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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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The MyoSure Portfolio of Devices for the Treatment of Intrauterine Pathologies and Heavy Menstrual Bleeding in the Office Setting

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Introduction

I am a gynecologic oncologist who is also working in the area of benign gynecology and both operating in the outpatient clinic and performing complex surgeries in the operating theater of the Queen Alexandra Hospital in Portsmouth and in my private practice in London. I primarily use a one-stop see-and-treat approach, which is endorsed by the UK's National Institute for Health and Care Excellence (NICE) guidelines for heavy menstrual bleeding (HMB) published in 2018.[1]

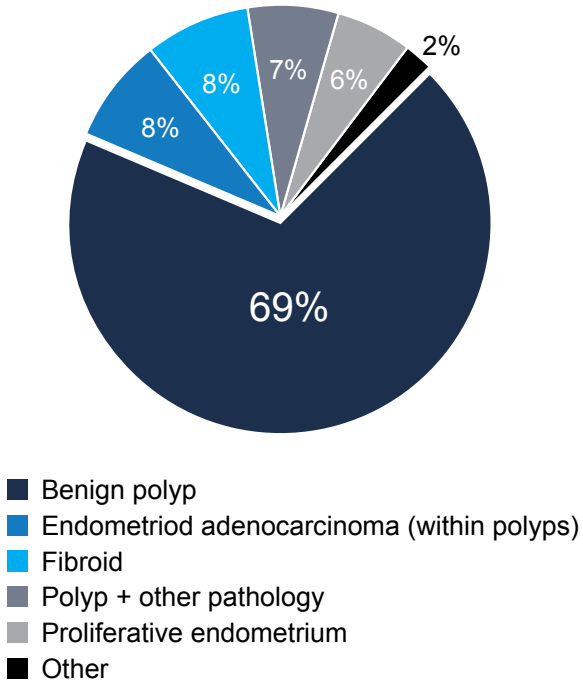
The MyoSure device portfolio, along with the NovaSure endometrial ablation system, plays a significant role in the ability of both clinics to offer patients a convenient office-based see-and-treat approach. The MyoSure technology is designed for ease of use in treating both polyps and fibroids. This ease of use has allowed us to raise the level of the service we provide, a fact reflected in the high levels of satisfaction expressed in the patient feedback we receive.

Employing MyoSure and NovaSure Procedures in the Office Setting

The patients I see in the see-and-treat setting fall mainly into two categories: patients with postmenopausal bleeding and premenopausal patients with HMB. For the former, we conduct baseline ultrasonography, and if the endometrium is found to be thickened, we perform a diagnostic hysteroscopy. If a polyp is present, I resect it immediately. Approximately 30% of patients with HMB in our practice have either submucosal fibroids or a polyp distorting the cavity, and I know that these kinds of pathologies can significantly impact menstrual function.[2] In these cases, I counsel the patient on the importance of normalizing the cavity to see what effect that has on menstrual function. Simply removing the pathology may improve menstrual function to a satisfactory degree. However, some patients prefer to take a more active approach to treatment. For these patients, if they have a polyp, I remove it and follow up with endometrial ablation using the NovaSure procedure.[3] If the cavity is significantly distorted with a type 0 or type 1 fibroid, I resect the fibroid and follow up with NovaSure endometrial ablation. However, with type 2 fibroids and some type 1 fibroids, if disruption of the myometrium is significant, immediate follow-up with the NovaSure procedure is contraindicated. In my experience, a significant number of patients receive satisfactory outcomes with treatment with MyoSure, but patients who continue to experience bleeding issues will usually undergo a subsequent NovaSure procedure as long as it is not otherwise contraindicated.

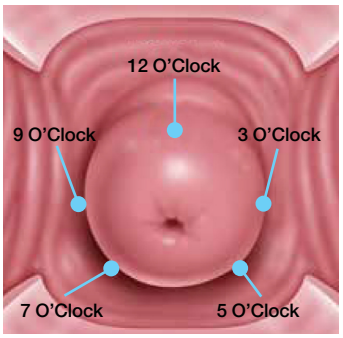
To assess the utility of the MyoSure procedure in a see-and-treat setting, my colleagues and I conducted a study of patients treated in our outpatient clinic with the MyoSure device. The pilot data from this study were presented at the European Society of Gynaecological Endoscopy meeting in 2014. Of the 100 patients in the original patient population, 63 were treated using the MyoSure LITE device, 32 using the MyoSure device, and 5 using the MyoSure XL device. The distribution of pathologies is shown in **Figure 1**. Consistent with other MyoSure studies, we found that in undertaking these procedures, 100% of the intrauterine pathologies were either completely resected or effectively biopsied, and 100% of tissue specimens were suitable for histologic assessment.[3-8] No complications were observed, and all the patients in the study provided positive feedback about their treatment experience. The mean treatment time was 80 seconds (range: 2 seconds–11 minutes, 24 seconds), and the mean fluid deficit was 231 mL (range: 0–1187 mL).[8]

Figure 1. Distribution of uterine pathologies observed in a study of 100 patients undergoing the MyoSure procedure



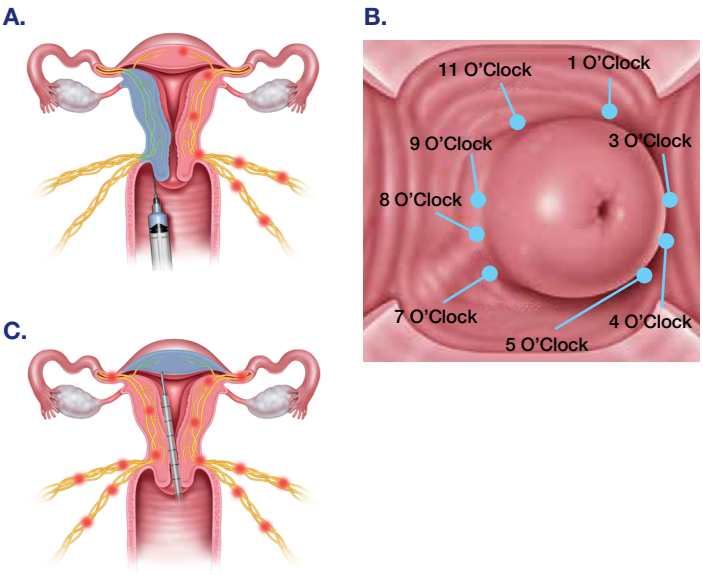
The outcomes of our studies confirmed my own experience with the MyoSure system in the office setting as part of a see-and-treat approach. Indeed, with rare exceptions, I perform all MyoSure procedures in an office setting, although they can also be performed in a variety of other outpatient and ambulatory settings. In the office setting, an anesthetist and anesthetic equipment are not needed, and sedation of the patient has not been necessary. An intracervical block is utilized when conducting a MyoSure procedure (**Figure 2**) and a paracervical block with fundal injection is utilized when performing a NovaSure procedure (**Figure 3**). If I see fundal pathology or cornual pathology, I may also use a fundal block, as these areas of the uterine cavity are more sensitive.

Figure 2. Injection site for intracervical block



Prior to the adoption of using the paracervical block with fundal injection, patients undergoing endometrial ablation consistently reported pain at about 6 out of 10 on a visual analog scale. Since its adoption, the mean patient pain score has been 1.1 out of 10—which is to say that patients have no significant pain with endometrial ablation, and many patients score zero, which is consistent with pain outcomes in other studies of the MyoSure procedure.[5,9,10] With appropriate training and underlying skills, competent practitioners should consistently perform these procedures without patients experiencing any significant pain.

Figure 3. Paracervical block (A), injection site for left paracervical block (B), and fundus block (C)



Using the Range of MyoSure Devices

As a rule, we always go with the smallest device that we think can achieve a completed treatment in less than 5 minutes, bearing in mind that these patients are not sedated (**Figure 4**). Even though there is no significant pain, we do not want to subject patients to a prolonged treatment while they are awake.

Figure 4. Applications for different MyoSure devices

	MyoSure **MANUAL** device	MyoSure **LITE** device	MyoSure **REACH** device	MyoSure **XL** device
MyoSure devices	*The* **right choice** *for small polyp removal and target biopsy*	*The* **right choice** *for tissue collection through visualized biopsy*	*The* **right choice** *for resection – including hard-to-reach areas*	*The* **right choice** *for large, hard fibroids*
Procedure	• Polypectomy (up to 1 cm) • Targeted endometrial biopsy	• Endometrial biopsy • Polypectomy ≤ 3 cm	• Polypectomy (all sizes) • Myomectomy ≤ 3 cm • Adhesiolysis • Uterine septum removal	• Polypectomy (all sizes) • Myomectomy ≤ 5 cm • Adhesiolysis • Uterine septum removal
Pathology	Directed Biopsy Polyps ≤ 1 cm	Polyps ≤ 3 cm	Polyps ≥ 3 cm Fibroids ≤ 3 cm	Fibroids ≤ 5 cm
	In Office ←			→ OR

Polyps

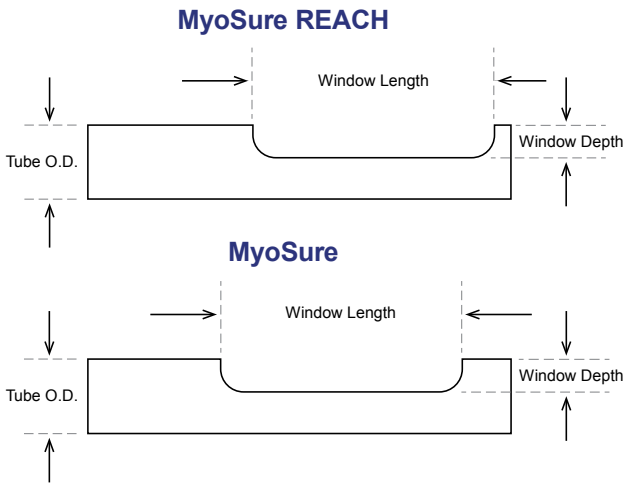
If polyps are in the main part of the uterine cavity, the MyoSure LITE device is my device of choice. For polyps in less accessible areas, such as the cornu or coming out of the fundus, I use the MyoSure REACH device to ensure that the polyp is resected all the way down to the base. I also use the MyoSure REACH device for larger polyps. The MyoSure LITE device is ideal for treating multiple small polyps; I have treated as many as six polyps at once with this device.

