Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence

The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.

Introduction
The purpose of this position statement by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) is to support the use of the midurethral sling in the surgical management of stress urinary incontinence, the type of urine leakage generally associated with coughing, laughing and sneezing.

Developed in the early 1990’s, midurethral slings (MUS) treat stress urinary incontinence (SUI) in a minimally invasive, generally outpatient procedure. This technique utilizes a small mesh strip composed of monofilament polypropylene placed through the vagina under the mid-urethra exiting from 2 small sites in either the suprapubic or groin areas.

SUI is a highly prevalent condition of involuntary urine leakage resulting from faulty closure of the urethra typically associated with coughing, sneezing or exertion. SUI is often a debilitating and bothersome condition that can substantially reduce a woman’s quality of life. Although non-surgical treatments such as pelvic floor exercises and behavioral modification are helpful in alleviating symptoms in some women [1], many proceed with surgery which is a more effective treatment [2].

In July 2011, the U.S. Food and Drug Administration (FDA) released a white paper [3] and safety communication [4] on the safety and effectiveness of transvaginal placement of surgical mesh specifically for pelvic organ prolapse. In addition, lawyers have publicly advertised their services, targeting women with transvaginal mesh placed for both pelvic organ prolapse and stress urinary incontinence (SUI), and the media has reported on the pelvic organ prolapse mesh litigation. We are concerned that the multimedia attention has resulted in confusion, fear, and an unbalanced negative perception regarding the midurethral sling as a treatment for SUI. This negative perception of the MUS is not shared by the medical community and the overwhelming majority of women who have been satisfied with their MUS. Furthermore, the FDA website states that: “The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.”[5].
Justification for the Position Statement

1. Polypropylene material is safe and effective as a surgical implant.
   Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over five decades, in millions of patients in the US and the world (personal communication with manufacturers of polypropylene suture and mesh). As an isolated thread, polypropylene is a widely used and durable suture material employed in a broad range of sizes and applications. As a knitted material, polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery. [6, 7] As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years [8].

2. The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history.
   A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of the MUS as a treatment for SUI [9]. There are greater than 2000 publications in the scientific literature describing the MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature [9]. The MUS has been studied in virtually all types of patients, with and without comorbidities, and all types of SUI. Multiple randomized, controlled trials comparing types of MUS procedures, as well as comparing the MUS to other established non-mesh SUI procedures, have consistently demonstrated its clinical effectiveness [9-12] and patient satisfaction [12]. Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy [8]. No other surgical treatment for SUI before or since has been subject to such extensive investigation.

3. Polypropylene mesh midurethral slings are the standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.
   Since the publication of numerous level one randomized comparative trials, the MUS has become the most common surgical procedure for the treatment of SUI in the US and the developed world. This procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI. There have been over 100 surgical procedures developed for the management of SUI and there is now adequate evidence that the MUS is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared to historic options that have been used to treat SUI over the past century. Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard for stress incontinence surgery [13]. Over 3 million MUS have been placed worldwide and a recent survey indicates that these procedures are used by > 99% of AUGS members [14].

4. The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI.
   The midurethral sling was not the subject of the 2011 FDA Safety Communication, “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse.”[3]. In this document, it was explicitly stated: “The FDA continues to evaluate the effects of using surgical mesh for the treatment of SUI and will report about that usage at a later date.” In 2013, the FDA website stated clearly that: “The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.” [5].
Conclusion
The polypropylene midurethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple outpatient procedure that allows them to return to daily life very quickly. With its acknowledged safety and efficacy it has created an environment for a much larger number of women to have access to treatment. In the past, concerns over failure and invasiveness of surgery caused a substantial percent of incontinent women to live without treatment. One of the unintended consequences of this polypropylene mesh controversy has been to keep women from receiving any treatment for SUI. This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years and has the full support of our organizations which are dedicated to improving the lives of women with urinary incontinence.

