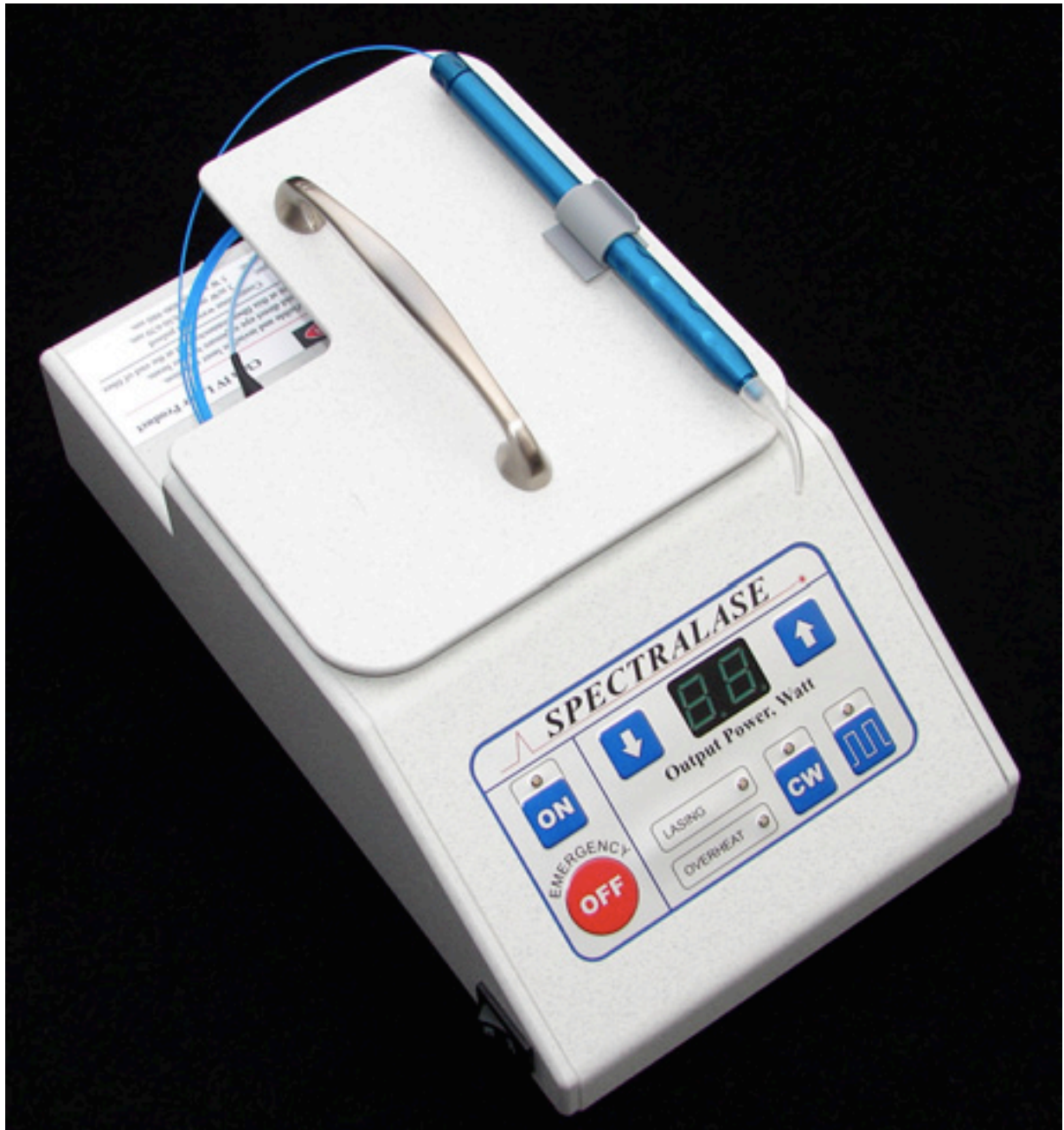


USER'S MANUAL



SPECTRALASE ELITE ***DENTAL DIODE LASER SYSTEM***

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INTRODUCTION

Spectrum Lasers Inc and Spectrum International Inc want you to be totally satisfied with your new laser and use it on a regular basis. Please contact us with any assistance that you may need. The Spectralase Diode Laser is meant to perform conservative soft tissue procedures easily and quickly. Most procedures can be performed with a TAC 20 topical anesthetic without bleeding, recession, swelling, or pain.

