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速別：普通件

密等及解密條件或保密期限：

附件：Safe Use of Surgical Staplers and Staples Letter to Health Care (附件請至本機關附件下載區以發文字號及發文日期下載。網址<https://ODDW.FDA.GOV.TW/DL/DL1/DLi100.aspx>) 識別碼：TRGQC2BU。

主旨：檢送美國食品藥物管理局就「手術縫合器/釘」發布安全

警訊1份，詳如附件，惠請轉知所屬會員，請查照。。

說明：

一、美國食品藥物管理近期重新檢視接獲「手術縫合器/釘」之不良事件通報案件，並提出下列建議事項予相關專科醫療人員，略述如下：

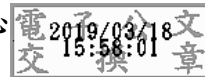
- (一)使用前應詳細閱讀縫合器之仿單及使用說明書。
- (二)依據縫合組織的類型及厚度大小，選擇合適的縫合釘。
- (三)若手術部位組織出現水腫、出血或壞死，則縫合器不適宜太接近這些部位。
- (四)應熟悉手術縫合的位置。
- (五)縫合器避免使用在大血管(如主動脈)上。
- (六)縫合器避免使用在脆弱的組織，即使沒有使用縫合釘，縫合器使用過程仍可能造成組織壞死。
- (七)若在手術過程發生縫合器故障，則應先夾緊血管，再從血管上釋放縫合器。

二、為確保病患使用醫療器材之安全，本署除將於本署網站公布旨揭產品之安全警訊外，並籲請醫師在進行旨揭產品之醫療行為時，應持續觀察患者術後情形及是否有不良反應發生。

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：台灣美容外科醫學會、台灣醫院協會、中華民國公立醫院協會、中華民國醫師公會全國聯合會、台灣家庭醫學醫學會、台灣內科醫學會、台灣外科醫學會、台灣兒科醫學會、台灣婦產科醫學會、中華民國骨科醫學會、社團法人台灣神經外科醫學會、台灣泌尿科醫學會、台灣耳鼻喉頭頸外科醫學會、中華民國眼科醫學會、台灣皮膚科醫學會、台灣神經學學會、台灣精神醫學會、台灣復健醫學會、台灣麻醉醫學會、中華民國放射線醫學會、台灣放射腫瘤學會、台灣病理學會、台灣臨床病理檢驗醫學會、中華民國核醫學學會、台灣整形外科醫學會、社團法人台灣急診醫學會、中華民國環境職業醫學會、台灣醫學中心協會、中華民國區域醫院協會、台灣社區醫院協會、中華民國基層醫療協會、台灣私立醫療院所協會、中華民國診所協會全國聯合會

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



Safe Use of Surgical Staplers and Staples – Letter to Health Care Providers

March 8, 2019

Dear Health Care Provider,

The U.S. Food and Drug Administration (FDA) is concerned by the increasing number of adverse events associated with surgical staplers and staples for internal use and is providing **additional recommendations for health care providers** to help protect patient safety and reduce the risk of adverse events associated with these devices. In addition, we are announcing **new actions** we intend to take to help ensure the safe use of these devices.

Because surgical staplers and staples for internal use are used as a system, the FDA analyzed the medical device reports submitted for both surgical staplers and implantable staples to obtain a comprehensive picture of the safety profile for these devices. Our analysis, which is ongoing, found that from January 1, 2011 to March 31, 2018, the FDA received over 41,000 individual medical device reports for surgical staplers and staples for internal use, including:

- 366 deaths,
- over 9,000 serious injuries, and
- over 32,000 malfunctions.

The FDA believes that many of the problems identified in these reports can be primarily attributed to surgical staplers for internal use because proper staple formation is largely contingent on proper function and use of the stapler.

Some of the most commonly reported problems in these adverse event reports include:

- opening of the staple line or malformation of staples,
- misfiring,
- difficulty in firing,
- failure of the stapler to fire the staple, and
- misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to the tissue).