Our Organizations
The American Urogynecologic Society (AUGS), founded in 1979, is the premier non-profit organization representing more than 1,700 members including practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, as well as researchers from many disciplines, all dedicated to treating female pelvic floor disorders (pelvic organ prolapse and urinary incontinence). As the leader in Female Pelvic Medicine and Reconstructive Surgery, AUGS promotes the highest quality patient care through excellence in education, research and advocacy.

SUFU, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, is a non-profit organization dedicated to improving the art and science of Urology through basic and applied clinical research in urodynamics and neurourology, voiding function and dysfunction, female urology and pelvic floor dysfunction, and to disseminate and teach these concepts. It is the oldest professional organization dedicated to this field consisting of interested physicians, basic scientists, and other health care professionals, and has grown to over 500 members.

Midurethral Sling Task Force
This position statement was drafted by members Charles Nager, Paul Tulikangas, and Dennis Miller from AUGS and Eric Rovner and Howard Goldman from SUFU.

Approved by the AUGS Board of Directors and the SUFU Board of Directors January 3, 2014.
References


Use of Synthetic Mesh (Sling) In the Treatment of Stress Urinary Incontinence

There has been a lot of discussion in the media about the use of synthetic material (mesh) in the treatment of the female pelvic floor and bladder problems. And while there remains much debate about the use of transvaginal mesh for prolapse repair, numerous experts regard suburethral mesh slings as the “gold standard” for the surgical treatment of stress urinary incontinence (SUI). In contrast to the transvaginal mesh kits used for the correction of vaginal prolapse, suburethral mesh slings were exhaustively researched prior to their approval by the FDA and there is a large body of research and experience for over 15 years in the U.S. and almost 20 years in Europe.

Below is an excerpt from the American Urological Association (AUA)’s Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence:

“Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries. Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction.

Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well. It is the AUA’s opinion that any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI.

Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5-10 years. This efficacy is equivalent or superior to other surgical techniques. There is no significant increase in adverse events observed over this period of follow-up. Based on these data, the AUA Guideline for the Surgical Management of Stress Urinary Incontinence (2009) concluded that synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques.”

The AUA’s position statement may be viewed in its entirety online at http://www.auanet.org/content/aua-policies/position-statements/stress-urinary-incontinence.cfm
The US Food and Drug Administration (FDA) released a series of communications regarding Stress Urinary Incontinence (SUI). This front-and-back handout includes some important excerpts from those communications. The FDA communications may be viewed in their entirety online at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345221.htm

CONSIDERATIONS ABOUT SURGICAL MESH FOR SUI

Mesh sling procedures are currently the most common type of surgery performed to correct SUI. In order to better understand the use of surgical mesh slings for SUI and evaluate their safety and effectiveness, the FDA held a panel meeting of scientific experts and conducted a systematic review of the scientific literature. For surgical mesh slings used for SUI, the panel and the FDA’s review found that:

- **The safety and effectiveness of multi-incision slings is well-established** in clinical trials that followed patients for up to one-year. Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up.

- Mesh sling surgeries for SUI have been reported to be **successful in approximately 70 to 80 percent of women** at one year. Similar effectiveness outcomes are reported following non-mesh SUI surgeries.

- The use of mesh slings in transvaginal SUI repair introduces a risk not present in traditional non-mesh surgery for SUI repair, which is mesh erosion, also known as extrusion.

- Erosion of mesh slings through the vagina is the most commonly reported mesh-specific complication from SUI surgeries with mesh. **The average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately 2 percent.** Mesh erosion is sometimes treated successfully with vaginal cream or an office procedure where the exposed piece of mesh is cut. In some cases of mesh erosion, it may be necessary to return to the operating room to remove part or all of the mesh.

- The long-term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA.

- The complications associated with the use of surgical mesh slings currently on the market for SUI repair are not linked to a single brand of mesh.

The most common complications for surgical mesh slings for SUI repair, in descending order of frequency, include: pain, mesh erosion through the vagina (also called exposure, extrusion or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse, bleeding, organ perforation, neuromuscular problems and vaginal scarring. Many of these complications require additional medical intervention, and sometimes require surgical treatment and/or hospitalization. **With the exception of mesh erosion, the above complications can occur following a non-mesh surgical repair for SUI.**
RECOMMENDATIONS FOR PATIENTS

BEFORE SURGERY

Ask your surgeon about all SUI treatment options, including non-surgical options and surgical options that do and do not use mesh slings. It is important for you to understand why your surgeon may be recommending a particular treatment option to treat your SUI.

