

A writing group was formed of experts from the American Urogynecologic Society and the International Urogynecologic Association. The group carefully reviewed the available evidence to provide considerations and recommendations for the current management of mesh-related complications. The following summary provides highlights of the joint position statement for patients.

### How do vaginal EBDs work?

Vaginal energy-based devices (EBDs) use lasers or radio waves to heat the skin or the tissues just beneath the skin. The devices are not surgical and are placed above the skin. They are used in and around the vagina to trigger responses from the body to help treat different conditions. These responses include increased collagen and elastin in the areas that are treated. Collagen and elastin help support the shape and structure of tissue.

The consensus statements focus on the use of vaginal EBDs for treatment of the following conditions:

- Dyspareunia
- Dysuria
- Fecal incontinence
- Labial hypertrophy
- Lichen sclerosus
- Overactive bladder
- Pelvic irradiation
- Pelvic organ prolapse
- Sexual dysfunction
- Stress urinary incontinence
- Urinary tract infection
- Vaginal dryness
- Vaginal laxity
- Vestibulitis
- Vulvodynia
- Vulvovaginal atrophy

#### Why were these consensus statements written?

The U.S. Food and Drug Administration (FDA) and international urogynecologic organizations recently issued statements about the use of vaginal EBDs. The American Urogynecologic Society felt it was important to provide guidance about treatment with vaginal EBDs in the form of consensus statements.

#### What are consensus statements?

A panel of experts reviews all evidence available about the topic. In this case, the use of vaginal EBDs. Statements are then drafted by the experts. The statements are based on the evidence. The statements are then grouped into topics. In this statement the 5 groups were:

- 1. Patients who are and who are not suited for treatment
- 2. Health care providers who are best suited to provide the treatment
- 3. The most effective devices and the conditions that benefit the most from treatment
- 4. Safety of the treatment
- 5. Treatment considerations such as the number of treatments needed and whether the treatments work better when combined with other treatments

The statements are then voted on in a rigorous process until only the most agreed upon expert opinion statements remain. Clinical consensus statements are most useful when there is not much (or limited) evidence about a topic, but guidance is needed.

#### What should I know about the evidence used for the statements?

- Two types of vaginal EBDs, CO<sub>2</sub> lasers and Er:YAG lasers, have demonstrated short-term effectiveness at treating the following conditions for up to 1 year, however, the information confirming this is limited to a few small studies:
  - Vulvovaginal atrophy
  - ° Vaginal dryness
  - <sup>°</sup> Menopausal dyspareunia

# PATIENT SUMMARIES Clinical Consensus Statement on Vaginal Energy-Based Devices\*



- Treatment with vaginal EBDs seems to be safe. However, the evidence is only available for short periods after treatment (up to 1 year). There is still no evidence about safety in the long term.
- The most effective number of treatments, or whether treatment can be more effective when used with other treatments, is not yet known.
- There was no evidence to determine which patients are or are not best suited for energy-based treatment.
- There was no evidence to determine which specific health care providers should be performing energy-based treatment. However, the doctors most suited to use this treatment are urogynecologists, gynecologists and female urologists who are comfortable treating vaginal conditions; these individuals should undergo standardized training.

## **Key Points**

- Vaginal EBDs are nonsurgical devices that are used to treat many conditions that affect your vagina, the tissues around your vagina, and your pelvic organs.
- The vaginal EBD consensus statements were written to give your doctor the most agreed upon expert opinions to help you make the best choices about vaginal EBD treatments.
- According to the evidence, two types of laser EBDs have proven short-term effectiveness ] in treating three conditions:
  - 1. vulvovaginal atrophy
  - 2. vaginal dryness
  - 3. menopausal dyspareunia
- According to the evidence, vaginal EBD treatment is safe in the short term, but long-term safety is still not known.

# Learn the Terms

Dyspareunia: Pain with sexual intercourse

Dysuria: Painful urination

Fecal incontinence: Accidental leakage of stool

Labial Hypertrophy: A condition in which the labia, or folds of skin on either side of the vaginal opening, are larger than normal Lichen sclerosus: A condition that causes the skin around the vagina become white and patchy and thinner than normal Menopause: The time after a woman has stopped having periods. Perimenopause is the time when periods might become irregular leading up to a time when there is no bleeding at all. Menopause begins when 12 months have passed since the last period. Overactive Bladder (OAB): Urinary urgency, usually with frequency and nocturia, and sometimes with urgency urinary incontinence. This occurs without an infection or other health problem.

**Pelvic Irradiation**: Symptoms that can affect women who have had a type of therapy called radiotherapy to treat cervical cancer. **Pelvic Organ Prolapse (POP)**: Dropping of the pelvic organs, such as the bladder, uterus, and rectum, caused by a loss of vaginal support

Sexual Dysfunction: A problem during any phase of sexual activity that prevents satisfaction from the sexual activity.

Stress Urinary Incontinence (SUI): Urine leakage with physical activity such as laughing, sneezing, lifting, or exercise.

**Urinary Tract Infection (UTI)**: The abnormal growth of bacteria in the urinary tract combined with symptoms like urgency and frequency of urination. The urine may also be cloudy, bloody or have a foul odor.

**Urogynecology**: An area of health care focused on conditions that affect the muscles of the bottom of the pelvis (called the pelvic floor), including pelvic organ prolapse (POP), urinary incontinence, and bowel control difficulties.

Vestibulitis: A burning-like or stinging pain at the opening of the vagina

Vulvodynia: A chronic pain in the vulva, or woman's external genitals

To review the consensus statement, go to: https://www.augs.org/assets/1/6/Vaginal\_Energy\_Based\_Devices.3.pdf.

This document was developed by the American Urogynecologic Society. This document reflects clinical and scientific advances and expert opinion as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Its content is not intended to be a substitute for professional medical judgment, diagnosis, or treatment. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient.

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