" section for more information. Continue the procedure with a new LithoVue Elite Ureteroscope, as appropriate.
- No modification of this equipment is allowed. Do not attempt to repair or alter any components/parts of the Console. The Console contains no operator serviceable components. All repairs and servicing are to be performed only by authorized Boston Scientific service personnel. See "SERVICE AND WARRANTY" section for additional information.

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Prior to installation, ensure that the selected hospital's electrical outlet has a proper ground connection and complies with the information listed on the label located on the rear of the Console.
- The use of accessories, a power supply and/or cables other than those specified or supplied as spare parts from Boston Scientific may increase electromagnetic emissions or decrease immunity of the LithoVue Elite System.
- When the LithoVue Elite System is used with other electrical medical equipment, the applied parts must be Type BF or Type CF applied parts.
- Components added to the system by the user must be certified to the respective IEC standards (IEC 60601-1 for medical equipment, IEC 60950 for data processing equipment, and IEC 60065 for A/V equipment) or other country equivalent. In addition, any person who connects additional equipment to the analog and digital interfaces installed by Boston Scientific is configuring a medical electrical system and is therefore responsible for ensuring that it complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical services department or your authorized representative. The use of component equipment not complying with IEC standards may lead to a reduced level of safety of the resulting capital. Power cords are considered part of the medical electrical system and must be compliant with the system.
- Use of the LithoVue Elite System adjacent to or stacked with other electrical equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- If the Console stops functioning during a procedure, follow the procedure described in "TROUBLESHOOTING" section.
- Using a Console contaminated with patient fluids can expose the operator or secondarily, the patient through clinician contact, to bio-hazardous materials. To prevent exposure to potentially bio-hazardous materials, visually inspect, clean, and disinfect the Console during and between uses using the cleaning procedure described in the "Cleaning and Disinfection Instructions" section.
- When considering the pressure readings, exercise clinical judgment as the clinical implication of intrarenal pressure measurements may vary depending upon a variety of patient and procedural factors.
- When the pressure limit set for the procedure is exceeded, before continuing to irrigate, exercise clinical judgment as the clinical implication of intrarenal pressure measurements may vary depending upon a variety of patient and procedural factors.
- Patients on anticoagulants or with coagulopathies should be managed appropriately.
- To ensure satisfactory performance, perform the prescribed inspections and operational checks on the LithoVue Elite Ureteroscope described in the LithoVue Elite Single-Use Digital Flexible Ureteroscope Instructions for Use before use. Failure to perform inspection and operational checks may result in patient injury such as burn, perforation, tissue damage, avulsion, and stenosis, and/or damage to the device and accessories. Additionally, verify the Console is properly installed. See the "INSTALLATION, CALIBRATION AND SERVICING" section for more information.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the LithoVue Elite System,

including cables specified by the manufacture. Otherwise, degradation of the performance of this equipment could result.

### **WARNINGS - LithoVue Elite with Pressure Monitoring Single-Use Digital Flexible Ureteroscope**

- Do not open packaging (carton or pouch) with a sharp object. Doing so may result in compromised sterility or damage to the ureteroscope.
- Do not use the ureteroscope in the presence of flammable fluids or gasses such as alcohol or oxygen. Doing so may result in fire and burns to the operator and patient.
- 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 ureteroscope 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. See the troubleshooting section for more information.
- Do not use excessive force while advancing or withdrawing the ureteroscope. Doing so can cause patient injury such as perforation, hemorrhage, urothelial damage, or damage to the ureteroscope. If resistance is felt during advancement or withdrawal of the ureteroscope, investigate the source of resistance (e.g., fluoroscopy, contrast injection) and take remedial action.
- 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 rely on the pressure readings if the pressure sensor is obstructed (e.g., tissue, biomass, debris, stone) since this may result in the pressure readings to be inaccurate. Doing so may result in excessive fluid/pressure to be delivered to the patient and may cause patient injury such as infection, distension, and other fluid overload related harms.
- 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 initiate laser firing while a laser fiber distal tip is still within the ureteroscope working channel or withdraw a laser fiber's distal tip back into the ureteroscope working channel while the laser is firing. Doing so may cause patient injury such as perforation and stenosis, and/or ureteroscope damage.

