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## HYSTEROSCOPIC MORCELLATION: MYOSURE® TISSUE REMOVAL SYSTEM

*Innovative Device Enables Incision-less, Fast  
Removal of Fibroids and Polyps*

For many years, hysteroscopic loop-electrode resectoscopy has been used for removing intrauterine pathology. However, use of a resectoscope for fibroid and polyp removal is fraught with potential complications including perforation, excessive fluid absorption and poor visibility<sup>1</sup>.

Hysteroscopic morcellation has been demonstrated to be both faster and easier to learn than traditional resectoscopy<sup>2</sup>. In addition to the OR, it can be performed in the office or an ambulatory setting. As the market's most versatile and fastest morcellating device, the *MyoSure® tissue removal system* can help OB/GYN surgeons realize significant cost savings and efficiency improvements, and treat more women with uterine pathology in a minimally invasive manner.

Henry A. Dominicus, MD, a gynecologist with a special interest in non-invasive surgical techniques who practices at WomanCare locations in Chicago, IL and the surrounding north and northwest suburbs, reports: "For years we have been treating women with fibroids inside the uterine cavity with an instrument that was cumbersome and inefficient. Many physicians including myself were hesitant to use these procedures because of the difficulty with the technology available to address this type of pathology. Now with the new MyoSure instrument, intrauterine pathology can be removed efficiently with this simplified technology."

### Feasible for any OB/GYN to learn

A physician who has used the MyoSure system since it first became available; Dr. Robert Zurawin is an associate professor in the Division of Gynecology of Baylor College of Medicine and currently serves as the fellowship director of Minimally Invasive



*MyoSure® hysteroscopic tissue removal system.*

Gynecologic Surgery. He specializes in alternative procedures to hysterectomy, with special interest in the treatment of fibroids and endometriosis using minimally invasive techniques that include robotic surgery.

Dr. Zurawin states: "MyoSure eliminates many of the difficulties that gynecologists have faced in the past, preventing them from doing hysteroscopies or hysteroscopic myomectomies. There have been complications from these procedures ranging from fluid overload to sodium and electrolyte imbalance to thermal injury<sup>3</sup>. I suspect that these problems are virtually eliminated with MyoSure and the new Aquilex™ fluid control system. It is now feasible for the average gynecologist to learn this procedure and offer more treatment options to patients with fibroids instead of just offering a hysterectomy or referring her to another doctor."

### Clinical trials

The MyoSure technology has been assessed in clinical trials. Interlace Medical, a privately held company that developed MyoSure and was acquired by Hologic (Bedford, Massachusetts) in 2011, initiated a multi-center clinical trial of the

MyoSure hysteroscopic tissue removal system in 2009<sup>4</sup>. In this clinical trial, 40 subjects who presented with intrauterine polyps and/or submucosal fibroids were enrolled in a randomized, controlled study conducted at five physician offices or day surgery settings<sup>4</sup>.

Principle investigator Andrea Lukes, MD, MHSc, FACOG, who founded Carolina Women's Research and Wellness Center after 10 years on the faculty of Duke University Medical Center, published results on 13 subjects within this clinical trial that demonstrated that women experienced minimal to no pain or discomfort during the MyoSure procedure when given a mild oral sedative together with a local anesthetic injected into the cervix<sup>4,5</sup>.

"I have personally performed about 120 MyoSure procedures, mostly in my office, with a few at an outpatient facility in Durham, N.C.," reports Dr. Lukes, who describes herself as a "huge supporter of MyoSure."

She explains why: "The MyoSure system is a more sophisticated way to remove abnormalities within the uterus than loop-electrode resectoscopy, which is somewhat of a laborious procedure that has tended to be done by more specialized OB/GYNs. MyoSure is a one-step procedure in which you have complete visualization of the operative field and few of the risks associated with resectoscopy. I am excited for more OB/GYNs to look at MyoSure and consider performing procedures either in their office or an outpatient surgical center."

#### **Suction-based, mechanical energy instead of electrical energy**

For women who want to preserve their reproductive capability, the MyoSure system is ideal. It enables incisionless, fast removal of fibroids and polyps without the high-frequency electrical energy used by resectoscopy, which can damage sensitive tissue. The MyoSure system employs mechanical energy

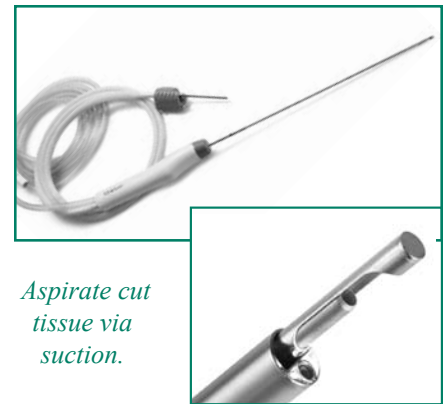
to cut tissue while utilizing suction to remove the tissue from the uterus, eliminating the need to make multiple passes through the cervix. The result is improved visualization and efficient removal of tissue.

With the MyoSure system, the cervix is dilated, the uterus is expanded via a saline solution, and a hysteroscope is inserted. MyoSure system consists of a hand-held tissue removal device comprising a mechanical-drive assembly connected to a drive cable and associated control box on one end, and a 3mm shaft on the other end of the device. The shaft is approximately 12cm long and equipped with an open channel that houses a rotating and reciprocating blade.

The MyoSure tissue removal device has a small 2.5mm inner blade that rotates and reciprocates within a 3mm outer tube at 6000rpm, presenting an outer bevel on the rotating blade edge that shaves down the tissue. When the side window is exposed to targeted tissue and the motor is activated, the rotating and reciprocating blade cuts the tissue within the channel. Cut tissue is aspirated through the device's shaft via suction coupled to the proximal end of the tissue removal device, and is collected in a tissue sock. Because there is no electrocautery used to resect the tissue, all tissue margins are intact for pathology.

In 2005, the TRUCLEAR™ hysteroscopic morcellator (Smith & Nephew, Andover, MA) was the first mechanical morcellator introduced for intrauterine pathology, and in 2009, the FDA approved the MyoSure system as a second hysteroscopic morcellation device. The two devices were compared in a study by Sarah Cohen, MD and James A. Greenberg, MD.

Dr. Zurawin states: "I have performed every manner of resectoscopy including monopolar and bipolar electrosurgical devices as well as the TRUCLEAR™ hysteroscopic morcellator. There is no



*Aspirate cut tissue via suction.*

one-size fits-all in medicine, and just as some patients with heart disease need a bypass, some need a stent and some need medication; you must individualize for every patient. Diagnostic hysteroscopy or a sonohysterogram will give you an idea of the extent of the fibroid or polyp, and MyoSure is ideal for those lesions totally contained within the uterine cavity."

"Our hospital has purchased the MyoSure system for the outpatient surgical center and the OB/GYNs love it," concludes Dr. Lukes. "Most have tried it at this point." ♦

For more information about the *MyoSure® tissue removal system*, please call 800-442-9892; visit our website at [Myosure.com](http://Myosure.com).

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