Fibroids

Similarly and in most cases, a fibroid up to 2–3 cm can be resected using the MyoSure REACH device. However, if a fibroid exceeds 2 cm, the volume of tissue being removed will increase the duration of treatment, so I tend to opt instead for the MyoSure XL device, which can resect tissue at a faster rate than the MyoSure REACH device. A type 2 fibroid is the only exception to this usage, particularly if its position in the uterine cavity is awkward. In that case, I might use the MyoSure REACH device because the small distance between the cutting window and the distal end on that device facilitates access to the fibroid and facilitates penetration into the intramural portion of the fibroid (**Figure 5**).

Figure 5. Specifications of different MyoSure devices

	Window Length (mm)	Window Depth (mm)	Window Size (mm^2)
MyoSure LITE	10.2	1.5	31
MyoSure REACH	14.0	1.8	54
MyoSure XL	14.0	2.4	98



Directed Biopsies:

For directed biopsies or a single small polyp, I always employ the MyoSure MANUAL device, which requires less setup time than the standard MyoSure devices, mainly because it obviates the need for a fluid management system. After a simple connection to the fluid source, the Manual device is ready to go. It has its own vacuum, activated by pumping the handle, which also activates the cutting device, so there is no need to attach the device to a power source. If the endometrial abnormality is specific and localized, particularly if it is in the uterine cornu, which is easily missed with blind biopsy, I use the MyoSure MANUAL device to do a directed biopsy.

Large Fibroids

The only real challenge for the MyoSure device is a large fibroid because of the volume of tissue to resect. In these cases, we offer to defer the resection procedure and pretreat patients with either a gonadotropin-releasing hormone analog or ulipristal acetate (a progesterone receptor modulator). If, for example, an 8-cm fibroid can be reduced to a 5-cm fibroid, the volume of tissue to resect is dramatically different. A calcified fibroid presents another challenging type of procedure. In such cases, even if the fibroid is only 2 cm in diameter, we use the MyoSure XL device, which has a larger cutting blade than the standard MyoSure device. On rare occasions when this procedure is not sufficient, loop resection is the next best option.

RPOC

I also see a small number of patients who have experienced pregnancy loss—first- or second-trimester miscarriages—and have continued to have some retained products of conception (RPOC) despite previous medical treatment. Our protocols require that these patients should be offered pharmacologic options as first-line treatment. If the RPOC fail to pass after 6 weeks, we offer surgical intervention. In the UK, many practitioners perform a blind surgical evacuation of the cavity, which is contrary to the guidelines of the British Society for Gynaecological Endoscopy (BSGE).[11] I use the MyoSure device for hysteroscopic assessment and removal of RPOC, and in these cases we typically use the MyoSure XL scope, which has an outer diameter of 7.25 mm. However, all MyoSure devices may be used for RPOC, including those employing a scope with an outer diameter of 6.25 mm. Our results with the MyoSure XL device for removing RPOC have been excellent, in keeping with data from other investigators who have employed the device.[12,13]

Comparison of MyoSure to Other Devices

In 2011, when hysteroscopic morcellation was first licensed in Europe, we adopted the MyoSure system at our hospital. Prior to that, my colleagues and I looked at other options, including the Bigatti Shaver (Karl Storz, Tuttlingen, Germany), which had an 8-mm diameter (the latest device is now 6 mm) and could be used to treat polyps and fibroids. We noted how heavy that instrument was and concluded that having the weight of the device on the perineum was not ideal and that use of such a heavy instrument to remove a simple polyp was unnecessary. An 8-mm device also requires significantly more dilation than a 6-mm device (as with the MyoSure system), and every extra millimeter of dilation represents an increased level of difficulty as well as an increased risk of perforation.[14] We further found that although the Bigatti Shaver is marketed as being reusable (up to five times), it is a very

complicated device to assemble. Such a complex device can be quite disruptive to practices seeking a smooth transition from diagnostic hysteroscopy to treatment, and for these reasons, we thought it was not well suited to the outpatient setting. Moreover, our hospital expressed some concern regarding the re-sterilization of these complex mechanical devices.

We also looked at the TruClear device (Medtronic, Fridley, MN), which has a small version that can be used for treating small polyps. While this device has the advantage of a diameter slightly smaller than the MyoSure device, a published study comparing the two devices found that TruClear was significantly inferior to MyoSure in its cutting action based on resection time and activation time (duration of device's running time during procedure),[15] a conclusion that mirrored our own experience with these devices. Furthermore, the introduction of the Omni™ Hysteroscope has reduced the diameter of the dilation to 5.5 mm for the MyoSure Manual, Lite, and Reach devices (previously 6.25 mm) and to 6 mm for the MyoSure XL device (previously 7.25 mm). For these reasons, I think the MyoSure device is really ahead of the field.

In assessing the difficulty of learning to use the MyoSure device, we were again impressed by its relative ease of use. The learning curve is short and made even simpler by the availability of both a computer simulator that allows the practitioner to become accustomed to using the device, as well as a live-model simulator, which together will help a surgeon raise their skills so that patients can be treated safely and effectively in the office setting.

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The MyoSure System Versus Loop Resection for the Treatment of Uterine Cavity Lesions

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Experience with MyoSure Device and Loop Resection

I have used the MyoSure tissue removal system for approximately 6 years and perform approximately 100 MyoSure procedures each year, primarily for leiomyoma and polyp resection, often in advance of using the NovaSure device for endometrial ablation. I typically use two of the available MyoSure device sizes: MyoSure LITE (**Figure 1**) and MyoSure XL. For nulliparous women who are postmenopausal, I use the MyoSure LITE device, and for those who have not entered menopause, I generally use the MyoSure XL device.

My experience treating intrauterine pathologies began with monopolar loop procedures about 25 years ago. I later switched to a bipolar loop (**Figure 2**), which I used for about 20 years to perform endometrial resection and to treat polyps, myomas, and intracavitary abnormalities, as well as correcting endometrial hypertrophy with metroplasty in patients unable to become pregnant. Of the many reasons I switched from the loop method to the MyoSure device, the most compelling was efficiency. When using a loop, it is necessary to repeatedly insert and remove the device from the uterine cavity because of the buildup of resected tissue and of blood, which must be removed to clear the cavity and allow visualization. Indeed, these obstacles increasingly compromise visualization over the course of the loop procedure.[1] Moreover, the repeated insertion and removal is inconvenient and time consuming for physicians, and the resulting increase in duration of the procedure is suboptimal for patients, particularly since the repetition increases the risk of perforation and injury associated with the loop's electrical charge. My own research has shown that loop resection results in a considerable burning of the myometrial tissue.[2] By contrast, with the MyoSure device—which is both ergonomically well designed and has the advantage of vacuum suction—once the device is inside the cavity, it can remain there, allowing rapid and efficient completion of the procedure.[1] Furthermore, the MyoSure device permits excellent visualization thanks to high-quality optics, reliable suction, which keeps the space clear from buildup of blood and chips, and the tissue trap, which captures cleared tissue for assessment by a pathologist.

