RESECTR™ TISSUE RESECTION DEVICE
Prescriptive Information

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

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 hysteroscopy 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 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.

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.

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 Boston Scientific 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 distension 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.

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