*HER*izon RD5™ RESECTING DEVICE

INSTRUCTIONS FOR USE

℞ ONLY

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. The physician using the device must be trained in hysteroscopy.

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1 ABOUT THIS MANUAL

This manual provides instructions for use of the *HER*izon RD5™ Resecting Device. It is essential that you read and understand all instructions before using the device. Pay particular attention to all contraindications, warnings, precautions and possible adverse events in this manual. Failure to thoroughly understand and follow all instructions may result in harm to the patient or user of the device.

2 WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Axora Medical representative.

The *HER*izon RD5 Resecting Device is for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and / or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and / or local government policy.

3 DEVICE DESCRIPTION

The *HER*izon RD5 Resecting Device is a battery powered, motor driven, and manually actuated hysteroscopic surgical instrument used to resect and remove tissue under direct visualization. The device is supplied sterile for single use only. The device is offered in a 5Fr size for compatibility with hysteroscopes that can accommodate instruments with a 1.65 mm or larger outer diameter. The device can be used with any fluid management system made with standard luer and/or stepped connectors.

TABLE 1: DEVICE MODEL

Catalog Number	Cannula Outer Diameter	Cannula Length	Resecting Window Length
5FR5PK, 5FR1PK	5F (1.65 mm)	36.3 cm	5.0 mm

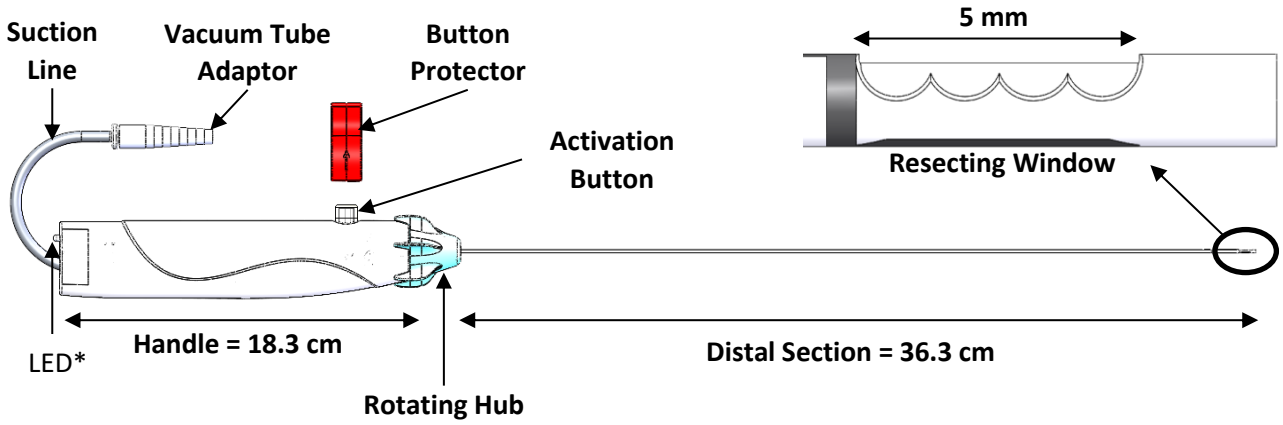


FIGURE 1: *HER*IZON RD5 RESECTING DEVICE

*LED – for possible future enhancement. LED is not functional in current device.

The *HER*izon RD5 Resecting Device consists of a distal and proximal (handle) section. The distal section is comprised of an outer cannula with an open Resecting Window at the distal end. A cutting element rotates within the lumen of the outer cannula to resect tissue within the Resecting Window.

The proximal section is comprised of a cylindrically shaped handle with an Activation Button. Depressing the Activation Button actuates a motor that spins a blade within the Resecting Window to resect and remove target tissue. Depressing the Activation Button also opens a mechanical valve within the handle body. When open, evacuation of resected tissue is enabled.

The *HER*izon RD5 Resecting Device is provided assembled with a vacuum tube port for use with a suction source. As tissue is resected, it is evacuated through the length of the device and out the vacuum tube port.

4 INTENDED USE/INDICATIONS FOR USE

The *HER*izon RD5 Resecting Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue such as endometrial polyps.