Figure 1. MyoSure LITE Device

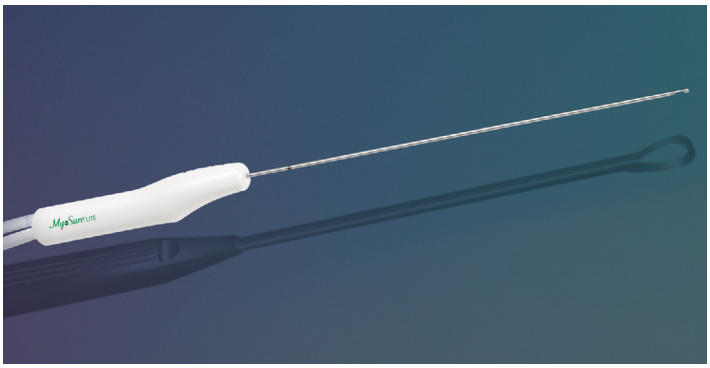

Figure 2. Cutting Loop

MyoSure Device Versus Loop Resection for Treatment of Intracavitary Lesions

A second important reason that I switched to the MyoSure device is its simplicity of use, which makes the procedure easier to learn. Compared with a morcellator like the MyoSure device, the learning curve for loop resection is much longer.[1,3] In addition, while the loop method involves electrical current and requires very careful positioning of the device to avoid doing damage, the MyoSure device simply needs gentle pressure against the lesion to mechanically remove tissue. Simplicity of use leads to several

procedural advantages. A systematic review and meta-analysis of studies comparing loop resection to hysteroscopic morcellation found that morcellation was associated with a lower rate of incomplete lesion removal, faster time to polyp removal, and a lower fluid deficit.[4]

Complications

The primary risks associated with loop resection include bowel injuries from perforations or from burns caused by the loop's electrical current, perforation of the uterine cavity, and uterine synechiae due to burning of the mucosa.[5-7] In my own experience, the largest risks are uterine perforation and, if the resection cuts too deeply into the myometrium, substantial bleeding, which can result in postoperative anemia. When I used a bipolar loop, I saw a complication rate of approximately 5%.[8,9] By contrast, the MyoSure procedure avoids the risk of thermal injury. With the MyoSure system, I have only observed one serious complication (an unusual case of intravasation resulting from a secondary perforation in a patient with a type 2 myoma and from whom I had removed 19 myomas a year earlier). This is consistent with the rate of complications observed in the medical literature with the MyoSure procedure.[10,11]

Complete Removal of Lesions

In my experience, the MyoSure procedure offers a higher rate of complete removal of lesions than loop resection, which is consistent with the medical literature.[4] It is not unusual for patients who have undergone loop resection to return for additional procedures,[12] whereas in my experience with the MyoSure system, complete resection is usually achieved with the initial procedure. The high rate of successful lesion removal with the MyoSure system in both office and ambulatory surgical care/hospital outpatient center settings is shown in the **Table**.[11]

Table. Outcomes of Uterine Polyp and Myoma Removal (Total Lesions=559) with MyoSure System at 34 US Office and ASC/HOPD Sites[11]

	Office (n=28)	ASC/HOPD (n=250)	*P* value
Polyps removed, %	99.3	99.9	0.09
Fibroids removed, %	86.8	85.8	0.14
Adverse events, % of patients	1.8	1.6	0.41
Resection time, min	6.0	5.8	0.10
Time in PACU, min	55.4	57.0	0.02
Physician satisfaction score of 4 or 5 out of 5, %	95	96	0.15

ASC/HOPD, ambulatory surgical center/hospital outpatient department; PACU, post-anesthesia care unit.

Pain, Recovery Time, and Patient Satisfaction

In my experience, the pain level associated with the MyoSure procedure is typically lower than loop resection, and patients often require no postoperative analgesia. In some cases, nonsteroidal anti-inflammatory drugs (NSAIDs) are prescribed. With loop resection, analgesia of some kind, usually NSAIDs or acetaminophen/paracetamol, is typical, and pain may persist for several days following the procedure.[7] Indeed, the experience of little or no pain after the MyoSure procedure accounts, in part, for its high degree of patient satisfaction.

Challenges to the Use of the MyoSure System in France

The key obstacles to wider adoption of the MyoSure system in France are related to reimbursement, culture, and perception. The MyoSure procedure is reimbursed as an ambulatory procedure in France, as it is elsewhere. However, the MyoSure procedure is performed in operating theaters, with general anesthesia and often hospitalization, which are generally unnecessary. The result is an essentially inexpensive procedure that is significantly overpriced and undercompensated. In addition, medical students and residents are taught that loop resection is the only viable treatment option for many conditions, and they are deprived of a wider knowledge of treatment options, such as the MyoSure device. MyoSure is narrowly (and mistakenly) perceived as a procedure primarily for challenging cases—for example, when it is necessary to avoid synechiae, as with patients who have difficulties with fertility. By contrast, in many other countries, including the Netherlands, the United Kingdom, the United States, and Canada, the broader utility of the MyoSure procedure is better understood and the procedure has been widely adopted. The situation in France would benefit from the availability of updated guidelines and a reformed reimbursement mechanism that ensured an understanding of the clinical utility of the MyoSure device and accessibility of the procedure to patients and physicians. Only when the MyoSure procedure is moved to the office setting and surgeons are apprised of its true value will the MyoSure system achieve the wider acceptance in France that it merits.

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MyoSure Versus TruClear

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I see between 90 and 100 patients per week in my office, with about two-thirds of my practice focused on gynecologic conditions and concerns. Prior to adopting the MyoSure system for uterine tissue removal, our local hospital-based surgery center utilized the TruClear morcellation system, which remained the standard instrumentation for removing polyps and fibroids for approximately 10 years. Before the introduction of the TruClear product, my own experience performing these procedures involved the use of a standard resectoscope with loop instrumentation. I have now been using the MyoSure system for the past 12 months and perform MyoSure procedures on at least a weekly basis, primarily for the treatment of polyps and fibroids associated with abnormal uterine bleeding. Having used both instrument systems extensively, I can offer some observations regarding their relative strengths and weaknesses based on my personal clinical experience.

In comparing the two systems, my clear preference is for the MyoSure system over the TruClear system. Although there are numerous points of comparison, the three decisive factors for me relate to ease of setup, the convenience of not having to switch between cutting instruments when encountering both soft- and dense-tissue lesions in the uterine cavity, and superior optics.

Ease of Setup

In my experience, the biggest differentiator between the MyoSure and TruClear systems relates to the complexity and time required for setup. Two issues contribute to this differentiation: the hysteroscopic fluid flow layout and the instrument design. I have found the TruClear system to be much more difficult to configure for use due to the complexity of the continuous flow feature, which involves multiple tubing connections—notably more than with the MyoSure device—and which requires additional instruction and training in how all the tubes need to be correctly attached in order to enable the device to work properly. Moreover, the presence of the extensive network of tubing is something with which the surgeon has to contend while performing a procedure, and consequently, the TruClear system can be unwieldy during operative hysteroscopic surgery. Additionally, the TruClear product requires completing a "window lock" procedure—an alignment of the cutting blade—on the instrument prior to use, requiring additional preparation before being able to continue with an operative procedure. In speaking with my operating room staff, I find that now that they have been exposed to the ease of the MyoSure system, they have considerable resistance to the TruClear system in comparison because of the challenges of configuration for that product.

The MyoSure system, by contrast, is far simpler to set up. The tubing is easily manageable, and the system has more of a plug-and-play design. For clinicians who perform simultaneous diagnosis and treatment (ie, see-and-treat), the advantage of the MyoSure system in terms of ease of setup is even more pronounced. The surgeon can insert the diagnostic scope, execute the "see" part of see-and-treat, and then easily convert to an operative procedure with limited delay because the fluid connections are straightforward and the cutting instrument does not require pre-procedural alignment. There is no need for instrument reconfiguration, and therefore none of the challenges associated with the TruClear format. After 10 years of working with the TruClear system, the ease of setup with the MyoSure system was a welcome surprise, and with my prior surgical experience, I found it easy to quickly become comfortable with the device.

Design and Configuration of Cutting Instruments

The TruClear system offers two types of cutting devices, one designed for cutting soft tissue and one designed for dense tissue (**Figure 1**). Each of these two instrument types is available in a smaller size (Mini) and a larger size (Plus). The soft-tissue instrument (**Figure 1A**) employs a rotary cutting action while the dense-tissue instrument (**Figure 1B**) uses a side-facing reciprocating cutting window. The soft-tissue instrument allows for closer resection to the level of the endometrium because of a shorter distance between the cutting blade and the tip. Although that shorter distance to the tip of the soft-tissue instrument permits better access to hard-to-reach tissue—such as in the uterine fundus—than does the dense-tissue instrument, it is limited by the nature of its design. In other words, the instrument works well on soft tissue but does not work on denser tissue, such as fibroids. This means that surgeons might need to switch cutting devices in the middle of the procedure should they encounter more dense tissue lesions while using the soft-tissue instrument.

Figure 1. Cutting Ends of the (A) TruClear Soft Tissue Shaver Plus and (B) TruClear Dense Tissue Shaver Plus

If it becomes necessary to switch cutting devices while performing a procedure, the surgeon has to manage not only the inconvenience and loss of time with the instrument exchange, but, as a recent literature review described, the added risk of uterine perforation when removing a first device and inserting a second device.[1] There would also likely be, in general, a downstream effect on cost in this scenario due to the increased operative time and the use of two different cutting devices for a single operation.

The MyoSure system employs a different strategy that largely avoids the need to switch instruments mid-operation. With the MyoSure system, the surgeon is able to choose an appropriately sized device that will allow for treatment of both soft-tissue and dense-tissue lesions. The MyoSure cutting instruments are currently available in four different sizes: the MyoSure MANUAL, MyoSure LITE, MyoSure REACH, and MyoSure XL devices (**Figure 2**).