Any surgery for SUI may put you at risk for complications, including additional surgery. One complication that may occur when mesh slings are used is vaginal mesh erosion, which could require additional surgery to resolve.

If mesh erosion occurs through the vaginal tissue, it is possible that men may experience penile irritation and/or pain during sexual intercourse.

Ask your surgeon the following questions before you decide to have SUI surgery:

- What surgical or non-surgical treatment options are available and what do you recommend to treat my SUI?
- Have you had specialized training in the surgical treatment of SUI, and if so, what type of training have you had with this particular product and/or procedure?
- What can I expect after surgery and what is the recovery time?
- If I also have pelvic organ prolapse, will that change how you treat my SUI?
- What if the surgery doesn’t correct my problem?
- Which side effects should I report to you after the surgery?
- Are you planning to use a mesh sling in my surgery? If so:
  - How often have you performed this surgery using this particular product? What results have your other patients had with this product?
  - What are the pros and cons of using a mesh sling in my particular case? How likely is it that my repair could be successfully performed without using a mesh sling?
  - Are recovery times different for mesh sling surgery compared to non-mesh surgery?
  - Will my partner be able to feel the mesh sling during sexual intercourse?
  - If I have a complication related to the mesh sling, how likely is it that the complication can be resolved? Will you treat it or will I be referred to a specialist experienced with mesh sling complications?
  - Is there patient information that comes with the product, and can I have a copy?

AFTER SURGERY

Continue with annual check-ups and follow-up care, notifying your health care provider if complications develop, such as persistent vaginal bleeding or discharge, pelvic or groin pain, or pain during sexual intercourse. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.

If you have complications or other symptoms:

- Discuss complications and treatment options with your health care provider. Only your health care provider can give you personalized medical advice.
- Consider getting a second opinion from a surgeon who specializes in female pelvic reconstruction if you are not satisfied with your discussion with your health care provider.
- Let your health care provider know you have a mesh sling, especially if you plan to have another surgery, plan to become pregnant or have other medical procedures.
- If you have had SUI surgery but do not know whether your surgeon used a mesh sling, ask your health care provider.
- Talk to your health care provider about any additional questions you may have.
Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence

FDA wants to inform you about the complications that can occur when surgical mesh is used to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI), and provide you with questions to ask your surgeon before having these procedures. This is part of our commitment to keep healthcare professionals and the public informed about the medical products we regulate.

FDA has received reports of complications associated with the placement of mesh through an incision made in the wall of the vagina. Although rare, these complications can have serious consequences. The reports have not been linked to a single brand or model of mesh.

The most frequent complications included erosion through the vagina, infection, pain, urinary problems and recurrence of the prolapse and/or incontinence.

In some cases, erosion of the mesh and scarring of the vagina led to discomfort and pain, including pain during sexual intercourse. Some patients needed additional surgery to remove the mesh that had eroded into the vagina. Other complications included injuries to nearby organs such as the bowel and bladder, or blood vessels.

Background
A pelvic organ prolapse (POP) occurs when a pelvic organ, such as your bladder, drops (“prolapses”) from its normal position and pushes against the walls of your vagina. This can happen if the muscles that hold your pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can drop at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

Pelvic organ prolapse can cause pain or problems with bowel and bladder functions or interfere with sexual activity.

Stress urinary incontinence (SUI) is a type of incontinence caused by leakage of urine during moments of physical stress.

Talking to your doctor
Before having an operation for POP or SUI, be sure to let your surgeon know if you’ve had a past reaction to mesh materials such as polypropylene.