All clinical procedures performed with *SPECTRALASE* diode laser must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The practitioner should always set the laser system for minimal exposure to the patient. Optimal parameters for laser surgery may be achieved by starting with the power as low as possible

and increase each parameter as necessary. Power levels affect precision of cut, rate of tissue

removal and thermal damage to adjacent tissues.

It is always best to use the lowest energy setting possible to achieve your goal while avoiding charring. Any dark brown or black char is the result of too much energy. Char must be lightly scrubbed away with 3% hydrogen peroxide with a micro brush or cotton roll.

This manual must be read thoroughly and understood prior to use of the laser system. Caution: The intended use is for dentists only. Adjustments to controls or internal parts may result in hazardous energy exposure.

INDICATIONS FOR USE

The device is intended to be used for a variety of surgical procedures in the oral cavity:

Dental Soft Tissue Indications For Incision, Excision, Vaporization, Ablation and Coagulation of Oral Soft Tissues, including:

Exposure of Un-Erupted and Partially Un-Erupted teeth, Access Gingivectomy and Gingivoplasty, Hemostasis and Coagulation, Treatment of Aphthous Ulcers, Frenectomy, Operculectomy, Recontouring Anterior tissues, Soft Tissue Crown Lengthening.

CONTRAINDICATIONS

All clinical procedures performed with *SPECTRALASE* diode laser must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to the treatment. Exercise caution for general medical conditions that might contraindicate procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, sleep apnea or an immune system deficiency. Medical clearance from patient's physician is advisable when doubt exists regarding the treatment. There are no known contraindications caused by laser light energy: pregnancy, pace makers, etc

LASER DESCRIPTION

The *SPECTRALASE* surgical diode laser system is designed to be compact, portable, reliable and user-friendly. It provides the practitioner with a versatile instrument for orthodontic soft tissue procedures. The diode laser energy at 810 nm is delivered through a flexible optical fiber. The system may be utilized for a wide variety of dental surgical and cosmetic procedures.

The laser system is contained within a compact lightweight plastic/metal housing and consists of a laser diode assembly with a self-contained cooling system, a slim power supply, front panel membrane switch/keypad with LED display all connected to a circuit board, which controls laser output power and other system parameters for laser proper functioning. The key-switch on the housing rear panel works as a safety switch, allowing only authorized personnel to turn the system into operating mode. The ON/OFF power rocker switch on the left front corner of the housing turns the system into waiting mode when only LED display is activated. The "ON" button on the front keypad turns ON red aiming laser beam and activates all power stand-by and safety features of the laser system. "OFF/Emergency" button de-activates all power functions and transfers the laser into waiting mode.

The laser output power is regulated in 30 steps by "arrow-up" and "arrow-down" buttons. When arrow button is held in depressed position, the system will advance itself up or down with a beep at each step. Appropriate LED display readings indicate the level of output power in Watts from the tip of 400 m or 300 m delivery fiber when laser operates in continuous wave (CW) mode. An operator can choose CW or pulsed operation mode by pressing "CW" or "pulse" button of

the keypad. The green LED, located in the “LASING” field, remains lit while operating in CW mode. It flashes while operating in the pulsed mode. When in this mode, the system delivers pulsed radiation at a repetition rate of 200 Hertz and a self adjusting pulse width. The average output

power in the pulsed mode is one half of the power in CW mode at the same setting.

