



# Transvaginal Mesh Implants

The Anapol Schwartz Perspective

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## WHAT IS TRANSVAGINAL MESH?

Transvaginal mesh is a medical device that is implanted into a woman's vagina. It is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material.

More than 75,000 women received transvaginal mesh implants in 2010 to strengthen weak pelvic muscles that fail to support internal organs. Incisions made inside the vagina and the tissue supporting the vagina will be strengthened with stitches. The mesh is placed underneath the vaginal skin. The mesh provides reinforcement of the weakened vaginal tissue.

The same mesh has been used to repair hernias. Mesh has many holes to allow body tissue to grow into the mesh. The mesh then provides a framework of support. The vaginal mesh looks like a sling or tiny hammock.

Vaginal meshes are considered a medical device because they are implanted in your body under an anesthetic. Vaginal meshes are made from a synthetic material and considered permanent.



## WHAT CONDITIONS IS TRANSVAGINAL MESH USED TO TREAT?

There are basically three reasons why some doctors prescribe surgery to implant vaginal meshes in their female patients.

According to their doctors, women need transvaginal mesh to be permanently implanted to reinforce their weakened vaginal wall to repair pelvic organ prolapse. Pelvic organ prolapse (POP) happens when the pelvic organs such as the bladder, uterus and bowel become so weak that the organs drop from their normal position and prolapse — or bulge — into the vagina. Pelvic organ prolapse is not life-threatening. However, women with POP have pelvic discomfort, disruption of their sexual, urinary, and defecating functions, and an overall decline in their quality of life.

The second problem that is sometimes treated by transvaginal mesh implants is stress urinary incontinence, or SUI. Stress urinary incontinence is caused by insufficient strength of the pelvic floor muscles, leading to involuntary urination. The intention behind the surgery is that a transvaginal mesh implant will help support the urethra to treat urinary incontinence. While very common, SUI is often written off as a natural part of aging. However, women of all ages can be affected by SUI. If left untreated — or dismissed as a “just live with it” condition — SUI will put severe restrictions on a woman's lifestyle.

Finally, the third common use of transvaginal mesh implants is to repair hernias.

The federal Food and Drug Administration (FDA), which regulates medical devices, has given permission for transvaginal mesh to be marketed and implanted. Medical experts say implants can be helpful for some women. However, recent events have caused some doctors and even the FDA to take another look at the devices.

## WHO MANUFACTURES TRANSVAGINAL MESH?

Recently, the dangers of transvaginal mesh devices have been publicized. Women and their doctors have been warned about the potentially serious side effects caused by these surgical devices. So far, the FDA has not issued a recall, nor have the manufacturers voluntarily taken the products off of the market.

Four companies manufacture the majority of transvaginal mesh devices, but each company [uses several different trade names](#) for the meshes. The current makers of transvaginal mesh surgical implants include:

- Johnson & Johnson: Johnson & Johnson's Ethicon Women's Health & Urology division makes vaginal mesh patches under brand names such as Ethicon TVT, Gynecare TVT Sling, Gynemesh PS, Gynecare Prolift Mesh, Gynecare Prolene Mesh, Prolene Polypropylene Mesh Patch, Secur, and others.
- C. R. Bard: Bard transvaginal mesh devices include Align, Avaulta Plus™, Avaulta Solo™ Synthetic Support System, BioSynthetic Support System, Faslatra® Allograft, Pelvicol® Tissue, PelviSoft® Biomesh, Pelvix™ Polypropylene Mesh, Pelvilace, Uretex, Ugytex, and others.
- American Medical Systems: American Medical Systems (AMS) manufactures vaginal mesh devices under the brand names Apogee®, BioArc®, Elevate®, In-Fast®, MiniArc®, Monarc®, Perigee®, and SPARC®.
- Boston Scientific: Boston Scientific transvaginal mesh patches include the Advantage™ Sling System, Lynx™ Suprapubic Mid-Urethral Sling System, Obtryx® Curved Single, Obtryx® Mesh Sling, Prefyx Mid U™ Mesh Sling System, Prefyx PPS™ System, and others.

If you have received a transvaginal mesh implant from any of these manufacturers, then it is important to be aware of the potentially serious side effects and to see your doctor if you exhibit any symptoms.





## WHAT ARE THE PROBLEMS WITH TRANSVAGINAL MESH IMPLANTS?

While the mesh makers say their medical devices are safe, various surgeons have spoken out that transvaginal mesh should be used in limited numbers and only by well-trained physicians on a limited number of specifically chosen patients who have a propensity for successful surgery.

Patients have claimed transvaginal mesh surgeries have led to internal injuries. Hundreds of lawsuits have been filed against the transvaginal mesh makers.

The Food and Drug Administration, which regulates medical devices, noted more than 1,000 adverse reports for transvaginal mesh implants from 2005 through 2007. From January 1, 2008, through December 31, 2010, the [FDA received 2,874 reports](#) of complications associated with transvaginal mesh implant devices used to repair pelvic organ prolapse and stress urinary incontinence. During that two year period, there were seven reported deaths associated with pelvic organ prolapse repairs. Three deaths were related to transvaginal mesh implant procedures – two were bowel perforations and one was a hemorrhage.

In July, 2011, the FDA issued [two safety alerts](#) for surgical mesh. One alert was for surgical mesh for pelvic organ prolapse (POP) and stress urinary incontinence (SUI); the second alert was for hernia repair. These alerts warned medical professionals of the large number of complications associated with implanting vaginal meshes. It's worth noting that these complications were not linked to a single brand of mesh. Many of the brands of hernia mesh medical devices have been recalled or no longer on the market while the medical devices geared to women for vaginal POP and SUI have not been recalled.

