Hystero-V™ Hysteroscope

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

Hystero-V Hysteroscope Model Number: 2530

UroViu Corporation
4546 El Camino Real, Suite 215
Los Altos, CA 94022 USA
+1 (650) 878-6686 Phone
email: cs@uroviu.com
www.uroviu.com

Trademark and Patent Information

About this document

This manual provides instructions on how to use the UroViu Inc. Hystero-V Hysteroscope safely and effectively for its intended use of visualization of the cervical canal and uterine cavity and obtaining an endometrial tissue sample (biopsy), and instructions to safely and effectively use the cannula with the UroViu Handle. For the purposes of this document, the word “cannula” refers to the Hystero-V Hysteroscope. 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 Handle Kit (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. Indications for Use

The Hystero-V Hysteroscope is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain endometrial tissue sample (biopsy) in an outpatient setting or in an office setting. The sample is used for cytologic and histologic diagnosis.

1.1.1. Generally recognized indications for diagnostic hysteroscopy with endometrial biopsy include: Symptomatic voiding dysfunction

- Abnormal uterine bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

1.2. Contraindications

1.2.1. Acute Pelvic Inflammatory Disease

1.2.2. Known Pregnancy

Hysteroscopy may be contraindicated by the following conditions depending on their severity or extent:

- Inability to distend the uterus
- Cervical Stenosis
- Cervical/Vaginal infection
- Uterine bleeding or menses
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

2. Symbols, Warnings and Precautions

This section contains important safety information related to use of the Hystero-V Hysteroscope. 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.

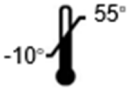
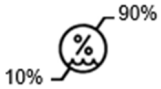
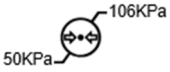
2.1. Symbol Legend

The following symbol conventions are used in this manual, and/or on the Hystero-V Hysteroscope 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.
	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.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.
			ISO 7000-2501	Graphical symbols for use on equipment.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 5.2.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.23	Symbols for use in the labeling of medical devices.
			ISO 7000-2609	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.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
			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	To indicate that caution is necessary when operating the device or control 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.	IEC 60601-1 Table D.1 symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7000-0434A	Graphical symbols for use on equipment

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
⚠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.
	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 Hystero-V Hysteroscope is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

2.2.2. The Hystero-V Hysteroscope is for use only by licensed health care providers with adequate training in hysteroscopy.

2.2.3. The Hystero-V Hysteroscope is only for use with the UroViu Handle (sold separately).

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

2.2.5. If a liquid distension medium is used, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to reduce the possibility of fluid overload.

2.2.6. Potential complications of Continuous Flow Hysteroscopy and endometrial biopsy include:

- Hyponatremia
- Hypothermia
- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter.
- Pulmonary edema
- Cerebral edema
- Infection
- Bleeding
- Pain

The use of normal saline as a distending medium and limiting the infused volume to less than 1000 mL is recommended to decrease the risk of the above complications. Intrauterine distension can usually be accomplished with pressures in the range of 35-75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

2.2.7. The Hystero-V Hysteroscope contains no user-serviceable components within its handle. To avoid electrical shock or damage, the unit must not be disassembled. Doing so will void the warranty.

2.2.8. Inspect the integrity of the unit and condition before powering-on the fully assembled Hystero-V Hysteroscope with UroViu Handle. Do not use the system if indications of external damage are observed.

2.2.9. Do not operate the Hystero-V Hysteroscope 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.

2.2.10. 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.

2.2.11. The Hystero-V Hysteroscope 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.

2.2.12. Failure to ensure that all environmental requirements are met may result in improper performance or damage to the electronic components within the Hystero-V Hysteroscope. See Section 4.2 Device Classification and Technical Specification for operating conditions.

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. Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.

2.3.3. For single patient use only. Do not reuse, reprocess, or attempt to re-sterilize the cannula.
2.3.4. Do not misalign the connectors between the removable cannula and the UroViu Handle during assembly, as damage may occur.
2.3.5. Do not allow any fluids or substances to be spilled into or around the removable cannula connector on the Hystero-V Hysteroscope handle, as damage to the electronics may occur.
2.3.6. 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.
2.3.7. When detaching the cannula from the handle, be sure that fluid does not contact the connector in the handle.
2.3.8. Before each use, check the outer surface of the cannula to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.
2.3.9. Please note that the temperature on the cannula tip might be slightly higher than room temperature but due to the low thermal mass of this part, occasional contact will not create a hazard to the patient.

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 Hystero-V Hysteroscope 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

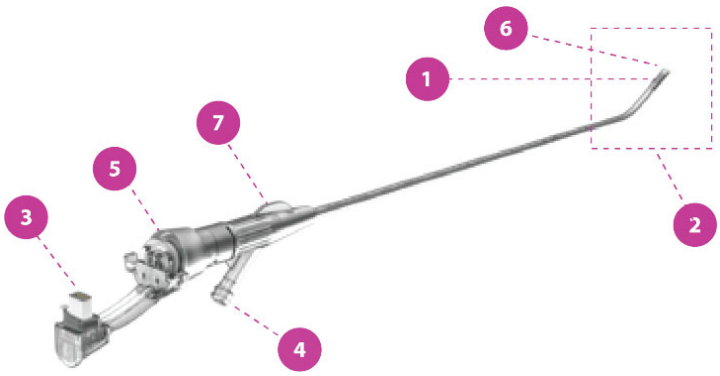
3.2.1. The Hystero-V Hysteroscope cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution and must be disposed of in accordance with local and/or state laws governing the collection of biohazardous medical devices with electronic components.