- Verify adequate visualization during laser usage to avoid additional complications associated with unintended scope/fiber movement or misdirected application of laser energy.
- 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.
- 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. Doing so can cause patient injury such as perforation, avulsion, hemorrhage, urothelial damage, or damage to the ureteroscope.
- 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. See the troubleshooting section for more information. Continue the procedure with a new ureteroscope, as appropriate.
- When considering the pressure readings, exercise clinical judgment as the clinical implication of intrarenal pressure measurements may vary depending upon a variety of patient and procedural factors.
- When the pressure limit set for the procedure is exceeded, before continuing to irrigate, exercise clinical judgment as the clinical implication of intrarenal pressure measurements may vary depending upon a variety of patient and procedural factors.
- Patients on anticoagulants or with coagulopathies should be managed appropriately.
- Do not place ureteroscope on a non-sterile object when not being used. Use of the device in a patient after contacting a non-sterile object could result in infection.
- Do not insert a wet, contaminated, or damaged connector cable plug into the console as poor video performance or damage to the system may result.
- Use only those fluids/lubricants recommended in the fluid compatibility section. Failure to do so may compromise ureteroscope functionality.
- The LithoVue Elite 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 such as burn, erectile dysfunction, hematoma, hemorrhage, nerve injury, perforation, reflux (genitourinary), restenosis, stenosis, and urinary retention.
- Follow the accessory instructions for use regarding inserting accessories into a flexible ureteroscope. Some accessories may be inserted or withdrawn in a ureteroscope with a deflected distal tip, some accessories should be inserted or withdrawn in straightened distal tip. Failure to follow the accessory directions for use may result in patient injury such as avulsion, perforation, stenosis, additional intervention, and an unretrieved device fragment, or accessory and ureteroscope damage or malfunction.
- To ensure satisfactory performance, perform the prescribed inspections and operational checks described in the device preparation section before use.

## **PRECAUTIONS – StoneSmart Connect Console**

- Only use the LithoVue Elite Ureteroscope in conjunction with the Console. Connection to other controller or workstation devices may cause device or property damage or operator injury.
- The LithoVue Elite Ureteroscope is not compatible with the LithoVue System Workstation.
- Only physicians with adequate ureteroscopic training should perform procedures with the LithoVue Elite Ureteroscope. Consult the medical literature regarding techniques, complications, and hazards prior to any procedure.
- Use the LithoVue Elite 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 ureteroscope shaft.
- Failure to thoroughly understand and follow all instructions, cautions and warnings provided in this User's Manual and the LithoVue Elite Ureteroscope Instructions for Use 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 Elite System to avoid any possible hazards due to device incompatibility.
- The illumination contained within the LithoVue Elite Ureteroscope handle may cause the ureteroscope to overheat, resulting in possible user harm such as burn, discomfort, pain and tissue damage. Therefore, if the ureteroscope is not to be used immediately for a procedure, it is recommended that the light be turned off until needed.
- When using the LithoVue Elite Ureteroscope with a laser lithotripsy device, all personnel within the treatment room shall wear protective laser eyewear in accordance with the laser manufacturer's instructions for use.
- Do not use accessories that fail to meet the compatibility requirements of the LithoVue Elite Ureteroscope as stated in the LithoVue Elite Single-Use Digital Flexible Ureteroscope Instructions for Use. Doing so may cause damage to the LithoVue Elite Ureteroscope, Console and/or accessory.
- Verify ground isolation when setting up and using accessories from different manufacturers. Failure to do so can result in user/patient injury such as electric shock, tissue damage, additional intervention, and prolonged procedure, and accessory malfunction leading to patient injury.
- 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 such as electric shock, or damage to the system due to the discharge of the cardiac defibrillator.
- The LithoVue Elite 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 "Fluid Compatibility" section of the LithoVue Elite Single-Use Digital Flexible Ureteroscope Instructions for Use.

- The LithoVue Elite Ureteroscope Connector Cable (hereafter referred to as Ureteroscope Cable) should connect to the Console Receptacle easily. If the Ureteroscope Cable does not connect, verify that the arrows on the Ureteroscope Cable and the Console Receptacle line up and that the Console Receptacle is not damaged. Forcing the Ureteroscope Cable into the Console Receptacle may damage the Ureteroscope and/or Console.
- Do not insert a wet, contaminated, or damaged Ureteroscope Cable plug into the Console Receptacle as poor video performance or damage to the system may result.
- Do not remove the Ureteroscope Cable from the Console by pulling on the cable as poor video performance or damage to the system may result. Slide the locking collar on the Ureteroscope Cable's plug toward the cable and pull the plug out to remove the cable.
- Placing the Console near other medical electrical equipment may result in electromagnetic interference (EMI) which may degrade the video image. Additionally, EMI from the Console 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 the equipment not working properly resulting in either a delay of the procedure or an adverse event.
- Spilling liquids on the Console can damage it or cause it to shut down. Do not place liquids above or near the Console.
- Inspect all cables and cords (cuts in insulation, fraying or broken wires, dirty or bent connector pins). Replace if damaged.
- Inspect the console enclosure to verify that there are no unacceptable damages to the console enclosure (e.g., chips, dents, scratches, or marks), degraded labels, connectors with signs of damage or excessive wear (dirty or bent connector pins), or image degradation on the touch screen. Contact Boston Scientific for service using the information found in "SERVICE AND WARRANTY" section.
- Power down the Console when not in use (i.e., at the end of a procedure). Do not power down the Console by unplugging the power cord from the hospital's electrical outlet until after the power button is pressed and power down is complete. Doing so may cause damage to the system or present electrical energy exposure to the user.

