



INTERNATIONAL CONTINENCE SOCIETY

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ISSVD/ICS comments on the FDA communication on the use of energy-based devices to perform vaginal 'rejuvenation' or vaginal cosmetic procedures

The International Society for the Study of Vulvovaginal Disease (ISSVD) and the International Continence Society (ICS), as leading societies in their fields, support the warning issued by the FDA on July 30, 2018, concerning the use of energy based devices (radiofrequency and LASER) for vaginal "rejuvenation" (a not-scientifically defined term), vaginal cosmetic procedures or procedures intended to treat vaginal conditions and symptoms related to menopause, urinary incontinence, or sexual function¹.

Despite the claim in recent papers that LASER use was cleared by the FDA for the treatment of vulvovaginal atrophy², that was not the case^{3,4}, as previously noted by the American College of Obstetricians and Gynecologists (ACOG) in 2016⁵.

Concerns on the use of LASER and radiofrequency are not new and have previously been raised by several authors^{6,7} and international societies, including the ACOG⁸ and the Society of Obstetricians and Gynecologists of Canada⁹. Furthermore, the ISSVD addressed this topic in its recommendations on female cosmetic genital surgery¹⁰.

The claim that the use of these energies for rejuvenation is different from that for the treatment of atrophy in selected patients (postmenopausal, breast cancer, pelvic radiation) is not sustained by evidence and is misleading.

In addition to the FDA warning, recent claims that LASER is a treatment option for women with vulvodynia and lichen sclerosus is not supported by scientific evidence and lacks biological plausibility.

Physicians have ethical responsibility to provide to patients accurate and current information regarding the efficacy and safety of innovative practices, in particular when adopting new approaches on the basis of promotions or marketing¹¹.

In the informed decision-making process relational factors should be considered, as sexuality in postmenopausal women is a complex mosaic of physical, psychological, socioeconomic, and cultural factors. A universal approach limited to vaginal mucosa is insufficient¹².

Based on the available evidence, we recommend against the use of LASER and radiofrequency for the treatment of lichen sclerosus, vulvodynia, urinary incontinence, vulvovaginal atrophy, or for "rejuvenation" (a commercial not scientifically defined term) out of the setting of properly designed clinical trials.

ISSVD PRESIDENT

Mario Preti

ISSVD Secretary General

Pedro Vieira Baptista

ICS TRUSTEE

Alex Digesu

ISC Secretary General

Sherif Mourad

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