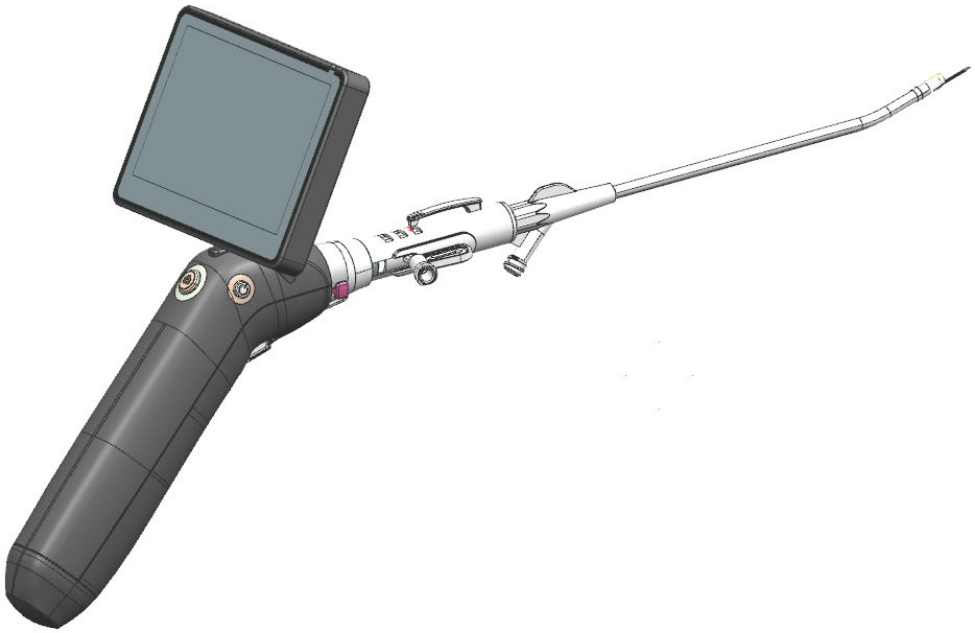
Uro-N Cystoscope
Instructions for Use



UroViu corporation

Simplify the scope of patient care

CAUTION	
⚠	SALE AND USE Federal law (USA) restricts this device to sale by or on the order of a physician.

Notice

Uro-N Cystoscope Model Number: 1115

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See www.uroviu.com/patents for list of applicable patents.

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About this document

This Instructions for Use (IFU) provides instructions on how to use the Uro-N Cystoscope while connected to the UroViu Handle safely and effectively for its intended use of visualization of the bladder and urethra as well as injection of therapeutic agents and solutions in the lower urinary tract under direct visual guidance. For the purposes of this document, the word “cannula” refers to the Uro-N Cystoscope. It is important to read and follow the information provided in this manual prior to use for proper performance, correct operation, and to ensure patient and operator safety. The user is responsible to thoroughly review these instructions and to operate this device as indicated as detailed in these instructions. Additional copies of this IFU may be found at www.uroviu.com, and for questions or requests for training and service contact Customer Service at cs@uroviu.com.

Instructions for Use originally issued in English.

Compatible with the UroViu 4500/5000/5000W Handle (sold separately).

Warranty

UroViu Corporation warrants that the device supplied is free from defects in materials or workmanship. This warranty is valid only if the product is supplied to the end user by an UroViu approved agent or distributor and has been maintained in accordance with procedures documented in the Instructions for Use. If failure occurs from manufacturing defects within 6 months of purchase, UroViu will replace the defective item.

1. Intended Use

1.1. Intended Use

The Uro-N Cystoscope is intended for injection of injectable therapeutic agents and solutions into target areas of the bladder and the lower urinary tract.