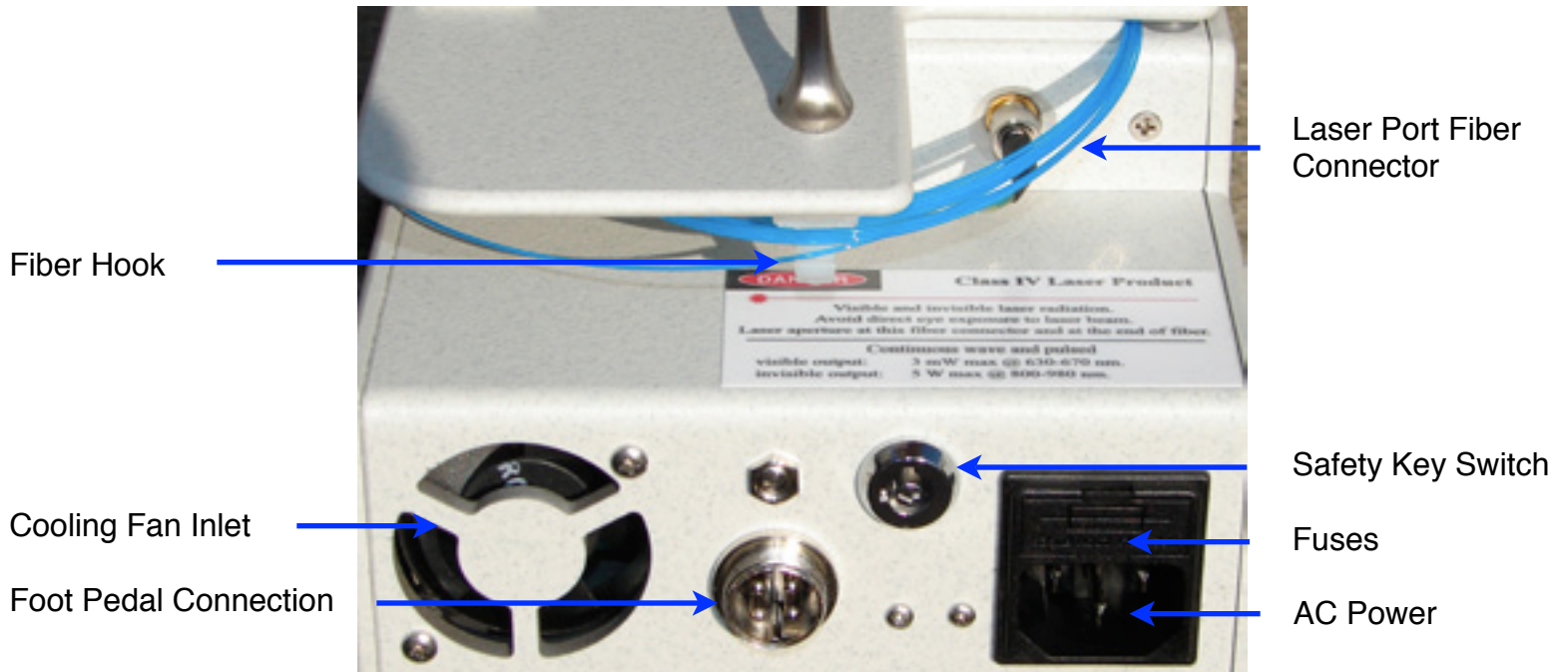
The red “Overheat” LED will illuminate and low-pitch buzzer will sound if the temperature of the laser diode reaches pre-set temperature limit of 35°C. The light should go off in 10 to 15 sec after cooling system is activated and cools the diode module. Should an emergency situation develop, the “OFF/Emergency” button must be depressed to shut down laser operation. To reactivate

the laser, the “ON” button should be depressed again.

AC power is provided to the system through a power cord plugged into the rear panel. This panel also has a receptacle for connecting the foot-switch and a regulator of red aiming beam intensity. Depressing the foot-switch activates the lasing process. Releasing the foot-switch stops the lasing.



Front view of *SPECTRALASE* diode laser.



Rear view of *SPECTRALASE* diode laser.

LASER BEAM DELIVERY SYSTEM

Flexible fibers or fiberoptic cables are the most accepted delivery systems for diode laser power. The *SPECTRALASE* diode laser accepts single core 200, 300, most commonly used 400 μm and other larger core diameter fibers mounted into SMA 905 connectors. In *SPECTRALASE* laser, the fiber's SMA connector is inserted into laser output port located on the recessed upper rear panel of laser housing. This housing shape was especially designed to provide fiber confinement within housing frame to avoid possible fiber damage when moving the laser inside the office or transporting it outside. The laser system comes with pre-wound fiber, and there is no reason to disconnect the fiber until it gets short and needs replacement with a new one. It's strongly recommended that a user gets acquainted how the fiber is wound under the top panel.

CAUTION: When installing a new fiber, do not touch the end of fiber SMA connector or place it on dusty / dirty surface. If contamination occurred, wipe the connector end by soft tissue soaked with 100% ethanol or isopropyl alcohol. Let it dry and then attached to the laser port.