5 CONTRAINDICATIONS

IMPORTANT: Failure to comply with Contraindications below may result in serious patient injury or death.

- Use of this device is contraindicated whenever hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications and the existing ACOG guidelines for the list of most current contraindications.
- Acute pelvic inflammatory disease.
- Inability to achieve adequate uterine distention and/or visualization.
- Cervical / vaginal infection.
- Known pregnancy.
- Cervical malignancies and/or invasive carcinoma of the cervix.
- Uterine Cancer
- Recent uterine perforation.
- Patients receiving anti-coagulant therapy or who may have bleeding disorders.
- Medical contraindication or intolerance to anesthesia.

6 WARNINGS

IMPORTANT: Failure to comply with the Warnings below may result in serious patient injury or death

- Any use of this Device, outside of the intended use is not recommended and may result in serious patient injury.
- For use only by medical professionals trained in hysteroscopy with powered instruments.
- Suspicion of pregnancy should suggest a pregnancy test before performance of hysteroscopy.
- Careful pre-operative assessment, including preoperative imaging, should be performed on each patient prior to a hysteroscopic tissue resection procedure to evaluate for conditions which may, depending on their severity or extent, affect the appropriateness of operative hysteroscopy. These include but are not necessarily limited to: evidence and level of placental invasion of the myometrium, location of the target tissue and degree of vascularization (Gutenberg Classification).
- Use care when handling medical devices to avoid damage or injury.
- Use direct and adequate visualization during use of the *HER*izon RD5 Resecting Device. If visualization is lost or becomes inadequate during the procedure, stop cutting immediately.
- Operating the device inside the uterine cavity with no tissue contact may result in the degradation and/or loss of uterine distension and visualization.
- If a uterine perforation is suspected or confirmed resection procedure must be terminated immediately.
- Do not use *HER*izon RD5 Resecting Device to remove myomas.
- Do not use in patients with an implant within their uterine cavity (e.g. IUDs) due to potential for damage to the implant.
- Do not use *HER*izon RD5 Resecting Device to resect tissue adjacent to an implant or suture material.
- Do not use *HER*izon RD5 Resecting Device to resect or cut implant or suture material.

- Do not use *HER*izon RD5 Resecting Device to resect or cut calcified tissue.
- Do not attempt to repair or to alter the device. The *HER*izon RD5 Resecting Device has no user serviceable parts.
- Do not attempt to remove, reuse or replace battery.
- Do not use if dropped, handle parts break, or separate.
- Do not intentionally bend or break cannula when disposing device.
- Use of this equipment adjacent to or stacked with other 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.
- Periodically irrigate the device to prevent accumulation of excised tissue in the surgical site.

7 PRECAUTIONS

- Before using, inspect the pouch for any breach of the package to ensure a sterile product, inspect product for any damage, and ensure device is free of foreign material.
- If pouch seal has been broken or product is damaged, do not use. Immediately return package and product to your Axora representative.
- Only use the *HER*izon RD5 Resecting Device prior to the "Use By" date noted on the package. Do not expose the *HER*izon RD5 Resecting Device to organic solvents.
- Make certain that the Resecting Window is closed prior to insertion / retraction into / from the uterine cavity.
- Exercise Care when inserting or removing the device. Insertion and removal of the device should be performed under direct visualization at all times.
- To avoid perforation, keep the device tip under direct visualization and exercise care at all times when maneuvering it or cutting tissue close to the uterine wall. Avoid using the tip of the tissue removal device as probe or dissecting tool.
- Do not allow the cutting window of the tissue removal device to touch any metallic object such as a hysteroscope. Damage to both instruments is likely.
- Never advance or withdraw the *HER*izon RD5 Resecting Device against resistance until the cause of the resistance is determined. Movement of the *HER*izon RD5 Resecting Device against resistance may result in tissue perforation, other injury, or damage to the medical device.
- Intrauterine distention can usually be accomplished with pressures in the range of 35-70 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use intra-uterine pressures greater than 75-80 mmHg.
- Ensure that a compatible vacuum system that can develop a vacuum of at least 150 mmHg is appropriately connected before commencing resection.
- Do not use if cutting head does not rotate upon activation of the Activation Button.
- The User should be aware that the handle may heat up during us but that is not a symptom of the device malfunctioning.
- Application of excessive force during device use may cause bending or kinking of the cannula rendering the device inoperable. Do not continue to operate the device if binding occurs.
- Do not operate the *HER*izon RD5 Resecting Device outside of a normal saline filled environment for an extended period as this may cause device damage.
- Dispose of device according to standard medical facility's standard operating procedures including handling of biohazardous, sharps, and alkaline batteries.