1.2. Indications for Use

1.2.1. Generally recognized indications for injection of solutions and medications into the bladder include:

- Neurogenic bladder with or without urinary incontinence,
- Over Active Bladder syndrome
- Increased frequency of urination,
- Scarring of the bladder neck (contracture) or within the urethra (stricture)
- Hunner's ulcer
- Urgency of urination

1.3. Contraindications

1.3.1. Evidence of ongoing urinary tract infection

1.3.2. Overwhelming coagulopathy

1.3.3. Impassable urethral structures

2. Symbols, Warnings and Precautions

This section contains important safety information related to use of the Uro-N Cystoscope. Other important safety information is repeated throughout this manual in sections that relate specifically to the precautionary information. Read all text surrounding all warning and precautionary information prior to performing any procedure with this equipment.

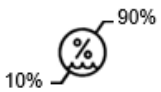
2.1. Symbol Legend

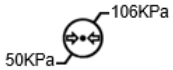
The following symbol conventions are used in this manual, and/or on the Uro-N Cystoscope product labeling.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1 #5.1.1	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.12	Symbols for use in the labeling of medical devices.
			ISO 7000 -3082	Graphical symbols for use on equipment.
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 #5.1.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.6	Symbols for use in the labeling of medical devices.
			ISO 7000-2497	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 #5.1.6	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.10	Symbols for use in the labeling of medical devices.
			ISO 7000-2493	Graphical symbols for use on equipment.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1 #5.1.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.5	Symbols for use in the labeling of medical devices.
			ISO 7000-2498	Graphical symbols for use on equipment.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 #5.1.5	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.4	Symbols for use in the labeling of medical devices.
			ISO 7000-2492	Graphical symbols for use on equipment.
	Medical Device	Indicates that the device is a Medical Device	ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
	Use by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 #5.1.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2607	Graphical symbols for use on equipment.
	Follow instructions for use	Refer to instruction manual/booklet.	IEC 60601-1 Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7010-M002	Graphical symbols – Safety colors and safety signs – Registered safety signs.
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 #5.2.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.8.2	Symbols for use in the labeling of medical devices.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
			ISO 7000-2501	Graphical symbols for use on equipment.
	DO NOT re-use	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO 15223-1 #5.4.2	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.2	Symbols for use in the labeling of medical devices.
			ISO 7000-1051	Graphical symbols for use on equipment.
	DO NOT resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 #5.2.6	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.22	Symbols for use in the labeling of medical devices.
			ISO 7000-2608	Graphical symbols for use on equipment.
	DO NOT use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 #5.2.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #6.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2606	Graphical symbols for use on equipment.
	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1. Type BF refers to classification of the nature of patient contact and degree of patient protection from risk of electrical shock.	IEC 60601-1 Table D.1. Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60417 #5333	Graphical Symbols for Use on Equipment.
⚠CAUTION	Caution	To indicate that caution is necessary when operating the device or control	IEC 60601-1 Table D.1 symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
		close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 7000-0434A	Graphical symbols for use on equipment
⚠WARNING	Alarm warning sign	Displayed on the ultrasound display screen to signify a potential or actual hazardous situation exists for physician awareness or response is required.	IEC 60601-1-8:2007+A11:2017 Annex C No. 1 Reference 60417-5307	General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 #5.3.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2626	Graphical symbols for use on equipment.
			EN 980 #5.21	Symbols for use in the labeling of medical devices.
	This side up	To indicate correct upright position of the transport package.	ISO 7000-0623	Graphical symbols for use on equipment.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 #5.3.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0632	Graphical symbols for use on equipment.
			EN 980 #5.17.3	Symbols for use in the labeling of medical devices.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1 #5.3.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2620	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1 #5.3.9	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2621	Graphical symbols for use on equipment.

2.2. **General Warnings**

The following warnings identify known operations, procedures or practices that should be heeded immediately or risk injury or death to patient or Operator.

