

Quanta System
LASER IN OUR DNA



Opera EVO

Dual Wavelength Laser



This brochure is not intended for the U.S. market.
Certain Intended Uses/Configurations/Models/Accessories are not cleared for U.S.

SURGERY



Opera EVO

LASER FOR MINIMALLY INVASIVE SURGERY

Opera EVO represents a hybrid laser with dual wavelength (1.9µm and 1.5µm), dedicated to minimally invasive surgery entailing incision, resection, ablation and coagulation of soft tissues in many medical specialties.

Both wavelengths are strongly absorbed by water (highly present in all tissues) resulting in a relatively constant cutting/vaporization speed during the procedure and effective hemostasis.

The delivery by means of flexible fibers of different diameters (200 - 1000 µm) allows to perform laser surgery with endoscopic, laparoscopic and open surgery approach.

General Overview

- ✓ Versatile soft tissue surgery
- ✓ Dual wavelength system
- ✓ Effective tissue hemostasis
- ✓ Precise cutting and ablation
- ✓ Confined effect on target
- ✓ No-contact ablation
- ✓ Wide range of fibers
- ✓ Compact design
- ✓ Settings saving/loading



COMPACT DESKTOP DESIGN

RFID Recognition System

Fiber Connection

Proximity Sensor for Automatic Aperture

Frontal Footswitch Connector

10.4" Touchscreen Display

DOUBLE FOOTSWITCH



Mode #2
(e.g. coagulation)

Ready / Standby
Switch

Mode #1
(e.g. cutting)

The double footswitch enables **immediate** switch from one emission mode to another, with **complete customization** of pedal-mode association. No bothersome interruptions are needed for settings readjustment.

Gastroenterology

Ablation and coagulation effectiveness of 1.9 μm laser comes in handy as alternative to APC surgery in GI field. With respect to APC however, this laser has the following advantages:

- No gas insufflation
- Greater tolerance in operative distance from target
- Confined effect and high precision

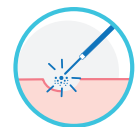
Should the effect by 1.9 μm laser be insufficient, the additional 1.5 μm wavelength increases the depth of penetration, fostering the overall sealing effect.



Thin fibers allow aspiration, washing and insufflation during the procedure and the use of instruments with small operative channel



The second wavelength (1.5 μm) allows to increase the hemostatic effect and depth of penetration, when needed



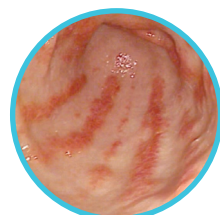
No need for contact with targeted tissue, with less risk of bleeding related to adhesions between fiber tip and coagulated spot



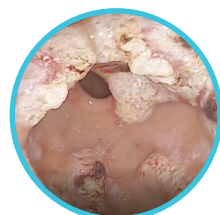
Confined action and high precision (thanks to the aiming beam)

Examples of GI treatments

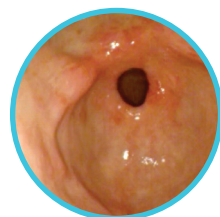
Ablation of vascular lesions with bleeding potential (e.g. GAVE)



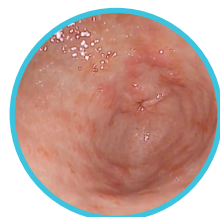
Before



After



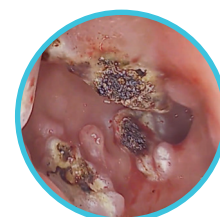
1 Month



3 Months



Ablation, resection, incision of soft tissues (e.g. Zenker Diverticulum)



Hemostasis of bleeding lesions

References:

Tontini et al (Endoscopy 2018, 50(04): S181-S182); In Vivo Endoscopic Hemostasis On Small Bowel Oozing Lesions: First Experience In The Emergency Setting with the Thulium/Erbium Laser System.
Siboni et al (Endoscopy International Open 2018; 06: E470-E473); Cricopharyngeal myotomy with thulium laser through flexible endoscopy: proof-of-concept study.
Tontini et al (UEG Week Wien Oct. 2018; P0558); Safety and Efficacy of the new Thulium/Erbium laser system in patients with gastrointestinal bleeding from vascular lesions.
Tontini et al (Endosc Int Open. 2017 Jun;5(6):E410-E415); Ex vivo experimental study on the Thulium laser system: new horizons for interventional endoscopy (with videos).
Tontini et al (Endoscopy. 2017 Apr; 49 (4): 365-370); Thulium laser in interventional endoscopy: animal and human studies.