LASER SYSTEM SPECIFICATIONS

Size: 9" (L) x 5.4" (W) x 3.5" (H)

Weight: 2.5 pounds

Wavelength: 980 + 10 nm

Operation modes: Continuous Wave and Pulsed at 200 Hz

Output power: 0.1 - 4 Watts to 7.0 Watts pulse amplitude

Calibration: External power meter

Fiberoptic port: Standard SMA 905 connector, compatible with 200 μ m diameter and up single-core fibers

Aiming beam: 650 nm diode laser, 2 mWatt maximum fiber output

Input power: 100-240 VAC, 50/60 Hz, 30 W

DISINFECTION

The *SPECTRALASE* diode laser system is not supplied in sterile condition, nor must it be sterilized before use. The following disinfecting procedures are recommended for the following fixtures and attachments to the device:

The disposable plastic hand-piece tips (or disposable plastic cannula) are supplied non-sterile by the manufacturer and are to be discarded in an infectious waste container (SHARPS) after each use. There is no re-use or re-sterilization procedure indicated.

The first step of fiber sterilization (prior to the stripping procedure) is to submerge the fiber tip in a solution of **BIREXse* (used in accordance with manufacture's specifications).

The hand-piece that secures the working end of the fiber is autoclavable and should be sterilized after each use. Loosen pressure nut, do not remove the nut to avoid losing the small compression washer inside the nut.

The membrane switches on the front panel of the device are not routinely contaminated by the procedure, since entire front panel should be covered with a protective clear adhesive barrier film replaceable after each patient. If they are touched without protective film, they should be wiped down with a solution of **BIREXse* and covered with a new protective cover.

The carrying handle on top of the device is not routinely contaminated by the procedure, but if touched, should be wiped down with a solution of **BIREXse* and covered with a protective clear adhesive barrier after each use.

The fiber stripper should only be used with a disinfected fiber. In case of contamination, it should be sprayed with **BIREXse* and rinsed with water and dried. It is not autoclavable.

The fiber trimming/cleaving scissors should only be used with a disinfected fiber. In case of contamination, it should be sprayed with **BIREXse* and rinsed with water. It is not autoclavable.

****BIREXse*: (or comparable product) Cleaner and disinfectant solution containing diluted o-phenylphenol and p-tertiary amyphenol; to be used in accordance with manufacturer's specifications.**

LASER SAFETY

The *SPECTRALASE* diode laser system is safe and reliable when used by trained personnel who take proper care in its operation.

CAUTION: The *SPECTRALASE* diode laser is a Class IV laser system. Precautions should be taken to avoid accidental exposure to both directed and reflected laser beams. Severe eye or skin damage may be caused by diffuse as well as speckle laser beam reflections.

The laser beam from any laser diode is usually not visible to the human eye, but it can seriously damage retinal tissue. **DO NOT** look directly into the laser beam aperture or into the working end of the optical fiber. Reflected laser light may also cause retinal damage. The reflection hazard exists several feet from the reflection point. Avoid aiming the laser beam in the direction of reflective surfaces.

DO NOT place any part of the body in direct line with the laser beam. All personnel in the operations area, including the patient, must wear eye protection. Contact lenses are not viable protection. Eye protection must be specific to the wavelength in use (980 + 10 nm). All laser safety glasses/goggles have a wavelength for indicated use stamped into the lens or eyepiece. Care must be taken to assure that everyone in the operations area is wearing the appropriate glasses. (Protective eyewear is marked with optical density >5 at 980 nm.)

DO NOT attempt to operate the laser system with any protective panels removed or if the fiber delivery system is improperly connected. The system is equipped with an interlock device for the protective housing/cover.

DO NOT attempt to defeat this system interlock or otherwise access the enclosures, as it is designed for your protection. High voltage is accessible within the laser system enclosure.

DO NOT attempt repairs of this system. Major service and maintenance should only be performed by a qualified *SPECTRALASE* Service Technician.

The *SPECTRALASE* diode laser system is equipped with a key-switch to limit operation of the equipment to authorized personnel. **DO NOT** store the key in or immediately around the laser system. All recommended practices for the safe use of lasers should be followed. Familiarity with the American National Standards Institute Z136.3 Document (and/or Laser Institute Safety Manual) is strongly recommended.

LASER SYSTEM SAFETY FEATURES

The *SPECTRALASE* diode laser system provides the following safety features for both the user and the patient:

A. Audible Lasing Signal

An audible signal (high pitch buzzing) sounds whenever the activation footswitch is depressed.

B. Laser Firing Delay

There is a brief delay between depressing the footswitch and the onset of laser activation. This allows the user adequate time to react if the footswitch is inadvertently depressed or laser operation should be aborted.

C. Enclosure Interlock

The laser system is protected by an enclosure interlock that will not allow electrical power to the unit if the cover is removed.

