

# Interlace Medical Initiates Clinical Trial of MyoSure™ for Office-Based Treatment of Submucosal Fibroids

Framingham Mass., March 30, 2010 - [Interlace Medical](#), Inc., today announced that it has initiated a multi-center clinical trial of the MyoSure Hysteroscopic Tissue Removal System. The purpose of this study is to demonstrate that women experience minimal to no pain or discomfort during a [MyoSure](#) procedure, when given a mild oral sedative together with a local anesthetic injected into the cervix. The study will enroll forty subjects at five sites who present with intrauterine polyps and/or submucosal fibroids 3 cm or less in size. Outcomes data will be submitted to a peer-reviewed journal for publication at the conclusion of the study.

“This study is an important step in determining whether the MyoSure treatment option is appropriate for use in a physician’s office-setting where its use may provide scheduling convenience for physicians, reduced anxiety and a smaller co-pay for patients and cost savings for insurers. While the MyoSure System has demonstrated an ability to treat all sizes of submucosal fibroids in an ASC or hospital outpatient setting, it’s small diameter and ability to remove a 3 cm. submucosal fibroid in 10 minutes or less of cutting time may encourage gynecologists to offer MyoSure treatment to patients who prefer not to have general anesthesia for such a short procedure.” said Bill Gruber President and CEO of Interlace Medical.

“I am extremely pleased to be part of this clinical study. As a practicing gynecologist it’s important for me to offer my patients effective treatment options. MyoSure is an excellent option for treating abnormal uterine bleeding caused by submuscosal fibroids and polyps. It’s safe, effective, and fast. Because no incision is required, patients experience little to no interruption from their daily lives.” said Andrea Lukes, M.D., lead investigator.

Patient recruitment is underway at each site, with a planned study completion by the end of March, 2010. Sites include: Andrea Lukes, M.D.- Durham NC; Kelly Roy, M.D.-Phoenix, AZ; James Presthus M.D. Minneapolis, MN; Michael Diamond and James Berman M.D.- Michigan and Ken Konsker, M.D. – Boca Raton, FL.

## About Myosure

The MyoSure Hysteroscopic Tissue Removal System received FDA 510(k) clearance on October 28<sup>th</sup>, 2009. The MyoSure procedure is a new and innovative treatment that enables incision-less, fast and safe removal of submucosal fibroids and provides effective relief of abnormal uterine bleeding symptoms. MyoSure is an ideal treatment option for women seeking to preserve uterine form and function.

## About Fibroids

Nearly 80% of all women will develop [fibroids](#) in their lifetime. The economic impact of fibroids is considerable. With an estimated 200,000 hospital admissions, costing more than \$2 billion per year, fibroids clearly have a significant public health impact. These estimates do not include medical costs incurred in outpatient settings, or nonmedical costs such as time lost from work, according to data reported by the Agency for Healthcare Research and Quality. The need for better solutions that reduce the economic burden associated with treating and managing fibroids continues to increase. Hysteroscopic Myomectomy is recognized by the American Academy of Obstetricians and Gynecologists (ACOG), as a safe and effective treatment of [Abnormal Uterine Bleeding](#) (AUB) caused by fibroids and [polyps](#) and is clinically proven to relieve AUB symptoms by greater than 90% with a less than 20% chance of recurrence at five years.

By developing cost effective, technologically advanced devices that improve patient care, reduce cost and provide procedural convenience to physicians, Interlace Medical addresses an ongoing need for safer, less invasive gynecology procedures.

For additional information visit [www.myosure.com](http://www.myosure.com) or contact:

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