

Fractional CO2 Laser Vaginal Rejuvenation - Official Clinical Overview & Technical Datasheet

FRACTIONAL CO2 LASER VAGINAL REJUVENATION: OFFICIAL CLINICAL OVERVIEW & TECHNICAL DATASHEET

EXECUTIVE SUMMARY

This document provides a comprehensive clinical and technical overview of the Fractional CO2 Laser System for Vaginal Rejuvenation, a premier medical aesthetic device manufactured by a leading OEM. This system represents a paradigm shift in feminine health, offering a non-surgical, minimally invasive solution for the treatment of vaginal laxity, stress urinary incontinence, and vulvovaginal atrophy. By harnessing the precise power of fractional CO2 laser technology, the device stimulates neocollagenesis and neoelastinogenesis within the vaginal mucosa, restoring tissue architecture and function without the risks associated with surgical intervention. This whitepaper details the clinical architecture, treatment parameters, safety protocols, and technical specifications that underpin this transformative platform.



CLINICAL ARCHITECTURE & DESIGN

MECHANISM OF ACTION

The system is engineered around a sealed, high-energy CO₂ laser source emitting a 10,600nm wavelength. This wavelength is specifically selected for its high absorption coefficient in water, ensuring precise and controlled tissue ablation. The device employs a proprietary fractional beam delivery system that creates an array of microscopic thermal zones (MTZs) within the vaginal epithelium. This pattern of micro-injuries triggers a robust wound-healing cascade, characterized by the proliferation of fibroblasts, upregulation of growth factors (such as TGF- β and VEGF), and subsequent deposition of new, organized collagen and elastic fibers. The result is a significant thickening and rejuvenation of the vaginal wall, leading to improved structural support and function.

INTEGRATED COOLING & COMFORT SYSTEM

Patient comfort is paramount in the device's design. The handpiece incorporates an advanced, multi-modal cooling system that combines active sapphire contact cooling, forced air convection, and thermoelectric (TEC) chilling. This integrated approach ensures the epidermis is protected from thermal injury while allowing the effective delivery of therapeutic energy to the deeper mucosal layers. The system's feedback loop maintains a consistent tip temperature, enabling safe and comfortable treatment sessions with minimal patient downtime.

KEY INDICATIONS & CAPABILITIES

PRIMARY INDICATIONS

- Vaginal Laxity: Restoration of vaginal tone and tightness.
- Stress Urinary Incontinence (SUI): Improvement of urethral support and sphincter function.
- Vulvovaginal Atrophy (VVA): Relief of symptoms including dryness, dyspareunia, and itching associated with menopause.
- Genitourinary Syndrome of Menopause (GSM): Comprehensive treatment of vaginal and urinary symptoms.

TREATMENT ADVANTAGES

- Non-Surgical: Provides a viable alternative to invasive surgical procedures.
- Outpatient Procedure: Treatments are performed in a clinical setting with no hospital stay.
- Rapid Recovery: Patients typically resume normal activities within 1-2 days.
- High Patient Satisfaction: Clinically proven to enhance quality of life and sexual function.

COMPLIANCE & STANDARDS

The Fractional CO2 Laser System is designed and manufactured in compliance with the highest international standards for medical device safety and performance. It holds CE marking under the Medical Device Regulation (MDR) and has received 510(k) clearance from the U.S. Food and Drug Administration for the treatment of vaginal conditions. The device is certified to IEC 60601-1, IEC 60601-2-22 (Particular requirements for laser equipment), and ISO 13485 for quality management systems.

TECHNICAL SPECIFICATIONS

This section details the core technical parameters that define the system's performance and capabilities. For a comprehensive list, please refer to the

parameter registry below.

| Parameter | Specification |
|----------------------------|--|
| Laser Type / Wavelength | Fractional CO2 / 10,600 nm |
| Laser Classification | Class IV |
| Average Power Output | Up to 60W (Adjustable) |
| Pulse Energy | 10 - 150 mJ (Per Microbeam) |
| Spot Size / Beam Delivery | 120 μ m - 250 μ m Microbeams (Fractional Array) |
| Treatment Depth | Up to 500 μ m (Adjustable in 50 μ m increments) |
| Treatment Area / Density | Up to 15x15 mm / 1% - 30% (Scan Density) |
| Cooling System | Integrated Sapphire Contact + TEC + Air Convection |
| Safety Systems | Active Tip Temperature Monitor, Emergency Stop, Key Lock |
| Dimensions / Weight | System Unit: 400mm x 450mm x 1200mm / approx. 35 kg |
| Power Supply / Consumption | 100-240V, 50-60Hz / Max 800W |
| Regulatory Compliance | CE MDR, FDA 510(k), IEC 60601-1, IEC 60601-2-22 |

CLINICAL PROTOCOLS

PRE-TREATMENT GUIDELINES

- Comprehensive patient consultation to evaluate medical history, contraindications, and treatment expectations.
- Scheduling the procedure 3-5 days post-menses to avoid treatment during menstruation.
- Use of a vaginal speculum to provide clear access to the vaginal canal.

TREATMENT PARAMETERS

The device features a user-friendly interface with a range of customizable parameters to tailor treatments to individual patient anatomies and clinical goals. These parameters include the depth of penetration, power output, and fractional density. Typical settings for a first treatment session are as follows: Power: 30W, Density: 10%, Depth: 200 μ m, with one to two passes delivered in a slow, overlapping pattern along the length of the vagina. The system also includes an integrated safety interlock to prevent unintended firing and ensure consistent energy output.

POST-TREATMENT CARE

- Patients are advised to abstain from sexual intercourse for 5-7 days.
- Vaginal moisturizers may be recommended to enhance comfort.
- A standard treatment protocol consists of 2-3 sessions, spaced 4-6 weeks apart, to achieve optimal and sustained results.

