Thulium Fiber Laser (TFL) - Official Clinical Overview & Technical Datasheet

DEVICE IDENTIFICATION & CLINICAL SCOPE

Thulium Fiber Laser (TFL) technology represents a paradigm shift in minimally invasive and non-invasive laser dermatology. Operating at a nominal wavelength of 1940 nm (or 1908-1940 nm depending on diode seeding), the Thulium Fiber Laser achieves the highest absorption peak in water among solid-state laser systems. This unique spectral characteristic enables extreme precision for vaporization, enucleation, incision, and coagulation of soft tissue, making it the reference standard for urology, dermatology, and aesthetic gynecology. This document specifies the OEM architectural design, clinical capabilities, and performance compliance of the next-generation TFL platform.

INTERNAL HARDWARE TOPOLOGY & OPTICAL SOURCE

The system employs a master oscillator power amplifier (MOPA) configuration based on a double-clad polarization-maintaining thulium-doped silica fiber. Pumped by high-brightness multimode laser diodes at 793 nm, the active fiber achieves population inversion in the $^3F_4$ energy manifold. The oscillator is stabilized via fiber Bragg gratings (FBGs) written directly into the core, delivering a center wavelength tolerance of ±3 nm. A two-stage amplifier chain elevates the output to maximum average power without spectral broadening. The resonator is hermetically sealed within a forced-air cooled chassis, while all optical interfaces utilize SMA-905 or QBH high-power connectors rated for >200 W CW equivalent. An integrated real-time power meter (thermopile sensor) provides closed-loop feedback to maintain energy stability at ±5% over the duty cycle.

EPIDERMAL PROTECTION MECHANISMS & SAPPHIRE ICE COOLING

The integrated handpiece features an advanced contact cooling array: a 4 mm thick sapphire window with anti-reflective coating (AR, R<0.5% @ 1940 nm) is thermoelectrically cooled (TEC) via a cascaded Peltier module, achieving surface temperatures between -5°C and +4°C within 150 ms of tissue contact. A closed-loop water circuit dissipates heat from the TEC hot side, and a skin temperature sensor (NTC type, accuracy ±0.3°C) triggers an automatic energy shutoff if

dermal temperature exceeds 42°C. This system enables high-fluence resurfacing with significantly reduced post-inflammatory hyperpigmentation (PIH) risk in Fitzpatrick skin types III–V.

TREATMENT ADVANTAGES & CLINICAL INDICATIONS

Compared to legacy Er:YAG (2940 nm) and CO_2 (10600 nm) lasers, TFL offers superior hemostasis (coagulation depth 0.3–0.5 mm vs <0.1 mm for Er:YAG), lower mechanical shock, and compatibility with small-bore fibers (core diameters 100–400 μm). The primary aesthetic indications include:

- Ablative fractional resurfacing (periocular, perioral, acne scars).
- Vaginal laxity and stress urinary incontinence (non-ablative thermal mode).
- Onychomycosis (1940 nm preferential absorption in fungal chitin).
- Benign skin lesion removal (seborrheic keratosis, syringoma, xanthelasma).
- Low-fluence collagen remodeling (with integrated cooling).

SPECIFICATION MATRIX

All values are measured at 23°C ±2°C, 30%–70% RH, after a 5-minute warm-up period. Medical-grade oxygen-free fiber terminations required.

Parameter	**Specification**
Laser Type / Wavelength	Thulium-doped fiber laser / 1940 nm (±3 nm)
Spectral bandwidth (FWHM)	< 2 nm
Maximum average power	40 W (class IIb) / optional 60 W (research)
Peak pulse power	Up to 200 W (with 200 µs pulse width)

Pulse width range	200 µs – 30 ms (selectable)
Repetition rate	Single shot – 500 Hz (CW mode optional)
Pulse energy range	0.1 J – 4.0 J per pulse
Spot size (contact)	100 µm, 200 µm, 400 µm, 600 µm interchangeable fibers
Aiming beam	635 nm, < 5 mW, Class 2 (red diode)
Cooling system	Integrated TEC + Sapphire + Water + forced air
Handpiece cooling tip temp.	-5°C to +4°C (adjustable)
Electrical requirements	100–240 VAC, 50/60 Hz, 8 A max
Dimensions (W x D x H)	360 mm x 420 mm x 860 mm
Weight	45 kg (99 lb) – main console
Display	10.4'' capacitive touchscreen, 1280 x 768
Data export	USB 2.0 / Ethernet / optional EMR integration

REGULATORY COMPLIANCE & QUALITY SYSTEMS

The TFL platform complies with the following directives and standards:

- Medical Device Regulation (EU) 2017/745 – Class IIb active device.

- FDA 21 CFR 1040.10 and 1040.11 (with variance for laser products).

- IEC 60825-1:2014 (Edition 3) – Laser safety classification: Class 4.

- IEC 60601-1 (Edition 3.1) – Medical electrical equipment general safety.

- IEC 60601-2-22 – Particular requirements for surgical, cosmetic, therapeutic laser equipment.

- ISO 13485:2016 certified manufacturing facility.

- RoHS 3 (EU 2015/863) compliant.

Each unit undergoes a 50-hour burn-in test, output power calibration against NIST-traceable reference heads, and a fiber connector end-face inspection prior to release. A built-in audit trail log (non-volatile memory, 10,000 cycles) stores all fired pulses with timestamp, fluence, and interlock status.