2.2.1. The Uro-N Cystoscope is for use only by licensed health care providers with adequate training in endoscopy.

2.2.2. The Uro-N Cyctoscope is only for use with the UroViu Handle (sold separately).

2.2.3. Choose a cannula size that is appropriate for the patient.

2.2.4. If a liquid distension medium is used, strict fluid intake and output surveillance is recommended.

2.2.5. Inspect the integrity of the unit and condition before powering-on the fully assembled Uro-N Cystoscope with UroViu Handle. Do not use the system if indications of external damage are observed.

2.2.6. Do not operate the Uro-N Cystoscope if any shipping damage or other defects to the cannula are noted during inspection. Immediately notify UroViu Corporation Customer Service if any defect is found.

2.2.7. Do not use the cannula if the sterile barrier is damaged or if the expiration date (use by date) printed on the label has passed.

2.2.8. The Uro-N Cystoscope cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution and must be disposed of in accordance with local and/or state laws governing the collection of biohazardous medical devices with electronic components.

2.3. **Cautions**

2.3.1. Federal Law restricts the device to sale by or on the order of a licensed health care professional.

2.3.2. For single patient use only. Do not reuse, reprocess, or attempt to re-sterilize the cannula.

2.3.3. Do not misalign the connectors between the removable cannula and the UroViu Handle during assembly, as damage may occur.

2.3.4. Do not alter the shape of the distal end of the cannula. Bending or kinking during or prior to use can damage integrity of the scope. While the cannula is semi-rigid, it should not be bent greater than 30 degrees prior to or during advancement in the urethra.

2.3.5. When detaching the cannula from the handle, be sure that fluid does not contact the connector in the handle.

3. Preparation for Use

3.1. Unpacking and Inspection

3.1.1. Each cannula comes sealed in a pouch and has been sterilized using Ethylene Oxide (ETO).
- Do not use, if sterile barrier is damaged.
- The expiration date (use by date) is shown on the package labeling. Check that the expiration date has not passed before use.

3.1.2. Packing Materials. Save the pouch until the successful completion of the procedure.
- In the rare event of a device malfunction, keep the pouch with cannula and follow facility/institution guidelines for the handling of biohazardous devices.
- Contact UroViu Corporation Customer Service for further instructions on reporting a device complaint.

3.1.3. Inspection. Inspect all components for damage during shipment, or discrepancies upon arrival.

WARNING	
⚠WARNING	Do not operate the Uro-N Cystoscope if any shipping damage or other defects to the cannula is noted during inspection. Immediately notify UroViu Corporation Customer Support if any defect is found.
⚠WARNING	Do not use the cannula if sterile barrier is damaged or if the expiration date printed on the label has passed.

3.2. Environmental Requirements

3.2.1. The Uro-N Cystoscope cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution and must be disposed of in accordance with local and/or state laws governing the collection of biohazardous medical devices with electronic components.

4. Description of Components

4.1. Product Description – the Uro-N Cystoscope is comprised of the following components:

4.1.1. Sterile, Single-use Cannula

The disposable single-use, hydrophilic coated cannula contains a miniature CMOS camera and light-emitting diodes (LED) illumination module at the tip. The tip of the cannula has a pre-curved 15° angle in the tip section. The cannula connects to the handle through a separate electrical connector for sending image data and receiving LED power. The cannula has an inner channel for the infusion of fluid. The fluid infusion is achieved by gravity and/or connection to a pressurized bag. The 23 Ga injection needle is embedded, its proximal end is a luer connector. The needle is controlled by a tab at the proximal end. The disposable cannula is sterilized and packaged in a sealed pouch. Figure 1 shows the disposable cannula.

