**Vaginal Rejuvenation Side Effects and Lawsuits**

The American Society of Aesthetic Plastic Surgery reported that in [3,494 vaginal rejuvenation surgeries](http://www.center4research.org/nips-tucks-designer-vaginas/) were performed in 2008 while 2,531 were performed in 2009. It is likely that the actual number is a lot higher as many of the doctors who do perform genital reconstructive surgery are gynecologists and obstetricians and these statistics are not recorded or tabulated by any agency or even the American College of Obstetricians and Gynecologists. Laser Vaginal Rejuvenation Institute of Los Angeles founder and director, Dr. David L. Matlock says that he has performed over 3,000 of these surgical procedures in the past 12 years.

**What is Vaginal Rejuvenation?**

The term “vaginal rejuvenation” covers a number of different types of surgery. It is also often refered to as a kind of female genital plastic surgery, vulvovaginal plastic surgery, female genital rejuvenation surgery, designer vagina surgery and female genital cosmetic surgery. Among the surgical procedures comprising female genital plastic surgery are vaginoplasty, labiaplasty, monsplasty, labia majoraplasty and clitoral hood reduction.

This type of surgery is advertised for women who experience tightness or looseness of the vagina, urinary incontinence, dryness, or pain during sexual intercourse. Surgeons use radio frequency waves, lasers, cryotherapy or other devices to tighten the tissues of the vagina.

In recent years, a number of companies have developed devices for vaginal rejuvenation. Most devices use lasers or radiofrequency to make it possible for surgeons to perform minimally or non-invasive procedures to tighten or rejuvenate female genital parts. The problem is that these devices have not been FDA-approved for these procedures and federal law prohibits companies that manufacture medical devices from marketing their products for purposes that are unapproved. Additionally, a large number of women have come forward and reported side effects or complications arising from vaginal rejuvenation surgical procedures.

**Potential Side Effects of Vaginal Rejuvenation**

Side effects of vaginal rejuvenation surgery include the following:

* Dryness
* Vaginal burns
* Adhesions
* Bleeding
* Numbness or loss of sensation
* Pain with sexual intercourse
* Scarring
* Significant chronic pain
* Infection

A lot of women are opting for vaginal rejuvenation, especially those who have gone through the rigors of childbirth. Although it is primarily thought of an aesthetic type of surgery to improve the female genital area’s appearance, there are a number of sound medical reasons to opt for vaginal rejuvenation, such as SUI, irritation of the labia minora or labia majora, better access to the clitoris, or weakness in the perineum. It should be noted that this procedure is not recommended to treat female sexual dysfunction or sexual problems. As with any type of surgical procedure, there are potential side effects that could have an impact on the decision of whether or not vaginal rejuvenation surgery is the best choice for optimal health.

Nerve Damage: The genital area of the female body is replete with nerve endings. Nerves can be damaged or severed during surgical procedures like vaginal rejuvenation, resulting in too much sensation, also called hyper sensation, or a lack of sensation, also known as hypo sensation. Because nerves do not usually regenerate, this side effect is permanent. There is no surgeon who can guarantee that this will not occur. This is why it is important to consider the risk before deciding whether or not to undergo the surgery.

Scarring: The goal of most vaginal rejuvenation surgeries is an improved genital appearance. Scarring from this type of surgical procedure will be internal, but it will be there. This could result in a loss of sensation or dead spots. Additionally, if the scarring is severe, additional surgery could be required.

Urine Retention, Rectal or Bladder Damage: The inability to urinate, or urinary retention, is a possible side effect of vaginal rejuvenation surgery. This can result in serious health issues such as damage to the kidney, or nephrosis, and immediate attention will be necessary to correct it. Additionally, this type of procedure can damage the bladder or rectum, although such instances are not common. Any surgery comes with risks. However, you can minimize the chances by conducting thorough research on the surgeon you choose, making sure that you pick one with experience in performing this type of surgery.

Bleeding and Infection: Because of where the surgery is performed, infections can occur if the patient does not maintain proper hygiene. For anywhere between 4 to 8 weeks, limitations will be put on lifting and activities to help in preventing excessive post-surgical bleeding. It is also required for patients to abstain from sex during this period in order to make a full recovery. It is imperative to follow the doctor’s instructions for a healthful healing.

