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LETTER TO THE EDITOR

In response to the FDA warning about the use of photomedicine in gynecology

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Abstract
To alert patients and health care providers about the use of energy-based devices to perform a vaginal "rejuvenation," cosmetic vaginal procedures, or nonsurgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function, the US Food and Drug Administration (FDA) has issued a warning about the effectiveness and safety of such devices. We agree with the FDA that certain devices (laser, radiofrequency, etc.) have been marketed inappropriately for uses that are outside of their cleared or approved intended uses. We want to position ourselves in the strict training of professionals so that the indications and techniques are used in the best possible way, knowing that, similar to any medical or surgical technique, the side effects can appear in the short and long term, and should be recognized and remedied.

Keywords FDA safety communication · Energy-based devices · Vaginal 'rejuvenation' · Vaginal cosmetic procedures

In response to the Safety Communication published on July 30, 2018 by the US Food and Drug Administration (FDA) regarding the use of vaginal devices (such as radiofrequency or laser) for the so-called vaginal rejuvenation, cosmetic vaginal procedures, or symptoms of menopause, urinary incontinence, or sexual function [1], we want to express our support for most of the considerations made. However, we would like to point out and emphasize the following:

- The Regulatory Agencies themselves must regulate the application and ensure the proper use of all existing medical devices and products. All devices and medical devices must have safety and security parameters; therefore, they must have the accreditation of the Regulatory Agencies.
- Knowing that the FDA only approved the carbon dioxide laser and the YAG laser for "incision, excision, ablation, vaporization and coagulation of body soft tissues in

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medical specialties, including aesthetic and gynecology" [2]. However, vulvovaginal atrophy or genitourinary syndrome of menopause (GSM), which is defined as a collection of symptoms and signs associated with a decrease in estrogen and other sex steroids involving changes to the labia majora/minora, clitoris, vestibule/introitus, vagina, urethra, and bladder was not listed specifically as an indication for treatment [3]. (These devices have been cleared for treating precancerous cervical tissue and genital warts, among other indications.)

- As several clinical practice guidelines highlight [4], different minimally invasive, ablative or non-ablative, energy-based treatment therapies may indeed provide a nonhormone option for GSM because these therapies activate *heat shock proteins* that subsequently activate growth factors, resulting in an increase in vascularity, collagen, extracellular matrix production, and vaginal epithelium thickness [5].
- The possibility of side effects is something inherent to medical practice with all medical and surgical treatments. With the inappropriate use of vulvovaginal energy application devices (laser, radiofrequency, etc.), regardless of the type and mode of application, the possibility of burns, scars, and other types of injuries are described in the literature [6].
- We are aware that the vaginal devices have been aggressively marketed to menopausal women with symptomatic genital atrophy. We agree that *marketing terms*, such as "vaginal rejuvenation" or "designer vagina," that create false expectations for patients and do not conform to the medical procedures indicated should be abandoned. Above all, we demand accurate and concrete information from two populations that are susceptible to the use of these methods, such as adolescents and cancer survivors.
- We insist that any professional who chooses to use these medical devices must be trained in a satisfactory manner to acquire the appropriate skills that entail a correct use of the technology and its application parameters, know the precise indications and avoid the possible complications and adverse effects, and ensure proper handling of any complications.
- The doctor must know the characteristics of the equipment offered in the market and will be responsible for using with the patients the equipment that has a serious and real scientific evidence to support its therapeutic effects. We are aware that there may be associated risks for patients derived from the technological quality of the devices used.
- We agree that long-term safety and efficacy studies using sham-controls are needed before energy-based treatments can be recommended as a standard therapy for GSM [7, 8]. Despite the lack of well-designed controlled studies, it should be noted that the latest published studies (most of them performed in Europe) in rigorous scientific journals assume the safety of these treatments as long as the indication and performance of the professional are correct. A systematic review and meta-analysis reported that laser intervention appears to be a safe and potentially effective nonpharmacologic intervention for GSM [9]. Another review found that this technology is promising for treating vulvovaginal atrophy, but cost issues must be addressed [10].

We must continue working on the correct accredited training to ensure a correct dissemination of knowledge and an appropriate use of technology in gynecological practice. However, we want to convey a message of peace of mind to the medical professionals and our patients about the safety data that we currently have and, above all, of the satisfaction reported by the patients.

Authors' contribution All authors contributed equally to writing this editorial.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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