resectr™

Tissue Resection Device

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resectr™
Tissue Resection Device

℞ ONLY

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

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.

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.

CONTENTS

(1) Resectr device
(1) Vacuum tube adapter

DEVICE DESCRIPTION

Resectrs are non-powered, hand-held, and hand-manipulated manual surgical instruments to dissect, resect, and / or remove tissue. Resectrs may be used through the working channel of an appropriately sized hysteroscope as an accessory instrument. Resectrs consist of a non-oscillating outer cannula, and an internal rotating-oscillating Blade. Resectr dimensions are determined by the model number:

Model	Cannula Outer Diameter	Cannula Length	Resecting Window Length
Resectr 5F	5F (1.65 mm)	35 cm	5.0 mm
Resectr 9F	9F (3.0 mm)	35 cm	7.5 mm

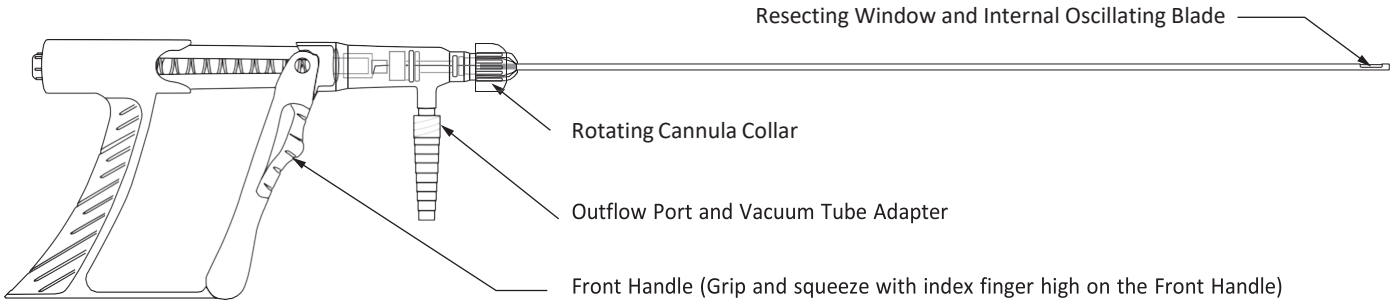

Figure 1. Resectr 5F and 9F

INTENDED USE / INDICATIONS FOR USE

Resectrs are single-use, non-powered, hand-held, and hand-manipulated manual surgical instruments intended to be used in various hysteroscopic surgical procedures to dissect, resect, and / or remove tissue.

CONTRAINDICATIONS

- Use of this device is contraindicated whenever rhysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.
- Acute pelvic inflammatory disease.
- Inadequate uterine distention and / or visualization.
- Cervical / vaginal infection.
- Known pregnancy.
- Cervical malignancies and / or invasive carcinoma of the cervix.
- Recent uterine perforation.
- Patients receiving anti-coagulant therapy or who may have bleeding disorders.
- Medical contraindication or intolerance to anesthesia.
- Severe anemia on patients undergoing hysteroscopic myomectomy.
- Inability to circumnavigate a myoma due to myoma size (e.g., predominantly intramural myomas with small submucous components).

WARNINGS

- The Resectr™ Tissue Resection Device has no other user serviceable parts. Do not attempt to repair or to alter the device.
- Any use of this Device, other than those indicated in these instructions is not recommended.
- For use only by physicians trained in hysteroscopy.
- Suspicion of pregnancy should suggest a pregnancy test before performance of hysteroscopy.
- Use care when handling and loading medical devices to avoid damage or injury.
- Use direct visualization during use of any Resectr device.
- Do not use Resectr to resect tissue adjacent to an implant or suture material.
- Do not use Resectr to cut suture material.
- Resectrs are not intended to resect calcified tissue.
- Do not intentionally bend or break cannula when disposing device.

PRECAUTIONS

- Before using, inspect the blister pouch for any breach of the package to ensure a sterile product and inspect product for any damage and ensure device is free of foreign material.
- If seal has been broken or product is damaged do not use. Immediately return package and product to your Axora Medical representative.
- Do not expose the Resectr device to organic solvents.
- Only use the Resectr device prior to the "Use By" date noted on the package.
- Resectr devices should only be manipulated under direct visualization.
- Make certain the Resectr Resecting Window is closed upon insertion / retraction into / from the uterine cavity.
- Never advance or withdraw any Resectr device against resistance until the cause of the resistance is determined.
- Movement of any Resectr device against resistance may result in medical device damage, tissue perforation, or other injury.
- Excessive force on the device handle(s) may cause bending or kinking of the cannula.
- Do not force the device handle(s) if binding occurs.
- 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 pressures greater than 75-80 mmHg.

