



THE MORCELLATION CONTROVERSY

Laparoscopic dual-port contained power morcellation: An offered solution

↘ Poor visualization is a criticism of large specimen removal through a minimally invasive approach. This technique improves visualization while preventing inadvertent spread of tissue.

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Minimally invasive surgery utilizing laparoscopy for hysterectomy and myomectomy has become more common in women with gynecologic pathology. The benefits of this approach compared with laparotomy include decreased hospital stay, shorter recovery and, in experienced hands, significantly decreased morbidity.¹⁻³

Approximately 600,000 hysterectomies are performed annually in the United States—30% of which are performed laparoscopically.⁴ The primary indication for surgical intervention is uterine leiomyoma. This pathology accounts for 40% of procedures.⁵

During these surgeries, electromechanical morcellation (EMM), or open “power”

morcellation, is commonly used to cut large tissue specimens into small pieces for removal and thereby avoid a larger incision. Concerns have been raised regarding the use of open power morcellation because of the risk of spreading an unrecognized malignancy.

Based on case reports and retrospective studies, the FDA issued a statement in April of this year discouraging the use of EMM for hysterectomy and myomectomy in women with uterine fibroids.⁶ The concern for inadvertent spread of an occult malignancy was the reasoning for the communication. Since that time, the FDA’s Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee held a public meeting in which the panel heard comments from patients, societies, and industry regarding their positions on the safety of laparoscopic power morcellation. The panel made several recommendations to the FDA but, at the time of this writing, the FDA has yet to issue a final decision.

Reaction to FDA’s action/inaction

The FDA’s “safety” communication was in response to the concern of a few who experienced a bad outcome believed to be secondary to open power morcellation of enlarged uteri or fibroid tumors. In its statement, the FDA estimated the risk of an occult sarcoma to be about 1 in 350 and stated that the risk

**IN THIS
ARTICLE**

Tissue extraction options for large specimens
page 15

Containment bag placement
page 16

Morcellator insertion
page 17



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of disseminating a sarcoma with morcellation is substantial. The FDA discouraged the use of the power morcellator during hysterectomy or myomectomy for uterine fibroids.

Many organizations, including the Society of Gynecologic Oncology, The American Association of Gynecologic Laparoscopists (AAGL), and the American College of Obstetricians and Gynecologists, issued less stringent statements regarding this technology.⁷⁻⁹ These organizations stated generally that there were too few data to make a statement at that time, advocated the collection of more data, and encouraged detailed informed consent to be given to patients undergoing these procedures.

However, the FDA's statement, and lack of a timely follow-up to clarify the role of the laparoscopic power morcellator in gynecologic surgery, has effectively stopped the use of this technology in its current form. In fact, in response to the statement, Ethicon Endosurgery has discontinued the distribution and sales of its power morcellator and many institutions have severely or completely restricted the use of this technology. The reason for these restrictions is that the medicolegal consequences of an adverse outcome would be very difficult to defend given the current, albeit premature, recommendations of the FDA. This statement makes it difficult to defend any adverse outcome that may occur in association with the use of the laparoscopic power morcellator. Furthermore, this statement by the FDA has largely prevented the medical community at large from collecting additional useful information to allow for a data-driven determination.

Power morcellation is not without risks. In fact, we outline them in this article. However, we believe that minimally invasive surgery should be allowed to continue to advance. In that vein, here we describe a technique of dual-port contained EMM. This surgical approach is performed under direct visualization—which solves the problem of poor visualization that hinders other contained EMM techniques.

Risks of power morcellation

The potential for inadvertent **spread of occult malignancy** is not the only risk of open EMM. Reports of disseminated leiomyomatosis, adenomyosis, and endometriosis also have been described from inadvertent tissue dispersion during open EMM with resulting **ectopic reperitonealization**.¹⁰⁻¹²

The procedure itself is not without risks. A recent systematic review documented 55 major and minor complications from EMM.¹³ Multiple organ systems were injured including bowel, urinary, vascular, and others, resulting in six deaths from these complications. The investigators concluded that “laparoscopic morcellator-related injuries continue to increase and short- and long-term complications are emerging in both the medical literature and device-related databases. Surgeon inexperience is descriptively identified as one of the most common contributing factors.”

All of the above risks must be weighed against the known benefits of laparoscopic surgery and presented to each patient to assist in deciding which route of surgery should be performed.

Tissue extraction options for large specimens

Large specimen extraction options during gynecologic surgery include:

Vaginal coring. Delivery through the vagina or colpotomy during vaginal or laparoscopic hysterectomy uses the technique of coring, which has long been established in our field.

Manual morcellation through a single incision. Mini-laparotomy or laparoendoscopic single-site surgery (LESS) incisions provide another option of removal with manual morcellation after laparoscopic hysterectomy or myomectomy. One study revealed that specimens up to 22 weeks in size can be placed in a large EndoCatch bag and morcellated extracorporeally by circumferentially coring with a scalpel.¹⁴

Contained power morcellation through a single port. Finally, the technique of contained EMM was recently described.¹⁵ This technique uses a large containment bag



The FDA has effectively stopped the use of laparoscopic power morcellation based on case reports and retrospective data, preventing the collection of more, useful data



FIGURE 1 Morcellator



Karl Storz Rotocut G2 Morcellator with spacers.

placed through a LESS incision with EMM being performed in an artificially created pneumoperitoneum. This technique isolates the specimen so that it can be morcellated without risk of exposing the patient to any malignant cells that might be unrecognized within the specimen.

