



Sapphire[®] plus
SOFT TISSUE MANAGEMENT

Sapphire[®] Plus STM 3W Diode Laser Instructions for Use

Table of Contents

| | |
|--|----|
| 1. INTRODUCTION..... | 4 |
| 2. WARNINGS AND CAUTIONS..... | 5 |
| Emergency Laser Power Termination | 6 |
| 3. SAPPHIRE® PLUS STM 3W DIODE LASER INDICATIONS FOR USE..... | 6 |
| 4. SAPPHIRE PLUS STM 3W DIODE LASER FACILITY AND ENVIRONMENTAL CONSIDERATIONS..... | 6 |
| Power Requirements (SAPPHIRE PLUS STM 3W Diode Laser) | 6 |
| Electromagnetic Environment Guidance | 7 |
| Heating and Ventilation..... | 7 |
| Lighting..... | 7 |
| Combustible Chemicals and Gases..... | 7 |
| Plume Evacuation..... | 7 |
| Operatory Access during Sapphire Plus STM 3W Diode Laser Use | 7 |
| 5. GENERAL SAFETY WITH THE SAPPHIRE PLUS STM 3W DIODE LASER..... | 8 |
| General Safety Considerations..... | 8 |
| Marketing Requirements Regarding Medical Device Safety (USA)..... | 8 |
| Statutory Licensure for Dental Laser Use | 8 |
| OSHA Provisions..... | 8 |
| Eye and Skin Protection | 9 |
| Emergency Shutdown Options..... | 9 |
| 6. SAPPHIRE PLUS STM/STM 3W DIODE LASER INSTALLATION AND SETUP..... | 9 |
| Instructions on Unpacking & Customer Service Assistance..... | 9 |
| Shipping Container Information..... | 10 |
| Contents of Shipping Container..... | 10 |
| Installing the Sapphire Plus STM 3W Diode Laser | 10 |
| 7. SAPPHIRE PLUS STM 3W DIODE LASER CONTROLS AND DISPLAYS..... | 12 |
| Sapphire Plus STM 3W Diode Laser Handpiece | 12 |
| Sapphire Plus STM 3W Diode Laser Unit Control Panel..... | 13 |
| Sapphire Plus STM 3W Diode Laser Power Level Adjustment..... | 14 |
| Continuous Wave and Pulse Mode | 14 |
| READY/SELECT Activation of STM 3W Diode Laser Unit | 14 |
| Aiming Beam | 14 |
| Laser Activation and Laser “ON” Indication | 15 |
| EMERGENCY DEACTIVATION of LASER..... | 16 |
| Battery Power Indicator..... | 16 |
| Sleep Mode..... | 16 |
| Error Codes..... | 16 |

| | |
|---|----|
| 8. SAPPHIRE PLUS STM 3W DIODE LASER OPERATION AND USE..... | 17 |
| Operating Modes | 17 |
| Continuous Wave (CW) Mode | 17 |
| Pulsed Energy Mode | 17 |
| Tissue Responses to Laser Energy..... | 17 |
| Installing & Replacing Single-Use Fiber Optic Tip | 18 |
| Initiating the Fiber..... | 19 |
| Changing Fiber Optic Tips..... | 19 |
| Setting Parameters | 19 |
| Hard Tissue Procedures..... | 20 |
| Cleaning Instructions..... | 20 |
| Calibration..... | 20 |
| 9. PROCEDURAL RECOMMENDATIONS FOR USING THE STM 3W DIODE LASER..... | 21 |
| Test Firing the Sapphire Plus STM 3W Diode Laser..... | 21 |
| Tip Initiation (when indicated) | 21 |
| Sapphire Plus STM 3W Diode Laser Use | 21 |
| Gingival Contouring with the Sapphire Plus STM 3W Diode Laser..... | 22 |
| Gingivectomy, Gingivoplasty and Papillectomy | 23 |
| Gingival Troughing & Tissue Retraction for Impressions | 24 |
| Sacular Debridement | 25 |
| Labial Frenectomy..... | 26 |
| Abscess Excision | 27 |
| Hemostasis..... | 28 |
| 10. SAPPHIRE PLUS STM 3W DIODE LASER SPECIFICATIONS | 29 |
| 11. SERVICING THE SAPPHIRE PLUS STM 3W DIODE LASER..... | 30 |
| 12. SYSTEM WARRANTY..... | 30 |

MANUFACTURER INFORMATION

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1. INTRODUCTION

The Sapphire® STM Diode Laser unit is a 3 Watt dental soft-tissue laser surgical/debridement device that plugs into the Sapphire Plus Light Source System. This “plug-and-play” unit offers dental clinicians the opportunity to add laser capability to the curing, whitening and lesion-detection functions of their Sapphire Plus platform. The Sapphire Plus STM 3W Diode Laser may be used for a variety of soft-tissue and modification and sulcular therapy procedures.

Dental professionals and staff who will use the Sapphire Plus STM 3W Diode Laser should receive proper laser use training prior to patient treatment with these devices. Applicable training programs for dental Laser use are available through the Academy of Laser Dentistry, dental schools, and many dental continuums. Your authorized Den-Mat® Holdings, LLC Representative can also provide the names of local dentists who have a Sapphire Plus STM 3W Diode Laser and may be able to provide additional guidance for new Sapphire Plus STM 3W Diode Laser Diode Laser users.

Safety is paramount when using any energy-based surgical instrument and your office should implement a safety program for the Sapphire Plus STM 3W Diode Laser. If your office does not already have a safety officer, one should be appointed to be responsible for understanding proper use, safe operation, and maintenance of the Sapphire Plus STM 3W Diode Laser system. Their duties should include training of office personnel in all aspects of system safety and management of the Sapphire Plus STM 3W Diode Laser and all accessories.

In addition to the information below, please refer to your Sapphire Plus Operator's Manual for additional safety and operational guidance.

Manufacturer's Laser Identification, output and standards label

The Sapphire Plus STM eW Diode Laser carries the Manufacturer's identification label affixed to the rear panel of the Sapphire Plus STM 3W Diode Laser Control Module.