Each of these devices is devised for a specific clinical situation. Rather than dividing the instrumentation based on capacity to cut soft- and dense-tissue lesions, the MyoSure instruments are designed to function optimally in several different therapeutic contexts. In my clinical practice, I rely most often on the MyoSure LITE device because of the frequency with which I encounter uterine polyps, which it addresses very well. The MyoSure REACH device is effective in removing fibroids up to 3 cm in diameter, while the MyoSure XL device is designed to treat a range of uterine pathology sizes, including larger fibroids.

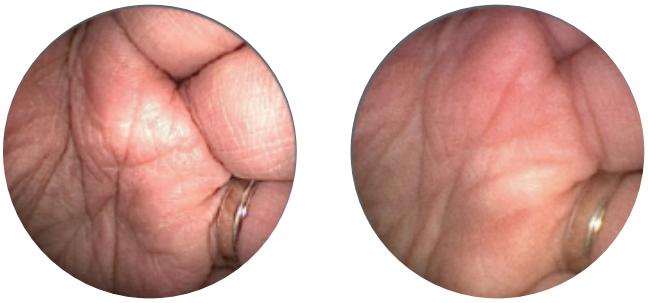
The MyoSure REACH device is designed to access the narrow corners of the uterus by configuring the cutting window up to within less than 1 mm of the distal end of the device. It is also able to remove both polyps and fibroids up to 3 cm in size. There is no equivalent to the MyoSure REACH device in the TruClear product line. The MyoSure REACH device obviates the need for two instruments—one device that can access difficult areas within the uterus (as with the TruClear soft-tissue device) and another to remove fibroids (as with the TruClear dense-tissue device)—as these functionalities are all contained in a single unit.

While I have not yet used the MyoSure MANUAL device in the clinical setting, this instrument gives surgeons the ability to perform procedures without external suction or fluid management equipment, a significant benefit in office-based or other applications. For the purpose of procuring tissue from within the uterus, the MyoSure MANUAL device can be used to obtain samples that are then aspirated into the tissue trap on the back of the device, allowing the surgeon to achieve visual confirmation of the captured specimen.

Optics and Visualization

The hysteroscopes designed to work with the MyoSure and TruClear systems are described as providing similar types of optical transmission. In my experience, however, the Hologic Omni™ hysteroscope designed to be compatible with the MyoSure suite of products is superior to that of the TruClear system, allowing better visualization while performing procedures (**Figure 3**). A clear and continuous view of the surgical field is understandably critical to optimizing procedural safety and efficacy, and improved visualization, especially compared to older instrumentation techniques such as loop resection, is one of the key advantages of current hysteroscopic morcellation technologies.

Figure 3. MyoSure Rod Lens Visualization



MyoSure Rod Lens Scope | **Fiber Optic Scope**

Figure 2. MyoSure Suite of Tissue Removal Devices

	MyoSure **MANUAL** device	MyoSure **LITE** device	MyoSure **REACH** device	MyoSure **XL** device
MyoSure devices	*The* **right choice** *for small polyp removal and target biopsy*	*The* **right choice** *for tissue collection through visualized biopsy*	*The* **right choice** *for resection – including hard-to-reach areas*	*The* **right choice** *for large, hard fibroids*
Procedure	• Polypectomy (up to 1 cm) • Targeted endometrial biopsy	• Endometrial biopsy • Polypectomy ≤ 3 cm	• Polypectomy (all sizes) • Myomectomy ≤ 3 cm • Adhesiolysis • Uterine septum removal	• Polypectomy (all sizes) • Myomectomy ≤ 5 cm • Adhesiolysis • Uterine septum removal
Pathology	Directed Biopsy Polyps ≤ 1 cm	Polyps ≤ 3 cm	Polyps ≥ 3 cm Fibroids ≤ 3 cm	Fibroids ≤ 5 cm

In Office ← → OR

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MyoSure MANUAL Device and the Benefits of Office-Based Hysteroscopy

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Introduction

I am an OB/GYN in private practice with a focus on gynecology and minimally invasive office-based surgery. About 10 years ago, I shifted most of the gynecologic procedures that I regularly perform from the operating room (OR) to an office or outpatient setting, including hysteroscopic procedures for diagnosis and biopsy, polyp removal, fibroid removal, intrauterine device removal, removal of retained products of conception (RPOC), and septum resections.

I see approximately 125 patients and perform 15 to 20 procedures each week, including five to ten office-based hysteroscopic procedures. The majority of these procedures are diagnostic, whereas a minority are operative. I have used both the MyoSure MANUAL and Resectr devices, which are my primary hysteroscopic resection instruments for the office setting; I also occasionally employ powered hysteroscopic morcellators for procedures performed in the office, similar to those performed in the OR.

MyoSure MANUAL for Office-Based Hysteroscopy

The MyoSure MANUAL tissue removal device is a single-use instrument, which, like the other devices in the MyoSure product line, is used for tissue resection and tissue removal under continuous hysteroscopic visualization. The MyoSure MANUAL device differs from the rest of the MyoSure line in that it is hand powered. It does not require fluid management capital equipment, nor does it need a controller or an external vacuum source. This makes it an ideal device for performing in-office procedures, such as removal of lesions and RPOC (we limit in-office procedures to RPOC of 5 cm or less), as well as biopsies, without the added burden and cost associated with ORs or a more complex setup. For an in-office setup, the MyoSure MANUAL device requires only a MyoSure hysteroscope, a 1-liter saline bag, and the outflow tubing that comes with the device.

I provide instruction for colleagues and preceptorships for surgeons on the subject of office-based hysteroscopy and the use of the MyoSure MANUAL device. The vast majority of OB/GYN surgeons have received training only in OR hysteroscopy with a fluid management system and a powered device, so they are not familiar with the use of a manual device. Fortunately, the MyoSure MANUAL device is designed for ease of use, and I have found that surgeons have little trouble mastering it, in no small part because it has been designed for an office setting to avoid the complexity and logistics of an OR. The main adjustment for surgeons is becoming accustomed to performing hysteroscopy in an office setting.

The amount of fluid used during a MyoSure MANUAL procedure is minimal, and there is little risk of significant fluid absorption since the pathology removed is typically small and can be removed quickly. A fluid bag hanging to gravity, with or without a pressure cuff, is more than sufficient in my opinion.

When advising clinicians on how to use the MyoSure MANUAL device, I have them start by resecting a single small polyp, which is relatively simple to perform, after which they can move on to operating on bigger polyps, multiple polyps, or sessile polyps. This, in turn, prepares surgeons to treat RPOC. For those who have previous experience performing hysteroscopy in the OR, I explain that it is a relatively easy transition to an office-based procedure. I usually have people do a few cases in the OR to begin with, but those proficient at OR hysteroscopy will be comfortable performing these procedures in the office after they have completed five or six cases in the OR setting. It is worth repeating that the issues they may run into are not usually related to the surgical device but simply a matter of acclimating to performing hysteroscopy in the office setting.

Benefits of Office-Based Tissue Removal

For the patient undergoing an office-based procedure with the MyoSure MANUAL device, there are numerous advantages over OR-based hysteroscopy. It is a more convenient and efficient procedure that reduces time spent in hospital. Complications are unusual and, if they do occur, are generally mild in severity.[1] Taken together, these benefits have been shown to result in high levels of patient satisfaction among those undergoing office-based hysteroscopy. A study of women undergoing polyp resection using a MyoSure LITE device in an outpatient setting with local anesthesia reported a patient satisfaction rate of 93% and average visual analogue scale pain scores of 2.7 (on a scale of 1 to 10).[1]

With regard to analgesia, we typically do not use intravenous sedation in our office as it is not required for the vast majority of patients. We use only oral sedation in addition to a paracervical

block when necessary. All patients are offered oral sedation, usually with diazepam or lorazepam, and depending on their anatomy, a cervical block is often used with a short- or medium-acting cervical local anesthetic agent.

The outpatient setting has been shown to be well suited to hysteroscopic procedures in numerous studies, including studies that have compared outcomes of hysteroscopy performed in the inpatient versus outpatient setting. Rates of successful resection of polyps and fibroids are generally similar between the two settings, but patient recovery time, the need for postoperative analgesia, and patient convenience all favor the outpatient setting.[2-4] A US study comparing hysteroscopy for abnormal uterine bleeding (AUB) in the two settings also found that office-based hysteroscopies cost less than one-third of those performed in the OR (**Table**).[5]

Table. Costs of Hysteroscopy for AUB in an Office Setting Versus an OR in a US Study[5]

	Office Hysteroscopy	OR Hysteroscopy
Physician fee	$1,356	$1,356
Anesthesia fee	$0	$1,190
Hospital fee	$0	$2,400
Total	**$1,356**	**$4,946**

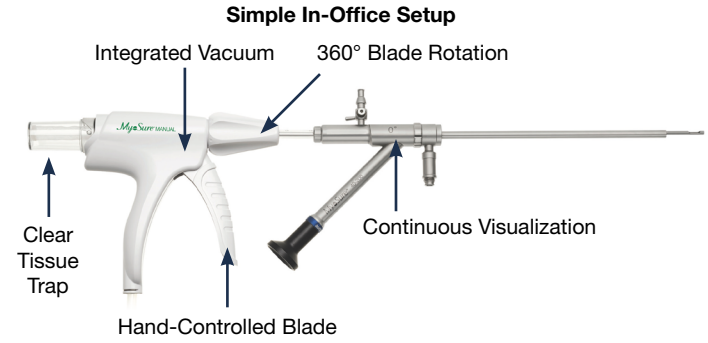
For the surgeon, operating in the office setting is exceptionally efficient, both in the sense of time management and in the sense of reimbursement for time used. At our clinic, the routine is to greet the patient, describe the procedure, and get consent. If needed, we will then do the paracervical block, after which I will leave the patient with the nurse and do one or two quick visits with other patients before coming back to perform the procedure. This kind of efficiency is far superior to that seen with such procedures performed in the OR.