Questions you should ask the surgeon before you agree to surgery in which mesh will be used:
- What are the pros and cons of using surgical mesh in my particular case? Can my repair be successfully performed without using mesh?
- If a mesh is to be used, what’s been your experience with implanting this particular product? What experience have your other patients had with this product?
- What’s been your experience in dealing with the complications that might occur?
- What can I expect to feel after surgery and for how long?
- Are there any specific side effects I should let you know about after the surgery?
- What if the mesh doesn’t correct my problem?
- If I have a complication related to the mesh, can the mesh be removed and what could the consequences be?
- If a mesh is to be used, is there patient information that comes with the product, and can I have a copy?

Reporting complications to the FDA
In order to help FDA learn more about possible problems with surgical mesh, it is important that both physicians and patients report complications that may be associated with this product.

You can report any problems to the FDA’s MedWatch Adverse Event Reporting program either online, by mail or FAX.
- Online : www.fda.gov/MedWatch/report.htm
- Mail : use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
  Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178
The Pelvic Health Coalition (PHC) is a broad-based coalition representing leading obstetric, urologic, and gynecologic healthcare professionals as well as the major industry leaders involved with developing innovative technologies used to treat pelvic health disorders.

In October of 2008 the FDA released a Public Health Notification (PHN) titled “Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair for Pelvic Organ Prolapse and Stress Urinary Incontinence”. Listed below are the Pelvic Health Coalition’s responses to this notification.

- The Public Health Notification (PHN) states that more than a 1,000 complications have been reported to the FDA in the last three years associated with surgical mesh devices used to repair pelvic organ prolapse and stress urinary incontinence.

- This represents approximately 0.1 percent complication rate when considering over 800,000 such procedures using mesh were performed during that time (2005-2007) in the United States (source: Millenium Research).

- Procedures that do not use a medical device mesh are not under the same FDA adverse event reporting requirements as procedures using the mesh device. The FDA does not have the ability to compare the numerator of the number of reported complications to the denominator of total mesh procedures performed in the US over the same time period of the reported complications to identify an incidence rate, as the total number of mesh procedures is not data which is available to the FDA.

- Information given to the public regarding the risks and benefits of a surgical mesh procedure should be contained within a broader and balanced discussion of the risks and benefits of any pelvic surgery without the use of mesh.

- Mesh-based pelvic organ prolapse and stress urinary incontinence procedures have been investigated in numerous clinical studies in the US and abroad. Many clinical studies have demonstrated the potential benefits of the devices, even with the complications noted in the Public Health Notification (PHN).

- The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) recently issued an interventional procedure guidance which stated that “The evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh.”

- With the exception of mesh erosion, clinical evidence supports that “traditional” non-mesh repairs (such as anterior colporrhaphy, Burch colposuspension) have similar incidence of the complications listed in the Public Health Notification (PHN). Additionally, there is clinical literature that concludes that non-mesh procedures have a higher incidence of recurrence than mesh procedures, which may lead to additional surgical procedures for patients.
FDA Update on Surgical Mesh

On July 13, 2011, The US Food and Drug Administration (FDA) released a Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. This handout includes important excerpts from that Update. The FDA Update can be viewed in its entirety online at www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.

Device
Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porcous 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.
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, neuromuscular 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.

FDA 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.

THIS HANDBOOK IS NOT MEANT TO SERVE AS A COMPREHENSIVE SUMMARY OF THE JULY 13, 2011 FDA SAFETY COMMUNICATION: UPDATE ON SERIOUS COMPLICATIONS ASSOCIATED WITH TRANSVAGINAL PLACEMENT OF SURGICAL MESH FOR PELVIC ORGAN PROLAPSE.

THE FDA UPDATE CAN BE VIEWED ONLINE IN ITS ENTIRETY AT WWW.FDA.GOV/MEDICALDEVICES/SAFETY/ALERTSANDNOTICES/UCM262435.HTM.

PRIOR TO YOUR SURGERY PLEASE MAKE SURE THAT ALL YOUR QUESTIONS AND CONCERNS HAVE BEEN ADDRESSED TO YOUR SATISFACTION. IT IS OUR PRIVILEGE TO HAVE YOU AS A PATIENT, AND WE HOPE THAT YOUR SURGICAL EXPERIENCE WILL BE AS PLEASANT AS POSSIBLE.