8 POSSIBLE ADVERSE EVENTS

Adverse effects are possible during surgical procedures including, but are not limited to:

- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels, and ureter;
- Hemoperitoneum;
- Post-op bleeding;
- Pelvic infection.

See the operator's manual of your hysteroscope and consult medical literature for possible adverse effects related to hysteroscopy.

9 HOW SUPPLIED

DO NOT USE IF PACKAGE IS OPENED OR DAMAGED. **DO NOT** USE IF LABELING IS INCOMPLETE OR ILLEGIBLE.

The *HER*izon RD5 Resecting Device is supplied sterile and intended for single use.
The shelf box contains:

(1) *HER*izon RD5 Resecting Device
(1) Button Protector
(1) Electronic Instructions For Use (eIFU) Insert

The *HER*izon RD5 Resecting Device is retained by a backer card contained within a breathable pouch for storage and transit. While packaged, the device cannula is protected with a cannula protector that can be separated from the device upon device removal.

The *HER*izon RD5 Resecting Device has no accessories but does require additional materials to be used. See Materials Required For Use section.

10 MATERIALS REQUIRED FOR USE

The *HER*izon RD5 Resecting Device is used in conjunction with:

- Hysteroscopy System
  This may include a camera, light source, monitor, sheath, introducer, and scope. Only use hysteroscopes with working channels compatible with 5Fr or larger sized devices.
- Fluid Delivery and Suction System
  These may include a saline source, pressure infusion bag, vacuum source (pump or wall suction with regulator), vacuum canister, vacuum tubing, tissue collection filter, or a fluid management system that includes these capabilities. Ensure vacuum systems used can produce vacuum settings up to 150 mmHg at a minimum.

11 DEVICE SET UP

1. Prior to opening the *HER*izon RD5 Resecting Device, inspect the package for signs of damage. If damage is identified, do not use the *HER*izon RD5 Resecting Device, and report the incident to Axora Medical Customer Service.
2. Remove device from packaging according to sterile transfer procedures.
3. If still attached, remove the cannula protector from the *HER*izon RD5 Resecting Device.
4. Remove the button protector to prepare the *HER*izon RD5 Resecting Device for use.
   Note: Inspect the device for damage. If damage is observed, do not use the device.
5. Prior to insertion into the working channel of the hysteroscope, briefly actuate the *HER*izon RD5 Resecting Device by pressing the Activation Button to ensure that the device has power.

Note: Do not operate the *HER*izon RD5 Resecting Device outside of a normal saline filled environment for an extended period as this may cause device damage.

6. Connect the device vacuum tube adapter to one end of the vacuum pump suction tubing.
7. Connect the opposite end of vacuum pump suction tubing to the specimen collection adapter according to vacuum source operator's manual or instruction.
    - Note: Typical vacuum pump settings range from 0 mmHg to 150mmHg. Higher vacuum settings can be used but may result in excessive suction and lead to inability to adequately distend the uterine cavity.
    - Note: Ensure that the vacuum suction source is active and connected to the *HER*izon RD5 whenever this device is inside the uterine cavity.

12 DEVICE OPERATION

1. With the hysteroscope positioned in the uterine cavity, gently insert the *HER*izon RD5 Resecting Device into the working channel of the hysteroscope until the device tip becomes visible on the monitor.
2. Under direct visualization ensuring the Resecting Window is fully exposed, position the Resecting Window on the target tissue by rotating the Rotating Hub, or by rotating the entire *HER*izon RD5 Resecting Device.
    - Note: Use the orientation laser markings to orient the Resecting Window.