MODEL: Sapphire Plus STM 3W Diode Laser
MANUF DATE: MMYYYY
SERIAL NO.: _ _ _ _ _
MANUFACTURED BY:
DEN-MAT® HOLDINGS, LLC
SANTA MARIA, CA 93455 USA
POWER INPUT: 5VDC from the Sapphire Plus PAC
WORKING BEAM WAVELENGTH: 808 ±5 nm
MAX POWER OUTPUT: 3WATTS
LASER CLASSIFICATION (per IEC 60825-1): Class 4
AIMING BEAM WAVELENGTH: 640 ± 10 nm
MAX. POWER OUTPUT: 2 MILLIWATTS
PULSE DURATION: 0.125 seconds Hz in PULSE: 4 Hz
COMPLIES WITH 21CFR 1040.10 & 1040.11 EXCEPT FOR
DEVIATIONS PURSUANT TO LASER NOTICE 50, DATED JULY 26,
2001. ALSO COMPLIES WITH IEC 60601-1; IEC 60601-2-22;
IEC 60825-1 and with Part 15 of the FCC Rules.

2. WARNINGS AND CAUTIONS



Warning: Visible and Invisible Laser Radiation – Avoid eye or skin exposure to direct or scattered radiation
WAVELENGTH: 808 nm MAXIMUM OUTPUT: 3W
WAVELENGTH: 640 nm MAXIMUM OUTPUT: 2mW
CLASS 4 Laser Product

Above Warning is affixed to the front panel of the Sapphire Plus STM 3W Diode Laser Control Module.



LASER APERTURE
at the end of handpiece (when handpiece attached)

Above label is positioned on the outlet cover for the laser handpiece.



Warning: Laser Safety Eye Protection **MUST BE WORN** by the Operator, Patient, Assistant, and anyone present when the laser is activated. Eye Protection must conform to Specification DIN EN207 Annex II of the Directive 89/686/EEC with optical density in 800nm-818nm of OD 4+ such as NoIR Laser Company filter model DII



Warning: Do not use in the presence of combustible or combustion supporting gases



Warning: Do not use in the presence of supplemental therapeutic oxygen supplies



Warning: Always test activate the device outside the mouth before using on a patient.

Caution: US Federal Law restricts the use of this device to use by or on the order of a dentist

Caution: Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Emergency Termination of Laser Emissions:

The Sapphire® Plus STM 3W Diode Laser has been designed with several methods to terminate the Laser energy if the operator wishes to deactivate the system in an emergency situation. These include an emergency shutoff switch, a key, a power switch, and removal of the power/communications cord from the Light Guide Port. Any of these may be used to terminate laser emissions from the Sapphire Plus STM 3W Diode Laser System.

3. SAPPHIRE PLUS STM DIODE LASER INDICATIONS FOR USE

The Sapphire Plus STM 3W Diode Laser is intended for use in performing intraoral soft tissue general, oral maxilla-facial and cosmetic surgery for ablating, incising, excising, vaporizing and coagulation of soft tissues using a fibre optic delivery system. Indications include:

- excision and incision biopsies
- hemostasis
- treatment of aphthous ulcers
- frenectomy
- frenotomy
- gingival incision and excision
- gingivectomy
- gingivoplasty
- incising and draining abscesses
- operculectomy; oral papillectomy
- removal of fibromas
- soft tissue crown lengthening
- sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- tissue retraction for impression
- vestibuloplasty

General guidelines for these procedures may be found in section 8 of this user instruction manual. In addition to receiving proper training in the use of dental Lasers, users should be familiar and experienced with these procedures using electrosurgical devices or traditional instruments before performing them on patients with the Sapphire Plus STM 3W Diode Laser. Non-experienced users should seek appropriate training or guidance before attempting clinical treatments with the Sapphire Plus STM 3W Diode Laser system.

4. SAPPHIRE PLUS STM LASER FACILITY AND ENVIRONMENTAL CONSIDERATIONS

In order to insure the safe use of the Sapphire Plus STM 3W Diode Laser in your facility, please check to make sure that the proposed location is compatible with the specifications listed below.

Power Requirements:

The Sapphire STM 3W Diode Laser Unit is powered by the Sapphire Plus System.

Power requirements for the STM 3W Diode Laser auxiliary power supply are as follows:

Input Power: 90-265 VAC at 47 – 63 Hz,
Output Power: +5 VDC at 6A maximum

Power requirements for the Sapphire Plus System (reference) are:

Input Power: 90-265 VAC at 47 – 63 Hz, 17A max at 120VAC

Electromagnetic Environment Guidance (per IEC 60601-1-2, sub-clause 6.8.3.201)

The Sapphire Plus STM 3W Dental Diode Laser (Class A) is suitable for use in all establishments other than domestic. It emits electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. Not recommended for use where life-supporting electrical equipment may be affected.

Floors should be wood, concrete, or ceramic tile. If floors are covered in synthetic material, the relative humidity should be at least 30%.

Mains power quality should be that of a typical commercial or hospital environment. The Sapphire Plus STM 3W Diode Laser does not require continued operation during power mains interruptions, merely it is recommended that the Sapphire Plus STM 3W Diode Laser should be powered from an uninterruptible power supply (UPS) or its battery.

Power Frequency Magnetic Fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Heating and Ventilation:

The room where the Sapphire Plus STM 3W Diode Laser is used should have an appropriate cooling and heating system so that the lasers can be operated within the optimal temperature range of 20° - 30°C (68° - 86° F). Avoid storing or transporting the lasers in temperatures below 0° Celsius (32° F).

Lighting:

Overhead lighting and/or dental unit light should provide enough illumination to allow proper operator visibility of the surgical site when activating the Sapphire Plus STM 3W Diode Laser intra-orally.

Combustible Chemicals and Gases:

All gases that are combustible or support combustion and are used in the operatory area where the Sapphire Plus STM 3W Diode Laser are being operated used must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in order to avoid possible combustion. Do not use in the presence of supplemental therapeutic oxygen supplies for patients with respiratory or related diseases.