MyoSure MANUAL Device vs Resectr Device

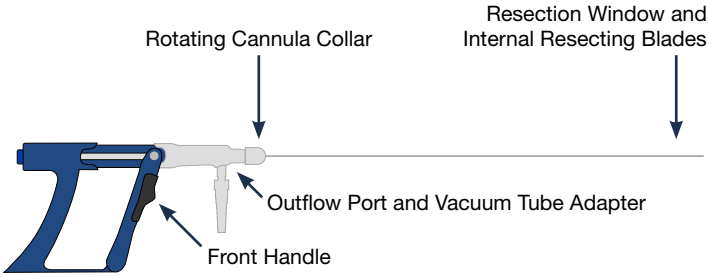
I have used both the MyoSure MANUAL device and Resectr devices quite extensively over the past couple of years. The MyoSure MANUAL, which has a cutting window 10.2 mm in length, is similar in size to the Resectr 9 French, whereas the Resectr 5 French is smaller, with a cutting window only 5 mm long.[6] Overall, both the MyoSure MANUAL and Resectr 9 French are excellent instruments that offer similar efficacy and utility, although the MyoSure MANUAL confers a few useful advantages. These include a more versatile rotation feature that allows for precise positioning of the cutting window and an integrated suction system that works when the handle is squeezed rather than a wall suction system, as is the case with the Resectr device.

Figure. Device Schematics

MyoSure MANUAL Device



Boston Scientific Resectr Device



Suction with the Resectr device requires an extra piece of tubing, a suction pump, a collecting canister, and a special bag that goes inside the canister. By contrast, the MyoSure MANUAL is an all-in-one device with an integrated vacuum that does not require an add-on pump or extra tubing. With MyoSure MANUAL, tissue specimens are collected in a trap at the back of the instrument, obviating the need for a separate collecting canister and bag. The add-on tubing and pump for the Resectr device means that it requires a little more time to use and a small additional expense compared with the MyoSure MANUAL.

With regard to other features, the MyoSure MANUAL handle is exceptionally well designed, with superb ergonomics, and the rotation of the shaft has been built to operate very smoothly. In addition, I find the MyoSure MANUAL to be slightly more rigid than the Resectr, which allows for more precise maneuvering and grasping of tissue within the uterine cavity. The MyoSure MANUAL and Resectr 9 French devices employ a similarly sized 6.25 OD hysteroscope, whereas the Resectr 5 French is smaller and thus fits a smaller hysteroscope.

Conclusions

One of the main obstacles to the adoption of office-based treatment with the MyoSure MANUAL is resistance among surgeons to the idea of office-based procedures, but this resistance can usually be overcome with a little coaching while the surgeon adjusts to the new setting. After that, most surgeons see a tremendous benefit in the efficacy of the MyoSure MANUAL device, the simplicity of its setup and use, cost savings, and high level of patient satisfaction.

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MyoSure Versus Blind Dilation and Curettage

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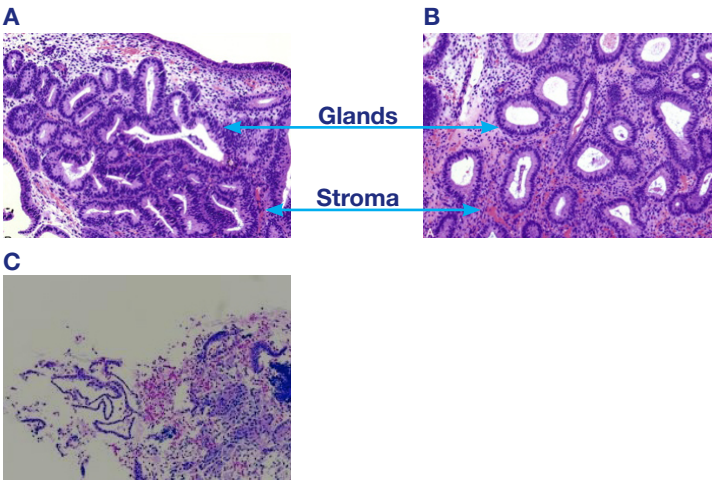
Operative hysteroscopy is intended for assessment and possible removal of endomyometrial abnormalities and, if tissue is removed, to provide definitive diagnosis through specimen histopathology. The quality and quantity of a tissue specimen is directly correlated with the accuracy and certainty of the pathology interpretation. Gynecologic surgeons may not readily recognize the impact of the tissue removal method used on diagnostic pathology, but pathologists, like myself, are certainly mindful of this relationship.

I became aware of the MyoSure tissue removal device (TRD) when I discovered that certain tissue samples I was receiving seemed of exceptionally high quality. Routinely, I review the surgeon's operative report, which details their intraoperative findings as well as a description of the procedure used to remove the tissue sent for pathologic examination. I quickly made the correlation that these high-quality specimens were coming from clinicians who were using the MyoSure TRD. The MyoSure TRD appeared to provide much better tissue samples for histopathology than tissue obtained from blind dilation and curettage (D&C) or biopsy alone. This was exemplified when tissue obtained using the MyoSure LITE device was compared to tissue obtained by blind D&C from the resected uteri of 7 postmenopausal women who had undergone hysterectomy for benign causes.[1] The investigators found that specimens obtained with the MyoSure TRD were significantly superior for the purposes of histologic assessment compared to those obtained by blind D&C (P=0.0006).[1]

Endometrial Histopathology

Most hysteroscopic procedures are performed for evaluation and possible treatment of abnormal uterine bleeding. Typical specimens include polyps, leiomyomata, and endometrial tissue, and the role of the pathologist is to exclude a malignant or premalignant lesion. In order to accurately diagnose the submitted sample, an adequate amount of tissue and intact tissue fragments are required. The diagnosis of endometrial cancer or precancer (complex atypical hyperplasia) is based on the architectural relationship between stroma and glands, which is possible only when the specimen is intact and free of artifact (**Figure 1**).

Figure 1. Glands and Stroma in High-Quality Tissue Samples (A and B) Compared to a Non-Intact Tissue Sample (C)*



*Weidner W, Peterson M. Uterus. In: Peterson M, Cote R, Suster S, Weiss L, eds. *Modern Surgical Pathology*. 2nd ed. Elsevier, Inc; 2009. Used with permission.

Artifacts in Tissue Specimens

Examples of obstacles affecting histopathology include crush and thermal artifacts, telescoping, and obscuring blood (**Figure 2**). A crush artifact is likely due to the disruption of tissue from scraping typically associated with curettage. Likewise, telescoping—glands within glands—occurs in response to tissue trauma, resulting in "intussusception" of glands. This may falsely lead to suggestion of complex hyperplasia. Thermal changes associated with techniques such as electrical loop resection of tissue may lead to marked distortion of the cells, making the distinction between benign and malignant processes next to impossible. With blind curettage, scraping of the intrauterine space for endometrial tissue or removal of lesions, such as polyps, can result in mechanical disruption and fragmentation of the tissue. In general, the presence of any artifact hinders the accuracy of the final histopathologic diagnosis. All of the artifacts described above can be eliminated by using the MyoSure system, which, by design, avoids these issues.

Figure 2. Tissue Artifacts: (A) Crush,[2] (B) Blood,[3] (C) Telescoping,[2] (D) Thermal*

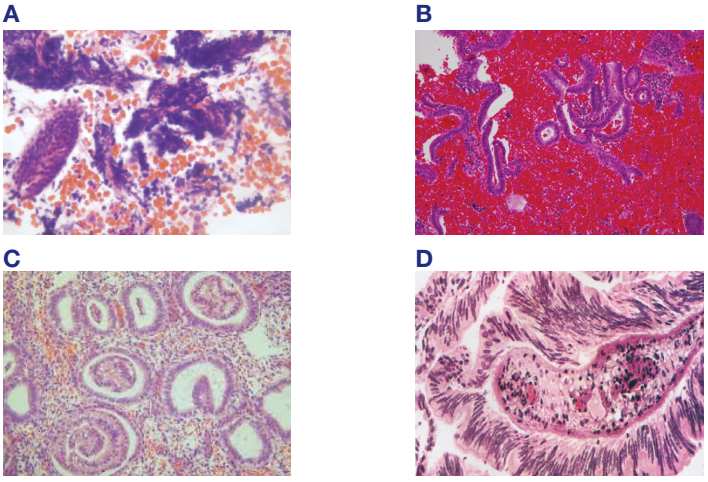


*Figure 2D courtesy of PathologyOutlines.com and the Armed Forces Institutes of Pathology. AFIP Fascicle, 3rd series.