### **PRECAUTIONS - LithoVue Elite with Pressure Monitoring Single-Use Digital Flexible Ureteroscope**

- Only use the LithoVue Elite Ureteroscope in conjunction with the StoneSmart Connect Console. Connection to other controller or workstation devices may cause device or property damage or operator injury.
- The LithoVue Elite Ureteroscope is not compatible with the LithoVue System Workstation.
- 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.
- 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.

- 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 ureteroscope shaft.
- 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 (Figure 6).

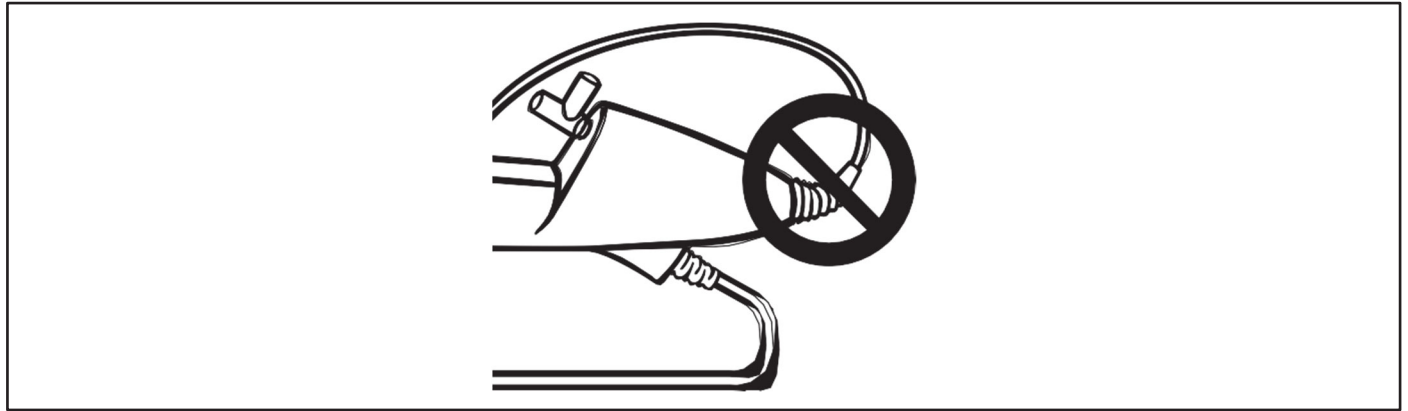



Figure 6. Do not bend the shaft sharply.

- 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.
- Failure to thoroughly understand and follow all instructions, cautions, and warnings provided in the LithoVue Elite Single-Use Digital Flexible Ureteroscope Instructions for Use and the StoneSmart Connect Console 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 Elite System to avoid any possible hazards due to device incompatibility.
- Placing the console near other medical electrical equipment may result in electromagnetic interference (EMI) which may degrade the video image. Additionally, EMI from the console may interfere with other equipment in the operating room.
- Verify ground isolation when setting up and using accessories from different manufacturers. Failure to do so can result in user/patient injury such as electric shock, tissue damage, additional intervention, and prolonged procedure, and accessory malfunction leading to patient injury.
- 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 remove the connector cable from the console by pulling on the cable as poor video performance or damage to the system may result. Slide the locking collar on the cable plug in the direction of the arrow and pull the plug out to remove the cable.
- The ureteroscope once plugged in will work for four hours.
- Electromagnetic compatibility\* (EMI) may occur on this instrument near equipment marked with the following symbol (  ). Electromagnetic interference may occur in this instrument near other portable



and mobile radio frequency (RF) communication equipment, for example, cellular phones. To check for EMI, verify the system's operation in which it will be used. Should EMI occur, employ mitigation measures like reorienting or repositioning the instrument or shielding its location. Placing this instrument near other medical equipment or mobile RF communications equipment may result in EMI, which may degrade the device performance.

\*Note: Inspect the electromagnetic interference from external equipment by observing to verify the Ureteroscope system's normal operation in the configuration in which it will be used. Verify all electrical equipment is working properly before starting the procedure.

## **ADVERSE EVENTS**

Possible complications include, but may not be limited to:

- Avulsion
- Bleeding
- Burn
- Discomfort
- Extravasation
- Fever
- Hematoma
- Infection
- Inflammation
- Laceration
- Pain
- Perforation (ureter, renal pelvis, or bladder)
- Sepsis
- Stenosis/Stricture
- Ureteral reflux
- Urinoma
- Urothelial damage.

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

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