



from JoAnn V. Pinkerton, MD, NCMP, Executive Director



FDA Mandating Vaginal Laser Manufacturers Present Valid Data Before Marketing August 1, 2018

On July 30, 2018, the US Food and Drug Administration (FDA) released an [FDA Safety Communication](#)¹ with the goal of alerting patients and healthcare providers to the fact that the use of energy-based devices (such as radiofrequency or laser) approved to treat gynecologic conditions but are also being used for various vaginal procedures such as vaginal “rejuvenation,” vaginal cosmetic procedures, and procedures intended to treat vaginal conditions and symptoms related to menopause, as well as for urinary incontinence or sexual function may be associated with serious adverse events.

FDA stated that “the safety and effectiveness of energy-based devices for treatment of these conditions has not been established” and warned that “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.”

FDA also stated that it “has not cleared or approved for marketing any energy-based devices to treat the symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function” including procedures for vaginal laxity, vaginal atrophy, dryness, or itching, pain during sexual intercourse, pain during urination or decreased sexual sensation.”

The American College of Obstetricians and Gynecologists in its [2016 Position Statement on Fractional Laser Treatment of Vulvovaginal Atrophy and US Food and Drug Administration Clearance](#)² reviewed the lack of sham-controlled or long-term data on vaginal lasers and stated that its members should be “cognizant of the evidence regarding innovative practices” and should be wary “of adopting new or innovative approaches on the basis of promotions or marketing.”

The North American Menopause Society (NAMS) Perspective

Treating vaginal atrophy, preventing or relieving painful sex and sexual dissatisfaction, reducing urinary incontinence, or improving pelvic floor function are all worthwhile endeavors, and new therapies are needed because many postmenopausal women are underdiagnosed and undertreated. These newer, minimally invasive, ablative or nonablative, energy-based treatment therapies may indeed provide a nonhormone option for genitourinary syndrome of menopause (GSM) because they improve vascularization and connective tissue within the vaginal canal. At present, however, there is a lack of adequate data on the long-term safety, efficacy, clinical outcomes, and short- and long-term adverse events of vaginal lasers and radiofrequency therapies being used.¹⁻⁴

NAMS applauds FDA for its mandate that vaginal laser manufacturers present valid data before marketing products for an array of uses when there remains concern about long-term safety and efficacy. The current products are FDA-approved for gynecologic use but lack the longer-term clinical trials required for FDA approval for the various proposed indications. Their use far exceeds the current data on safety and effectiveness. An increasing number of publications report on small numbers of women, with varying durations from 12 weeks to 12 months, using the therapies for vulvovaginal atrophy, sexual satisfaction or improvement in dyspareunia, incontinence, or pelvic floor laxity.^{5,6} What we need are prospective, randomized, sham-controlled trials to provide an adequate control arm to account for the placebo effect and trials of longer duration beyond 12 months, with adequate inclusion and exclusion criteria and with validated measures of the various outcomes. Randomized sham-controlled trials are possible, as evidenced by two recent publications: one using a radiofrequency⁷ and one using a YAG laser.⁸

The new energy-based therapies may turn out to be an appropriate choice for many women, particularly for those concerned about breast cancer risk.⁹ However, until more robust data are available, leading to FDA approval for the various above-mentioned indications, NAMS recommends that healthcare providers discuss the benefits and risks of all available treatment options for vaginal symptoms, including over-the-counter lubricants, vaginal moisturizers, and FDA-approved vaginal therapies such as vaginal estrogen and

intravaginal dehydroepiandrosterone and oral therapies such as hormone therapy and ospemifene to determine the best treatment for women with GSM. When discussing vaginal energy-based therapies, informed discussion should include that these are FDA-approved devices for gynecology but have not received FDA approval for vaginal rejuvenation or procedures for GSM, sexual function, incontinence, or pelvic laxity and that even though short-term data are promising, more robust, sham-controlled, and longer-term data are needed.

Similar concerns are raised about the increasing number of women undergoing various types of vaginal surgeries, such as labioplasty, vaginoplasty, and "G spot" amplification, to enhance appearance or for sexual gratification without long-term evaluation of benefits or adverse events as women age. Women requesting vaginal procedures for cosmetic or sexual satisfaction should have a careful examination to determine whether surgical procedures are needed or have a discussion of the variety of "normal external genitalia," and if patients are determined to undergo surgery, they should be informed about the lack of data on efficacy and the potential complications of infection, altered sensation, dyspareunia, adhesions, scarring, or problems with vaginal stenosis with age.¹⁰

Complications identified from treatments for vaginal "rejuvenation" or vulvovaginal procedures can be filed at [MedWatch, the FDA Safety Information and Adverse Event Reporting Program](#).

NAMS has long stood by its position that treatment choices should be based on ethical standards of nonmaleficence (avoiding actions that cause harm) and beneficence (working for the good of patients and society), and this includes using evidence-based therapies.

JoAnn V Pinkerton, MD, FACOG, NCMP

*Executive Director, The North American Menopause Society
Professor, Department of Obstetrics and Gynecology
University of Virginia Health System*

Sheryl A Kingsberg, PhD

*President, The North American Menopause Society
Professor, Departments of Reproductive Biology and Psychiatry
Case Western Reserve University School of Medicine*

References

1. FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication. July 30, 2018.
2. The American College of Obstetricians and Gynecologists. Fractional Laser Treatment of Vulvovaginal Atrophy and US Food and Drug Administration Clearance: Position Statement. May 2016.
3. Streicher LF. [Vulvar and vaginal fractional CO2 laser treatments for genitourinary syndrome of menopause](#). *Menopause*. 2018;25(5):571-573.
4. North American Menopause Society. [Commentary](#). *Menopause e-Consult*. June 2015;11(3):1-4
5. Samuels JB, Garcia MA. Treatment to external labia and vaginal canal with CO2 laser for symptoms of vulvovaginal atrophy in postmenopausal women [published online ahead of print April 13, 2018]. *Aesthet Surg J*.
6. Pagano T, De Rosa P, Vallone R, et al. Fractional microablative CO2 laser in breast cancer survivors affected by iatrogenic vulvovaginal atrophy after failure of nonestrogenic local treatments: a retrospective study. *Menopause*. 2018;25(6):657-662.
7. Krychman M, Rowan CG, Allan BB, Durbin S, Yacoubian A, Wilkerson D. Effect of single-session, cryogen-cooled monopolar radiofrequency therapy on sexual function in women with vaginal laxity: the VIVEVE I trial. *J Womens Health*. 2018;27(3):297-304.
8. Blaganje M, Šćepanović D, Žgur L, Verdenik I, Pajk F, Lukanović A. Non-ablative Er:YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: a randomized controlled trial. *Eur J Obstet Gynecol Reprod Biol*. 2018;224:153-158.

9. Faubion SS, Larkin LC, Stuenkel CA, et al. Management of genitourinary syndrome of menopause in women with or at high risk for breast cancer: consensus recommendations from The North American Menopause Society and The International Society for the Study of Women's Sexual Health. *Menopause*. 2018;25(6):596-608.
10. Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 378: Vaginal "rejuvenation" and cosmetic vaginal procedures. *Obstet Gynecol*. 2007;110(3):737-738.