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衛生福利部食品藥物管理署　函

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密等及解密條件或保密期限：
附件：US FDA就「動力絞碎器」發布之訊息內容

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主旨：檢送美國食品藥物管理局(以下簡稱US FDA)就「腹腔鏡動力絞碎器用於子宮瘤相關手術」發布之最新安全訊息(詳如附件)，請惠予轉知所屬會員，請查照。

說明：

一、US FDA對於醫師使用腹腔鏡動力絞碎器(laparoscopic power morcellation)進行婦科相關手術提供最新訊息，略述如下:

(一)應當使用合法的腹腔鏡動力絞碎器組織封閉系統(containment system)，且該組織封閉系統應與腹腔鏡動力絞碎器相容。

(二)建議腹腔鏡動力絞碎法僅限用於經過適當評估必須進行子宮肌瘤切除術或子宮切除術之女性。

(三)如已知或懷疑欲絞碎組織中含有惡性腫瘤時，請勿使用腹腔鏡動力絞碎器。

(四)以下情況請勿使用腹腔鏡動力絞碎器去除含有疑似肌瘤的子宮組織:

1、更年期或50歲以上。

2、經陰道或小切口開腹手術去除組織（整體）者。

(五)向患者說明潛伏性癌症的風險（在預處理評估期間無

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法識別的癌症），及子宮肌瘤手術期間使用腹腔鏡動力絞碎器可能會擴散癌症並降低其長期生存率。

(六)向患者說明潛伏性癌症包括子宮肉瘤的風險會隨著年齡的增長而增加，尤其是50歲以上的女性。

(七)進行非封閉式動力絞碎手術與良性子宮組織的擴散有關，如寄生性肌瘤和瀰漫性腹膜平滑肌瘤。

二、為確保病患安全，本署已於本署網站公布旨揭產品之安全警訊，並籲請醫師進行相關醫療行為時，應完整告知病人所有醫療器材和手術方法可能出現之風險與助益。

三、另依嚴重藥物不良反應通報辦法第3條規定略以，因藥物所引起之嚴重藥物不良反應發生時，醫療機構、藥局、藥商應依本辦法填具通報書，連同相關資料，向全國藥物不良反應通報中心通報(通報網頁入口:本署網站首頁>業務專區>通報及安全監視專區>通報入口(我要通報)>醫療器材不良事件通報)。違者，可依藥事法第92條處辦。

正本：台灣婦產科醫學會、台灣婦癌醫學會、台灣婦產科內視鏡暨微創醫學會、台灣婦科醫學會

副本：財團法人藥害救濟基金會全國藥物不良反應通報中心

署長吳秀梅

UPDATE: The FDA recommends performing contained morcellation in women when laparoscopic power morcellation is appropriate

Date issued: February 25, 2020

The U.S. Food and Drug Administration (FDA) is updating our 2014 safety communication (https://wayback.archive-it.org/7993/20170404182209/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm42444 (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on laparoscopic power morcellators to provide new information on the safe and effective use of laparoscopic power morcellation for gynecologic procedures. **The FDA recommends performing laparoscopic power morcellation for myomectomy or hysterectomy only with a tissue containment system, legally marketed in the U.S. for use during laparoscopic power morcellation and performing these procedures only in appropriately selected patients.** Tissue containment systems used during laparoscopic power morcellation are intended to isolate and contain tissue that is considered benign. Based on bench and animal testing, use of a containment system confines morcellated tissue within the containment system.

The FDA continues to recommend limiting the use of laparoscopic power morcellation to certain appropriately selected women undergoing myomectomy or hysterectomy. In addition, FDA recommends that when morcellation is appropriate, only contained morcellation be performed.

Recommendations for Patients

- Discuss all options available to treat your condition with your health care provider. There are risks and benefits associated with all medical devices and procedures.
- If your health care provider recommends laparoscopic hysterectomy or myomectomy, ask
    - If power morcellation will be used;
    - Why power morcellation use is appropriate for you;
    - Whether a containment system will be used; and
    - If other treatment options are available.
- If you have undergone a myomectomy or hysterectomy for fibroids, be aware that tissue removed during the procedure is usually tested for the presence of cancer.
    - If you were informed these tests were normal, continue routine follow-up with your health care provider.
    - If you have any questions or concerning symptoms, consult your health care provider.
- Know that additional surgical treatment options are available for women with symptomatic uterine fibroids. These include traditional surgical hysterectomy and myomectomy, performed either vaginally or abdominally, laparoscopic hysterectomy and myomectomy without morcellation, and laparotomy using a smaller incision in the abdomen.