Vaginal rejuvenation is a relatively new type of surgery, and it has been stated by the American College of Obstetrics and Gynecology that adequate studies have not been conducted to date to assess the procedures’ long-term safety and rates of complications. Whether performed from medical necessity or elective, any surgical procedure carries risks for complications or side effects. It is extremely important to remember that you must choose the surgeon who performs the surgery carefully and make sure to follow the instructions regarding care before and after the procedure for the best results.

**Three Primary Laser Platforms**

One of the hottest topics in urology nowadays is women’s health, and vaginal health in particular. The laser vaginal rejuvenation world is a fast-paced one, with companies coming up with a new laser platform nearly every month. These latest treatments provide urologists many potential opportunities as well as challenges.

When assessing the laser vaginal rejuvenation market, it is important for urologists to form their research around treatment indications as well as proposed laser mechanism of action. At present, there are three basic categories that are used for this purpose: CO2, radio frequency (RF), and erbium:YAG (Er:YAG).

* CO2: This is a fractionated laser that operates at a wavelength of 10,600 nm. This is a relatively short wavelength that allows for more superficial supervision of the tissue. Genitourinary syndrome of menopause (GSM) is the most common indication for laser vaginal therapy, although companies are also touting efficacy in the treatment of stress urinary incontinence (SUI). CO2 can also be used on the vulva and as a treatment for lichen sclerosis (LS).
* Radiofrequency (RF): This is a laser that generally penetrates tissue more deeply, which is why it is indicated for vaginal laxity. With radio frequency, the frequency is lower while the wavelength is relatively longer, allowing for deep tissue heating. There are also a number of RF platforms that treat GSM. On the other hand, some platforms advertise for SUI treatment with a combination of internal and external applicators.
* Erbium: Er:YAG is ablative, operating at 2,940 nm. This technology is used in different platforms alone or in combination with a diode that operates at 1,470 nm – this is known as a hybrid fractional laser. Er.YAG’s proposed action of mechanism is similar to CO2 in that it stimulates neocollagenesis. The controlled thermal injury also leads to angiogenesis. This platform carries the same indications as CO2 and is currently being marketed for GMS, SUI and LS.

**Vaginal Rejuvenation Procedure**

All of the laser platforms can be used in a doctor’s office or clinic. A topical anesthetic is typically applied to the area that needs to be treated for 10 to 20 minutes. The medical professional applies the laser energy internally to the vagina’s epithelium through probes or externally with adaptors. Treatments take anywhere between 5 and 10 minutes. The total time of your office visit will be 30 to 45 minutes. Between 3 and 5 treatment sessions spaced 4 to 6 weeks apart are suggested for most platforms to get optimal results. Following the procedure, you do not need to worry about downtime.

Contraindications for the procedures include active urinary tract or vaginal infection, active genitourinary cancer, undiagnosed cervical or vaginal lesions, and pregnancy, including 3 months after pregnancy. A relative contraindication is pelvic organ prolapse that is greater than stage II. Experts do not recommend the therapy for women who have had mesh prolapse surgery in the past.

Depending on the specific procedure that the patient chooses, the cost of vaginal rejuvenation can range from $4,000 to $10,000. This type of surgery is considered a cosmetic surgery by most insurance companies, which is why they do not offer coverage. However, in cases where vaginal rejuvenation surgery is performed to correct a medical condition that is legitimately covered, the patient may be eligible for cost reductions.

**Avoiding Vaginal Rejuvenation Surgery**

With stories popping in magazines and all over the Internet, vaginal rejuvenation is becoming a common cosmetic surgical procedure. What you may not know is that even though it is considered cosmetic surgery, it is still surgery and a lot more invasive than people are made to believe. Vaginal rejuvenation should be considered as a last resort, like any other type of surgery. The fact that a laser is used to perform the procedure gives the impression that it is non-invasive and perfectly safe. However, as mentioned already, it does not come without risks.