Plume Evacuation:

Plume evacuation should be addressed when vaporizing tissues. A high volume vacuum system should be used and 0.1 micron or less high filtration masks that are suitable for virus and bacterial control should be worn by Clinicians, operators and auxiliary staff in the vicinity of procedures being performed with the Sapphire Plus STM 3W Diode Laser system.

Operatory Access During Sapphire Plus STM Diode Laser Use:

Access to the treatment area should be restricted while the lasers are in use. A sign indicating "LASER IN USE" should be placed in a designated area adjacent to the treatment area entry location.



5. GENERAL SAFETY WITH THE SAPPHIRE® PLUS STM DIODE LASER

General Safety Considerations:

Safe use of the Sapphire Plus STM 3W Diode Laser is the responsibility of the entire dental team including the doctor, any system operators and the dental office safety officer. Protocols for the safe use of Lasers have been developed by medical and dental professionals, scientists and laser manufacturers. These protocols should be followed when using the Sapphire Plus STM 3W Diode Laser system. Dental professionals have also developed protocols and guidelines for Laser use on oral soft tissues which should be employed when using the Sapphire Plus STM 3W Diode Laser system.

Marketing Requirements Regarding Medical Device Safety (USA):

The United States Food and Drug Administration has control over the sale and use of the all medical devices including the Sapphire Plus STM/STM 3W Diode Laser. Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control are required to certify compliance with the regulations and furnish various reports to the Center for Devices and Radiological Health (CDRH). For manufacturers of medical lasers (such as the Sapphire Plus STM 3W Diode Laser system), additional review by the FDA of the safety and effectiveness of the device is required. Companies who intend to market a medical laser or equivalent device must receive authorization from the FDA to permit the device into commercial distribution. The premarket notification (510(k)) process used for the Sapphire Plus STM Diode Laser systems is applicable for devices that are documented to be substantially equivalent to existing legally marketed Class II devices.

Statutory Licensure for Dental Laser Use:

Usually, states or provinces do not have a specific licensure requirement for use of surgical Laser devices by dentists. Many states do, however, require hygienists who will be using Lasers to attend licensure training that includes both a lecture and hands-on experience. The license applicants are then required to pass a proficiency test for certification prior to using Lasers. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Such training would be appropriate for use of the Sapphire Plus STM Diode Laser system.

OSHA Provisions:

Worker safety is the responsibility of the employer and is regulated by OSHA (Occupational Safety and Health Administration), a division of the U.S. Department of Labor. OSHA recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers. For more information see OSHA Technical Manual (TED 1-0.15A) Section III, Chapter 6, 1999. Den-Mat® Holdings recommends implementation of a safety program for the safety of your patients and office staff in connection with the use of the Sapphire Plus STM 3W Diode Laser. Den-Mat Holdings also recommends checking and complying with applicable state and provincial safety and health organization requirements.

Eye and Skin Protection:

While the Sapphire Plus STM 3W Diode Laser is in use, doctors, system operators, auxiliary staff, patients, and anyone attending them in the operatory must wear the appropriate safety eyewear that has been designed for use with the 700-plus nm wavelengths associated with Lasers. Eye Protection must conform to Specification DIN EN207 Annex II of the Directive 89/686/EEC with optical density in 800nm-818nm of OD 4+ such as NoIR Laser Company filter model DI1.

Nominal Ocular Hazard Distance (NOHD) is the distance from the source of laser emission to the point where it no longer exceeds its Maximum Permissible Exposure (MPE – highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin). The Nominal Hazard Zone (NHZ) is the space within which the level of direct, reflected, or scattered radiation during normal operation exceeds the appropriate MPEs. The outer limit of the NHZ is equal to the NOHD. The NOHD for persons wearing recommended safety glasses is shown in Table 1 below.

| Radiation Source | MPE mW/cm2 | Divergence Angle | NOHD (inches/cm) | |
|--------------------------|---------------|------------------|------------------------|---------------------------------|
| | | | Without eye protection | With Recommended Eye Protection |
| Fiber Optic Tip (direct) | 1.66 | 9° (± 1°) | 155/393.7 | 1.55/3.94 |
| Reflected from tissue | 1.66 | n/a | 0.25/0.63 | 0.0025/0.0063 |

Table 1 NOHD

Never point the Sapphire Plus STM 3W Diode Laser tip directly at the face, eyes or skin of anyone while emitting energy.

Emergency Shutdown Options:

Perform any of these actions to terminate laser emissions in the event of a real or perceived emergency:

1. Release the handpiece activation button
2. Depress the emergency “STOP” button
3. Remove your foot from the Foot Switch
4. Turn the key counterclockwise to the “OFF” position
5. Switch the Power switch (on rear of Sapphire Plus Light Source unit) to the “OFF” (O) position
6. Unplug the Power Cord from the wall outlet or rear receptacle of the Sapphire Plus Light Source Unit
7. Unplug the power/communication cord from the Light Guide Port

6. SAPHIRE PLUS STM DIODE LASER INSTALLATION AND SETUP

Instructions on Unpacking & Customer Service Assistance:

A Den-Mat® Holdings, LLC Customer Service Representative can provide assistance when you are ready to remove the Sapphire Plus STM 3W Diode Laser from its shipping container. Please do not attempt to unpack the Sapphire Plus STM 3W Diode Laser and install or setup the unit without reading this section first. Please refer to your Sapphire Plus Operator’s Manual for additional installation and setup guidance. If you are unsure about any aspect of the assembly, call your Den-Mat Holdings, LLC Customer Service Representative for assistance.



Shipping Container Information:

The shipping container you received with your Sapphire® Plus STM 3W Diode Laser was specially designed to safely transport the Laser. In the unlikely event that you need to return the Laser for service or repair, please retain the original shipping container.

Contents of Sapphire STM Shipping Container:

The contents of the shipping container should include the following:

- (1) Sapphire Plus STM 3W Diode Laser “plug-in” unit
- (1) Sapphire Plus STM 3W Diode Laser Handpiece
- (3) Protective Glasses – Laser Safety
- (1) Package of 5 disposable, single-use Fiber Optic Tips
- (1) Auxiliary Power Supply
- (1) Sapphire Plus STM 3W with Laser Owner's Manual
- (1) Sapphire Plus STM 3W Diode Laser Instructions for Use (IFU)
- (1) Safety Sign
- (1) Warranty Information

Notice: Use of any cables or accessories other than those provided by Den-Mat Holdings, LLC may damage the device and may result in increased RF emissions or decreased immunity of the equipment.

