**FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse**

**Date Issued:** July 13, 2011

**Audience:**

* Health care providers who implant surgical mesh to repair pelvic organ prolapse and/or stress urinary incontinence
* Health care providers involved in the care of patients with surgical mesh implanted to repair pelvic organ prolapse and/or stress urinary incontinence
* Patients who are considering or have received a surgical mesh implant to repair pelvic organ prolapse and/or stress urinary incontinence

**Medical Specialties:** gynecology, urogynecology, urology, general surgery, internal medicine, family practice, emergency medicine

**Device:**Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence.

**Background:**
**Pelvic Organ Prolapse**
Pelvic organ prolapse (POP) occurs when the tissues that hold the pelvic organs in place become weak or stretched. Thirty to fifty percent of women may experience POP in their lifetime with 2 percent developing symptoms. When POP happens, the organs bulge (prolapse) into the vagina and sometimes prolapse past the vaginal opening. More than one pelvic organ can prolapse at the same time. Organs that can be involved in POP include the bladder, the uterus, the rectum, the top of the vagina (vaginal apex) after a hysterectomy, and the bowel.

**Stress Urinary Incontinence**
Stress urinary incontinence (SUI) is a leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercise.

**Purpose:**
On Oct. 20, 2008, the FDA issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat POP and SUI.

Based on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern.

The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk. This Safety Communication provides updated recommendations for health care providers and patients and updates the FDA’s activities involving surgical mesh for the transvaginal repair of POP.

*The FDA continues to evaluate the effects of using surgical mesh to repair SUI and will communicate these findings at a later date.*

For detailed information, please see: [Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse.](http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf)1

**Summary of Problem and Scope:**
In the Oct. 20, 2008 FDA Public Health Notification, the number of adverse events reported to the FDA for surgical mesh devices used to repair POP and SUI for the previous 3-year period (2005 – 2007) was “over 1,000.” Since then, from Jan. 01, 2008 through Dec. 31, 2010, the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI, with 1,503 reports associated with POP repairs and 1,371 associated with SUI repairs. Although it is common for adverse event reporting to increase following an FDA safety communication, we are concerned that the number of adverse event reports remains high.

From 2008 – 2010, the most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage, and emotional problems. Many of these complications require additional intervention, including medical or surgical treatment and hospitalization.

In order to better understand the use of surgical mesh for POP and SUI, the FDA conducted a systematic review of the published scientific literature from 1996 – 2011 to evaluate its safety and effectiveness. The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. The FDA continues to evaluate the literature for SUI surgeries using surgical mesh and will report about that usage at a later date.

In particular, the literature review revealed that:

* Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair.
* Mesh placed abdominally for POP repair appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
* There is no evidence that transvaginal repair to support the top of the vagina (apical repair) or the back wall of the vagina (posterior repair) with mesh provides any added benefit compared to traditional surgery without mesh.
* While transvaginal surgical repair to correct weakened tissue between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results.

The FDA’s literature review found that *erosion* of mesh through the vagina is the *most common and consistently reported mesh-related complication* from transvaginal POP surgeries using mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication.

*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification*. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.

Both mesh erosion and mesh contraction may lead to severe pelvic pain, painful sexual intercourse or an inability to engage in sexual intercourse. Also, men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion.

The complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh.

Recommendations for Health Care Providers:

As stated in the Oct. 20, 2008 Public Health Notification, the FDA continues to recommend that health care providers should:

* Obtain specialized training for each mesh placement technique, and be aware of the risks of surgical mesh.
* Be vigilant for potential adverse events from the mesh, especially erosion and infection.
* Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
* Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
* Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh.
* Provide patients with a copy of the patient labeling from the surgical mesh manufacturer if available.