D. Key switch

The laser system is equipped with a key-switch and cannot be turned ON until the key is inserted.

CLINICAL PRECAUTIONS FOR LASER SAFETY

CAUTION: Laser treatment may result in inadvertent exposure of adjacent tissues. Undue exposure can result in damage to tissue, vessel perforation and bleeding. The practitioner should always set the laser system for minimal exposure to the patient. Optimal parameters for laser surgery may be achieved by starting with the power as low as possible and increase each parameter as necessary. Power levels affect precision of cut, rate of tissue removal and thermal damage to adjacent tissues.

Only practitioners who are thoroughly trained in laser procedures, safety precautions and techniques for the use of laser power delivery systems should use this laser. A thorough understanding of the material presented in the User's Manual is highly recommended. The laser can ignite non-metallic materials. All combustible materials must be removed from the operations area or should be kept moist during the procedure. The laser can ignite preparation solutions containing alcohol and/or acetone. **DO NOT** leave puddles of preparation solution in the operations area. Vapors may build up under surgical drapes and create a safety hazard.

CAUTION: Avoid inadvertent laser firing. Turn the laser OFF with the safety keyswitch when not in use for an extended period of time.

DO NOT place the footswitch in an area where it may be accidentally depressed.

DO NOT use the laser system in the presence of flammable anesthetic gases. The use of lasersafe endotracheal tubes and other laser-safe accessories is recommended. Many materials not normally considered flammable could be ignited in the presence of high oxygen and nitrous gas mixtures. An acute awareness of the build up of the gases as a hazard should be maintained.

CAUTION: Avoid tissue splatter on the working end of the delivery fiber, this will create localized heating, which may cause the fiber tip to char and fail. If backscatter occurs, wipe the fiber with alcohol gauze. Allow alcohol to evaporate before continuing the lasing process. Re-cleave the fiber if necessary.

SYSTEM UNPACKING, INSTALLATION AND TRANSPORTATION

UNPACKING

Immediately upon receipt of the *SPECTRALASE* diode laser system, the user should inspect the shipping carton in the presence of delivery courier. If there is any damage to the outer package, request the courier to sign a Notice of Damage receipt. Save all cartons for inspection. Thoroughly inspect device carry case and inside components for damage and for missing items. Unpack all components carefully and verify the presence of all components on the packing slip. Notify Spectrum Int'l, Inc. immediately if there are any missing components. Please keep the shipping box during laser warranty period for possible service/upgrade returns.



INSTALLATION

Place the laser on a suitable table, cart, shelf, etc. with a minimum depth of 12 inches to accommodate the laser with all rear panel attachments in place. Connect the provided power cord and foot switch cable to the proper receptacles on the rear of the laser.

Examine how the fiber is wound under the top panel. Free the end of the fiber from attaching tape if any and **carefully** un-wind the fiber from the gap under top panel for about 1.5 to 2 feet. Be particular careful when crossing panel-ball junction; **DO NOT** allow fiber bending radius less than 1". Slightly curved fiber should easily slip through panel-ball touch point with light click. To wind the fiber back, use one hand fingers to press the round bunch of fibers to the top panel at the rear of the laser, and use the other hand fingers to **lightly** pull the fiber forward simultaneously spooling the fiber into the top panel gap. Do not rush and allow the fiber to slip without a tension through ball-panel junction.

- A. Plug the power cord into a standard AC grounded power outlet.
 - B. Insert the key into the key-switch on the rear panel and turn it clockwise to the vertical position. Remove the key from the switch.
 - C. Turn the rocker power switch on the housing front left corner to the ON position. LED display should light-up and read "0.0".
 - D. Press the ON button of the keypad on the laser front panel. Its green LED should illuminate, and red aiming beam should come ON.
 - E. Press and hold "Arrow-up" keypad button, the display readings should go from 0.0 to 4.0. with beeps and by 0.1 steps. Press and hold: Arrow-down" button and watch display values going from 4.0 to 0.0
 - F. Terminate the installation procedure by pressing OFF/Emergency button and turning power rocker switch and key-switch to the OFF position
- Hard carry case