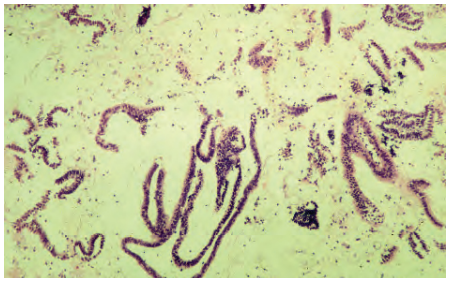
Tissue Quantity

The tissue removed by blind curettage may reflect only a small proportion of the cavitary surface area. A study of 50 resected uteri from women who had undergone blind D&C in advance of hysterectomy found that in over 60% of cases, less than half of the uterine cavity had been curetted, while in 16% of cases, less than one-quarter of the cavity had been curetted, increasing the likelihood of false-negative results in women with focal lesions.[4] Because all tissue submitted for histopathologic examination is subject to laboratory processing prior to microscopic review, further degradation of volume may occur, which is especially problematic when tissue volume is limited to begin with. In the previously noted pilot study, the mean tissue volume procured by the MyoSure LITE device was 1411 ±775 mm^3 compared with 1 ±2 mm^3 using blind D&C.[1] A published analysis of the accuracy of endometrial sampling evaluated outcomes from 12 studies that included 1209 women with postmenopausal bleeding who had undergone either blind D&C (5 studies) or hysteroscopic-directed biopsy and/or curettage (7 studies). The results showed that in 8 of the 12 studies that reported on the adequacy of tissue procured, insufficient material for histology was obtained in a total of 31% of patients.[5]

Clinical Significance of Inadequate Tissue Specimen

The management of patients without a pathologic diagnosis due to an insufficient amount of tissue can be a clinical dilemma (**Figure 3**). In 1 study, 45% of women with inadequate tissue from endometrial sampling or curettage underwent a second procedure or hysterectomy.[7] Insufficient samples can significantly impact clinical diagnosis and patient management. For example, approximately 5% of women with abnormal uterine bleeding and polyps have only focal malignancy.[8] These malignant and premalignant changes can be identified only if the entire lesion is excised and without excessive fragmentation. A German study of 83 postmenopausal women examined rates of successful removal of endometrial polyps by blind techniques, such as Randell forceps and curettage. Curettage alone was associated with complete removal in only 8% of cases, while the addition of forceps increased the rate to 41%. In over half of the cases in the German study, a subsequent hysteroscopy was required to achieve complete extraction of pathology.[9]

Figure 3. Inadequate Tissue in Sample[6]



Increasing Awareness of the Value of the MyoSure System from a Pathology Perspective

In my experience, the difference between samples obtained for histologic analysis using a MyoSure device compared with blind D&C is striking. I often have to write “Nondiagnostic due to insufficient tissue” or “No evidence of malignancy in this limited biopsy specimen” in the pathology report for samples obtained by blind D&C, whereas this is not the case with samples obtained by a MyoSure procedure. Samples from blind D&C often consist of nothing but mucous and blood with minimal to no tissue present for evaluation. It is worth considering the implications for a patient who has undergone anesthesia and endured an entire surgical procedure when the outcome is no interpretable pathology because insufficient tissue was sampled.

In my opinion, the tissue samples obtained with the MyoSure system appear to be of higher quality due to maintained tissue architecture and the absence of artifacts that are frequently seen with specimens removed with curettage or electrothermal loop. Having that structure in a tissue sample—allowing for a full thickness assessment of the endometrium and keeping the stroma and glands intact—makes it possible for pathologists to effectively evaluate endometrial hyperplasia and look for invasion into the myometrium if carcinoma is present. It also allows for accurate and definitive classification of the tumor type. This is not to say that myometrium is absent in curetted specimens; in fact, myometrium is frequently identified in endometrial curettings, but it is typically fragmented and uninterpretable relative to the endometrium.

Unfortunately, little has been done to drive awareness among pathologists about the differences in surgical techniques for obtaining tissue samples. When I bring these differences to the attention of my colleagues, they immediately recognize the superiority of the samples from surgeons who employ the MyoSure device compared with those obtained by blind D&C. However, this information does not generally make its way back to the clinicians choosing the devices and performing the procedures. My hope is that surgeons can be made more aware of the clinical implications of obtaining high-quality tissue samples in order to improve outcomes for the patients they treat.

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Challenging Pathology and Expanded Use of the MyoSure System

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Introduction

The MyoSure system comprises a spectrum of hysteroscopic devices designed to remove targeted pathology from within the endometrial cavity, including polyps, selected submucous leiomyomas, and retained products of conception (RPOC). The core technology includes a rotating and reciprocating blade within a hollow probe with a side (distal) cutting window used to transect tissue and aspirate it via suction into a removable tissue trap. This electromechanical technology enables the performance of procedures previously accomplished only with other systems, in particular, radiofrequency (RF) electrosurgical resectoscopes. With the MyoSure system, these procedures can often be performed in an office setting under local anesthesia.

The electromechanical design, combined with the ability to perform procedures using saline or other physiological solutions, has created the opportunity to effectively, efficiently, and safely deal with complex intrauterine pathology, in many instances under local anesthesia and in a procedure-room setting rather than an operating room. As with all hysteroscopic surgery, safe and effective execution requires that surgeons (1) identify and evaluate patients carefully using a detailed history and appropriate imaging techniques, (2) be intimately familiar with the required equipment and skilled in its use, and (3) understand how to minimize risks and recognize and effectively manage complications should they occur.

To emphasize, it is essential that surgeons are capable of personally evaluating the uterine images when considering a patient for hysteroscopic surgery. This evaluation would preferably consist of transvaginal uterine sonography (TVUS) and sonohysterography (SHG), and, if available and necessary, magnetic resonance imaging (MRI) to directly assess volumes. Such information cannot be adequately derived from reading clinical reports. Previous diagnostic hysteroscopy may also inform the surgeon's evaluation, and in environments with different diagnostic protocols or where TVUS is unavailable, diagnostic hysteroscopy may be the primary or sole means of diagnosis. However, diagnostic hysteroscopy alone cannot be used to evaluate the myometrium and uterine serosa to evaluate Müllerian anomalies or to distinguish Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) type 2 leiomyomas that can be safely removed hysteroscopically from those that require an alternative approach, such as type 2-5 lesions.

Patient Identification

Endometrial Polyps

Women with endometrial polyps typically present with infertility or intermenstrual or spontaneous postmenopausal bleeding. The presence of abnormal uterine bleeding (AUB) should prompt the acquisition of a detailed history and performance of a targeted physical examination designed to evaluate the patient for the spectrum of potential causes or contributors to the symptoms. For polyps, a key component of this investigation is TVUS, ideally including the instillation of saline or gel fluid contrast, a study called SHG. This process is as effective and sensitive as diagnostic hysteroscopy and can be quickly and easily performed by the gynecologist in an office setting, allowing for polyp identification and efficient procedure planning. The size and number of polyps will help inform gynecologic surgeons about the surgical requirements, including the necessary equipment and, if applicable, the procedural setting.

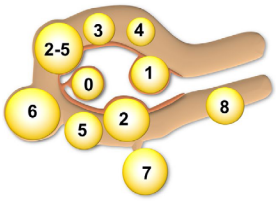
Leiomyomas

Patients with submucous leiomyomas typically present with infertility and/or heavy menstrual bleeding. Although the presence of leiomyomas may be suggested by physical examination, it is more likely that TVUS or diagnostic hysteroscopy will be the initial method of identification. Critical to treatment planning is the characterization of the leiomyomas according to their size, number, and relationship to the endometrial cavity and uterine serosa using the FIGO leiomyoma subclassification system (**Figure**).[1] Small, single FIGO type 0 and superficial type 1 myomas of less than 3 cm in diameter are relatively simple to remove using the MyoSure system, whereas deep type 1 myomas, type 2 myomas, and large or multiple coexisting submucous tumors present clinical challenges. Type 3 myomas are generally difficult to remove using any hysteroscopic technique, and it is important for the surgeon to identify the presence of type 2–5 leiomyomas as these must be approached differently, most often abdominally via laparoscopy or laparotomy. It is also important to differentiate leiomyomas from adenomyomas[2] as the latter require techniques for effective removal that are highly individualized and still in development.

Figure. FIGO Leiomyoma Classification Subsystem[1]

FIGO Leiomyoma Subclassification System

Polyp		**C**oagulopathy
Adenomyosis		**O**vulatory dysfunction
Leiomyoma	**Sub**mucous	**E**ndometrial
Malignancy & hyperplasia	**O**ther	**I**atrogenic
		Not otherwise classified



SM-Submucous	0	Predunculated intracavitary
	1	<50% intramural
	2	≥50% intramural
	3	Contacts endometrium; 100% intramural
O-Other	4	Intramural
	5	Subserous ≥50% intramural
	6	Subserous <50% intramural
	7	Subserous pedunculated
	8	Other (specify, eg, cervical, parasitic)
Hybrid	Two numbers are listed, separated by a hyphen. By convention, the first number refers to the relatioship with the endometrium while the second refers to the relationship to the serosa. An example is given below.	
(Contacts both the endometrium and serosal layer)	2-5	Submucous and subserous, each with less than half the diameter in the endometrial and peritoneal cavities, respectively.