In addition, the FDA also recommends that health care providers:

* Recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.
* Choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives.
* Consider these factors before placing surgical mesh:
	+ Surgical mesh is a permanent implant that may make future surgical repair more challenging.
	+ A mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.
	+ Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient’s quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.
	+ Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal POP surgery with mesh.
* Inform the patient about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally and the likely success of these alternatives compared to transvaginal surgery with mesh.
* Notify the patient if mesh will be used in her POP surgery and provide the patient with information about the specific product used.
* Ensure that the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

**Recommendations for Patients:**
**Before Surgery**
Be aware of the risks associated with surgical mesh for transvaginal repair of POP. Know that having a mesh surgery may put you at risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

Ask your surgeon about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why your surgeon may be recommending treatment of POP with mesh.

In addition, ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:

* Are you planning to use mesh in my surgery?
* Why do you think I am a good candidate for surgical mesh?
* Why is surgical mesh being chosen for my repair?
* What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?
* What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
* Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?
* If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
* What can I expect to feel after surgery and for how long?
* Which specific side effects should I report to you after the surgery?
* What if the mesh surgery doesn’t correct my problem?
* If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
* If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?
* If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

**After Surgery**

* Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.
* Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
* Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
* Talk to your health care provider about any questions you may have.

If you had POP surgery, but do not know whether your surgeon used mesh, ask your health care provider at your next scheduled visit.

**FDA Activities:**
The FDA is working in several areas to assess and improve the safety and effectiveness of urogynecologic mesh products. The FDA will:

* Convene the Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee, on September 8-9, 2011.The panel will discuss and make recommendations regarding the safety and effectiveness of transvaginal surgical mesh for POP and SUI.
* Explore regulatory solutions to answer questions about the safety and effectiveness of urogynecologic mesh products that are now being marketed and those that will be reviewed for marketing in the future.
* Continue to monitor adverse events reported to FDA associated with surgical mesh used to repair POP and SUI, as well as assessing any and all data as it becomes available.

**Reporting Problems to the FDA:**
Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with surgical mesh, we encourage you to file a voluntary report through MedWatch, 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](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)2 should follow the reporting procedures established by their facilities. Device manufacturers must comply with the [Medical Device Reporting (MDR) regulations](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)3.

To help us learn as much as possible about the adverse events associated with surgical mesh to repair POP and SUI, please include the following information in your reports, if available:

* Manufacturer's name
* Product name (brand name)
* Catalog number
* Lot number
* Size
* Date of implant
* Date of explant (if mesh was removed)
* Details of the adverse event and medical and/or surgical interventions (if required)
* Type of procedure (e.g., anterior or posterior repair, sacral colpopexy, sling procedure for SUI)
* Surgical approach: (e.g., vaginal, abdominal, laparoscopic)
* Reason for mesh implantation: (e.g., POP of the uterus, bladder, rectum, vaginal apex or bowel, SUI)
* Specific postoperative symptoms experienced by the patient with time of onset and follow-up treatment

**Contact Information:**
If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

*This document reflects the FDA’s current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices.*

**Society of Female Urology and Urodynamics (SUFU) Response: FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for pelvic Organ Prolapse (July 2011)**

On July 13, 2011 The FDA released an update on the safety and effectiveness of transvaginal placement of surgical mesh for pelvic organ prolapsed (POP) on their website. (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>.) The Society for Female Urology and Urodynamics (SUFU) as the leading Urologic organization in the field of Female Pelvic Medicine and Reconstructive Surgery (FPMRS) did NOT assist in the creation of this FDA document nor were we consulted or offered an opportunity to review it or edit it prior to its posting on July 13, 2011.

It should be recognized that SUFU remains firmly committed to advancing the field of FPMRS clinically and academically through teaching residents and fellows as well as producing high quality scholarly activity through clinical and basic science investigation. All of these efforts are ultimately targeted towards providing the best possible care for our patients.

Pelvic organ prolapsed and its related symptoms is a highly prevalent condition. Pelvic organ prolapsed, though often associated with urinary incontinence, is a separate condition. It is important to recognize that the updated FDA report did not include synthetic mesh materials currently surgically implanted for the treatment of stress urinary incontinence or mesh used for abdominal or laparoscopic repair of pelvic organ prolapsed (i.e. sacrocolpopexy) in the most recent warning.

