

FDA's Warns Against Use of Energy-Based Devices: The VELA[®] Safety Communication



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Abstract

Objective: The aim of this short review is to react to the oversimplification to the US Food and Drug Administration (FDA) Safety Communication [1] to alert patients and healthcare providers that the use of Energy-Based Devices (EBD), as fractional ablative carbon dioxide (CO₂) laser, are not approved to treat Stress Urinary Incontinence (SUI) and Genitourinary Syndrome of Menopause (GSM) and may be associated with serious adverse events. This strong statement could interfere worldwide in the lay public and medical community consideration of all laser procedures.

Methods: Revision of the available literature the use of the non-ablative Vaginal Erbium Laser (VEL[®]) SMOOTH[®] technology.

Results: The VEL-SMOOTH[®] produces effective, non-invasive procedure for the safe treatment of GSM and SUI.

Conclusion: VEL-Smooth[®] can offer a new, long term therapeutic option, to improve the quality of life, allowing women to choose, considering the limits and the balance between benefits and risks associated with each therapeutic approach.

Abbreviations: FDA: Food and Drug Administration; EBD: Energy-Based Devices; CO₂: carbon dioxide; SUI: Stress Urinary Incontinence; GSM: Genitourinary Syndrome of Menopause; VEL[®]: Vaginal Erbium Laser; VELA: Vaginal Erbium Laser Academy

Introduction

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 (EBD), as fractional carbon dioxide (CO₂) laser, approved to treat some gynaecologic conditions but also marketed and used for different indications such as cosmetic procedures, vaginal "rejuvenation," vaginal atrophy, urinary incontinence may be associated with serious adverse events. FDA declared 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" [1]. FDA stated that "the safety and effectiveness of energy-based devices for treatment of these conditions has not been established" and "... may lead to serious adverse events, including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain."

The VAGINAL ERBIUM LASER™ ACADEMY (VELA) is an independent scientific organization devoted to women's health and quality of life by developing and implementing the innovative Vaginal Erbium Laser (VEL[®]) SMOOTH[®] technology for functional vaginal restoration, for the treatment of mild-moderate SUI (Stress Urinary Incontinence) and GSM (Genitourinary Syndrome of Menopause - Atrophy) [2-6]. The VEL-SMOOTH[®] produces non-ablative, controlled hyperthermia followed by vasodilatation and collagen remodelling, resulting in overall restoration of vaginal tissues [2-4]. There is no tissue damage, drilling, ablations, bruises, bleedings or burning. This is why the treatment is absolutely safe and multiple repetitions cannot cause any problem in the long-term run. Conversely using other laser systems including CO₂ and Erbium YAG without the Smooth[®] technology, the mechanism of action is ablation, using scanners to deliver micro-beams for drilling, that provokes micro wounding and tissues regeneration through wound healing process. Fractioned beams with CO₂ lasers are meant to stimulate a tissue repair around the tissue

ablation/carbonization [2]. Safety of the treatment has always to be the first concern. At variance of other laser technologies, with the VEL-SMOOTH® we can treat at full beam all the vaginal walls, without damage of mucosa layers [2-4]. The VEL-SMOOTH® tissue regeneration is completely non-ablative and involves not only the very superficial (0.02-0.05 mm) heat-shocking mechanism, but also includes a unique self-regulating safety feature, not available with other technologies [2-4]. Fractional ablative lasers (ie CO₂) are more aggressive and potentially could provoke more and harsh adverse effects. Other, non-laser EBD (as radiofrequency and ultra sound) devices recently appeared in the market, claiming efficacy and safety, but with scanty data and very few studies to support the claims.

Thus, after a careful reading of the warning, our first remark was: the FDA is right. However, we think that this strong statement could interfere worldwide in the lay public and medical community consideration of all laser procedures. All lasers are not created equal. We understand the FDA's announcement is primarily a warning to laser manufacturers not to promote their devices for unapproved gynaecological procedures. Various energy-based technologies may have different clinical applications. Although thousands of patients have been treated and the potential danger became real only in few women, the rule of *primum non nocere* (first don't harm) must be respected. At variance of fractional, ablative CO₂ laser, the second-generation vaginal laser with the VEL-Smooth® technology being a non-ablative does not harm the vaginal tissues; the procedure is intrinsically safe and holds a very unique position. These characteristics of VEL-SMOOTH® is responsible for the extraordinary safety and the proven clinical efficacy when used for thermotherapy to alleviate GSM and mild-moderate SUI.

In 5 years of clinical use of VEL-SMOOTH® worldwide no serious Adverse Events were reported by the VELA® Members in thousands of patients treated. Using VEL-SMOOTH® we may rarely see mild side effects (mainly oedema, vaginal discharge and in some patients persisting leucorrhoea for few days, with spontaneous recovery). A large number of clinical studies were performed in order to test and confirm the safety and efficacy of the VEL-SMOOTH® thermotherapy. These studies have already resulted in scientific papers published in some of the most respected international scientific journals [2,3].

Back in the 2016 The American College of Obstetricians and Gynaecologists in its Position Statement on Fractional Laser Treatment of Vulvovaginal Atrophy [7] emphasized the lack of sham-controlled or long-term data on vaginal lasers. The ACOG affirmed 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." We cannot agree more. A number of prospective observational studies show the effectiveness and safety of VEL-SMOOTH®, confirmed by randomized sham-controlled data [8]. Long term studies demonstrate that the effects of VEL-SMOOTH® treatment are comparable to that exerted by local hormone treatment for GSM, and women satisfaction is so high that 85% of treated women decided to repeat the VEL procedure [6]. Nowadays we can say that the ACOG statement should be updated. We know that a lot of work must be done in this field. However, we cannot accept the deny of clinical evidences, due to possible harms induced by completely different and more invasive laser technologies. We hope that this controversy might be an opportunity to shed more light upon differences among the EBD marketed for GSM and SUI. In this view the vast clinical experience and the scientific evidences indicate that VEL-Smooth® can really be seen as an effective, non-invasive ambulatory procedure. VEL-Smooth® can offer a new, long term therapeutic option to improve the women quality of life, considering the limits and the balance between benefits and risks associated with each therapeutic approach.

Conflict of Interest Disclosures

The Authors do not have financial or commercial relationships with the manufacturers of devices used in different studies. No financial support has been given from Public or Private Companies for this work.

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