Dual Thulium Laser Clinical Study Report Download - Official Clinical Overview & Technical Datasheet

EXECUTIVE SUMMARY

This document serves as the definitive clinical and technical reference for the Dual Thulium Laser System, a state-of-the-art medical aesthetic device engineered for superior versatility and patient outcomes. The following overview synthesizes data from comprehensive clinical study reports, detailing the device's architecture, treatment capabilities, and integration protocols. As a Class IIb medical device, it is designed to meet the rigorous demands of modern dermatology and med-spa practices, offering a synergistic approach to skin resurfacing, tissue tightening, and targeted chromophore clearance. The Dual Thulium platform distinguishes itself through its unique 1927nm and 1940nm wavelength emission, providing a continuum of ablative and non-ablative effects to address a broad spectrum of indications with minimal downtime.

CLINICAL ARCHITECTURE & DESIGN

The Dual Thulium Laser System is built upon a foundation of advanced solid-state laser engineering. Its core architecture comprises a dual-resonator cavity that independently generates and controls 1927nm and 1940nm wavelengths. This design allows for real-time switching or blending of wavelengths within a single pulse, enabling practitioners to precisely modulate the depth and intensity of energy deposition. The system is equipped with a high-speed galvanometric scanner for fractional delivery, ensuring rapid treatment times and consistent micro-thermal zone (MTZ) creation. The integrated epidermal protection system utilizes a proprietary contact cooling mechanism that maintains the skin surface at a controlled temperature, significantly enhancing patient safety and comfort during high-fluence treatments. Robust thermal management is achieved through a closed-loop

water-cooling circuit with multiple sensors, ensuring operational stability and laser diode longevity.

KEY INDICATIONS & CAPABILITIES

Clinical studies have validated the Dual Thulium Laser System for a wide range of aesthetic and dermatological indications. Primary applications include the treatment of photodamage, including actinic keratosis and pigmented lesions, where the 1927nm wavelength demonstrates exceptional affinity for superficial melanin and water. The 1940nm wavelength, with its deeper penetration profile, is highly effective for dermal remodeling, stimulating neocollagenesis and neoelastinogenesis for the reduction of fine lines, wrinkles, and acne scars. The device's unique ability to deliver both ablative micro-channels and non-ablative dermal heating in a single session provides a customizable approach to skin rejuvenation. Furthermore, the system supports a variety of treatment patterns and spot sizes, allowing for precise adjustment to different body areas and skin types. This versatility, combined with a low adverse event profile documented in clinical reports, positions the Dual Thulium Laser as a premier solution for practices seeking a comprehensive skin management platform.

COMPLIANCE & STANDARDS

The Dual Thulium Laser System is manufactured in compliance with ISO 13485:2016 for medical device quality management and conforms to all applicable IEC 60601 series standards for medical electrical equipment and laser safety. The device bears the CE mark for distribution within the European Economic Area and has received FDA 510(k) clearance for specific indications. The clinical study report download incorporates data from trials conducted under Good Clinical Practice (GCP) guidelines, ensuring data integrity and patient safety. Robust cybersecurity measures and data privacy protocols are built into the device's software, compliant with HIPAA and GDPR regulations to protect patient information. The system's access controls and audit trail features facilitate seamless integration into clinical workflows while maintaining the highest standards of regulatory compliance.

TECHNICAL SPECIFICATIONS

Parameter	**Specification**
Laser Type	Dual Thulium Solid-State (1927nm & 1940nm)
Operating Modes	Pulsed, Continuous, Fractional
Pulse Duration	0.5 - 10 ms
Maximum Pulse Energy	Up to 50 J/cm² per wavelength
Spot Size	1mm - 10mm diameter (adjustable)

Delivery System	Articulated Arm with Scanner or Fiber-Coupled Handpiece
Cooling System	Integrated Sapphire Contact Cooling + Water/Air Convection
Dimensions (W x D x H)	480mm x 560mm x 1100mm
Weight	Approx. 75 kg
Power Supply	220-240V, 50/60Hz, 15A
Interface	15.6" Color Touchscreen with Graphical Protocol Editor
Regulatory Certification	CE (MDD/MDR), FDA 510(k)
Standards	ISO 13485, IEC 60601-2-22, IEC 60825-1

CLINICAL PROTOCOLS

Clinical studies have established a series of optimized treatment protocols to maximize efficacy and safety. For photorejuvenation, a typical protocol employs the 1927nm wavelength with a pulse energy of 10-20 mJ per MTZ, delivered in a fractional pattern with a coverage density of 5-15%. For deeper dermal remodeling, the 1940nm wavelength is utilized at pulse energies of 20-40 mJ per MTZ, with a lower coverage density to promote deeper tissue coagulation.

The system's proprietary software facilitates the creation of custom protocols, allowing practitioners to adjust parameters such as pulse width, spot size, and scan pattern. Pre-treatment preparation includes a thorough skin assessment, cleansing, and the application of a topical anesthetic as needed. Post-treatment care focuses on moisturization and sun protection. The clinical study report download provides detailed parameter matrices and patient selection criteria to guide practitioners in achieving consistent, high-quality results.