

The Women's Health Group's Response to the FDA's announcement concerning MonaLisa Touch Treatment

FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication:

<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm>

Recently, the FDA issued a warning to companies to stop using the phrase “vaginal rejuvenation” in the marketing of certain devices promoted for the treatment of menopause symptoms, urinary incontinence, or sexual function. Moreover, the FDA notes reports of pain, scarring, and vaginal burns have been reported. Since we do promote the use of our new vaginal laser, the **MonaLisa Touch** system, we here at The Women's Health Group want to comment on and provide our response to these statements as quickly as possible.

First, **we always want to emphasize that our main concern is for the safety and well-being of our patients.** We emphasize that we believe the **MonaLisa Touch** system to be completely safe and beneficial for our patients.

When devices malfunction or cause harm, these claims are forwarded to the FDA and recorded in a large government database sorted by device. We have searched this database for complaints related to the **MonaLisa Touch** system reported over the last four years. **Over the last four years, there are no issues reported to the FDA related to the MonaLisa Touch used for the treatment of postmenopausal vulvovaginal atrophy or for any other reason.** We want to reassure you, our patients. We have not relied on the company to provide this data. We did the search for poor outcomes, of any sort, ourselves. While other devices made by other manufacturers may have had poor outcomes, there are simply none reported on our device, the **MonaLisa Touch**. **The MonaLisa Touch is safe and efficacious and the results we are getting are phenomenal.**

Medical procedures are not without risk. Complications may indeed occur on a rare basis with any device. This is why it is important to receive your care for dryness, atrophy, urine loss, and sexual dysfunction from experienced, well-trained specialists in gynecology. At the Women's Health Group, we reassure you that all our treatments are performed by board certified gynecologists, each with decades of experience using CO2 laser in the treatment of women's vaginal disorders. Again, your health and well-being are the most important things to us, and we welcome the opportunity to discuss how our laser device, the MonaLisa Touch, is the most effective and safe laser on the market today.

It works and works safely. If you are interested in making an appointment or learning more about the **MonaLisa Touch** please contact our clinical care coordinator, Julie Barentine at 303-280-2229 extension 1104.

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