POSSIBLE ADVERSE EFFECTS

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

- 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 for adverse effects related to hysteroscopy.

MATERIALS REQUIRED FOR USE

- Hysteroscopy system, which may include a camera, light source, monitor, sheath and introducer.
- Fluid delivery and suction, which may include a saline source, pressure infusion bag, vacuum source (pump or wall suction with regulator), vacuum canister, vacuum tubing, tissue collection filter, or an integrated fluid management system that includes these capabilities.

PREPARE RESECTR

1. Remove from packaging.
2. Grip the Front Handle with index finger high on the Front Handle.
   IMPORTANT: Do not squeeze with the index finger low on the Front Handle. Only squeeze the Front Handle with index and middle fingers in the first two positions.
3. Test squeeze Front Handle 1-2 times to verify movement of the Oscillating Blade inside the Resecting Window.
   NOTE: If the Resecting window is open, Rotate the Cannula Collar so that the Oscillating Blade closes the Resecting Window (see photo below).

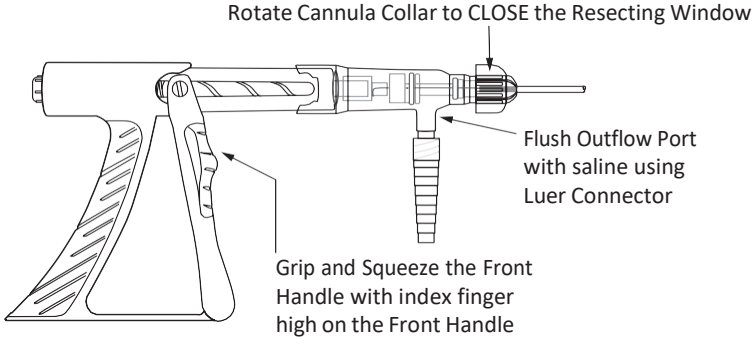

Figure 2. Resectr Preparation

HOW SUPPLIED

- The Resectr™ Tissue Resecting Device is a single use device supplied sterile using an ethylene oxide (EO) process. Package includes:
  (1) Resectr device
  (1) Vacuum tube adapter
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

HANDLING AND STORAGE

- Store in a cool, dry, dark place.

OPERATION

1. Insert hysteroscope into patient according to current best practices and visualize target tissue. Physiologic distention media such as normal saline is recommended for uterine distention.
2. Connect vacuum suction tubing to the Outflow Port and / or Vacuum Tube Adaptor of the Resectr.
3. CONFIRMSETUP: For hysteroscopic systems with integrated outflow ports either keep the out flow port closed or connect outflow port to canister or table drape via gravity. For hysteroscopes with a removable outflow channel the outflow channel should be removed during operative use.

