CO2RE® System: US FDA Clearance Status

Candela™ is committed to helping provide treatment options to patients based on Science, Results and Trust.

The CO2RE system has been FDA cleared since 2009. In the United States, the CO2RE system is intended "for use in surgical applications requiring ablation, vaporization, excision, incision, and coagulation of soft tissues in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee)." In addition, the product is cleared for specific indications based on each medical specialty. Specifically, the CO2RE system has FDA clearance for many gynecology indications, such as treating soft tissue in gynecology, hemangiomas, and benign and malignant tumors.

While there is always a risk with any type of medical or aesthetic procedure, the overall safety and effectiveness of the CO2RE system is well established and is supported by numerous publications, and/or ongoing studies within the medical community. We believe in the value of science and are grateful to the researchers and clinicians providing on ongoing research studies.

Candela, the product manufacturer, has determined that the CO2RE® Intima laser device used to treat vulvovaginal conditions has minimal risks. The risks associated with the use of the CO2RE® Intima device have been demonstrated in research studies to be minimal and limited to the skin surface. While the CO2RE® Intima device is a medical device cleared by the FDA for use in treatment of certain dermatological, and gynecological conditions, the use of the CO2RE® Intima device for vaginal rejuvenation or as a treatment for (a) relieving signs of childbirth and aging; (b) restoring vaginal tone, flexibility and shape; (c) treating dryness, itching and pain; (d) enhancing sexual function or (e) for cosmetic improvement, is 'off-label' as it has not yet been approved or cleared by the FDA for such uses. Patients are encouraged to discuss this with us during their initial consultation for treatment and are required to consent to this 'off-label' use of the CO2RE® Intima laser device for the treatments before they start.

Since January, Candela has been engaging with the FDA to expand our current gynecology indications related to Women's Health. Rigorous clinical study designs, in progress, will allow the FDA to evaluate the safety and efficacy of future indications.

The CO2RE Intima device has been used for several years by many practitioners and patients for: relieving signs of childbirth and vaginal aging; restoring vaginal tone, flexibility and shape; treating dryness, itching and pain; enhancing sexual function; decrease stress incontinence; and for cosmetic improvement. There have been very minimal complaints and complications.

Given our excellent results of the CO2RE Intima treatments and no complications, we at RiverSong Plastic Surgery in conjunction with Syneron Candela Corporation, have decided to continue providing the CO2RE Intima treatment, understanding that it is OFF LABEL per the FDA.