The [FDA pointed out](#) that, based on the new data, it is not clear whether transvaginal POP repairs using mesh is more effective than other, non-mesh utilizing repairs in patients with POP, and the mesh may expose great risks to patients.

The following are problems have been linked to transvaginal mesh:

- Fistulas
- Infections
- Internal bleeding
- Mesh erosion into the vagina, bladder, intestines, and uterus
- Mesh shrinkage
- Mesh migration
- Organ perforation
- Pain
- Pain during sexual intercourse for both partners
- Punctures to the bladder, blood vessels, bowels or other organs in the lower abdomen
- Recurrence of POP or SUI, or both
- Urinary problems, including painful urination
- Vaginal wall narrowing

There have also been reports of recurring prolapse, vaginal scarring, vaginal shrinkage, and emotional problems related to the mesh. These complications often result in a patient requiring additional treatment, including surgery and further hospitalization.

There is another important difference between the 2008 and 2011 reports. In 2008, the FDA advised that the complications associated with vaginal mesh products were rare. According to the Updated Public Health Information published on July 13, 2011, the [FDA has now concluded](#) that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare.**"

## WHAT IS THE GOVERNMENT DOING TO HELP?

The [Food and Drug Administration](#) made recommendations to healthcare professionals in October, 2008, and issued more urgent warnings in July 2011. In these publications, the FDA has made the following recommendations for patients with transvaginal mesh:

- Continue with your annual checkup, and other routine checkups and follow-up care.
- 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.
- 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.

Equally important are the actions that the FDA has **not** taken. The FDA has not banned the use of mesh products for vaginal implant surgeries. It has not forced a recall of specific brands used to treat pelvic organ prolapse or stress urinary incontinence. It has not required mandatory follow-up studies of patients with these implants. It has issued product warnings to physicians, but not directly to the consumers who will have those devices implanted inside their bodies.

Some doctors would like to see a registry to follow patients who already have implants. Other medical experts have suggested that more clinical trials are needed to establish whether the benefits of transvaginal mesh outweigh the risks. Again, the FDA has not yet acted on these recommendations.

The Food and Drug Administration is a helpful agency, but it is [simply not responding fast enough on this issue](#). The FDA took three years to communicate their concerns to physicians. In 2010 alone, nearly 100,000 patients were treated for POP and 75,000 of them received a mesh implant. Better information might have made a difference in the treatment decision of those patients.

The FDA's stern warnings will be helpful for some women. Their doctors will pay attention to the warnings and plan safer alternatives to vaginal mesh implants, where their patients' conditions permits. For some women, however, the FDA warnings are too late. They are already suffering.

This highlights the need for patients to be proactive in their treatment.





## WHAT OPTIONS ARE THERE IF I HAVE BEEN INJURED?

If you are reading about transvaginal mesh implants, it is likely that you, your partner, or a loved one has had or is about to have this surgery. You are understandably concerned about the risks from mesh implants.

Because the FDA is currently limiting its role to issuing warnings only, it falls on the patient herself to pursue justice if a transvaginal mesh implant has led to avoidable suffering. Fortunately, our [robust justice system](#) provides allies for the patients who have been harmed.

More than 400 lawsuits are pending in New Jersey state court against Johnson and Johnson's Ethicon brand for injuries allegedly caused by several transvaginal mesh products. Those lawsuits allege that Johnson & Johnson knew the products were unreasonably dangerous but continued to manufacture and sell them regardless. Likewise, more than 100 women have filed lawsuits over complications from Bard Avaulta vaginal mesh products. Legal action has been filed on behalf of women who had failed surgery using SPARC® brand transvaginal mesh patch produced by American Medical Systems.

If you or a loved one have suffered or been injured from a defective transvaginal mesh implant, you may be entitled to compensation. It is important for you to understand your legal rights and options.

## WHOM SHOULD I CONTACT?

If you or a loved one has suffered adverse effects related to transvaginal mesh surgery, [transvaginal mesh attorneys in Philadelphia](#) can help you understand what your legal options are, and whether you are eligible to receive compensation for your suffering.

Many legal websites are now advertising their services as transvaginal mesh failure lawyers. So how do you make a decision? Just pick a name out of a directory, at random?

Of course, we have a recommendation for a transvaginal mesh failure lawyer—[Anapol Schwartz](#). And this recommendation is based on solid achievements—a proven track record: Eleven of Anapol Schwartz's lawyers have received jury verdicts in excess of one million dollars, and virtually every attorney has participated in obtaining multiple settlements over one million dollars.

- Jim Ronca, shareholder at law firm Anapol, Schwartz, Weiss, Cohan, Feldman and Smalley, P.C., recently achieved \$19.9 million in collective settlements on behalf of consumers injured by Bayer AG's blood-preserving drug Trasylol. Ronca settled 20 cases in the national multidistrict litigation (MDL), for which he was co-lead counsel, and 19 cases in the coordinated Pennsylvania litigation, where he was liaison counsel.
- Sol Weiss earned a \$68.5 million dollar settlement for 168 people seriously injured by the statin drug Baycol. Sol negotiated the settlement with Bayer, which withdrew the medication from the market.
- Barry Hill negotiated another \$46 million in Baycol settlements with Bayer for a separate group of clients.

[Anapol Schwartz](#) (1-866-735-2792) represents people just like you, small businesses, and the injured in class action lawsuits throughout the country, seeking money damages and other relief in the federal and state court systems. Most importantly, they have attorneys specializing in legal action on behalf of women injured by transvaginal mesh implants.

Their achievements are many. More importantly, their clients become their causes. You won't know whether or not Anapol Schwartz law firm is right for you until you contact them, communicate, and feel comfortable with them.