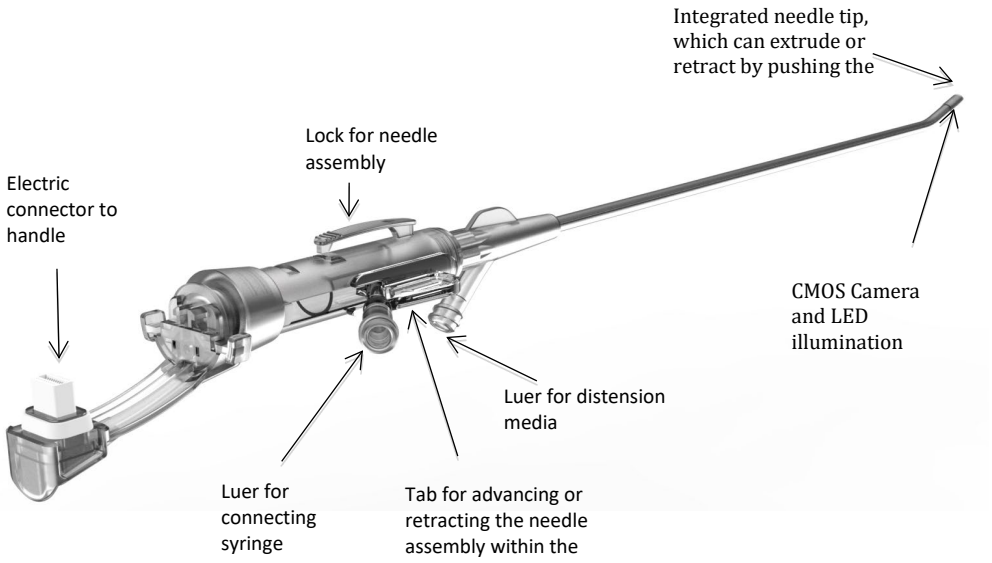


Figure 1. The disposable cannula of the Uro-N Cystoscope.

4.2. Device Classification and Technical Specification

4.2.1. Device Classification: FDA Class II, HH Device Classification

4.2.2. Technical Specifications

Sterile, Single-use cannula	
Working Length	269 mm
Maximum Insertion Portion Width	4.85 mm
Pre-curved tip angle	15°
Direction of view	15°
Distension Fluid Lumen Cross-section	2.6 mm^2
Distension Flow Rate	120 mL/min
Site Requirements – Operating conditions	
Operating Temperature	10°C to 28 °C
Operating Humidity	10% - 70%
Air Pressure	70 KPa – 106 KPa
Transport and Storage	
Temperature	-10°C to 55°C
Relative Humidity	90% RH @ 60°C to 10% RH @ 0°C
Atmospheric Pressure	50 KPa - 106 KPa

5. Basics of Operation and Procedure

5.1. Cannula attachment and detachment

In preparation for use, attach the cannula to the electrical connector on the UroViu Handle per the following:

5.1.1. Peel apart the proximal end of the package.

5.1.2. Rotate the sterile single-use disposable cannula to ensure that the USB male connector aligns with the USB female connector within the handle.

5.1.3. Connect the cannula to the UroViu Handle and press it fully into place until a subtle “click” of the connector detent mechanism is felt.

5.1.4. Once cannula is connected, insert the male USB connector of the disposable cannula into the USB female connector on the handle. See Figure 2.