TRANSPORTATION

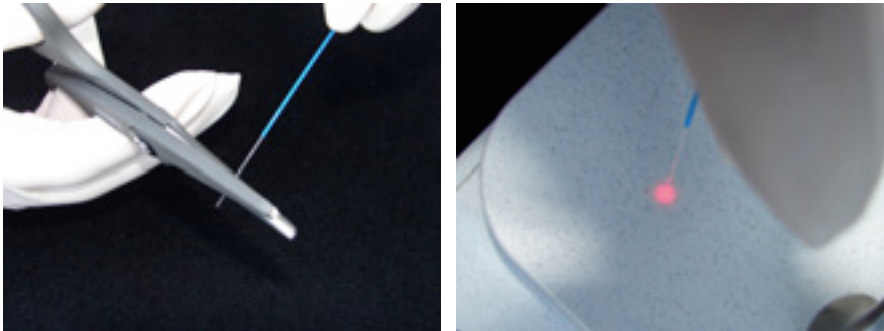
In the event that the laser system is to be relocated (this does not include moving within the office or facility):

- A. Remove a hand-piece from the fiber by slightly loosening compression nut. Accurately wind the fiber into top panel gap and secure its loose end with a tape to the top panel or laser housing. DO NOT allow fiber bending radius less than 1". Disconnect the footswitch cable and power cord from the rear of the laser Place the laser into its space in the carry case. The hand-piece could be left in its holding clip.

- B. Pack footswitch and power cable.
- C. Place all accessories in their pouch.
- D. Place laser safety goggles in protective bags.



Fiber Stripping

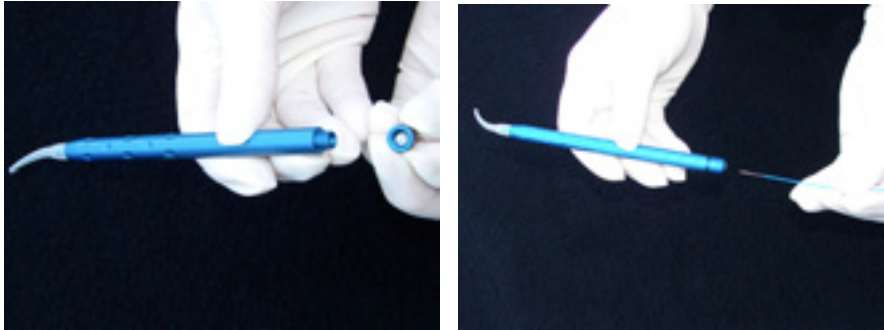


Fiber Cleaving

FIBER STRIPPING/CLEAVING PROCEDURE

Proceed to the fiber stripping and cleaving procedures only after fiber disinfection / sterilization is completed. The supplied *Micro-Strip* MS-1-FS fiber-stripping device should be used with the proper fiber guide and blades for each different size of delivery fiber. The 0.031 fiber guide and royal blue color blades should be used for stripping the 400 μm fiber. Instructions for using *Micro-Strip* are provided in a separate brochure that is located in accessories pouch.

We recommend that red aiming laser beam is turned ON during fiber cleaving procedure. After 1-1.5 inches of fiber plastic coating is stripped away from the distal end of the fiber, hold the scissors perpendicular to the fiber and shear off about 3 mm of bare fiber. Always wear safety goggles during fiber cleaving procedure. Check if the shape of red aiming beam is round by shining it on a perpendicular surface. If the shape is not close to round (slight “comet” tail is all right), the fiber cleavage/trimming should be repeated.



HAND-PIECE ASSEMBLY

The next step is to insert the prepared fiber through the hollow core of the hand-piece and secure in place with the compression washer and pressure nut, utilizing light finger pressure. Care should be taken so not to damage the fiber's protective plastic coating by using excessive turning force on the pressure nut. Only light pressure is required to secure the fiber firmly in place. The following sequence is recommended:

1. Loosen the pressure nut. Do not remove nut to avoid losing the small compression washer inside the nut.
2. Insert the free end of the fiber through the pressure nut and compression washer. Make sure that fiber end is stripped from insulation for about 1- 1.5 inches.
3. Loosely screw the compression washer and pressure nut onto the hand-piece.
4. Feed the fiber all the way through the hand-piece and feed the end of the fiber through the plastic tip/cannula while slightly twisting the tip and gently pushing the fiber through it. Firmly attach the cannula onto hand-piece tip.
5. Adjust the fiber so that it extends beyond tip/cannula orifice approximately 5 mm. Carefully tighten the pressure nut until the fiber is secured within the hand-piece.

The assembled unit is now ready for use.

