

# VersaVue™ Single-Use Flexible Cystoscope

## Prescriptive Information

Refer to the device user manual for complete instructions on device use.

## Intended Use/Indications for Use

The Cystoscope is intended to provide endoscopic procedure and surgical treatment within the lower urinary tract. The Cystoscope is intended to provide visualization via displaying unit. The Cystoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.

## Contraindications

Cystoscope must not be used if the procedure may endanger the patient according to the opinion of a qualified physician.

- Febrile patients with urinary tract infections (UTIs) or severe coagulopathy
- Patients with acute infection (acute urethritis, acute prostatitis, acute epididymitis)
- Patients with known unpassable urethral stricture

## Warnings

- The Cystoscope is a single-use device and must be handled in a manner consistent with accepted medical practice for such devices to avoid contamination of the Cystoscope prior to insertion.
- The Cystoscope images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.
- **Do not** insert active endoscopic accessories before the distal end of the endoscopic accessory can be seen on the displaying unit and is protruding at a sufficient distance from the distal end of the Cystoscope, as this may result in patient injury or damage to the Cystoscope.
- **Do not** use the Cystoscope if it is damaged in any way or if any part of the functional check fails (see section 3).
- **Do not** attempt to clean, sterilize, and reuse the Cystoscope as it is a single-use device. Reuse of the product can cause contamination, leading to infections.
- The Cystoscope is not intended to be used when delivering oxygen or highly flammable anesthetic gases to the patient. This could potentially cause patient injury.
- The Cystoscope is not intended to be used in MRI environment.
- **Do not** use the Cystoscope during defibrillation.
- Only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.
- **Do not** use excessive force when advancing, operating, or withdrawing the Cystoscope.
- Patients should be monitored during use.
- Always watch the live endoscopic image on the displaying unit when advancing or withdrawing the Cystoscope, operating the bending section. Failure to do so may harm the patient.
- **Do not** use the Cystoscope if the product sterilization barrier or its packaging is damaged.
- The distal tip of the Cystoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the distal tip and the mucosal membrane as long, sustained contact with the mucosal membrane may cause mucosal injury.
- When withdrawing the Cystoscope, the distal tip must be in neutral and non-deflected position. Do not operate the control lever, as this may result in injury to the patient and/or damage to the Cystoscope.
- **Do not** advance or withdraw the Cystoscope, or operate the bending section, while endoscopic accessories are protruding from the distal tip of the working channel, as this may result in injury to the patient.
- Always make sure that the bending section is in a straight position when inserting or withdrawing an endoscopic accessory in the working channel. Do not operate the control lever and never use excessive force, as this may result in injury to the patient and/or damage to the Cystoscope.

- Always perform a visual check according to the instructions in this User Manual before placing the Cystoscope in a waste container.
- Electronic equipment and the Cystoscope system may affect the normal function of each other. If the system is used adjacent to or stacked with other equipment, observe, and verify normal operation of both the system and the other electronic equipment prior to using it. It may be necessary to adopt procedures for mitigation, such as reorientation or relocation of the equipment or shielding of the room in which it is used.
- Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.
- Be careful to check whether the image on the screen is a live image or a recorded image and verify that the orientation of the image is as expected.
- To avoid risk of electric shock, the system must only be connected to supply mains with protective earth. To disconnect the system from supply mains, remove the mains plug from the wall outlets.
- If any malfunction should occur during the endoscopic procedure, stop the procedure immediately and withdraw the Cystoscope.
- Insert the syringe completely into the working channel port before instilling fluid. Failure to do so may result in the fluid spilling from the working channel ports.
- Using energized electrosurgical equipment in conjunction with the Cystoscope may disturb the image.
- **Do not** perform laser surgical procedures or procedures with high frequency endoscopic accessories if flammable or explosive gases are present in the patient's lower urinary tract as this may result in injury to the patient.
- Patient leakage currents may be too high, when using energized endoscopic accessories. Only energized endoscopic accessories classified as "type CF" or "type BF" applied parts shall be used with the Cystoscope to minimize the total patient leakage current.
- User shall be familiar with safety precautions, guidelines, and proper use of the laser devices, including, but not limited to, proper eye and skin protection, when using compatible laser devices.
- There is no guarantee that all instruments solely using the minimum working channel size will be compatible. The Compatibility of instruments should be tested before the procedure.
- Cystoscope is a single-use device. Any use beyond 4 hours or frequently plug in and unplug Cystoscope may result in blurry images.