Many effective treatments exist for pelvic organ prolapsed including pelvic floor exercise, support devices such as pessaries, and a variety of surgical interventions. Surgical techniques have evolved over the last 50-100 years in an effort to effectively, safely, and durably fix this condition. Historically, many surgeries designed to treat some types of pelvic organ prolapsed had unacceptably high failure rates in long term studies. Most recently, synthetic mesh has been utilized by many surgeons as an adjunctive technique to improve the long term results of surgical repair. Research and innovation over the past 2 decades has identified certain types of synthetic mesh that are less optimal for vaginal surgery leading to their removal from the US marketplace. Some of these now unavailable and early mesh iterations may be responsible for several of the complications included in the FDA posting.

The contemporary incorporation of mesh into surgical repair has pros and cons. Mesh may improve long term anatomic results of surgery as compared to no-mesh repairs for some types of prolapsed but is also associated with risks to the patient including vaginal extrusion, erosion, sexual dysfunction, urinary tract injury, pain and other complications. However, it is important to recognize that many of these complications are not unique to mesh surgeries and are known to occur with non mesh procedures as well. SUFU is unable to make universal recommendations for or against the utilization of vaginal mesh based on the scientific evidence base currently available. There exists a population of patients for whom mesh has potential benefit. For these individuals, it may be appropriate to consider the implantation of transvaginal mesh if the potential risks and benefits are understood by the surgeon and the patient. It is SUFU’s position that consideration for the use of mesh should be done on an individual, case by case basis and only after and informed discussion between the patient and surgeon.

Specifically with respect to the updated FDA posting, SUFU is unequivocally supportive of the following statements:

* Surgeons require rigorous training in the principles of pelvic anatomy, and pelvic surgery as well as in proper patient selection for pelvic organ prolapsed (POP) reconstructive procedures. Such measures should be in place PRIOR to attempting implantation of surgical mesh for prolapse.
* Prior to utilization of mesh in pelvic floor repair, surgeons should be properly trained in specific mesh implantation techniques.
* Prior to implantation of mesh, the surgeon should be competent in recognizing intraoperative and postoperative complications as well as comfortably and completely managing these adverse events. Such adverse events include those involving the urinary and gastrointestinal tracts.
* Prior to implantations surgical mesh for the treatment of pelvic organ prolapsed, the surgeon and patient MUST have a proper informed consent discussion regarding the risks, benefits, alternatives and indications for the use of mesh.

In addition, SUFU agrees with the following FDA recommendations:

* Recognize that many cases of POP can be treated successfully without mesh
* Choose mesh surgery only after weighing the risks and benefits of surgery with mesh vs. all other alternatives
* Consider that surgical mesh is a permanent implant which can make future POP repairs more challenging, can cause complications which require additional surgery, and can be difficult or impossible to remove
* Inform patients about treatment alternatives that do not require mesh placement
* Notify patients when mesh will be used, and provide the patient with information about mesh
* Ensure that the patient understands the risks of mesh surgery and the limited long-term outcomes data

It is important to inform patients who have had vaginal mesh surgery for pelvic organ prolapsed and are satisfied with their surgery without complications, that there is no need to have the mesh explanted. SUFU recognizes that the long term ramifications of vaginal mesh are not yet clearly understood and therefore recommends that patients undergo routine check-ups and follow-up care as needed and inform their healthcare provider should any problems or bothersome symptoms arise.

Finally, given the increasing numbers of commercial products available for the treatment of pelvic organ prolapsed, as well as the increased numbers of surgeons performing these procedures, SUFU is supportive of a review of the FDA 510k approval process for synthetic mesh delivery systems.

SUFU supports ongoing and future research on this topic in order to clarify the appropriate role of synthetic mesh in the treatment of affected individuals. Optimal patient outcomes are accomplished through teaching, research and clinical care. These are the cornerstones of the SUFU mission.

Patient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

Physician Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_