Please check to insure that all items are accounted for.

Installing the Sapphire Plus STM 3W Diode Laser:

Each of the items listed below should be inspected and the instructions followed:

Sapphire Plus STM 3W Diode Laser unit - The Sapphire Plus STM 3W Diode Laser unit must be plugged into the Sapphire Plus system to operate. Confirm that the Sapphire Plus Light Source Unit system power is “OFF”. If there is an adapter ring installed in the jack of the Sapphire Plus system, remove the adapter and install the Sapphire Plus STM 3W Diode Laser unit. This unit will not only power and control the Sapphire Plus STM Diode Laser Handpiece, but it also replaces the adapter ring and allows use of all other Sapphire Plus attachments. Users should allow the Sapphire Plus STM 3W Diode Laser unit to remain in the Sapphire Plus system at all times for proper and most convenient use of the Sapphire Plus STM 3W Diode Laser. After installing the Sapphire Plus STM 3W Diode Laser unit, switch the Sapphire Plus Light Source Unit system power to “ON”.

Power Switch - The power switch for the Sapphire Plus Light Source Unit is located on the rear panel of the Sapphire Plus unit near the center of the panel. This switch must be in the “ON” position when the unit Sapphire Plus STM 3W Diode Laser unit is to be used. There is no power switch on the Sapphire Plus STM 3W Diode Laser unit.

Operating Key Switch - The key switch is the major circuit power control for non-Laser functions of the Sapphire Plus Light Source System. In order to operate the Sapphire Plus STM 3W Diode Laser unit, the Sapphire Plus Light Source Unit key must be turned to the “OFF” position and removed (the Sapphire Plus system display will indicate “Lo cd”). The key must then be inserted into the key switch in the Sapphire Plus STM 3W Diode Laser unit and turned to the “ON” position to place the unit in STANDBY status. The Sapphire Plus STM 3W Diode Laser unit display will only enter STANDBY status if the STM Diode Laser Handpiece is attached to the unit. If the handpiece is missing, the laser power display will read ‘E5’ indicating that the handpiece is absent. Prior to leaving the office, your safety officer should check to see that the key switch has been turned off, removed and stored in a safe place.

Sapphire Plus STM 3W Diode Laser Handpiece – Disconnect any existing handpieces and/or adapter inserts from the Light Guide Port of the Sapphire Plus STM 3W Diode Laser unit. Insert the Sapphire Plus STM 3W Diode Laser power/communication cord plug into the Light Guide Port on the Sapphire Plus STM 3W Diode Laser unit and confirm that it is fully seated. When the STM Diode Laser Handpiece cord is fully seated in the Light Guide Port, and the Key Switch on the STM 3W Diode Laser unit is in the “ON” position the auto-detect feature will place the Sapphire Plus STM 3W Diode Laser unit in STANDBY status, this is indicated by ‘0.8’ in the Laser Power display and a green LED next to ‘CW’.

Door Interlock Switch – The Sapphire STM may be equipped with a Y-shaped mini-phono connector that permits use of a door interlock switch in the event that a dedicated laser treatment room with wired door interlock is desired. If installed, the laser would shut off anytime the door is opened, in theory, to protect the person’s eyes who is entering the room. If the interlock switch is desired, you may purchase parts from a local electronics store. Call Den-Mat® Holdings, LLC Customer Service for information regarding these parts. To install the switch, insert the switch’s plug into the smallest jack on the Y-shaped connector and then insert the Y-shaped connector’s plug into the Footswitch jack on the side panel of the control module. Call DenMat Holdings, LLC customer service and ask for the door interlock connector if you’d like to use this feature.

Sapphire Plus STM Footswitch (optional) – An optional footswitch is available from Den-Mat Holdings, LLC that permits handsless control of laser emissions. To use the footswitch, insert the male plug into the jack on the side of the control module. If you have installed a Door Interlock Switch (see above), insert the footswitch plug into the larger of the two jacks on the Y-shaped connector.

Sapphire Plus STM 3W Diode Laser Auxiliary Power supply – In some cases of extended periods of Sapphire Plus STM 3W Diode Laser use or if the Sapphire Plus system is rarely used, sufficient power for operation of the Sapphire Plus STM 3W Diode Laser Handpiece may not be available. In these rare cases, identified by a red battery indicator light, users should attach the Sapphire Plus STM 3W Diode Laser Auxiliary Power supply. If allowed to continue to discharge, the power level will be too low to initiate laser emissions and ‘E3’ will appear in the LASER POWER display. To use the Sapphire Plus STM 3W Diode Laser Auxiliary Power unit, plug the unit into an available 120 VAC (or 240 VAC) wall outlet and attach the small, low-voltage plug to the jack on the side panel of the Sapphire Plus STM 3W control module.

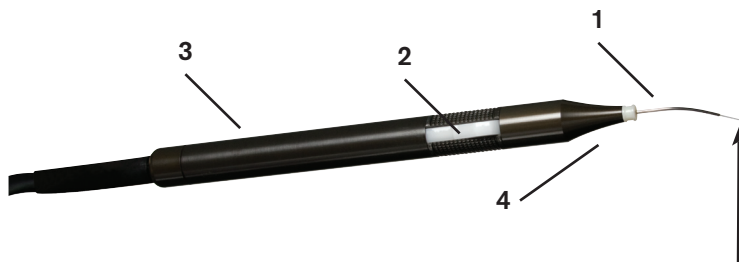
Sapphire Plus STM 3W Diode Laser Assembly Instructions Summary:

1. Switch the Sapphire Plus Light Source Unit system power to “OFF”
2. Plug the Sapphire Plus STM 3W Diode Laser unit into the Sapphire Plus Light Guide Port.
3. Switch the Sapphire Plus Light Source Unit power to “ON”
4. Attach the Sapphire Plus STM 3W Laser Handpiece to the Light Guide Port in the Sapphire Plus STM Laser unit
5. Attach the foot switch (optional)
6. Place the Sapphire Plus Light Source system key in the OFF position and remove the key
7. The Sapphire Plus Light Source unit system control console will display “Lo cd” (Locked)
8. Insert the key into the key switch in the Sapphire Plus STM 3W Diode Laser unit and turn the switch to the “ON” position
9. The display on the Sapphire Plus STM 3W Diode Laser unit will show the default output 0.8W and the CW Mode Selection LED will glow green.
10. If the power level for the Sapphire Plus STM 3W Diode Laser unit is low (identified by a RED battery indicator, and later by ‘E3’ in the laser power display), attach the Sapphire Plus STM 3W Diode Laser Auxiliary Power supply.