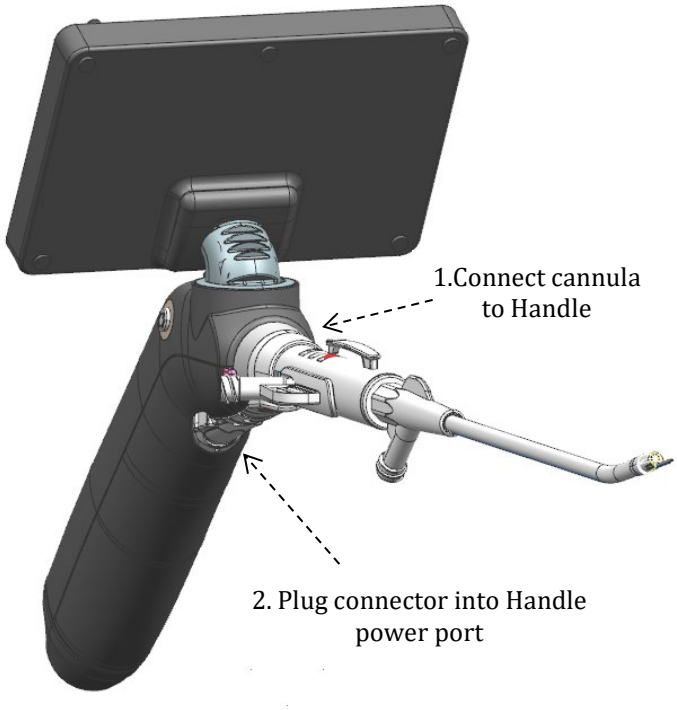


Figure 2. Attach Cannula to Handle

5.2. Bladder Injection Procedure

PRIOR TO THE Injection

5.2.1. Open the pouch containing the sterile cannula and remove the cannula while maintaining sterile conditions.

5.2.2. Open the pouch containing the sterile cannula and remove the cannula while maintaining sterile conditions. See figure 3.