If you need the results provided by laser vaginal rejuvenation, it is important to keep in mind that there are safer options that cost less and do not come with the risk of complications or side effects. There are creams available on the market to tighten the vagina as well as improve dryness in the vaginal area and increase libido and sexual pleasure. You can achieve these results without surgery.

**FDA Warnings About Laser devices for Vaginal Rejuvenation**

The U.S. Food and Drug Administration (FDA) announced that it has issued warnings to several companies to put an end to marketing laser devices for procedures that are billed as “vaginal rejuvenation.” They said that these procedures were treatments that are dangerous and deceptive.

The FDA initially approved for lasers and other similar energy-based devices to be put out into the market to treat life-threatening conditions, such cancer and genital warts, or surgical procedures including hysterectomies. Lasers and other energy-based devices are not approved for any type of procedure for vaginal rejuvenation. Companies are prohibited by federal law from marketing medical devices for purposed that are unapproved.

However, in the last few years, several companies that manufacture these kind of devices have left no stone unturned in heavily promoting the use of lasers for symptoms that are related to menopause, vaginal atrophy, sexual function and urinary incontinence. Additionally, lasers and other products used for vaginal health in cosmetic, spa treatments have become increasingly common and very popular among younger women.

These devices are used in some treatments to reshape or destroy vaginal tissue. The companies manufacturing these devices say that they can solve some problems that are related to dryness and other issues. The FDA does not agree. However, although the agency originally approved the devices only for certain treatments, doctors can legally use them for off-label conditions.

In July 2018, the FDA issued a Safety Communication to warn that there are serious safety risks associated with vaginal rejuvenation. Furthermore, it added that the devices are being deceptively marketed for uses that have not been approved by the agency.

The FDA also stated that there are concerns about the deceptive marketing of these devices and how it could prevent some patients from receiving appropriate treatment for the serious medical conditions that they suffer from. The agency said that the full extent of the risks is still not known, but has found cases, scarring, vaginal burns, long-lasting pain and other side effects that have been mentioned earlier following the treatments. 14 reports of adverse events that are related vaginal rejuvenation treatments 1 have been received by the FDA, including significant pain and burning sensations.

**Companies Warned By the FDA**

The FDA is warning doctors and women that devices available on the market that purport to make cosmetic vaginal alterations have not been approved by regulators for that purpose and could lead to painful and dangerous side effects.

The agency has issued warnings to seven companies stating that their radiofrequency- or laser-based products are being marketed inappropriately as providing “vaginal rejuvenation” procedures. The companies have made claims that the devices have the ability to tighten the vagina or treat symptoms of conditions that have already been mentioned above.

The FDA has also received reports of incidences in which companies are marketing the devices to women who are having signs of early menopause and have been treated for breast cancer. The agency stated that it is egregious to deceptively market a dangerous procedure without any proven benefit, including two women who have received treatment for cancer.

The FDA has not approved any non-surgical devices on the market to treat any of these conditions. Instead, as mentioned earlier, they have been approved to destroy precancerous vaginal or cervical tissue as well as genital warts. The agency has found that when the devices are used outside of their approved purpose, they have resulted in pain during urination or sex, burning of the vagina, and scarring. They said that they were deeply concerned about women being harmed by these devices.

The companies that the FDA issued warnings to include Alma Lasers, BTL Industries, BTL Aesthetics, InMode, Cynosure, Thermigen and Sciton. They were given 30 days to respond to the concerns of the agency. If they fail to do so, then the FDA will take other measures, which could include asking the manufacturers to remove devices from the market entirely. The agency is also asking the public to report any incidents that they have had while using the devices.

The letters issued to laser device manufacturers are considered a step short of a formal warning. The agency asked the companies to provide details on their product and the basis on which they are assuming approval.

There has been a lot of pressure on the FDA to speed up the approval of medical devices. According to critics, device approvals by the agency are already moving at an extremely fast pace and occurring with insufficient oversight. In its announcement, the agency said that they would strengthen their device studies after being approved for sale.

The American College of Obstetricians and Gynecologists has also issued several statements that note that the MonaLisa Touch and other devices do not have clearance or approval from the FDA for treating symptoms of menopause, as advertised. The college said that obstetrician-gynecologists should be aware of the evidence when it comes to the use of new and innovative practices and should also be wary of adopting any medical approaches that are “new and innovative” on the basis of just marketing or promotions.

