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INSTRUMENT REVIEW

# Gynecare Morcellex Sigma®

## Manufacturer: ETHICON Women's Health & Urology, A Division of ETHICON, INC., a Johnson & Johnson company, Somerville, NJ 08876-0151, USA, © ETHICON, INC. 2005

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The use of electronic power morcellators in gynecological laparoscopy has been long established. New trends in treatment approaches for intramural and subserosal uterine myomas, and most importantly the introduction of laparoscopic supracervical hysterectomy, required development of new advanced systems, which further simplified the application of safe and efficient morcellators [1, 2].

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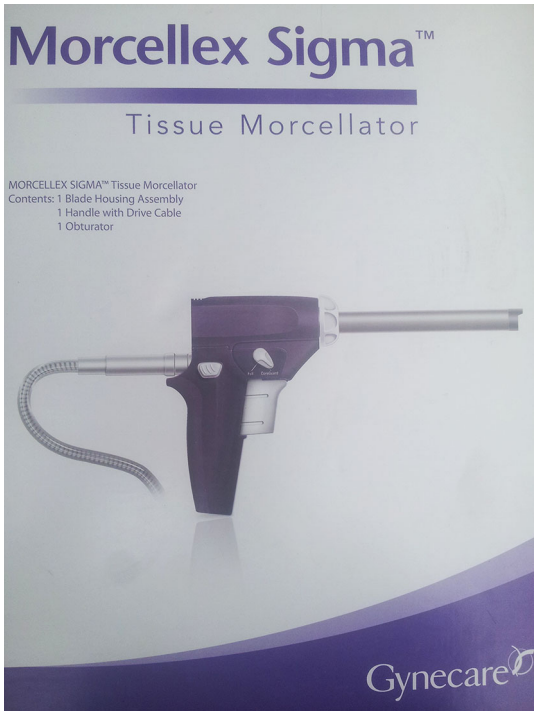
In the last few years, laparoscopic surgeries together with the more recent addition of robotic surgeries have allowed us to perform advanced operations in the gynecological field, including resection of large uteri up to 22 weeks (measured as size of a pregnant uterus) either total hysterectomy or supracervical hysterectomy and dissection of large and many uterine myomas. In such cases, the use of a well-designed morcellator is paramount for the ease of the patient (i.e., less operation/anesthesia time, no need for laparotomy, etc.) and for the surgeon (i.e., lightweight- 479 gr, ergonomically adapted) [2–4].

The Gynecare Morcellex Sigma is a brand new tissue morcellator designed for the above-mentioned purposes [2, 4]. The fibroid uterus can have multiple myomas which vary in size, shape, and consistency. The surgeon has to overcome these challenges. The Gynecare Morcellex Sigma is a third-generation morcellator (Diva-1999, Morcellex-2006)




engineered and built by Johnson and Johnson, USA. It is a single-patient-use device. The device is inserted into the patient with the use of a provided obturator. The device allows tissue to be grasped with a standard grasping instrument extended through its lumen. The tissue can be drawn up inside the device's central lumen into the inner stationary sheath as the exposed blade cuts the tissue. The surgeon can activate the morcellator via a foot pedal or via hand trigger in the detachable handle. The device can operate in either coring or peeling mode based on the degree of exposure of the blade and placement of the rotatable coreguard. The device has a reducer cap to allow acceptance of 5–12 mm instruments without the loss of pneumoperitoneum. The morcellator is connected by cable to a variable-speed, reversible generator named Motor Drive Unit (MDU) which drives the rotation of the blade at a controlled speed and direction.

The morcellator is engineered for the utmost reliability and performance. Not only does it provide for smooth, efficient tissue morcellation, but it also eliminates many of the challenges often associated with the procedure. It allows ultimate precision through the intuitive trigger which automatically exposes and activates the blade. The morcellator facilitates the surgeon in morcellating tissue and removes it through small abdominal incisions. As a result, patients experience less pain, minimal scaring, and a faster return to normal activity.

Among its advantages, the morcellator reduces the operative time and the risk of hernia formation. The latter is because of the absence of tearing or stretching of the fascia. The speed of the blade is four times faster than those of the previous generations, and the durability of the blade is longer as well. This is especially important in cases of large uteri and calcified myomas. The speed range is 125–1,000 rpm. The sleeve length is 13.5 cm, which is shorter in order to act closer to the abdominal wall and reduce the risk of injury to related intra-abdominal organs.

In April 2014, the Food and Drug Administration (FDA) announced the following concerning laparoscopic uterine power morcellation in hysterectomy and myomectomy [5]. Based on the FDA analysis of currently available data, it is estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma, a type of uterine cancer that includes leiomyosarcoma or endometrial stromal sarcoma.

If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, then there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's likelihood of long-term survival. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids.

The AAGL (Advancing Minimally Invasive Gynecology Worldwide) reply was that the association encourages future research and development as well as anticipates continued improvements in safety for all patients.

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