

MyoSure[®] Tissue Removal System

Summary of Risks and Considerations

All treatment options for intrauterine pathologies have benefits, warnings, precautions, and risks. Before making a final decision, you should discuss these with your doctor.

Not all women are candidates for the MyoSure tissue removal procedure.

Your doctor will explain the risks of all treatment options. The MyoSure hysteroscopic tissue removal system is intended to be used by gynecologists who are trained to resect and remove tissue using a hysteroscope. Such tissue includes submucous myomas, endometrial polyps and retained products of conception. The MyoSure hysteroscopic tissue removal system should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies or previously diagnosed uterine or endometrial cancer.

How does the MyoSure tissue removal procedure work?

This simple hysteroscopic procedure is used to perform a procedure called a myomectomy (removal of fibroids) or polypectomy (removal of polyps), which may be causing your heavy bleeding. It allows your doctor to eliminate the unwanted uterine tissue without having to remove or even cut the uterus. Your doctor inserts an instrument (hysteroscope) through the vagina to visualize the inside of your uterus in order to identify the fibroid, polyp or other tissue. A tool is then inserted through the vagina to remove the tissue.

Is the MyoSure procedure right for me?

Women with heavy or long-lasting periods caused by submucosal fibroids or endometrial polyps may be candidates for the MyoSure procedure. Your doctor can help you decide if the procedure is right for you. If your doctor rules out more serious causes of abnormal uterine bleeding, you may be a good candidate for the MyoSure procedure. It's important to note that only women with submucosal fibroids are eligible for a hysteroscopic myomectomy. Fibroids located within the uterine wall cannot be removed with this technique.

Can I still become pregnant after the MyoSure procedure?

Unlike the surgical removal of intrauterine tissue through the abdomen, the MyoSure hysteroscopic procedure requires no cuts or incisions in the skin. Your uterus form and function are retained. As a result, this is an ideal treatment option if you are looking to reduce heavy menstrual bleeding caused by polyps or fibroids, yet still want to preserve your chances for having children in the future.

What can I expect after the MyoSure procedure?

Some women will experience some mild cramping after a myomectomy or polypectomy procedure. Your doctor may recommend an over-the-counter pain reliever if cramping persists. You should be able to resume your normal activities within 2 days.

Very few patients experience complications following the procedure.¹ However, you should call your doctor right away if you develop:

- A fever higher than 100.4°F (38°C)
- Worsening pelvic pain that is not relieved by ibuprofen or other prescribed medicine
- Nausea, vomiting, shortness of breath, dizziness
- Bowel or bladder problems
- A greenish vaginal discharge (reddish, yellowish or brownish is normal)

What will my periods be like after the MyoSure procedure?

In myomectomy procedures, the overall effectiveness for reducing heavy bleeding caused by pathology is greater than 90% and has a recurrence rate of less than 10% at 2 years.² In polypectomy procedures, the overall effectiveness for reducing heavy bleeding caused by pathology is also greater than 90% and has a recurrence rate of less than 3% at 2 years.³ However, every woman is different. Plan to give your body about three months to fully heal on the inside and resume its normal cycle. Then, you and your doctor should be able to tell what your cycle and your periods will be like.

Other considerations

The MyoSure procedure is done on an outpatient basis, typically under local anesthesia. Anesthetics are medicines that may be used to prevent pain during the procedure. There are risks associated with the use of any medicines, even local anesthetics. Talk to your doctor about the risks of the particular anesthetic recommended for you.

Additional warnings, precautions, and risks.

If you think you may be pregnant, be sure to let your doctor know. A pregnancy test should be performed before the MyoSure procedure is done.

Myomectomy is very effective, but fibroids can re-grow. The younger you are and the more fibroids you have at the time of myomectomy, the more likely you are to develop fibroids again in the future. Women nearing menopause are the least likely to have recurring problems from fibroids after a myomectomy.

Heavy menstrual bleeding is a type of abnormal uterine bleeding (AUB), which is the first symptom in 95% of cases of endometrial cancer.⁴ The 5-year survival rate for women diagnosed with stage 1 endometrial cancer is 90%.⁵ If you are a post-menopausal woman with heavy bleeding, it's important to contact your doctor and discuss your symptoms.

