Vol. 3 Issue 3 (Dec 2014)

MEDICAL DEVICE Alert

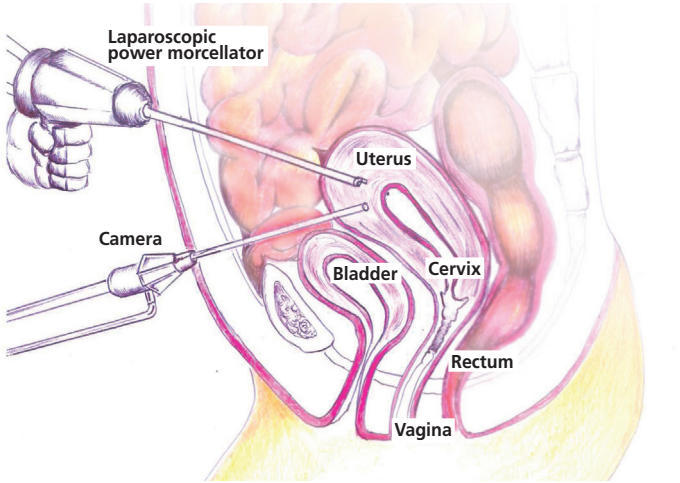
# Risk of spreading unsuspected uterine sarcoma following use of laparoscopic power morcellators in the removal of uterine fibroids

HSA would like to provide an interim update on the latest outcomes from the US Food and Drug Administration's (FDA) review on the potential risk of spreading unsuspected uterine sarcoma following use of laparoscopic power morcellators (LPMs) in the removal of uterine fibroids. HSA is currently conducting a benefit-risk assessment of this safety concern and will update healthcare professionals on the outcome of our review when it is completed.

## Use of laparoscopic power morcellators in the removal of uterine fibroids

Among the options to treat uterine fibroids, surgical interventions such as hysterectomy or myomectomy are considered the most common. These procedures may be performed by traditional large incision surgeries or via minimally invasive laparoscopic procedures. In hysterectomy and myomectomy procedures, LPMs may be used, and surgeons have been using these devices to treat symptomatic uterine fibroids since their introduction in the 1990s.

LPMs are electrical surgical instruments used for laparoscopic surgeries, including general and gynaecologic surgeries. They break up bulky mass, by means of a tube-shaped blade, for retrieval through the abdomino-pelvic cavity. These minimally invasive techniques were developed as an alternative to traditional surgery, and offer the advantages of less bleeding and pain, lower risk of overall morbidity and mortality, and shorter hospital stays.[1]




***Picture illustration of the use of laparoscopic power morcellator in gynaecologic surgery***

## Review by US Food and Drug Administration (FDA)

On 17 April 2014, the US FDA issued a safety alert on the increased risk of spreading unsuspected cancer tissue with the use of LPMs and advised against the use of LPMs for the removal of uterine fibroids. This advice was made in consideration of the potential for LPMs to spread previously undetected cancer cells in the abdomino-pelvic cavity as well as the lack of reliable methods to accurately detect and differentiate uterine sarcoma (or other malignancies) from non-malignant fibroids preoperatively.[2]

The US FDA's review estimated that 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids was found to have an unsuspected uterine sarcoma, whereas previous estimates had put the rate closer to 1 in 7,000. Of the cases where the uterine sarcoma was not detected, spreading or upstaging of the unsuspected cancer may occur in approximately 25 - 65 % of these cases. Outcomes of the review suggested that the use of LPMs during uterine fibroid removal procedures may spread the undetected cancer within the peritoneal cavity, potentially worsening the patient's prognosis and likelihood for long-term survival.[3]

In November 2014, the US FDA issued a safety communication to warn against the use of LPMs in the majority of women undergoing myomectomy or hysterectomy for treatment of uterine fibroids.[4] This was in view of the risk of spreading unsuspected cancer and the availability of alternative surgical options for most women Manufacturers of LPMs were recommended to strengthen their product labelling in accordance to the US FDA's Immediately in Effect (IIE) guidance.

The US FDA advised healthcare professionals to be aware of the following[4]:

- LPMs are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are
  - peri- or post-menopausal
  - candidates for en bloc tissue removal, e.g., through the vagina or mini-laparotomy incision.
- LPMs are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.
- The use of LPMs during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

## Local situation

There are several LPMs registered locally for use in general surgeries and gynaecology (Table 1).

***Table 1. Registered LPMs and their distributors***

| Device Name | Product Owner / Local Distributor |
|---|---|
| • Rotocut Morcellator<br>• Sawalhe Morcellator | Karl Storz GmbH & Co. KG / Karl Storz Endoscopy Singapore Sales Pte Ltd |
| • PlasmaSord Morcellator<br>• VarioCarve Morcellator | Olympus Winter & Ibe GmbH / Olympus Singapore Pte Ltd |
| • Morce Power Plus Electronic Morcellator | Richard Wolf GmbH / Servicom Medical (Singapore) Pte Ltd |

To date, HSA has not received any local adverse event report on the spread of unsuspected uterine cancer associated with the use of a LPM.

HSA is closely monitoring the international developments on this issue and has embarked on a review of the use of LPMs in local clinical practice. In the meantime, healthcare professionals are advised to take note of the above safety information. HSA will provide an update on the recommendations relevant to our local context in due course.

## Call for adverse event reporting

Prompt adverse event reporting of medical devices to HSA helps to ensure that knowledge on the benefit-risk profile of the devices remains current. Healthcare professionals are encouraged to report any suspected adverse event or complaint related to the use of LPMs to the Vigilance and Compliance Branch at Tel: +65 6866 3538, Fax: +65 6478 9069, or report online at http://www.hsa.gov.sg/ae_online.

***References***

1 *Gynecol Surg. 2013;10:117–22.*
2 *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm*
3 *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM404148.pdf*
4 *http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm424443.htm*



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