Stapler and/or staple malfunctions or misuse may result in prolonged surgical procedures or unplanned, additional surgical interventions, which may lead to other complications, such as:

- bleeding,
- sepsis,
- fistula formation,
- tearing of internal tissues and organs,
- increased risk of cancer recurrence, and
- death.

RECOMMENDATIONS:

- Read and carefully follow the stapler manufacturer's instructions for use.
- Have a range of staple sizes available and select the appropriate size cartridge for the tissue type and thickness.
 - If you have difficulty squeezing the handle of the stapler, you may need to select a different size staple.
 - Avoid using the stapler on tissue that is too thick or too thin for the selected staple size, as this could result in staple malformation.
 - Be aware that different companies may use different color schemes on the cartridges to indicate different staple sizes.
- Consider other options if the patient's tissue is edematous (swollen with fluid), friable (tissue that readily tears, fragments, or bleeds when gently palpated or manipulated), or necrotic (death of tissue), as the staples may be less likely to securely approximate tissue.
- Be familiar with the structures around the intended staple site.
 - Check that unintended structures, such as urinary bladder, or foreign objects, such as clips, are not in the staple line.
- Avoid using on large blood vessels, such as the aorta.
- Avoid clamping the stapler on delicate tissue, as clamping can still cause injury even if no staples are fired.
- If a malfunction of the stapler occurs while applying staples across a blood vessel, then clamp or ligate the vessel before releasing the stapler, while the stapler is still closed on the tissue.

FDA ACTIONS

To further promote the safe and effective use of surgical staplers and staples for internal use, the FDA intends to issue a **draft guidance** for public comment in 2019, which will describe proposed recommendations to manufacturers of surgical staplers and staples for internal use about information to include in their product labeling.

Due to the increased number of adverse events reported to the FDA, the agency also plans to hold an open public meeting of the **General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/default.htm)** in 2019 to discuss whether **reclassifying surgical staplers for internal use as Class II (/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm)** medical devices would be appropriate. Currently, surgical staplers for external and internal use are regulated as Class I medical devices, which do not require a premarket submission to the FDA. Reclassifying surgical staplers for internal use as a Class II device would subject them to premarket notification and allow the FDA to establish mandatory special controls to help mitigate known risks of the device.

The FDA will announce the meeting, including details about how to participate, on the **FDA Advisory Committee calendar (/AdvisoryCommittees/Calendar/default.htm)** webpage and in a Federal Register notice at least 15 days prior to the scheduled date.

In addition, we are aware that many more device malfunction reports during this time frame (from January 1, 2011 to March 31, 2018) were submitted as **Alternative Summary Reports (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072029.htm)**. We are conducting an ongoing analysis of both these reports and of medical device reports received since March 31, 2018. The results of this analysis, when complete, will be available to the public along with the materials for the upcoming advisory committee meeting. These devices are not currently

eligible for alternative summary reporting or [voluntary malfunction summary reporting \(https://www.federalregister.gov/documents/2018/08/17/2018-17770/medical-devices-and-device-led-combination-products-voluntary-mal-function-summary-reporting-program\)](https://www.federalregister.gov/documents/2018/08/17/2018-17770/medical-devices-and-device-led-combination-products-voluntary-mal-function-summary-reporting-program).

The FDA continues to work with hospitals and professional societies to **encourage training and education** associated with the use of these devices.

The FDA **routinely monitors postmarket performance** of marketed devices. We will continue to collect and analyze all available information related to surgical staplers and staples to better understand the risks and benefits. The FDA will keep the public informed as new information becomes available.

REPORTING PROBLEMS TO THE FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products.

If you suspect or experience a problem with surgical staplers or implantable staples, we encourage you to file a voluntary report through [MedWatch \(/Safety/Med-Watch/default.htm\)](#), the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA's [user facility reporting requirements \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm\)](#) should follow the reporting procedures established by their facilities.

CONTACT INFORMATION

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 1-800-638-2041 or 301-796-7100.

Sincerely,

/s/

William Maisel, MD MPH
Chief Medical Officer
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More in [Letters to Health Care Providers \(/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm\)](#)