Many women already have low blood counts (anemia) due to heavy bleeding, so they are at a higher risk of problems due to blood loss. Your doctor may suggest ways to build up your blood count before surgery.

Fluid overload due to absorption of the fluid used in the cavity to perform the procedure can occur. In such cases, the procedure may need to be stopped during the removal of larger fibroids, so that fluid overload does not occur. A second procedure would then be scheduled to remove the remaining fibroid several months later.

The MyoSure procedure may also not be appropriate for some women with the following conditions, depending upon their severity or extent:⁶

- Inability to distend uterus
- Cervical stenosis
- Cervical/vaginal infection
- Uterine bleeding or menses
- Known pregnancy

- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

Anticipated post-procedural complications

For any hysteroscopic procedure to remove intrauterine pathology, commonly reported postoperative events included the following:

- Abdominal cramping and pain
- Bleeding
- Fever
- Nausea, vomiting, shortness of breath or dizziness
- Increased greenish discharge

Other adverse events

Unlike the removal of fibroids through the abdomen, a hysteroscopic myomectomy requires no cuts or incisions in the skin. The recovery period is quick and in a clinical study, the overall complication rate was less than 1% for myomectomies and polypectomies.⁷ However, as with all intrauterine hysteroscopic procedures, serious injury or death can occur. The following adverse events have been reported in association with hysteroscopic intrauterine tissue removal procedures:

- Severe anemia⁶
- Hemorrhage⁸
- Uterine perforation⁸
- Damage to the cervix⁸
- Adhesion formation
- Inability to circumnavigate a myoma due to myoma size, e.g., predominantly intramural myomas with small submucous component⁶
- Excessive absorption of the distention media into the vascular system, which can cause metabolic disturbances,⁹ pulmonary edema, hyponatremia, cerebral edema, and even death.⁹
- Potential life-threatening bleeding that may occur when removal of retained products of conception is done in patients with evidence of placenta accreta, placenta increta or placenta percreta.
- Eventual re-growth of fibroids

References: 1. American Society for Reproductive Medicine. Uterine Fibroids: A Guide for Patients. Patient Information Series 2003.http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/uterine_fibroids.pdf 2. Emanuel MH, Wamsteker K, Hart AA, Metz G, Lammes FB. Long – term results of hysteroscopic myomectomy for abnormal uterine bleeding. *Obstet Gynecol.* 1999;93:743-748 (II-2) 3. Ayas S, Gurbuz A, Eskicirak E, Selcuk S, Alkan A, Eren S. Follow – up and hysteroscopic evaluation of the uterine cavity after hysteroscopic polypectomy. *SAJOG.* 2011;17:10-13 4. Litta P, Merlin F, Saccardi C, et al. Role of hysteroscopy with endometrial biopsy to rule out endometrial cancer in postmenopausal women with abnormal uterine bleeding. *Maturitas.* 2005;50(2):118. 5. The American College of Obstetricians and Gynecologists (ACOG). Practice bulletin no. 149: endometrial cancer. *Obstet Gynecol.* 2005;125(4):1006-1026. 6. Data on file, Hologic, Inc. 7. Jansen FW, Vredevoogd CB, Van Ulzen K, Hermans J, Trimbos JB, Trimbos – Kemper TCM. Complications of hysteroscopy: a perspective, multicenter study. *Obstet Gynecol.* 2000;96:266-270. 8. Cooper JM, Brady RM. Intraoperative and early postoperative complications of operative hysteroscopy. *Obstet Gynecol Clin North Am.* 2000 Jun. 27(2):347-66. 9. Emanuel MH, Hart A, Wamsteker K, et al. An analysis of fluid loss during transcervical resection of submucous myomas. *Fertil Steril.* Nov 1997. 68:881-6.

Important Safety Information: The MyoSure hysteroscopic tissue removal system is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas, endometrial polyps and retained products of conception. It is not appropriate for patients who are or may be pregnant, or are exhibiting pelvic infection, cervical malignancies or previously diagnosed uterine cancer.

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