**Botched Labiaplasty**

Before discussing botched Labiaplasty, let us find out what exactly the surgery is and who is a candidate for the procedure. Also known as labia reduction surgery or labia surgery, Labiaplasty is a surgical procedure that is designed to reduce the size of the smaller inner vaginal lips, called the labia minora. Needless to say, as with any other type of surgery, it is extremely important to select a Labiaplasty surgeon with experience and specialization in the procedure.

Appearance of the labia minora naturally varies from one woman to the next. There are a large number of women who are born with large labia minora or experience changes in their labia’s appearance after childbirth. While some women want to get a labiaplasty done purely for cosmetic reasons, there are others who may have large labia minora that cause irritation or discomfort. Labia reduction surgery may also help in resolving symptoms that women with large labia minora experience, including:

* Pain/discomfort/irritation/pulling with intercourse
* Pain/discomfort/irritation/pulling with certain activities/clothing/exercise
* Irritation with prolonged walking or sitting
* Inability to wear certain clothes/bikini/lingerie
* Multi-directional stream of urine
* Odor and other issues related to hygiene
* Dissatisfaction with the appearance of the labia due to length, pigmentation or asymmetry
* Previous labiaplasty that requires surgical correction
* Inhibition from sexual activity or embarrassment or self-consciousness due to extra tissue

When labiaplasty has gone wrong, the results that the patient receives are less than desirable. In many cases, experienced surgeons can repair a botched labiaplasty. However, it is important to remember that once the labia are cut, it is not possible to put them back. This is why it is imperative that you choose a surgeon who is skilled and experienced and has experience in labiaplasty.

Labiaplasty is performed under either local or general anesthesia in an outpatient surgery center. Depending on the complexity of each individual case, the procedure may take about 60 to 90 minutes. During this type of surgery, surgeons use a scalpel to contour the labia. Depending on the needs and wishes of the patient, a labiaplasty can:

* Reduce both labia
* Reduce only one side to make the labia symmetrical in size
* Remove pigmented edges so that they are pink and look more youthful. In some cases, women prefer keeping the darkened labia and a labiaplasty can also accomplish this.

**Importance of Choosing a Highly Experienced Labia Surgeon**

Many people regard labiaplasty as a simple surgery. They think that it is just a matter of cutting off the labia minora that is enlarged. This is far from the truth. Labiaplasty is an intricate, complex surgical procedure and requires a high degree of expertise in order to achieve the results that patients desire. The last thing you want is to entrust this delicate part of your body to a surgeon who does not have adequate experience in performing this type of surgery. You should keep in mind that a plastic surgeon may or may not have the expertise needed to perform this type of vaginal cosmetic surgery successfully. This is why it is critical to consider the labiaplasty surgeon’s training and experience when considering labia surgery for any reason.

**Causes of a Bad Labiaplasty**

When patients have undergone a bad labiaplasty, it is usually because they have had the procedure performed by an unqualified, inexperienced cosmetic surgeon or gynecologist who did the first surgery for labia reduction after showing them a few pictures. You might be surprised to learn that this happens quite frequently.

A patient may talk to a doctor who says that they perform this type of procedure and offer to do it for a “good” or low price. The end result may not only be the physical damage done to the labia, but also psychological damage to the patient.

It is important to keep in mind that at this time, there are relatively few doctors across the US, even the world, with the knowledge, experience and skill to perform a high-quality labiaplasty that is aesthetically pleasing, or the additional procedures in conjunction with this type of vaginal rejuvenation surgery that may be required to get the correct and desired results.

**Labiaplasty Malpractice Lawsuits**

Botched labiaplasty procedures are increasing significantly in recent years. Many women opt for labiaplasty and other vaginal rejuvenation surgical procedures for largely aesthetic reasons and the unfortunate truth is that they are often misinformed by various sources, including manufacturers of laser devices for vaginal rejuvenation, regarding the risks and side effects that come with these procedures. The vast majority of advertisements of such devices and procedures promise women that not only will they have aesthetically-pleasing labia, but also experience more sexual pleasure by undergoing labiaplasty or other vaginal rejuvenation surgeries.