7. SAPPHIRE® PLUS STM 3W DIODE LASER CONTROLS AND DISPLAYS

Sapphire Plus STM 3W Diode Laser Handpiece:

The Sapphire Plus STM 3W Diode Laser handpiece includes the components and functions as shown below:



Avoid Exposure-Laser Radiation is emitted from this aperture

Sapphire Plus STM 3W Diode Laser Handpiece Components

1. Removable, Disposable single-use Fiber Optic Tip
2. Activation Switch
3. Main Handle Barrel
4. Collar for Removable Tip
5. Sanitary, disposable single-use Barrier Sleeve (not shown).

Sapphire Plus STM 3W Diode Laser Unit Control Panel:

The Sapphire Plus STM 3W Diode Laser Unit Control Panel has the following features and control functions:

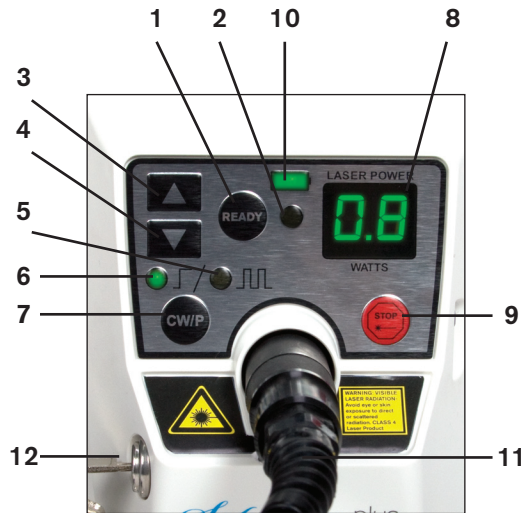




Figure 1

1. "READY" Button
2. "READY" Indicator Light
 - Green in "READY" status
 - Red flashing indicates low power, 120 VAC auxiliary power connection required
 - Aiming beam fires (unless aiming beam turned off)
 - Unlit in "STANDBY" status
3. "UP" adjustment for Laser Power
4. "DOWN" adjustment for Laser Power
5. "PULSE" mode indicator for Laser Power. Symbol: 
6. "CW" (CONTINUOUS WAVE) mode indicator for Laser Power. Symbol: 
7. "CW/P" (CONTINUOUS WAVE/ PULSE) Mode Toggle Button for Laser Power
8. Laser Power Level Indicator
9. "STOP" (EMERGENCY STOP) Button
10. Battery Power Indicator
11. Power/Communication Cord (plugged into Light Guide Port)
12. Unit key switch



Sapphire® Plus STM 3W Diode Laser Power Level Adjustment:

Power can be adjusted by using the UP and DOWN arrow keys to increase (UP) or decrease (DOWN) the power setting. The power level setting will be displayed by the Laser Power Level Indicator. Upon initial power up, the unit defaults to the CW mode and the indicator light next to CW on the control panel will turn on. The power setting will default to 0.8 Watts and will be displayed in the LASER POWER window. Power can be increased or decreased in 0.1w increments or by holding the up or down key to scroll to desired setting.

Aiming Beam:

The Sapphire Plus STM 3W Diode Laser provides a visible light that illuminates the site at which the Laser working beam will be active, allowing the operator to aim the beam before and during activation. The Aiming Beam is active in READY status and therefore also serves as a visual indicator of READY status at the Handpiece. The aiming beam is adjustable from its maximum setting of 2mW to 0mW (OFF) in 20% increments.

To set Aiming Beam output, press and hold the READY button for 5 seconds, the aiming beam will begin firing at its default setting of 0.4mW. Use a piece of articulating paper as a target to gauge the desired output of the aiming beam. The Laser Power Display will show 'A 1'. Press the DOWN button to turn off the Aiming Beam. The Display will read 'A 0'. Pressing the UP button increases Aiming Beam output incrementally to its maximum of 2mW, 'A 5'. Press the READY button to select the desired Aiming Beam output and exit the Aiming Beam setting mode. The STM will be READY (to fire the working beam) at this point.

Continuous Wave  and Pulse Mode :

Continuous Wave (CW) or 4 Hz Pulse modes for Laser power delivery may be selected by pressing the “CW/P” toggle key. The indicator light for the selected mode will glow green.



STAND-BY, CW Mode 0.8W (default) output



STAND-BY, P Mode 0.8W (default) output

READY Activation of Sapphire Plus STM 3W Diode Laser Unit:

Press the READY button in either CW or PULSE to change from STANDBY to READY status and prepare the unit for activation of the laser working beam. A GREEN indicator will glow next to the “READY” button, identifying that the unit is in “READY” status. Changing the mode or power level releases the unit from “READY” status, requiring the user to select the new setting by pressing the READY button again. Settings may not be changed when the laser working beam is activated. Pressing the READY button without changing the Laser power level or mode toggles the system back to STANDBY status.



Laser in READY Mode @ 0.8W output

Laser Activation and Laser “ON” Indication:

The Sapphire Plus STM 3W Diode Laser working beam can be activated using either the handpiece or foot switch, but not both at the same time. The system uses the device that is plugged in first and locks out the second. Unplug the footswitch from the Sapphire Plus STM Diode Laser Unit if it will not be used.