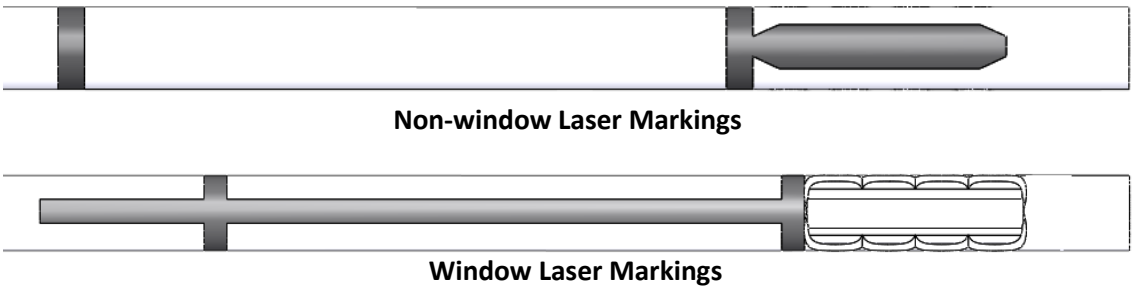


FIGURE 2: ORIENTATION LASER MARKINGS FOR ORIENTING RESECTING WINDOW

- CAUTION: While positioning the *HER*izon RD5 Resecting Device near target tissue, excessive force may cause the device cannula to bend and decrease the cutting performance and may lead to perforation of the uterine wall. Do not force, or push, the Resecting Window into tissue.

3. Once the Resecting Window is in place, resection can be started by fully depressing and holding the Activation Button to begin resection and enable suction flow. Slowly guide the resecting window across the target tissue. Resected target tissue is collected into the specimen collection container.
    - WARNING: If there are visibility issues, immediately stop cutting. Clear the field of view and ensure adequate visibility before continuing the procedure.
    - WARNING: Pressing and holding the Activation Button will activate tissue resection. Ensure the Resecting Window is not adjacent to non-target tissue before pressing the Activation Button.

4. When the target tissue resection is complete, depress the Activation Button for a few seconds to ensure that the residual resected tissue is transferred from the device into the tissue trap.
5. Remove the *HER*izon RD5 Resecting Device from the hysteroscope.
6. Disconnect vacuum suction tubing from the *HER*izon RD5 Resecting Device.

13 DISPOSAL

Dispose of the entire device according to facility policies and procedures regarding biohazardous materials, sharps waste, and alkaline battery disposal. Do not attempt to remove the battery. Do not attempt to reuse the device. Do not intentionally bend or break cannula when disposing device.

14 STORAGE AND HANDLING

The *HER*izon RD5 Resecting Device is intended to be transported and stored in an environment that is kept within the following conditions, as defined by Table 2.

TABLE 2: STORAGE AND HANDLING CONDITIONS

Temperature	-10°C to 50°C
Relative Humidity	15% to 85% RH non-condensing
Atmospheric Pressure	50 to 105 kPa

15 TROUBLESHOOTING

TABLE 3: TROUBLESHOOTING GUIDE

Observed Problem	Resolution
Low or Loss of Suction	• Confirm that the suction canister lids are sealed and canister filters are not wet if applicable. • Confirm the *HER*izon RD5 Resecting Device is not clogged and/or the vacuum suction tubing is not kinked or occluded. Position device away from the tissue and press the Activation Button to confirm *HER*izon RD5 Resecting Device is aspirating by observing the flow of fluid in the suction line. • Check adequate tube connections to device suction line and to vacuum suction source.
To Prevent Poor Visibility	• Activating *HER*izon RD5 Resecting Device by pressing the Activation Button will enable suction and fluid outflow and can clear the field of view. • Suction can be reduced to minimize the amount of blood being pulled from tissue. Consider reducing suction to improve distention and visibility, as long as resecting performance is maintained. • Confirm that inflow pressure is adequate.