Characterization of submucous leiomyomas requires some combination of TVUS, SHG, and MRI. Diagnostic hysteroscopy also has a role, although on its own, it is limited with respect to determining the myometrial involvement of leiomyomas, including identification of the presence of the type 2–5 tumors not appropriate for hysteroscopic surgery. Endoscopic evaluation of the endometrial cavity also has limited utility for identifying arteriovenous malformations or adenomyomas. These limitations can be addressed if diagnostic hysteroscopy is coupled with transabdominal ultrasound to aid in this process, although this approach can be compromised in women who are obese or when the uterus is retroverted and retroflexed.

The outer free margin (OFM) is that zone of myometrium that exists between the deepest aspect of the leiomyoma and the uterine serosa. The minimum acceptable OFM varies from surgeon to surgeon depending in part on their degree of expertise, but it generally is about 5 mm for most skilled operators.[3,4] Although TVUS, and especially SHG, is often sufficient, available evidence suggests that MRI may be best for characterizing the myometrial involvement of leiomyomas and may be particularly helpful in identifying type 2–5 tumors or deep type 2 fibroids in which the myoma or OFM is below the threshold of safety.[5,6]

Retained Products of Conception

Identification of patients with RPOC requires the combination of an index of suspicion combined with TVUS, SHG, and/or diagnostic hysteroscopy. The ideal circumstance is the patient with a delayed presentation, when bleeding is not acute and heavy and when the uterus has involuted to an acceptable size and the cervical canal is narrow enough to both facilitate effective hysteroscopic access and maintenance of intrauterine pressure for visualization. Acute and immediate postpartum hemorrhage or any hemorrhage that is high volume (with or without evidence of hypovolemia) should be managed with different techniques as appropriate to the clinical situation.

MyoSure-Based Surgical Procedures

Large or Multiple Endometrial Polyps

Relatively small endometrial polyps of 1.5 cm or less in maximum dimension can effectively be removed under hysteroscopic direction by any of a number of techniques, including the MyoSure MANUAL or the MyoSure LITE devices. However, large polyps, particularly those greater than 3 cm in diameter, and multiple polyps present challenges to the clinician. The “traditional” techniques for dealing with these circumstances have typically involved the use of a monopolar or bipolar RF uterine resectoscope fitted with a loop electrode to morcellate and remove the tissue. Although this is generally an effective technique, it may be more difficult to perform in a procedure-room environment under local anesthesia. In addition, for multiple polyps, the impact of RF energy applied to multiple locations may have an adverse impact for patients desiring to preserve or enhance fertility. The use of electromechanical morcellation may be a superior approach in this circumstance as treatment times are short compared with other techniques,[7] and the minimization of RF use would, at least hypothetically, reduce trauma in cases of multiple endometrial polyps.

Deep Type 1 and Type 2 Submucous Leiomyomas

Hysteroscopic removal of deep type 1 and type 2 leiomyomas has always been a challenge for the hysteroscopic surgeon, and it is clear that if surgical removal is appropriate, some of these tumors should be dealt with via an abdominal approach (laparoscopic or laparotomic). Such circumstances exist with large tumors, generally defined as those greater than 5 cm in diameter, or when the OFM is below the threshold of comfort for the surgeon, which typically falls somewhere between 5 and 10 mm for experienced surgeons.

The side-fenestration design of the MyoSure and similar systems is effective for anterior, posterior, and laterally located FIGO type 0 and superficial type 1 leiomyomas. However, when the MyoSure device is used alone, removal of deep type 1 and type 2 tumors in these locations is difficult and, in some instances, impossible. Similarly, even fundally located, superficial type 1 myomas may not be accessible, despite design modifications to the MyoSure REACH device. RF resectoscope-based techniques face similar but not identical limitations and difficulties.

A number of approaches to this problem have been proposed and developed since the early 1990s, aiming to facilitate the effective and efficient removal of these tumors in a single surgical session when possible. Some approaches simply involve repeating the same procedure several times, typically with 1–2 months between operations, relying on the myometrium to contract and push the remaining leiomyoma into the endometrial cavity.[8] Other approaches have involved a primary procedure to create an incision into the pseudocapsule and a secondary procedure, eg, 2 months later, in which an RF needle, laser, or electromechanical system is used to

complete the extraction of the tumor.[9,10] Still others have used blunt dissection in the pseudocapsule following initial partial resection, which is, in turn, followed by electrosurgical morcellation and removal.[11,12]

We have described a technique using an RF needle to incise into the pseudocapsule, blunt dissection within the pseudocapsule, and then morcellation and extraction using the MyoSure electromechanical system.[13] This approach has allowed us to remove the spectrum of deep type 1 and type 2 leiomyomas up to 5 cm in diameter, regardless of location, and usually in a single session. This experience has been acquired only in an office environment using local anesthetic techniques.[14] How this procedure will function in an operating room under general anesthesia is unclear. Dissection into the pseudocapsule preserves myometrial integrity but can also enhance systemic absorption of distension media, making continuous monitoring of distension media mandatory. Should the predetermined maximum allowable deficit be reached prior to completion of the myomectomy, the procedure is stopped and completed at a later date.

A video description of the pseudocapsule incision technique has been published in the medical literature.[13] It is important that, in addition to a detailed imaging evaluation, patients are medically prepared prior to any myomectomy. Such preparation should generally be at least 4 weeks in duration and may take the form of systemic progestins (eg, medroxyprogesterone acetate 20 mg twice daily), combined estrogen-progestin contraceptive preparations (oral or vaginal administration), or gonadotropin-releasing hormone (GnRH) agonists, as appropriate. GnRH agonists may also reduce the volume of the leiomyomas, as well as improve visualization by reducing myometrial perfusion, and reduce the volume of systemic absorption.[15]

Intraoperatively, there is often value in performing a transabdominal ultrasound simultaneously with myomectomy of type 2 tumors.[16] This approach may directly facilitate removal in some instances and may also reduce the risk of perforation, particularly when the OFM is relatively thin.

Another circumstance arises when a patient has multiple submucous leiomyomas. The surgeon should carefully evaluate their location and plan a staged process with two or more procedures when myomas lie across from one another in the endometrial cavity. Such an approach should reduce the incidence of intrauterine adhesions by allowing each endometrial surface to regenerate independently.

Retained Products of Conception

Hysteroscopic technique in the management of RPOC remains an evolving process. It is recognized that most cases of Asherman syndrome are related to the use of uterine curettage in women with delayed postpartum or postabortal hemorrhage associated with RPOC.[4,17,18] There is also evidence that hysteroscopically directed removal may be superior to blind evacuation of the uterus when the presence of intrauterine adhesions is used as an outcome.[4] However, the differential impact on future fertility has not been directly studied. Nevertheless, it seems clear that intrauterine trauma can be minimized with hysteroscopic technique, and the MyoSure system, in addition to other side-fenestration systems, is well designed to meet this challenge.[19]

Conclusions

The MyoSure system can be used to remove endometrial polyps and leiomyomas that challenge the hysteroscopic surgeon, often in an appropriately equipped office procedure room under local anesthesia. For most type 1 and type 2 leiomyomas, the process is made more feasible, or at least is optimized, with the use of additional instrumentation. The role of hysteroscopy in the management of RPOC is still under evaluation, but it is apparent that it may have compelling advantages over other techniques. The MyoSure system is designed to optimize the targeted removal of such of tissue while minimizing trauma to the normal endometrium. It remains critical that the surgeon appropriately evaluates all women with any of these disease entities before performing hysteroscopy, regardless of the location of the procedure. This evaluation should include the direct examination of images whether they are based on ultrasound, diagnostic hysteroscopy, or MRI techniques.

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MyoSure for Improving Fertility Outcomes

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Introduction

I have been practicing in the area of reproductive health since 1990 and currently see approximately 400 new patients per year. My work is primarily focused on helping patients achieve conception, and the surgical procedures I perform are typically secondary to that goal. Most of these procedures involve addressing intrauterine pathologies, since optimizing conditions in the uterus is likely to have a beneficial effect on fertility.[1] Submucosal fibroids, in particular, represent a high risk for pregnancy loss, and although the risk associated with asymptomatic polyps is less clear, the fact that the endometrium overlying these polyps is abnormal and associated with substantial inflammation means that uterine polyps may have a negative impact on fertility. In the context of a patient who is already struggling to conceive, optimizing the uterine cavity is usually a standard part of an infertility treatment plan.[2]

There are no randomized controlled trials that have examined the precise influence of uterine pathologies on either spontaneous or assisted conception, but numerous studies have demonstrated a correlation between normalization of the uterine cavity through the removal of abnormalities and both higher rates of successful conception—via intrauterine insemination (IUI) or in vitro fertilization (IVF), or spontaneously—and lower rates of pregnancy complications.[2-8] Moreover, hysteroscopic polypectomy, in advance of IUI or IVF, has been shown to be cost-effective, low risk for most patients, and well-tolerated, whether performed in the operating room (OR) or in an office setting.[3,9-11] Given the benefits of the MyoSure procedure and the high degree of patient tolerance, normalization of the uterine cavity via hysteroscopy makes sense for the vast majority of infertility patients with submucosal fibroids and uterine polyps.