Thoracic Surgery

Cutting precision and sealing effect by Opera EVO allow safe lung resection, with effective aero/hemo-stasis along incision margins.

The use of optical fibers allows to perform resections with both laparoscopic and open surgery approach, using dedicated handpieces and accessories facilitating the surgical procedures.

The shallow depth of penetration and ablation efficiency further come in handy in the endoscopic treatments of airway tree (e.g. obstruction debulking).



Precise cutting allowing to spare healthy tissues



Excellent aero/hemo-stasis already while cutting



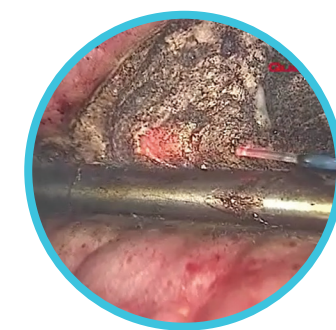
Suitable for Open, VATS and Endoscopic surgery

Examples of Thoracic Surgery treatments

- Lung resection
- Soft tissue ablation
- Endoscopic airway treatment



Pulmonary Nodule Resection in Open Surgery



VATS Resection

References:

Zhang et al (Chin J Thorac Cardiovasc Surg, June 2017, 33(06)); Clinical applications of Thulium laser in thoracoscopic resection of pulmonary nodules.
Droghetti et al (Lasers Med Sci. 2016 Jul 2); Pleurodesis with Thulium Cyber Laser versus talc poudrage: a comparative experimental study.
Marulli et al (Lasers Med Sci. 2013 Feb; 28(2):505-11); A prospective randomized trial comparing stapler and laser techniques for interlobar fissure completion during pulmonary lobectomy.
Scanagatta et al (48th STS Annual Meeting, January 2012; P97); Feasibility and safeness of laser pulmonary anatomic resection in patients with incomplete fissures. Results of a randomized, phase II, controlled trial.
Scanagatta et al (Tumori, 98:90-93, 2012.); Pulmonary resections: cytostructural ferent-wavelength lasers versus electrocautery.

Fibers

The laser energy emitted by Opera EVO laser is delivered to the target by thin flexible fibers. Depending on the chosen approach and the surgical equipment in use, the surgeon can choose among different fiber diameters and fiber types



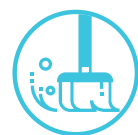
AVAILABLE DIAMETERS

200, 272, 365, 550, 800 and 1000 μm



REUSABILITY

Reusable optical fibers (disposable model available too)