### **EMC (Electromagnetic compatibility)**

During installation and operation of the device, observe the following instructions:

- When operating the device simultaneously with other electronic equipment, please ensure the Cystoscope is kept at least 30 cm (12 inches) from other electronic equipment, including all cables specified by the manufacturer.
- **DO NOT** use or stack the device near, on, or under other electronic equipment to avoid electromagnetic interference with the operation of the device.
- **DO NOT** use the system with portable and mobile radio frequency communication systems because they may have an adverse effect on the operation of the device.
- Only use cables and accessories specified for the device. Unapproved cables and accessories could cause electromagnetic interference and degrade the Cystoscope's operation.

### **Cautions**

- Have a suitable backup system readily available for immediate use so the procedure can be continued if a malfunction should occur.
- Be careful not to damage the insertion cord or distal tip when using sharp devices such as needles in combination with the Cystoscope.
- Be careful not to damage the insertion cord or distal tip when using energized devices in combination with the Cystoscope.
- Be careful when handling the distal tip and do not allow it to strike other objects, as this may result in damage to the equipment. The lens surface of the distal tip is fragile and visual distortion may occur.

- Do not exert excessive force on the bending section as this may result in damage to the equipment. Examples of inappropriate handling of the bending section include:
  - Manual twisting.
  - Inserting it into a pre-shaped tube or body cavity with the bending direction not aligned with the curve of the tube.
- Keep the Cystoscope handle dry during preparation, use and storage.
- Do not use a knife or other sharp instrument to open the pouch or cardboard box.

**Potential Adverse Events**

- Bleeding
- Reaction to Topical Anesthesia
- Pain or discomfort
- Hematuria
- Dysuria-pain and discomfort on voiding
- Increase voiding frequency
- Urethral narrowing due to scar tissue formation
- Urinary tract infections
- Mucosal injury
- Perforation of bladder

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.  
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URO-1731205-AA NOV 2023

# VersaVue™ Tablet and VersaVue™ Video Box

## Prescriptive Information

Refer to the device user manual for complete instructions on device use.

## Intended Use/Indications for Use

The VersaVue Tablet and VersaVue Video Box are plug-and-play visualization modules that are used with disposable VersaVue Cystoscopes to project images onto a monitor.

## Contraindications

Visualization module must not be used if the procedure may endanger the patient according to the opinion of a qualified physician.

- Febrile patients with urinary tract infections (UTIs) or severe coagulopathy
- Patients with acute infection (acute urethritis, acute prostatitis, acute epididymitis)
- Patients with known unpassable urethral stricture

## Warnings

- No modification of this equipment is allowed.
- If the device cannot be turned on, please contact BSC for support
- **Do not** modify this equipment without authorization of the manufacturer.
- No service should be done without authorization of BSC.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- **DO NOT** use VersaVue Tablet and VersaVue Video Box if the device is damaged in any way.
- Keep VersaVue Tablet and VersaVue Video Box away from electromagnetic apparatuses (include but not limited to MRI machines, life support equipment, etc.) to avoid malfunction.
- It can be unsafe to interconnect this equipment with other equipment (including Network or Data couplings), accessories, detachable components, cables, and materials not described in the Instructions for Use as part of the equipment or system.
- Please read the manual carefully before using this device.
- An external display is not suggested to be used as the primary display.

## Cautions

- Avoid strikes from objects and sharp devices such as needles against VersaVue Tablet and VersaVue Video Box and be careful not to connect incompatible devices.
- **Do not** expose VersaVue Tablet and VersaVue Video Box directly to sunlight or any high temperature to prevent damage to the device.

## Potential Adverse Events

- Bleeding
- Reaction to Topical Anesthesia
- Pain or discomfort
- Hematuria
- Dysuria-pain and discomfort on voiding
- Increase voiding frequency
- Urethral narrowing due to scar tissue formation
- Urinary tract infections
- Mucosal injury
- Perforation of bladder

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician. Manufactured by Medimaging Integrated Solution Inc. Distributed by Boston Scientific.