

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

Date Issued:

July 30, 2018

Audience:

- Patients considering any vaginal "rejuvenation" or cosmetic vaginal procedure, or procedures intended to treat vaginal conditions and symptoms related to menopause, urinary incontinence, or sexual function
- Health care providers who perform vaginal procedures using energy-based devices

Specialties:

Primary Care, Obstetrics and Gynecology, Plastic Surgery, General Surgery

Device:

Energy-based devices - commonly radiofrequency or laser - that have received FDA clearance for general gynecologic tool indications, including, but not limited to, the destruction of abnormal or pre-cancerous cervical or vaginal tissue and condylomas (genital warts).

Purpose:

To alert patients and health care providers that the use of energy-based devices to perform vaginal "rejuvenation," cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.

Summary of Problem and Scope:

We are aware that certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. *The safety and effectiveness of energy-based medical devices to perform these procedures has not been established.*

Vaginal "rejuvenation" is an ill-defined term; however, it is sometimes used to describe non-surgical procedures intended to treat vaginal symptoms and/or conditions including, but not limited to:

- Vaginal laxity
- Vaginal atrophy, dryness, or itching
- Pain during sexual intercourse
- Pain during urination
- Decreased sexual sensation

To date, we have not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function. The treatment of these symptoms or conditions by applying energy-based therapies to the vagina may lead to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain.

Recommendations for Patients:

- Be aware that the safety and effectiveness of energy-based devices to perform vaginal "rejuvenation" or cosmetic vaginal procedures has not been established.
- Understand that the FDA has not cleared or approved any energy-based medical device for vaginal "rejuvenation" or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence, or sexual function.
- Discuss the benefits and risks of all available treatment options for vaginal symptoms with your health care provider.
- If you have undergone treatment for vaginal "rejuvenation" and experienced a complication, you are encouraged to file a report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program \(/Safety/MedWatch/HowToReport/ucm085568.htm\)](#).

Recommendations for Health Care Providers:

- Be aware that the safety and effectiveness of energy-based devices to perform vaginal "rejuvenation" or cosmetic vaginal procedures has not been established.
- Understand that the FDA has not cleared or approved any energy-based medical device for vaginal "rejuvenation" or vaginal cosmetic procedures, or for the treatment of vaginal symptoms related to menopause, urinary incontinence, or sexual function.
- Discuss the benefits and risks of all available treatment options for vaginal symptoms with your patients.
- If any patients experience adverse effects from procedures that involved the use of energy-based devices to perform vaginal "rejuvenation", cosmetic procedures, or treat genitourinary symptoms of menopause, sexual dysfunction, or urinary incontinence, please file a report through [MedWatch, the FDA Safety Information and Adverse Event Reporting program \(/Safety/MedWatch/HowToReport/ucm085568.htm\)](#).

FDA Activities:

We are aware that certain device manufacturers may be inappropriately marketing their energy-based devices for the uses noted above that are outside of their cleared or approved intended uses. [We have contacted \(/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm\)](#) these manufacturers to share our concerns and will be monitoring their claims about uses of their products.

In addition, we will continue to monitor reports of adverse events associated with this issue and will keep the public informed if significant new information becomes available.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with procedures marketed as vaginal "rejuvenation". If you experience adverse events associated these procedures, we encourage you to file a voluntary report through [MedWatch \(/Safety/MedWatch/default.htm\)](#), the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to [FDA's user facility reporting requirements \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm\)](#) should follow the reporting procedures established by their facilities.

Other Resources:

- The American College of Obstetricians and Gynecologists Committee Opinion - [Vaginal "Rejuvenation" and Cosmetic Vaginal Procedures](https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Vaginal-Rejuvenation-and-Cosmetic-Vaginal-Procedures) (<https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Vaginal-Rejuvenation-and-Cosmetic-Vaginal-Procedures>)
- The American College of Obstetricians and Gynecologists Position Statement - [Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance](https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Fractional-Laser-Treatment-of-Vulvovaginal-Atrophy-and-US-Food-and-Drug-Administration-Clearance) (<https://www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Fractional-Laser-Treatment-of-Vulvovaginal-Atrophy-and-US-Food-and-Drug-Administration-Clearance>)

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

More in [Safety Communications](#)
(</MedicalDevices/Safety/AlertsandNotices/default.htm>)

[2018 Safety Communications](#)
(</MedicalDevices/Safety/AlertsandNotices/ucm592582.htm>)

[2017 Safety Communications](#)
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