LASER OPERATION PROCEDURE

A. Check to see that the connectors for the power cord, footswitch cord and fiber optic cable at the rear panel are properly secured.

B. Turn key-switch clockwise to the vertical position and turn power rocker switch to ON position. Press the ON button of the keypad. Observe that green LED indicator light of the button comes ON. Make sure that the aiming red laser beam is visible from the working end of the fiber. Adjust its intensity to a desirable level if needed.

C. Place appropriate wavelength specific (OD>5 at 810nm) eyewear for operator, assistant and patient.

D. Set the laser output power to its value of 0.6 Watts by pressing "arrow-up" button a few times. Place the fiber tip at a distance of about 15 mm from a piece of fiber initiating / test film and depress the footswitch to activate the laser.

An audible high pitch tone will be heard, indicating activation of the laser diode power supply. When laser emission begins, the operator will observe a rapid melting of the initiating film. This indicates normal power output of laser system and its readiness for patient applications.

E. The operator may now proceed with patient tissue treatment in accordance with developed treatment protocols.

F. Press OFF/Emergency button when the laser is not in use in order to prevent accidental firing. Observe that green LED indicator of "ON" switch goes off. After all sterilizing/ disinfecting procedures are completed, press the ON button and proceed to the next treatment (the laser system does not require warm-up time).

G. When treatment is completed, press OFF/Emergency button, turn the power and the keyswitch to OFF positions and remove the key. Remove laser-warning signs from all entrances to the operations area.

WARNING: This laser system is very sensitive to back reflections into the laser module which may damage or destroy the facet of the laser diode. Avoid pointing the fiber and focused beam directly into a surface that will reflect the beam directly back into the fiber tip.

CAUTION: Never operate the laser without an attached optical fiber to avoid uncontrolled laser radiation.

All clinical procedures performed with *SPECTRALASE* diode laser must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The practitioner should always set the laser system for minimal exposure to the patient. Optimal parameters for laser surgery may be achieved by starting with the power as low as possible and increase each parameter as necessary. Power levels affect precision of cut, rate of tissue removal and thermal damage to adjacent tissues.

It is always best to use the lowest energy setting possible to achieve your goal while avoiding charring.

LIMITED WARRANTY

The *SPECTRALASE* diode dental laser is warranted to be free from defects in material and workmanship for a period of 36 months from the date of shipment. Hand-pieces, fibers and other accessories are warranted to be free from defects in material and workmanship for a period of 60 days from the date of shipment.

In order to comply with this warranty, all internal adjustments or modifications must be made by Spectrum International, Inc. or its authorized representative. The liability of Spectrum International, Inc. under valid warranty claims is limited to repair or replacement at Spectrum International, Inc. facility or purchaser's place of business, at the option of Spectrum International, Inc.

This warranty doesn't cover defects or damage to the laser and its accessories that result from: improper operation or misuse; accident or neglect such as dropping the Product onto hard surfaces; contact with water, rain, extreme humidity or heavy perspiration; contact with extreme heat; spills of food or liquid. The warranty doesn't cover physical damage to the surface of the

Product, including scratches, cracks or other damages to the housing, front keypad or other externally exposed parts.

The forgoing warranty is exclusive and in lieu of all other warranties, whether written, oral, or implied, and shall be the purchaser's sole remedy and Spectrum International, Inc. sole liability under contract or warranty or otherwise for the Product.

Spectrum International, Inc. disclaims any implied warranty of merchantability or fitness for particular purposes. In no event shall Spectrum International, Inc. be liable for any incidental or consequential damages or for any incidental or consequential damages arising out of or in connection with the use or performance of the Product delivered hereunder.

PARTS AND SUPPLIES:

TAC 20 Topical: C-Lido 20%, Tetra 4%, Phen 2%, Gel, \$29 per 20 gram jar, Professional Arts Pharmacy Lafayette, LA 888-237-5053

Clear Tips: Laser Dental Innovations, 877-753-5054

Multi-Purpose Laser Tips: Ultra Dent Mac Tips #1361 800-552-5512

Laser Safety Glasses: Noir Laser Co 800-521-9746

Fuses: (2) 1 Amp 250 V

Laser Parts: Spectrum Lasers Inc 925-788-3954

Laser Fibers: Thorlabs Inc 400um,

Micro Stripper: Micro Electronics Inc,

Cleaver: Kyocera Ceramic Scissors,

Hand Piece: Dental Laser Innovations

Foot Pedal: Aquiline Inc

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