



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance

Position Statement

Several media outlets have described fractional carbon dioxide (CO₂) laser as “approved” or “cleared” by the U.S. Food and Drug Administration (FDA) for the treatment of vulvovaginal atrophy (<http://www.medicaldaily.com/fda-approves-mona-lisa-touch-laser-vaginal-dryness-caused-vaginal-atrophy-313184>, <http://www.realself.com/question/seattle-wa-the-monalisa-touch- and-work>, and <http://blogs.webmd.com/womens-health/2015/07/how-to-treat-vaginal-dryness-in-menopause.html>). The purpose of this Position Statement is to advise obstetrician–gynecologists and patients that this technology is, in fact, neither approved nor cleared by the FDA for the specific indication of treating vulvovaginal atrophy.

Under its 510(k) process, the FDA has cleared a fractional CO₂ laser (DEKA SmartXide² CO₂ laser) for the indications of “incision, excision, ablation, vaporization, and coagulation of body soft tissues in medical specialties, including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery”¹. In addition, another

¹U.S. Food and Drug Administration. Re: trade/device name: DEKA SmartXide2 Laser System [letter]. Silver Spring (MD): FDA; 2014. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf13/k133895.pdf. Retrieved May 19, 2016.

Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance

Page 2

laser system (Cynosure Inc., RevLite Q-Switched Nd: YAG Laser System) has been cleared by the FDA for incision, excision, ablation, vaporization of soft tissue for general dermatology, and dermatologic and general surgical procedures for coagulation and hemostasis². It is important to note that although there are a number of indications enumerated for this technology, the specific indication for the treatment of vulvovaginal atrophy is not listed.

Preliminary observational data have shown some potential benefits with the use of this technology in treating patients with vulvovaginal atrophy³⁻⁵. However, these observational trials do not evaluate the use of concomitant treatments, and they lack long-term follow-up (trials assessed follow-up at 12 weeks). No randomized trials or comparative effectiveness studies have been published (www.medscape.com/viewarticle/846960). Although initial data indicate potential utility, additional data clearly are needed to further assess the efficacy and safety of this procedure in treating vulvovaginal atrophy, particularly for long-term benefit.

Obstetrician–gynecologists 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 marketing⁶. It is critical that patients are provided with accurate information regarding the efficacy and safety of treatment options, particularly when considering emerging technology. One component of this information is an accurate description of the FDA’s clearance or approval terminology. Obstetrician–gynecologists have an ethical responsibility to provide accurate and current information to patients in order for them to be fully engaged in the informed decision-making process.

Approved by the Executive Board: May 2016

² U.S. Food and Drug Administration. Re: trade/device name: RevLife Q-Switched Nd:YAG Laser System [letter]. Silver Spring (MD): FDA; 2014. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf13/k133254.pdf. Retrieved May 19, 2016.

³ Salvatore S, Nappi RE, Parma M, Chionna R, Lagona F, Zerbinati N, et al. Sexual function after fractional microablative CO(2) laser in women with vulvovaginal atrophy. *Climacteric* 2015;18:219–25.

⁴ Salvatore S, Nappi RE, Zerbinati N, Calligaro A, Ferrero S, Origoni M, et al. A 12-week treatment with fractional CO2 laser for vulvovaginal atrophy: a pilot study. *Climacteric* 2014;17:363–9.

⁵ Stefano S, Stavros A, Massimo C. The use of pulsed CO2 lasers for the treatment of vulvovaginal atrophy. *Curr Opin Obstet Gynecol* 2015;27:504–8.

⁶ Innovative practice: ethical guidelines. ACOG Committee Opinion No. 352. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2006;108:1589–95.