5.2.3. Attach the cannula to the handle. See figure 4.

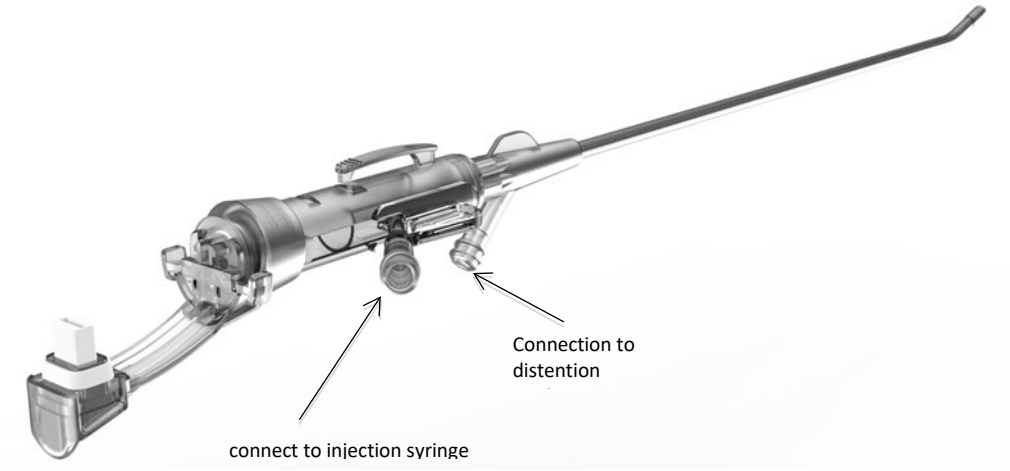


Figure 3. Uro-N Cannula

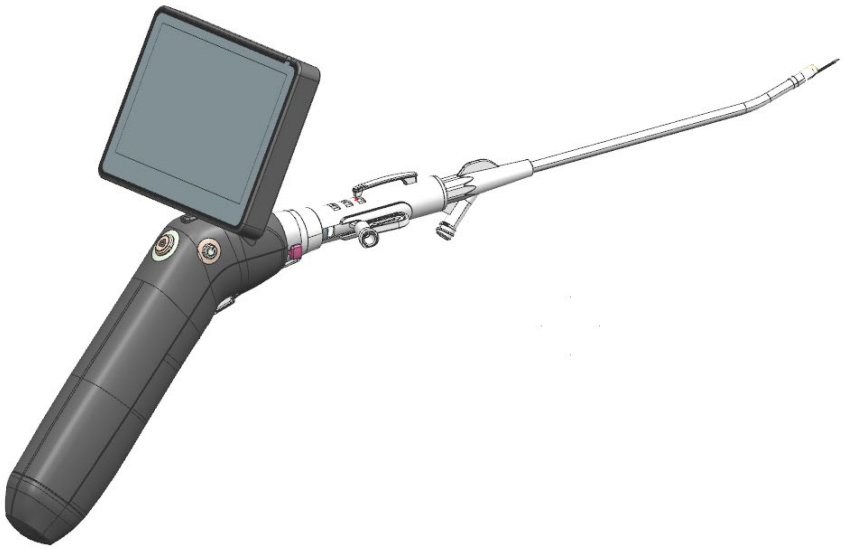


Figure 4. Connect Cannula to UroViu Handle

5.2.4. The cannula has a hydrophilic coating. Prior to insertion, activate the coating by wiping the cannula with a sterile 4x4 that has been moistened with saline or sterile water.

5.2.5. Prior to advancement, ensure that the injection needle is completely retracted into the cannula.

5.2.6. Prepare therapeutic agent or solution intended for injection per office standards or standard operating procedure in a Luer lock syringe

INJECTION INTO THE BLADDER WALL

5.2.7. Position, prep and drape the patient per standard office/clinic procedure for cystoscopy. If desired, a topical anesthetic gel may be used per office standard practice.
5.2.8. Advance the Uro-N Cystoscope per urethra until it reaches the bladder.
5.2.9. Identify the target area for injection.
5.2.10. Advance the needle until it is visible on the display and using a short stabbing motion advance the cannula into the target area per standard practice.
5.2.11. Attach the filled syringe to the injection tubing and proceed to inject desired amount of agent or solution.
5.2.12. Repeat this procedure per local standard of care until all intended sites have been injected (treated).
5.2.13. At the end of the injection procedure, retract the needle into the cannula and withdraw the Uro-N Cystoscope completely. Turn the scope off by pressing and holding the Power On/Off button for 1 second.

AFTER REMOVAL OF THE CYSTOSCOPE FROM THE PATIENT

5.2.14. Hold the handle vertically so that the cannula is below the handle and any fluids drain away from the handle. Disengage the connector and gently pull the cannula straight out from the handle, taking care that fluid does not drip into the connector of the handle. Dispose of the cannula per section 2.2.8.

6. Maintenance

6.1. Uro-N Cystoscope is a single use device and does not require maintenance, service, or installation.
6.2. Disposable cannula handling/care
The cannula is designed as a single-use, disposable item. Dispose of the cannula in accordance with Section 2.2.8.

7. Storage and Shipping

7.1. The Uro-N Cystoscope is shipped in a carton containing two (2) individually packaged, sterile cannula pouches.
7.2. Ship and store in conditions per Section 4.2.2.
7.3. Additional storage requirements:
- Store Uro-N Cystoscope in its original 2 pack carton in a dry location.
- Do not store on the floor.
- Do not stack items on top of the carton or pouch.

8. Technical Assistance

For technical information or assistance, contact UroViu Corporation Customer Service or your local UroViu Corporation representative.

Information regarding system serial number and current software version is available from Customer Service.

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9. Troubleshooting Guide

The information in this section is intended to provide simple steps that can be performed by a user for identifying the primary cause, and possible simple solutions that can be resolved on-site, to basic problems that may be encountered while operating the Uro-N Cystoscope.

Any issues determined to be beyond the scope of the basic user troubleshooting steps provided in these Instructions for Use should be communicated to the UroViu Corporation Customer Service as mentioned in Section 8.

Problem	**Test**	**Action**
When handle is powered ON, there is no image on screen	Is the cannula tip LED illuminated?	If NO, change to new cannula If YES, contact UroViu Customer Care
Poor picture quality		Clean cannula tip with a sterile, clean, soft wipe. Ensure that both the cannula and the connector are fully inserted into the handle ports. If the steps above to do not correct the picture quality, contact UroViu Customer Care.
Image on screen flickers or has lines across it		Ensure that both the cannula and the connector are fully inserted into the handle ports. If this does not correct the picture quality, contact UroViu Customer Care.
Loose component or poorly fitting connection		Do not use device Contact UroViu Customer Care for return.