MyoSure Device

I use the MyoSure device to treat intrauterine abnormalities in my patients. The MyoSure technique is a minimally invasive outpatient procedure that can be performed relatively quickly; as such, it is associated with very little patient discomfort or recovery time, which benefits patients as well as surgeons.[10] This technology constitutes a dramatic advance in the field compared with older techniques, such as dilatation and curettage, and older hysteroscopic instruments, which is why it is surprising that more surgeons are not taking advantage of it. Many clinicians still employ blind dilatation and curettage, typically sampling less than half of the endometrial lining and almost never removing all the pathologies present in the uterus.[12] This often means that they are not solving the problem but simply delaying it.

I have been practicing long enough that I have direct experience with the older, more primitive methods of treating intracavitary pathologies. I have performed blind dilatation and curettage, blind uterine polypectomy, contact hysteroscopy, CO_2 hysteroscopy, Hyskon hysteroscopy, and hysteroscopy using both unipolar and bipolar resectocopes. Like others, I have used polyp forceps and microscissors and found them to be entirely inadequate with respect to the likelihood of complete removal and the time required for resection. Indeed, a study comparing polypectomy with grasping forceps or microscissors versus polypectomy by resectoscope found an increased rate of polyp recurrence when either forceps or microscissors were employed.[13] Anyone who has performed uterine polypectomy in this way understands the frustration of chasing a soft polyp around the uterine cavity, which is like trying to grab a small, greased piglet that does not want to be caught. Once you finally have a good grasp, the instruments remove very little tissue and only with a struggle akin to pulling teeth. In my experience, it is very unlikely that one pass with hysteroscopic graspers or scissors will completely remove the pathology. Thus, the surgeon must spend an inordinate amount of time repeating the process, chasing the polyp and struggling to make repeated small bites in a frustrating effort to remove it. In contrast, using the MyoSure device, which also provides suction and aspiration, is like having a skilled second assistant inside the uterus. It holds the pathology still while engaging a morcellating action that is smooth and simple to control, which in turn facilitates simple and quick removal of the pathology. For resecting intrauterine fibroids and polyps, it is exactly what I need to quickly and effectively remove all pathology in an easy and elegant way, making the overall experience far better—not just for me, but also for my patients.[3]

The efficacy of the MyoSure procedure in treating uterine pathologies in a fertility setting was the subject of a retrospective case series study of which I was a coauthor. The study included 62 patients with uterine pathologies from two different clinics—

including 33 from my own institution—who were either infertile or who had experienced recurrent pregnancy losses.[1] All patients underwent removal of intrauterine pathology with the MyoSure tissue removal system; the primary outcomes were subsequent rates of pregnancy and live births. Of the 62 patients, 44 became pregnant after the MyoSure procedure, a significantly higher rate than the baseline pregnancy rate ($P<0.0001$). Six of these 44 became pregnant a second time after miscarrying, for a total of 50 pregnancies (**Table**). Thirty-nine (89%) of the initial 44 patients who became pregnant delivered a healthy infant. From the 44 patents who became pregnant, 67 lesions were observed. Of these, 47 (70%) were polyps, 14 (21%) were fibroids, and 6 (9%) were another type of lesion, such as synechiae.[1]

Table. Fertility Outcomes in Patients Undergoing the MyoSure Procedure[1]

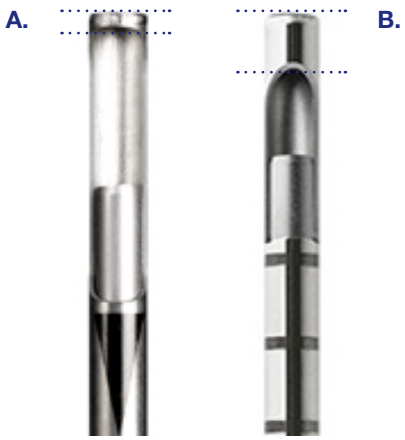
Pregnancy, n (% of patients)	**44 (71)**
Mean time to pregnancy, months	8.4
Time range, n (% of pregnancies)	
1–3 months	12 (27)
4–6 months	9 (20)
7–12 months	13 (30)
>12 months	10 (23)
Mean age at pregnancy, years	36.8
Age >35 years, n (% of pregnancies)	26 (59)
Total pregnancies [including second pregnancies], n	**50**
Live birth, living child, n (%)	39 (78)
Stillbirth, antepartum [>20 weeks], n (%)	2 (4)
Spontaneous abortion [≤20 weeks], n (%)	7 (14)
Ectopic pregnancy, n (%)	1 (2)
Ongoing at last follow-up, n (%)	1 (2)

Advantages of the MyoSure System in the Fertility Setting

Because I work specifically in the fertility setting, patients generally come to my department as referrals. Almost all of my patients receive a uterine cavity evaluation, either a saline hysterosonogram or a hysterosalpingogram, and all of them get a pelvic sonogram. Patients who have a uterine abnormality on imaging will then undergo a hysteroscopy. The imaging gives me a good idea of what I am going to encounter before surgery.

When performing a MyoSure procedure, I like to use a thin instrument, such as the Omni hysteroscope or MyoSure hysteroscope, to minimize the amount of dilation, since most of my patients are infertile and are, thus, usually nulliparous. For most procedures, I use the MyoSure REACH device, and I rely on the MyoSure LITE device for polyps. When treating particularly large lesions, I may use the MyoSure XL device. I have, on occasion, used the TruClear morcellator device, but I prefer the MyoSure device because of its excellent visualization and ease of use. The blade window of the MyoSure REACH device extends nearly to its tip (**Figure**), leaving a very small dead space of less than 1 mm, which makes it well suited for most intracavitary fibroids, in addition to it being thinner and less bulky than the larger TruClear device.[14,15]

Figure. Comparison of Distal Ends of the (A) MyoSure REACH Device and (B) TruClear Dense Tissue Shave Mini



Perforations are very rare[16-19] with the MyoSure device, in part due to avoidance of the electricity associated with resectoscopes (either unipolar or bipolar), and because the surgeon does not have to continually insert and remove the device to clear out chips, as required when using a resectoscope. With the MyoSure system, the suction function removes the blood and debris from the uterine cavity, facilitating direct visualization and making the procedure easier to perform, while decreasing operating time.[14,20] Direct visualization is further enhanced by the excellent MyoSure optics and has the additional advantage of reducing the risk of perforations.[11,17] Adhesions (synechiae) are also rare with the MyoSure system, particularly compared with resectoscopes, because the MyoSure device does not cause thermal damage to the lining of the uterus.[1,17]

Bleeding

A major concern of mine when I transitioned from using a resectoscope to using a morcellator was how to handle bleeding, since a feature of the resectoscope is that the electrical current allows for coagulation. I was pleasantly surprised to find that, in fact, there was not much difference in the rate of bleeding when performing a MyoSure procedure compared with performing a procedure using a resectoscope.[21] When I do anticipate heavier bleeding, as with particularly large vessels, there are ways of

minimizing it through preoperative use of an agent such as norethindrone or a gonadotropin-releasing hormone agonist such as leuprolide, or the intraoperative use of vasopressin (if the anesthesiologist has approved it for the patient) administered either into the cervix or into the fibroid directly with a Cook needle (Cook Medical, LLC, Bloomington, IN).[22] I employ a 7 French gauge Cook needle with a length of 240 cm (model LDVI-25-240).

Patient satisfaction with the MyoSure procedure is high, and recovery time is short.[10,11,17] In my setting, I use anesthesia and advise patients to avoid working the day of surgery and the day after. However, if anesthesia is not administered, patients will generally be able to return to work the day after the procedure. During the day of surgery, patients may experience some bleeding and cramping. Beyond that, I advise patients to avoid sex, swimming, and baths for a week or two after the procedure. Depending on how much resection was performed and the patient's individual characteristics, I may use adjuvant therapy to decrease the risk of postoperative adhesions, such as an intrauterine stent (pediatric Foley), postoperative estrogen (if deep-vein thrombosis risk is low), and antibiotics.

Conclusions

The MyoSure device is an easy instrument to use and easy to learn. In my case, as with many surgeons, I had performed a large number of hysteroscopies before I switched to the MyoSure device. With that previous experience, using instruments and devices far more difficult than the MyoSure procedure, I found it very easy to adapt to the device, and it is certainly far easier to use than a resectoscope. Taken together, the MyoSure device is a remarkable tool that resolves significant intrauterine pathology very easily and effectively with very little morbidity or complications, and I would encourage others to try it.[10,11,17,21] Considering that MyoSure simulators are available, it is easily accessed and can be learned relatively quickly. I have found it useful to start on simple cases, such as small polyps in healthy patients with otherwise normal anatomy, and leverage the expertise of Hologic representatives, who are extremely helpful with OR setup and equipment setup, orientation, and troubleshooting, in addition to intraoperative troubleshooting and helpful tips and tricks for specific situations.

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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.

HOLOGIC®

MyoSure® Tissue Removal Simplified