檔　　號：
保存年限：

正本

衛生福利部食品藥物管理署　函

機關地址：11561 臺北市南港區昆陽街161-2號
傳　　真：
聯絡人及電話：謝宛芝02-27877572
電子郵件信箱：wanchih@fda.gov.tw

241
新北市三重區重新路五段609巷6號3樓之3

受文者：台灣醫療暨生技器材工業同業公會

台灣醫療暨生技器材工業同業公會
收 106. 05. 08 文
檔號: 1063j2

發文日期：中華民國106年5月3日
發文字號：FDA器字第1061602450A號
速別：
密等及解密條件或保密期限：
附件：2016年1月4日「FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks」之安全資料1份。

主旨：有關「經陰道網膜修補術治療骨盆腔臟器脫垂之手術網片」(Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair)(以下簡稱經陰道手術修補網)類醫療器材許可證中文仿單加註警語乙事，惠請轉知所屬會員知悉，請查照。

說明：

一、查美國食品藥物管理局（U.S. FDA）曾發布安全資訊提醒健康照護人員及病人，應注意經陰道手術修補網所引起之併發症，並請醫師審慎考量使用治療骨盆腔臟器脫垂之手術方式，及確保病人已被充分告知經陰道手術修補網之潛在併發症。該局另於2016年將經陰道手術修補網之產品風險等級由中風險性提升至高風險性，並再次提醒健康照護者及病人應注意放置經陰道手術修補網所引起之併發症。(如附件)

二、旨揭產品經本署評估後，為提醒使用醫師注意使用旨揭產品之潛在併發症，進而告知病人，以維護病人安全，故惠請協助轉知所屬會員，持有旨揭產品許可證之藥商，請於文到2個月內，另案向本署申請仿單加註以下警語：「植入經陰道手術修補網，可能引發網膜糜爛或突

出、網膜收縮而引起之陰道縮短、狹窄或疼痛，以及臟器(包括膀胱、腸道、血管)穿孔等併發症」之許可證仿單變更作業(期限內申請該變更案得免繳規費)。

三、另請貴會轉知會員留意衛生福利部106年4月6日衛授食字第1061601595號公告之預告修正「醫療器材管理辦法」第三條附件一、第四條附件二草案內容。

正本：台灣先進醫療科技發展協會、台灣醫療暨生技器材工業同業公會、中華民國醫療器材商業同業公會全國聯合會、台灣省醫療器材商業同業公會聯合會、臺北市醫療器材商業同業公會、新北市醫療器材商業同業公會、臺中市醫療器材商業同業公會、彰化縣醫療器材商業同業公會、嘉義市醫療器材商業同業公會、臺南市醫療器材商業同業公會、高雄市醫療器材商業同業公會、台北市歐洲商務協會、台北市日僑工商會、德國經濟辦事處、台灣區塑膠製品工業同業公會、台灣省進出口商業同業公會聯合會、台北市進出口商業同業公會、新北市進出口商業同業公會、桃園市進出口商業同業公會、台中市進出口商業同業公會、台中縣進出口商業同業公會、台南市進出口商業同業公會、台南縣進出口商業同業公會、高雄市進出口商業同業公會、高雄縣進出口商業同業公會、台北市生物技術服務商業同業公會、高雄直轄市醫療器材商業同業公會、台北市美國商會政府及公共事務部(美國商會醫療器材委員會)、台北市國際工商協會、臺北市儀器商業同業公會、嘉義市儀器商業同業公會、臺中市儀器商業同業公會、高雄市儀器商業同業公會、桃園縣儀器商業同業公會

副本：

署長 吳秀梅

FDA News Release

FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks

For Immediate Release

January 4, 2016

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm480312.htm)

The U.S. Food and Drug Administration today issued two final orders to manufacturers and the public to strengthen the data requirements for surgical mesh to repair pelvic organ prolapse (POP) transvaginally, or through the vagina. The FDA issued one order to reclassify these medical devices from class II, which generally includes moderate-risk devices, to class III, which generally includes high-risk devices, and a second order that requires manufacturers to submit a premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP.

The orders will require manufacturers to address safety concerns, including severe pelvic pain and organ perforation, through a rigorous PMA pathway to demonstrate safety and effectiveness. The actions apply only to mesh devices marketed for the transvaginal repair of POP. These orders do not apply to surgical mesh for other indications, like stress urinary incontinence (SUI) or abdominal repair of POP.

"These stronger clinical requirements will help to address the significant risks associated with surgical mesh for repair of pelvic organ prolapse," said William Maisel, M.D., M.P.H., deputy director of science and chief scientist for the FDA's Center for Devices and Radiological Health. "We intend to continue monitoring how women with this device are faring months and years after surgery through continued postmarket surveillance measures."

Surgical mesh has been used by surgeons since the 1950s to repair abdominal hernias; in the 1970s, gynecologists began implanting surgical mesh for the abdominal repair of POP and, in the 1990s, for the transvaginal repair of POP. In 2002, the first mesh device with this indication was cleared for use as a class II moderate-risk device, and there are five manufacturers who are currently marketing this product.

Over the past several years, the FDA has seen a significant increase in the number of reported adverse events associated with the use of surgical mesh for transvaginal POP repair, and an advisory panel of experts recommended in 2011 that more data is needed to establish the safety of the device. The FDA has since taken several actions to warn doctors and patients about the use of surgical mesh for transvaginal POP repair.

Manufacturers of surgical mesh to treat POP transvaginally will have 30 months, as required by federal law, to submit a PMA for devices that are already on the market. Manufacturers of new devices must submit a PMA before those devices can be approved for marketing.

POP (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm262299.htm) occurs when the muscles and tissue of the pelvic floor become stretched, torn or weakened and can no longer support pelvic organs such as the bladder, bowel or uterus; as a result, the organs drop from their

experience low back pain or pelvic pressure, painful intercourse, constipation or urinary problems such as leakage or a chronic urge to urinate.

Doctors may perform surgery on women with POP who have significant symptoms, often using a minimally invasive transvaginal technique to reduce recuperation time. Surgical mesh may be permanently implanted during this surgery to reinforce the weakened pelvic floor muscles and repair POP, but over the past several years the FDA has received thousands of reports of complications involving the use of mesh for transvaginal POP repair. The most common problems reported include severe pelvic pain, pain during intercourse, infection, bleeding, organ perforation and urinary problems from mesh eroding into surrounding tissues.

To warn doctors and patients about the use of surgical mesh for transvaginal POP repair, the FDA has:

- Issued safety communications in 2008 and in 2011 warning doctors and consumers about an increase in adverse event reports related to mesh used for urogynecological procedures;
- Convened an advisory panel in September of 2011 to solicit recommendations on actions to take regarding urogynecologic surgical mesh for transvaginal POP repair;
- Issued orders to manufacturers in January 2012 to conduct postmarket surveillance studies to address specific safety and effectiveness concerns related to surgical mesh used for transvaginal repair of POP; and
- Issued two proposed orders in May 2014 to reclassify the devices from class II to class III and to require manufacturers to submit a PMA application.

Manufacturers may choose to submit a PMA before the 30-month deadline.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media

Deborah Kotz (mailto:deborah.kotz@fda.hhs.gov)
301-796-5349

Consumers

888-INFO-FDA

Related Information

- FDA: Medical Devices (/MedicalDevices/default.htm)
- FDA: Urogynecologic Surgical Mesh Implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm)
- Recommendations for Patients (PDF - 76KB) (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262756.pdf)

Follow FDA

Follow @US_FDA (https://twitter.com/US_FDA)
(/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

Follow FDA (https://www.facebook.com/FDA)
(/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)