When the Sapphire Plus STM 3W Diode Laser is in READY and the ACTIVATOR button on the Sapphire Plus STM 3W Diode Laser handpiece or the footswitch is depressed and held down, the active mode indicator will turn from GREEN to RED and an audible “chirp” will be heard, indicating that the laser working beam has been activated. After a 100 micro-second delay, the Sapphire Plus STM 3W Diode Laser handpiece will begin delivering laser emissions to the target tissue by means of the disposable 400 micrometer Fiber Optic Tip. Releasing the handswitch ACTIVATOR button or footswitch immediately deactivates the laser.

NOTE: Fiber Optic Tip must be installed to permit aiming beam or working beam laser emission.



Sapphire Plus STM 3W Diode Laser control panel showing that the laser working beam is emitting in CW at 0.8 W.

EMERGENCY DEACTIVATION of LASER:

The Sapphire® Plus STM 3W Diode Laser unit may be deactivated at any time by pressing the Emergency “STOP” button (#9, Figure 1). This action deactivates the unit function in any mode, at any power setting, and whether or not Laser working beam is activated. To reset the unit for use, depress and hold down the “STOP” button for 5 seconds.

Battery Power Indicator:

The Sapphire Plus STM 3W Diode Laser uses one rechargeable lithium-ion battery to power the unit. If the battery charge drops below 3.4V, the Battery Power Indicator will change from green to amber. This is usually not a concern unless the unit is intended to be used for an especially extended procedure (greater than 20 minutes), particularly if the procedure requires for the laser to be operated in the continuous wave mode at outputs greater than 2.0W. If the battery is discharged below 3.0V, the Battery Power Indicator changes from amber to red. This indicates that very limited power remains and that the Auxiliary Power Supply should be plugged into a wall outlet from the DC jack on the side panel of the Sapphire Plus STM. If battery power is allowed to continue to fall, ‘E3’ will appear in the LASER POWER display, indicating that laser emissions are not possible. When battery is charged the indicator will glow green.

Sleep Mode:

The Sapphire Plus STM 3W Diode Laser has several power saving and safety features. If the Sapphire Plus STM 3W Diode Laser is placed in READY state and left unchanged for five minutes, the device will switch to STAND-BY mode.

Similarly, if the device is in STAND-BY mode and is inactive for a period of ten minutes, it will go into SLEEP mode where all displays and LED indicators will be OFF. To ‘wake’ the Sapphire STM from ‘sleep,’ press any button and the STM will become active in STAND-BY mode, showing ‘CW’ at 0.8W on the displays.

Error Codes:

The following error codes may appear in the LASER POWER display window:

- E1 – Output power out of calibration; recalibrate at manufacturer
- E2 – Over temperature
- E3 – Low battery; recharge or replace battery
- E4 – No power; no output or drive current
- E5 – No handpiece; laser handpiece not inserted

8. SAPPHIRE PLUS STM 3W DIODE LASER OPERATION AND USE

Operating Modes:

The Sapphire Plus STM 3W Diode Laser will deliver energy in either continuous wave (CW) or Pulsed (P) mode, a 'temporal emission' mode (time related mode). Selection of the appropriate mode will allow the operator to optimize control of target tissue temperatures and the efficiency of energy delivered. The pulse duration (0.125 seconds) and the number of pulses per second (4) have been fixed by the manufacturer using an adjustable duty cycle. Therefore, the operator will need to adjust only the laser power and mode.

Continuous Wave (CW) Mode:

The CW mode is generally the fastest way to ablate tissues but heat can build up and cause collateral damage to adjacent tissues. Cool the tissues being treated by using periodic blasts of air from a triplex syringe and high speed suction. You may also use water to cool in areas where there is prolonged exposure to the Sapphire Plus STM's 3W Laser beam. Avoid using the air syringe when you have an opening in soft tissue adjacent to or within the surgery site, as an air embolism may occur resulting from air captured within the tissue during the cooling process.

Pulsed Energy Mode:

Pulsing the Sapphire Plus STM 3W Diode Laser energy will allow some cooling of the tissue between emissions of energy. The "duty cycle" is the percentage of the time that the system is emitting energy. The pulses per second, the duty cycle and the energy intensity per pulse determine the average power.

In the pulsed mode, the Sapphire Plus STM 3W Diode Laser is programmed to deliver 4 pulses per second with a duty cycle of 50%. It produces 1 energy pulse with 1 period of rest with no energy between each pulse. The result will be an average power per second that will be 50% of the laser's setting. Therefore, when using pulsed energy, you will have to adjust your power upward in order to achieve the same rate of work at the same power set in CW.

Tissue Responses to Laser Energy:

Maximum results will be achieved by regulating the power and the speed that the operator moves the Fiber Optic Tip. Tissue charring is an undesirable after-effect of too much power, or the tip moving too slowly. Always use the least amount of power that is required to complete your procedure. The ideal tissue response will show little or no discoloration after treatment and there will be less residual damage and faster healing. Avoid penetrating or damaging the periosteum, and do not attempt to use the laser on alveolar bone. Because the 808 nm laser energy is attracted to melanin and hemoglobin, power must be reduced when treating patients with darker soft tissue. Always begin with the lowest power you can use to remove or modify target tissue.

Installing and Replacing Single-Use Fiber Optic Tips

The Fiber Optic Tips conduct laser energy from the laser diodes to the tissues. These fibers are made of silica with a polymer cladding.

Note that there are potential hazards when inserting, steeply bending, or improperly securing the Fiber Optic Tips to the handpiece. Failure to follow these recommendations may lead to damage to the fiber or delivery system and/or harm to the patient, staff, or laser operator. The STM unit should either be OFF or in STAND BY when removing or installing a new Fiber Optic Tip.

Laser Emissions

As the aiming beam passes down the same fiber delivery system as the working beam, it provides a good means of checking the integrity of the delivery system. If the aiming beam spot is not present at the distal end of the delivery system, its integrity is reduced (make certain that the aiming beam is turned ON), or it looks diffused, this is a possible indication of a damaged or malfunctioning delivery system. If the issue is not resolved by use of another Fiber Optic Tip, return the system to the manufacturer for repair. Remember that the aiming beam can cause eye injury, too. Do not direct the beam towards the eyes of patient or staff.

NOTE: Laser emissions are mechanically blocked until the Fiber Optic Tip is installed.