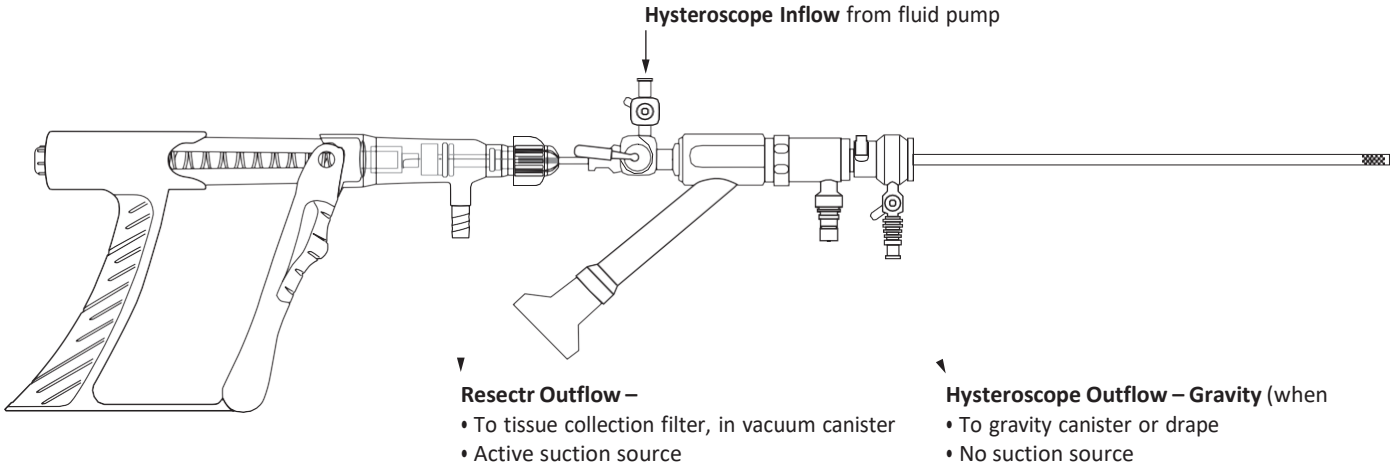

Figure 3. Resectr with Hysteroscope

4. Insert the Resectr tip into the working channel of the hysteroscope until the tip is visible on the monitor.
5. Under direct visualization, position the Resecting Window adjacent to the target tissue by rotating the Cannula Collar with thumb and index finger, rotating the hysteroscope, or rotating the entire Resectr device.
6. IMPORTANT: Aspiration may be used to pull tissue into the Resecting Window. Aspiration increases when the Oscillating Blade is in the open position inside the Resecting Window and aspiration decreases when the Blade is positioned to close the Resecting Window. Do not force, or push, the Resecting Window into tissue.
7. Squeeze Front Handle Grip to rotate the Resectr Oscillating Blade. Each full actuation of the handle rotates the blade 3X in each direction. Squeeze as needed to remove target tissue.
8. To aspirate fluids and tissue, slowly squeeze the Front Handle and / or rotate the Cannula Collar to position the Oscillating Blade into the open position in the Resecting Window.
9. To improve aspiration, position device away from the tissue and squeeze the Front Handle several times while the suction is on.

DISPOSAL

WARNING

Do not intentionally bend or break cannula during disposal.

1. Remove Resectr with the hysteroscope from the patient or from the working channel of the hysteroscope.
2. Remove vacuum suction tubing from the Resectr and dispose of the entire device according to facility policies and procedures regarding biohazardous materials and sharps waste.

TROUBLESHOOTING TIPS

LOW OR LOSS OF SUCTION

- Confirm that the suction canister lids are sealed and canister filters are not wet if applicable.
- Confirm the Resectr is not clogged and/or the vacuum suction tubing is not kinked or occluded. Squeeze the Front Handle slowly to open the Resecting Window and confirm the Resectr is aspirating.

POOR UTERINE DISTENTION

- Ensure the fluid distension source (e.g. saline bag) clamp is open.
- Check the cervix for fluid leakage and consider adding and/or adjusting tenaculum at the cervix as needed.
- Ensure inflow tubing is connected correctly to the proper port on the hysteroscope.
- Confirm that the inflow pressure is adequate.
- For hysteroscopic systems with integrated outflow ports, consider partially and / or completely closing the stop cock on the hysteroscope outflow valve if necessary to improve distention.
- Make certain the Resectr™ Resecting Window is closed on insertion into the uterine cavity.

VISIBILITY ISSUES

- Squeezing Resectr Front Handle to open the Resecting Window will increase aspiration 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.

TISSUE RESECTION & ASPIRATION ISSUES

- Ensure that the Resectr Resecting Window is oriented adjacent to the target tissue when squeezing Front Handle to initiate Resecting function.
- High pressure and flow rates with regulated suction through the Resectr can improve aspiration of tissue into the Resecting Window and improve tissue resection.
- Maintain optimal fluid and suction balance.

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 sterilizationof this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Axora Medical's control directly affect the instrument and the results obtained from its use. Axora Medical's obligation under this warranty is limited to the repair or replacement of this instrument and Axora Medical shall not be liable for any incidental or consequential loss, damage or expensedirectly or indirectly arising from the use of this instrument. Axora Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Axora Medical assumes no liability with respect to instrumentsreused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for aparticular purpose, with respect to such instruments.

CUSTOMER SERVICE/TECHNICAL SUPPORT

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

REF Catalog Number

 Consult instructions for use.

 Contents

EC REP EU Authorized Representative

 Legal Manufacturer

LOT Lot

 Recyclable Package

 Use By

AUS Australian Sponsor Address

ARG Argentina Local Contact

 For single use only. Do not reuse.

 Do Not Resterilize

 Do not use if package is damaged.

STERILE EO Sterilized using ethylene oxide.

Legal Manufacturer

Axora Medical
1000 Hamlin Court
Sunnyvale, CA 94089 USA
Customer Service: 855-646-7874

Do not use if package is damaged.

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