However, there can be many complications that can arise with any cosmetic surgery, including labiaplasty, even if it is performed by the most careful surgeons. The result of a botched labiaplasty surgery is, in the majority of cases, caused by an inexperienced surgeon, the technique that the surgeon uses, or a surgeon who is not bothered about performing a procedure that produces an ideal aesthetic and functional result.

In potential cases for medical malpractice or defective products involving botched labiaplasty or any other cosmetic surgery on the genital area, it is important to get honest and objective answers. You should seek the help of a lawyer who has experience in handling such cases and can provide straightforward answers and proper legal advice. They can provide the aggressive legal representation you need to hold the manufacturers of laser devices or the surgeons liable for the complications or serious side effects you experienced as a result of their negligence.

**Claims Made by Vaginal Rejuvenation Device Manufacturers**

As mentioned above, the FDA has contacted several companies that manufacture and sell laser and radiofrequency devices for rejuvenation purposes. The sole intention of agencies such as the Women’s Health Technologies Strategically Coordinated Registry Network is to help in addressing and bringing to light the lack of evidence into the treatment of pelvic floor disorders and other conditions.

Despite their lack of approval from the FDA, manufacturers are actively marketing their devices for treating symptoms related to menopause. Cynosure’s website says that its product, the MonaLisa Touch is a clinically proven laser treatment that is simple and safe and ideal for painful menopause-related symptoms, including intimacy.

Alma Lasers, another company that the FDA has warned, states in its website that its product, the FEMILIFT, is a laser-assisted procedure uses a CO2 laser to provide vaporization and thermal effect to help in improving vaginal irregularities.

A Venus Concept website, which the FDA letter to BTL Aesthetics mentions, says that its product, the Venus Fiore System is designed to address mons pubis reduction, labia skin tightening and internal vaginal health restoration.

All of these claims and more are questioned in the letters by the FDA.

A medical aesthetics division of Hologic, Cynosure said that the company was aware of the FDA letter and ensured that they were taking the contents seriously. It stated that they are evaluating the letter in full and will work with the FDA to make sure that all product communications adhere to regulatory requirements.

**Lawsuits Against Manufacturers of Devices for Performing Vaginal Rejuvenation**

Unfortunately, cosmetic surgery, including vaginal rejuvenation, is growing in popularity among women all over the world. The pressure to look “perfect” in every way has pushed many women, including young girls, to opt for vaginal rejuvenation surgery. What is even more unfortunate is that a large number of the women who have undergone this type of procedure have been diagnosed with complications or side effects resulting from the treatment.

The truth is that the deceptive marketing of the devices is the main cause of the side effects and complications suffered by women who have undergone vaginal rejuvenation. As mentioned already, the manufacturers claim that their devices are safe and effective for this type of surgery regardless of not being approved by the FDA for these purposes.

Only a qualified lawyer can determine whether you are eligible to file a lawsuit against a manufacturer of a laser used for vaginal rejuvenation treatment. Many law firms are currently offering free case evaluations for women who have undergone this type of surgery and suffered complications or side effects as a result.

In most cases that involve medical devices, it is alleged that a product was sold with defects in its design, manufacture or marketing process. This typically refers to the failure of a company to warn medical professionals and patients of a certain potential complication. In lawsuits involving vaginal rejuvenation, patients may be able to take legal action against the manufacturers of such devices in light of claims that they failed to adequately warn doctors as well as patients about the risk of scarring, vaginal burns and other serious side effects.

**File a Vaginal Rejuvenation Lawsuit**

If you or a loved one has been diagnosed with a side effect or complication caused by vaginal rejuvenation surgery, you should immediately seek the help of an experienced and trustworthy lawyer to help you file a lawsuit against the manufacturer of the device used in the surgery. The lawyer will evaluate your case and determine if you have a viable case against the company. If so, you can go ahead and file a vaginal rejuvenation lawsuit against the company and obtain compensation for the injury and other adverse events you have experienced as a result of their product.