Observed Problem	Resolution
Poor Tissue Resection & Suction	• Ensure that the *HER*izon RD5 Resecting Window is oriented correctly towards and adjacent to the target tissue when pressing the Activation Button to initiate the Resecting function. • Higher pressure and flow rates with regulated suction through the *HER*izon RD5 Resecting Device can improve suction of tissue into the Resecting Window and improve tissue resection. • Maintain sufficient infusion of fluid and adequate suction during resection.
Loss of Visibility	• Stop operating device immediately

16 LIMITED WARRANTY

Axora Medical warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Axora's control directly affect the instrument and the results obtained from its use. Axora's obligation under this warranty is limited to the repair or replacement of this instrument and Axora shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Axora neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Axora assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

17 CUSTOMER SERVICE/ TECHNICAL SUPPORT

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

Contact Axora Medical Customer Service for customer or technical support.
Call +1 (855) 646-7874

18 SYMBOL GLOSSARY

Symbol	Standard	Symbol Title	Description
GTIN	N/A	GTIN	Indicates global trade item number
℞ ONLY	21 CFR 801.109	Prescription only	Requires prescription in the United States of America.
MR	ASTM F2503-20	MR Unsafe	Unsafe in magnetic resonance environment
	IEC 60417	Type BF (body floating) Applied Part	Applied Parts that make direct electrical contact with the patient, except not directly to the heart

Symbol	Standard	Symbol Title	Description
IPX2	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code).	Manufacturer-determined degree of particle and water ingress protection, where... N1= degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8)
	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer	Sterilized using ethylene oxide	Indicates a medical device that has been ethylene oxide
		Unique device Identifier	Indicates a carrier that contains unique device identifier information
		Recyclable Package	Indicates component can be recycled
		Manufacturer	Indicates the medical device manufacturer
		Date of manufacture	Indicates the date when the medical device was manufactured
		Use-by date	Indicates the date after which the medical device is not to be used
		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
		Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified
		Do not resterilize	Indicates a medical device that is not to be resterilized
		Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
		Keep away from sunlight	Indicates a medical device that needs protection from light sources
		Keep dry	Indicates a medical device that needs to be protected from moisture
		Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
		Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
		Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or

Symbol	Standard	Symbol Title	Description
			that the current situation needs operator awareness or operator action to avoid undesirable consequences
		Do not re-use	Indicates a medical device that is intended for one single use only
		Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
		Not made with natural latex	Not made with natural latex
	N/A	Contents	Package content

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Made in Hungary

APPENDIX A- DECLARATIONS AND PERMISSIBLE DEVICE CONDITIONS

TABLE 4: DECLARATION OF ELECTROMAGNETIC IMMUNITY

Immunity Test	Test Level / Limits	Electromagnetic Environment / Recommendations
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 ±4 ±8 ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radio Frequency (RF) Common Mode IEC 61000-4-6	3V 0.15MHz - 80MHz; 6V in ISM bands between 0.15MHz and 80MHz; 80% AM at 1kHz (SIP/SOPs)	Not Applicable – device is battery operated
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels typical commercial or hospital environments.
Clause 8.10	See 8.10 in IEC 60601-1-2	RF communications devices should be at levels typically found in a hospital environment.
IEC 61000-4-39/Clause 8.11	65 A/m 134.2 kHz PM 2.1kHz 7.5 A/m 13.56 MHz PM 50kHz	RFID equipment devices should be at levels typically found in a hospital environment.

TABLE 5: DECLARATION OF ELECTROMAGNETIC EMISSIONS

Emissions Test	Test Level / Limits	Electromagnetic Environment / Recommendations
CRISPR 11 Radiated Emissions	Class A Group 1	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

TABLE 6: GUIDANCE AND MANUFACTURER'S DECLARATION OF ELECTROMAGNETIC IMMUNITY

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7GHz; 80% AM at 1kHz	3 Vrms 3 V/m	WARNING: 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 *HER*izon RD5 Resecting Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *HER*izon RD5 Resecting Device.			

TABLE 4: STORAGE, TRANSPORT, AND OPERATING CONDITIONS

Condition	Temperature	Humidity	Atmospheric Pressure (kPa)
Storage and Transport	-10°C to 50°C	15 to 85% RH Non-condensing	50 – 105
Operation	10°C to 30°C	30 to 75% RH Non-condensing	86 – 106