Each of these techniques allows many patients to consider a minimally invasive option for their surgery. However, the ability to safely morcellate a very large uterus or myoma may be limited by visualization, and the experience of the surgeon is often critical in the successful performance of these procedures.¹⁶

Therefore, at Washington University-

FIGURE 2 Containment bag



20×20-inch bag is drape film—durable and resistant to fluid strike-through to keep contents secure, yet soft enough to be gentle on organs and tissues.

we have developed a technique using dual ports, with isolation of the uterus or myomas to improve visualization and prevent spillage of malignant tumor or dispersion of other benign tissue.

Dual-port EMM: Technique, tips, and tricks

Our technique of dual-port contained EMM allows the removal of large fibroids or uteri much larger than 20 weeks in size safely under direct visualization through a 15-mm incision. The technique uses:

- Karl Storz Rotocut tissue morcellator with spacers (**FIGURE 1**)
- 15-mm trocar
- 5-mm balloon trocar
- 20×20-inch containment bag (**FIGURE 2**).

Containment bag placement

Once the specimen is free, we place it to the right or left side of the abdomen. The 15-mm trocar is placed through the umbilicus while visualizing from a lateral trocar site. We then fan-fold the containment bag and introduce it through the 15-mm trocar, keeping the bag oriented with the opening anterior (**FIGURE 3**). The bag is then grasped at the opening along the drawstring with an atraumatic grasper.

TIP: Care must be taken when introducing the bag in order to avoid tearing or making a small hole in it.

The leading edge is then introduced into the deepest part of the pelvis, and the remainder of the bag (left outside of the abdomen) is then fed cephalad into the abdomen.

Once the bag is completely in the abdomen, we orient the bag with the opening as wide as possible. This allows placement of a very large specimen. Once the specimen is within the containment bag, the drawstring is pulled tight and the mouth of the bag is removed through the 15-mm trocar site at the umbilicus.

The abdominal lateral gas port is opened to allow the intra-abdominal pneumoperitoneum to escape. A 5-mm trocar is placed into the bag through the opening at the umbilicus and the containment bag is insufflated with



For this technique, a containment bag is introduced through a 15-mm trocar at the umbilicus while visualizing from a lateral trocar site

FIGURE 3 Containment bag insertion



Keep the containment bag opening oriented anterior when introducing it through the 15-mm trocar.

carbon dioxide and the insufflation pressure is set to 30 mm. The laparoscope placed through this trocar allows the artificial pneumoperitoneum being created to be observed (VIDEO).

TIP: The containment bag covers the entire abdominal cavity and should be fully distended. If it does not distend fully, a hole in the bag may be present and the bag must be replaced.

At this point, we place a balloon trocar at the lateral trocar site and into the bag under direct visualization. The balloon tip is inflated and pulled up tightly against the bag and abdominal wall (FIGURE 4). This allows a tight seal so there is no gas leak or spillage of the morcellated specimen. The laparoscope is placed through this trocar and the insufflation tubing is moved to this port.

Morcellator insertion

The morcellator is introduced through the umbilicus under direct visualization using the short morcellator blade in most instances. Spacers are used to set the length of the morcellator within the containment bag. The tip of the morcellator should be approximately 3 cm to 4 cm within the bag but well away from the retroperitoneum. Remember, **any bag will be cut easily by the morcellator and should be thought of as peritoneum only and not a tough barrier.** Serious injuries could otherwise develop.

At this point, place the patient flat or out of Trendelenburg position. Morcellation may now proceed.

TIP: Morcellation is best performed with the morcellator perpendicular to the abdomen under direct visualization using a 30° laparoscope to optimize the view. Morcellation in this position uses gravity to facilitate “peeling” of the specimen during morcellation and allows for faster removal.

Before removing the morcellator, inspect the containment bag for any large pieces that may have been dispersed during the morcellation process and remove them. Once there are only small fragments remaining, remove the morcellator, allowing the carbon dioxide to escape. Deflate the balloon tip on the trocar.

Now the containment bag with the remaining specimen may be removed through the umbilicus, while simultaneously removing the balloon-tip trocar from the bag.

A safe minimally invasive approach

This technique has allowed us to safely remove specimens larger than 1,500 g while keeping them in a contained environment with no spill of tissue within the abdomen.

Tracking and adaptation needed

The FDA safety communication has severely limited the practice of morcellation in the minimally invasive gynecologic surgical setting. Many hospitals around the country have reacted by placing significant restrictions on the use of EMM or banned it outright. This action may reverse the national trend of increasing rates of laparoscopic hysterectomy

WATCH THE VIDEO!

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*Free QR readers are available at the iPhone App Store, Android Market, and BlackBerry App World.



FIGURE 4 Inflated balloon trocar




A. Direct visualization of a balloon trocar, placed at the lateral trocar site and into the containment bag. A tight seal is achieved by inflating the balloon tip and pulling it tightly against the bag and abdominal wall. **B.** Kii Advanced Sleeve (Applied Medical).

CONTINUED ON PAGE 24



and force many practitioners to return to open surgery.

Currently, it is unclear what the true risk of tissue extraction is whether it is performed via EMM or manually. Large national databases including the BOLD database from the Surgical Review Corporation, as well as AAGL, must be initiated to track these cases and their outcomes to guide therapy. In the meantime, in order to continue to offer a minimally invasive approach to gynecologic surgery, new techniques and instrumentation in the operating room will need to be modified to adapt to these new guidelines. This is vital to maintain or even reduce the rates of open hysterectomy and associated morbidity while diminishing the potential risks of inadvertent benign as well as malignant tissue dispersion with tissue extraction. 

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