

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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