4. Description of Components

4.1. Product Description – the Hystero-V Hysteroscope is comprised of the following components:

4.1.1. Sterile, Single-use Cannula

The disposable single-use cannula contains a miniature CMOS camera and light-emitting diodes (LED) illumination module at the tip. 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 attaching either a pre-filled syringe directly to the Luer connector or through a tubing set attached to a pressurized bag. The sterile, single-use cannula is packaged in a sealed pouch. Figure 1 shows the disposable cannula. The distal lens surface is coated with hydrophilic material.



1. CMOS camera
2. Tip section
3. Keyed Electric connector
4. Infusion port
5. Handle Mechanical connector
6. Outflow port
7. 'Fin' for indicating the cannula orientation

Figure 1: Sterile, Single-use Hystero-V cannula

4.2. Device Classification and Technical Specification

4.2.1. Device Classification: FDA Class II, HH Device Classification Type BF applied part

4.2.2. Technical Specifications

Sterile, Single-use cannula	
Z runlgj#Dhqjwk	587#p p
R xwvlgh#Glp hqvlrqv#	715#p p
Suh0fxuyhg#Wls#Dqjdn	58¶#•#8¶
Iorlg#Dxp hq#Furvv0vhfwlrq#	51;#p p ^{5}#
Site Requirements – Operating conditions	
Operating Temperature	10°C to 28°C (50°F to 82.4°F)
Operating Humidity	10% to 70%
Air Pressure	70 KPa – 106 KPa
Transport and Storage	
Temperature	-10°C to 70°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. Fluid Delivery System
Fluid infusion is achieved by gravity and/or attaching a pressurized bag to the cannula's standard Luer lock adapter port.

5.2. Cannula attachment and detachment
In preparation for use, attach the cannula to the electrical connector on the UroViu Handle per the following:

5.2.1. Peel apart the proximal end of the package.

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

5.2.3. Connect the cannula to the UroViu Handle and press it fully into place until a subtle "click" of the connector detent mechanism (1) is felt.

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

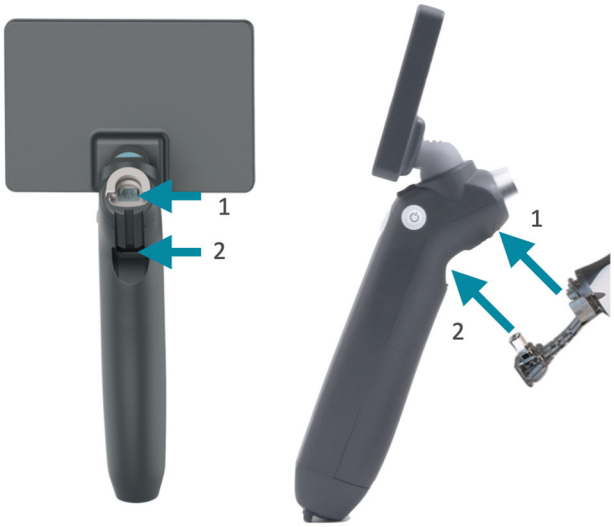


Figure 2: Cannula Attachment

5.3. **PRIOR TO THE EXAMINATION**

5.3.1. Open the pouch containing the sterile cannula and remove the cannula while maintaining sterile conditions.
5.3.2. Open the pouch containing the sterile cannula and remove the cannula while maintaining sterile conditions.
5.3.3. Attach the cannula to the handle. Refer to Section 5.2 Figure 2.
5.3.4. Connect tubing from the source of the fluid to the Luerlock connector port (infusion port) on the side of the Hystero-V Hysteroscope. See Figure 3.

Figure 3: Connect Fluid Tubing

5.3.5. Flush the fluid through the cannula until all air bubbles have cleared from the tubing.
5.3.6. 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.
5.3.7. The cannula comes with a pre-curved tip at an angle of 25° ± 5°. The curve of the tip is similar to that of most conventional cervical dilators. User should not bend the cannula tip section.
5.3.8. The cannula is inserted through the cervical canal, with fluid flowing, while viewing the image as is standard procedure for introduction of a hysteroscope.

5.4. **REMOVAL OF THE SYSTEM**

5.4.1. Hold the handle vertically so 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 handle, taking care that fluid does not drip into the connector of the handle. Dispose of the cannula according to institutional procedures.
5.4.2. The Hystero-V Hysteroscope 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.

6. Maintenance

6.1. Hystero-V Hysteroscope 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 2.2.11.

7. Storage and Shipping

7.1. The Hystero-V Hysteroscope is shipped in a carton containing four (4) individually packaged, sterile cannula pouches.

7.2. Ship and store in conditions per Section 4.2.2.

7.3. Additional storage requirements:

- Store Hystero-V Hysteroscope in its original 4 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.

UroViu Corporation
4546 El Camino Real, Suite 215
Los Altos, CA 94022
+1 (650) 397-5174 phone
+1 (650) 388-1420 fax
email: cs@uroviu.com

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 Hystero-V Hysteroscope.

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.