

Response to FDA Safety Communication dated July 13, 2011

To Our Patients:

In the past few months there has been some conflicting information released about the use of synthetic mesh materials for the repair of pelvic organ prolapse. Clinical research, by some physicians, demonstrate very favorable results with improvement in anatomy and quality of life, while other studies suggest no benefit and potential risks. Interestingly these studies are often conducted on the very same mesh or procedure, yet yield very different outcomes and conclusions. The FDA recently released a new statement (July 13, 2011) concerning the complications that have been reported about vaginal mesh. Understandably, the FDA tends to “hear” from physicians and patients only about the negative outcomes or problems, not positive results.

Many effective treatments exist for pelvic organ prolapse 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 prolapse 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 designs may be responsible for several of the complications included in the FDA posting. Of note, 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 prolapse (i.e. sacrocolpopexy) in the most recent warning.

Numerous clinical studies have been conducted on mesh and non-mesh repairs for prolapse. The clinical data demonstrates that transvaginal anterior mesh repair for prolapse has higher success rates than non-mesh repair within the first year of implant. Additionally, in head-to-head trials, adverse event rates between mesh and non-mesh groups are not statistically different.

The contemporary incorporation of mesh into surgical repair has pros and cons. Mesh may improve long term anatomic results of surgery as compared to non-mesh repairs

for some types of prolapse but is also associated with risks to the patient. Complications can occur during any surgical procedure and mesh complications can and do happen. The key to decreasing the risk of these complications is to place the mesh properly. This requires the correct surgical technique for dissection (preparing the space within the pelvis in which the mesh will 'lie'), delivery (bringing the mesh to the optimal attachment sites) and setting or "adjusting" the mesh material.

The physicians at Associated Urologists of Orange County have been using mesh during vaginal surgery for many years with excellent results. In order for us to feel confident about counseling our patients on the success of vaginal mesh, we have done extensive research and continue to monitor our patients long after they have had the mesh implanted. The most common risks of mesh placement include exposure of mesh material, and/or pain with intercourse.

We have helped develop the proper techniques, have trained the other physicians, and lead the region and the county in experience with proper mesh placement. We are committed to providing our patients with effective surgical techniques while focusing on safety. We strive to meet the needs of our patients with evidence-based solutions and will continue to deliver the most appropriate care based on each individual case. We hope this information provides you with a better understanding and a more balanced perspective to vaginal mesh surgery and also relieves you of any unnecessary concerns.

Sincerely,

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