The fiber is relatively flexible, but can be broken if bent at an angle that is too sharp or a radius that is too small. Protein debris from gingival tissue accumulates on the fiber during surgery and the extreme heat that develops will deteriorate the Tip. Fibers can fracture if a blackened area greater than 3 – 4 mm develops. This is especially important when using the Sapphire[®] STM Laser for periodontal pocket debridement. Stop lasing and regularly wipe off the tip with a 2 x 2 gauze sponge that has been wet with water to avoid the accumulation of protein debris. Do not use flammable solvents such as alcohol when cleaning a hot tip. Replace the disposable, single-use Fiber Optic Tip as necessary and for each new patient.

The disposable, single-use Fiber Optic Tips are provided in a sealed package. Each Fiber Optic Tip contains a pre-cleaved, pre-stripped piece of fiber. They are designed for single-use only and should be discarded after use. Confirm the integrity of the package before use; if damaged, do not use the Tips. Special care should be taken not to break or snap the fiber when removing Tips from packaging. Do not touch the ends of the fiber.



Installing the Fiber Optic Tip

To install a new Tip, hold the collar of the tip between your thumb and forefinger, align the proximal (polished) end of the fiber with the handpiece receptacle and firmly press the Tip onto the handpiece.

To remove a worn Fiber Optic Tip, gently grip the Sapphire Plus STM Fiber Optic Tip between forefinger and thumb and pull it directly away from the handpiece.

Initiating the Fiber:

Some procedures call for the Fiber Optic Tip to be 'initiated.' 'Initiation' prepares the tip of the fiber to retain heat by fusing a thin layer of pigment on the end. The easiest way to initiate a tip is by lightly moving the end of the fiber across a piece of articulating paper with the unit set to 1W CW (see below). The Tip will retain pigment from the paper and will glow. Do not exceed contact time of 1 second.

Changing Fiber Optic Tips:

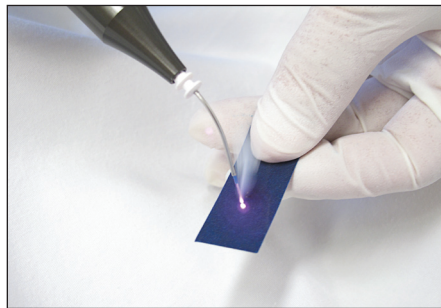
The STM 3W Fiber Optic Tips are not intended to be stripped or cleaved; they are ready for use straight from the package. Change tips:

- Between patients
- If the silica fiber burns to within 1 or 2mm of the jacket; if a blackened area greater than 3 – 4 mm develops
- If tissue build-up on the end of the tip prevents effective transfer of laser energy

Setting Parameters:

Review your power and mode requirements and then depress the mode toggle button to select either Continuous (CW) or Pulsed mode operation. The mode you have selected will be identified by the green light adjacent to the symbols for CW or PULSE on the front panel.

Select power output by pressing the up or down arrow buttons until you have reached the desired level. The default power setting is 0.8 Watts and will be displayed in the LASER POWER window when the unit is powered-up.



Tip Being Initiated

Hard Tissue Procedures:

The Sapphire® Plus STM 3W Diode Laser is not indicated for hard tissue procedures. The Sapphire Plus STM 3W Diode Laser is attracted to melanin, hemoglobin and to some extent to water and oxygenated hemoglobin. Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to such energy could cause patient discomfort and even lead to possible pulpal necrosis.

Cleaning Instructions:

Refer to the Sapphire Plus Operator's Manual for cleaning and sanitizing the Light Source Unit.

Sapphire Plus STM 3W Laser Control Module – Clean the Sapphire Plus STM 3W Diode Laser by using a mild, non-abrasive disinfectant. Do not saturate the control panel with liquid. Wipe with a damp towel and dry completely.

The Sapphire Plus STM 3W Diode Handpiece and Cable should be cleaned using a liquid disinfectant similar to BIREX or CIDEX. Do not spray disinfectant directly onto the handpiece as this may damage the ON/OFF switch or penetrate into the microprocessor or laser optics. Apply with a gauze sponge or wipe. Please wear gloves.

Calibration:

The Sapphire Plus STM 3W Diode Laser uses solid-state circuitry to continuously monitor power output and adjusts the power supplied to the laser diode to maintain the output at the user defined setting. If the output levels are more than $\pm 20\%$ of the set value, the unit will shut off power to the laser diode, an audible signal will sound and 'E1' will appear in the LASER POWER display window. If this happens, the unit should be turned off and allowed to sit for about five (5) minutes, then turned on again. If the laser performs without the alarm sounding, the microprocessor has been able to make adjustments and the unit will function. If the alarm sounds upon restarting, the unit will need to be sent for re-calibration by Den-Mat® Holdings, LLC Service Department.

We suggest that your practice establish an internal calibration program for your laser. Recalibration is recommended at least once per year based on typical usage.

Recalibration may be performed by DenMat Holdings, LLC by returning the unit. As an alternative, you may purchase a calibrated hand-held power meter approved for use with 808 nm devices to check power output. The laser should be set at 1, 2, and 3 W with output checked at each level. The output display on the hand-held meter should be within 20% of each setting. If not, replace the fiber tip and recheck power outputs. If output displays are still outside the 20% tolerance, return the unit to Den-Mat for recalibration. There are no methods available for the user to adjust the calibration of the unit and the handpiece must not be opened by the user for any reason.

9. PROCEDURAL RECOMMENDATIONS FOR USING THE SAPPHIRE PLUS STM 3W DIODE LASER

The following procedure guidelines are provided as a guide only and have been developed based on information provided by experienced laser users and educators. Always review the patient's history to evaluate possible contra-indications for use of local anesthesia or other complications.

Fiber Optic Tips are designed for single-use only and should be changed between patients. See Section "Installing Single-Use Fibre Optic Tips" (p 18, above) for details.

Test Firing the Sapphire Plus STM 3W Diode Laser:

Always test-fire the Sapphire Plus STM 3W Diode Laser prior to using it intra-orally. Using a power setting of 1.0 W Continuous Wave, place the Sapphire Plus STM 3W Diode Laser in the READY mode. Activate the working beam for 1 - 2 seconds while aiming the Fiber Optic Tip onto a 2 X 2 gauze sponge moistened with water. Do not use alcohol or any other combustible material to wet the 2 X 2 sponge, as it may ignite.