Recommendations for Health Care Providers

- Perform laparoscopic power morcellation with a legally marketed laparoscopic power morcellation containment system when morcellation is appropriate. The containment system should be compatible with the laparoscopic power morcellator.
- The FDA continues to recommend limiting the use of laparoscopic power morcellation to certain appropriately selected women undergoing myomectomy or hysterectomy; and when morcellation is appropriate, only contained morcellation be performed.
- Do not use laparoscopic power morcellators in gynecologic surgery when the tissue to be morcellated is known or suspected to contain malignancy.
- Do not use laparoscopic power morcellators for removal of uterine tissue containing suspected fibroids in patients who are:
    - post-menopausal or over 50 years of age, or
    - candidates for removal of tissue (en bloc) through the vagina or via a mini-laparotomy incision.
- Tell patients about the risk of occult cancer (cancer that cannot be identified during pretreatment evaluation) and inform them that use of laparoscopic power morcellators during fibroid surgery may spread cancer and decrease their long-term survival.
- Tell patients that the risk of occult cancer, including uterine sarcoma, increases with age, particularly in women over 50 years of age.
- Be aware that uncontained power morcellation has been associated with the spread of benign uterine tissue, such as, parasitic myomas and disseminated peritoneal leiomyomatosis.

Making Surgeries with Laparoscopic Power Morcellators Safer Through Containment Systems

Use of laparoscopic power morcellators allow for minimally invasive surgical procedures, which, when compared to open abdominal surgery, typically reduce the risk of infection and shorten the post-operative recovery period. However, when used in myomectomy (surgical procedure to remove uterine fibroids (https://medlineplus.gov/uterinefibroids.html), which are noncancerous growths in a woman's uterus) or hysterectomy (surgical procedure to remove a woman's uterus) procedures, there is an increased risk of spreading unsuspected cancer and benign tissue within the abdomen and pelvis. The risk of unsuspected cancer increases with age, particularly in women over 50 years of age. Women with unsuspected uterine sarcoma who undergo morcellation of presumed fibroids are at risk for cancer to spread within the abdomen and pelvis.

Due to this increased risk, the FDA continues to recommend limiting the use of laparoscopic power morcellation to certain appropriately selected women undergoing myomectomy or hysterectomy. In addition, FDA recommends that when morcellation is appropriate, only contained morcellation be performed.

One strategy to mitigate this risk is to use a tissue containment system during laparoscopic power morcellation procedures. The containment system is intended to isolate and contain tissue that is considered benign. Based on testing, use of a containment system confines morcellated tissue within the containment system, which may prevent the peritoneal spread of cancerous tissue

A containment system cannot prevent against the potential spread of cancer that might result from:

- Tissue that spreads due to manipulation of the tissue before it is placed into the tissue containment system or
- Cancer that may have already spread through the blood, lymphatic system or fallopian tubes (transtubal transport) before the surgical procedure.

Laparoscopic power morcellators should be used with compatible containment systems. Currently, FDA has granted marketing authorization for one containment system and continues to encourage innovation in this area. The containment system labeling describes the types of morcellators that are compatible with it. To support marketing, the containment system manufacturer must conduct testing to support the compatibility criteria described in the labeling.

FDA Actions

The FDA continues to encourage development of innovative ways to better detect uterine cancer and the development of containment systems (/news-events/press-announcements/fda-allows-marketing-first-kind-tissue-containment-system-use-certain-laparoscopic-power) designed for gynecologic surgery. The FDA will continue to review adverse event reports, peer-reviewed scientific literature, and information from patients, health care providers, gynecologic and surgical professional societies, and medical device manufacturers. We will inform the public of any significant new information.

For historical information about the FDA's actions, please see **Laparoscopic Power Morcellators** (/medical-devices/surgery-devices/laparoscopic-power-morcellators)

Reporting Problems to the FDA

If you suspect or experience a problem with laparoscopic power morcellation, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect that a morcellator or specimen bag has malfunctioned or contributed to a serious injury or adverse outcome, the FDA encourages you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

Health care professionals employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Hospitals are required to report some adverse events related to medical devices. Federal regulations require user facilities to report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must also report a medical device-related serious injury to the manufacturer or to the FDA, if the medical device manufacturer is unknown.

Hospitals should report the spread of unsuspected cancer when using laparoscopic power morcellation for hysterectomy or myomectomy in women with symptomatic uterine fibroids, as a serious injury.

Questions

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov) or call 800-638-2041 or 301-796-7100.

Resources

- **Laparoscopic Power Morcellators** (/medical-devices/surgery-devices/laparoscopic-power-morcellators)
- FDA Statement: FDA Takes New Steps to Increase the Safety of Laparoscopic Power Morcellators when used in Gynecologic Surgeries (/news-events/press-announcements/fda-takes-new-steps-increase-safety-laparoscopic-power-morcellators-when-used-gynecologic-surgeries)