CLEANING

Reusable fibers can be sterilized by Sterrad® and steam sterilization



STERILIZATION TRAY

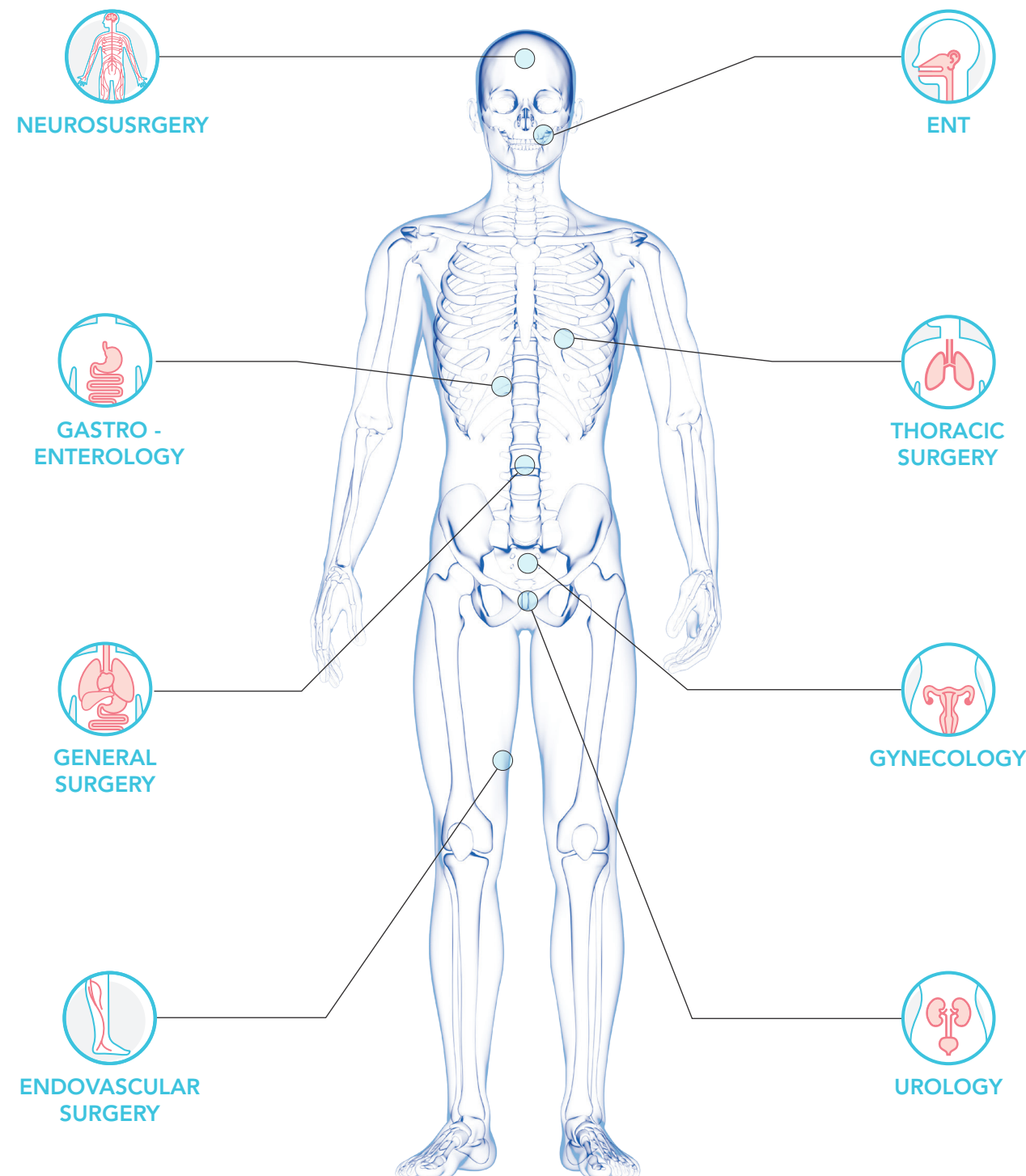
Dedicated fiber and tool sterilization tray available (optional)

FIBER DIMENSIONS

Core Diameter [μm]	200	272	365	550	800	1000
Outer Diameter [μm]	375	420	570	750	1200	1450
Outer Diameter [Fr]	1.1	1.3	1.7	2.3	3.6	4.4
Outer Diameter [G]	26	25	23	20	16	15

Applications

Opera EVO represents the ideal surgical tool to perform incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissues in many surgical specialties. Its features make such laser extremely versatile and suitable for the use also in ambulatory setting.



Technical Specifications

Laser Sources	1.9 μm + 1.5 μm
Average Power	Up to 30 W @ 1.9 μm ; 10 W @ 1.5 μm
Treatment Mode	Single wavelength or combined emission
Emission Mode	CW, pulsed and single pulse
Beam Delivery	Wide range of flexible silica fibers
Aiming Beam	520 nm (adjustable <5 mW) - Class 3R
Fiber Recognition	RFID System
Laser Class	4 (IEC / EN 60825-1:2007)
Device Cooling System	Closed water circuit/water air exchanger
Electrical Requirements	200-230 Vac, 50/60 Hz, 1.5 kVA 240 Vac, 50 Hz, 1.5 kVA
Dimensions and weight	49,5 cm (W) x 63,6 cm (D) x 38,3 cm (H) - 40 kg

VISIBLE AND INVISIBLE LASER RADIATION

Avoid eye skin exposure to direct or scattered radiation

Laser product: Class 4

Aiming beam: Class 3R



Note: National local authorities may put restrictions to the parameters indicated in the above table, or may limit or remove certain intended uses. Specifications are subject to change without notice.

Quanta System products are manufactured according to the International standards and have been cleared by the most important International notified bodies.

The Company is UNI EN ISO 9001:2015 and EN ISO 13485:2016 certified. Quanta System S.p.A. was founded in 1985 and belongs to the El. En. Group (a public company listed in the Star segment of the Italian Stock Exchange) since January 2004.

The company, divided into three business units (medical, scientific and industrial) is specialized in manufacturing of laser and opto-electronic devices.

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