Tip Initiation (When Indicated):

Not all soft tissue procedures require contacting tissue with the fibre tip. Those procedures that do not require contact will use a Fiber Optic Tip that has NOT been initiated, because to be effective in non-contact mode, laser energy must flow unimpeded from the Tip. See section "Initiating the Fiber" (page 19) for guidance.

Sapphire Plus STM Diode Laser Use:

NOTE: Before using the Sapphire Plus STM 3W Diode Laser for patient treatment, it is recommended that a sanitary, disposable single-use Barrier Sleeve be placed on the Handpiece to minimize soiling the Handpiece and reduce the chance for patient-to-patient cross-contamination.

Depress the Handpiece actuator switch or the Foot Pedal and make short quick strokes at the lowest power that you can to remove the target tissues while lightly contacting it. Release the Handpiece actuator switch or the foot pedal and use a clean 2 X 2 gauze sponge moistened with water to remove debris from the Fiber Optic Tip. Do not use flammable liquids to wet the sponge.

Place the Sapphire Plus STM 3W Diode Laser in Standby Mode until you are ready to start another procedure.

Turn the key counterclockwise to the "OFF" position if you are not going to be starting another procedure.

Record the Powers and total procedure times used for each procedure in the patient's chart. For example:

Patient Name: Mary Jones

Procedure: Gingivectomy # 6 and # 7

#6 procedure time 90 seconds @ 1.0 Watts CW air cooled

#7 procedure time 60 seconds @ 1.1 Watts CW air / water spray

Gingival Contouring with the Sapphire® Plus STM 3W Laser:

Tip: Initiated

Mode: Continuous Wave

Power: 0.8 W

Anesthesia: Local, as required

Technique: Contact

1. After anesthesia is profound, insert a periodontal probe into the sulcus down to the crest of the bone.
2. Measure that depth from the crest of the gingiva to the bone. Note the reading and reduce it by 2.5 mm.
3. Make a stick mark in the facial gingiva at a point 2.5 mm above the crest of the bone. Always leave 2.5 mm or more of gingival tissue above the crest of the bone when performing a soft tissue contouring procedure, so as to not infringe upon the biological width of the tooth.
4. Angle the Fiber Optic Tip slightly toward the incisal and make a series of 2-3 mm quick strokes with the Tip as you remove tissue and establish the new line for the crestal gingiva.



Gingivectomy, Gingivoplasty and Papillectomy with the Sapphire Plus STM 3W Diode Laser:

Tip: Initiated

Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Local, as required

Technique: Contact

1. Using a periodontal probe, record the depth of the pocket to be treated and evaluate its condition, either acute or chronically inflamed.
2. If there is no apparent exudate present, use the periodontal probe to define the height of contour that is to be establish.
3. With the patient anesthetized, carefully place a stick mark along the facial aspect of the gingiva to create a reference for the incision path.
4. With the Fiber Optic Tip angled slightly toward the occlusal or incisal, remove the diseased tissue down to the previously marked incision line.
5. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
6. Taper and festoon the crestal gingiva as needed and then quickly remove the diseased epithelium and restore anatomical contour.

Note: Remember to avoid touching the root whenever possible and move quickly while near the bone or root.
7. Flush the pocket using a warm saline solution or hydrogen peroxide.
8. Record powers used and treatment times in the patient's chart.



Gingival Troughing & Tissue Retraction for Impressions with Sapphire[®] Plus STM 3W Diode Laser:

Tip: Initiated

Mode: Continuous Wave

Power: 0.8 W

Anesthesia: Topical or Local, as required

Technique: Contact

1. Following preparation of the tooth, cleanse the area (optional) with H₂O₂ and then rinse with a light spray of water.
2. Air dry with low volume flow of air.
3. Lightly contact the sulcus lining just inside the crest of the gingival angling the tip away from the tooth.
4. Using very light pressure, begin emitting as you make small paint brush like strokes tracing the area of the tooth that needs to be exposed or where the restoration margins are not completely visible.
5. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
6. Create a small trough between the tooth and gingiva. This will allow you to achieve a high quality optical image, scan or impression.
7. You may also choose to recontour abnormal gingival tissue to achieve better esthetics in a fraction of the time with greater precision for outstanding results



Sucular Debridement with the Sapphire Plus STM Diode Laser:

(Including removal of sulcular tissue and granulation tissue)

Tip: Initiated

Mode: Pulsed

Power: 0.8 W

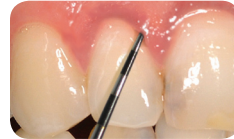
Anesthesia: Topical or Local, as required

Technique: Contact

Time: 30 seconds

Technique: Contact

1. After conventional instrumentation has been completed, insert the Fiber Optic Tip to the full pocket depth.
 2. Gently probe the pocket to get a sense of its geometry.
 3. Begin to emit Laser energy to the diseased epithelial lining.
 4. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
 5. Keep the Fiber Optic Tip parallel to the root surface or tilted slightly toward the gingival tissue during treatment in order to maximize ablation of the inflamed tissue.
 6. While keeping the Fiber Optic Tip in contact with the epithelium, move the Fiber Optic Tip in both horizontal and vertical directions, covering the epithelium and adjacent inflammatory connective tissue. Move the tip smoothly and at a moderate speed. Debride all granulation tissue.
- You may use a fine water spray during laser treatment for rinsing.
 - Remove plume and debris with the high volume evacuation.
 - The total amount of time for this procedure is a function of the extent of the diseased soft tissue. In general, treat pockets 6 millimeters or less for approximately 30 seconds and pockets greater than 6 millimeters for 45 seconds.
 - If the patient experiences noticeable discomfort, lower the power setting.



Anesthetic may be administered as required.

Labial Frenectomy with the Sapphire® Plus STM 3W Diode Laser:

(and Frenotomy procedures)

Tip: Initiated

Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Local, as required

Technique: Contact

The procedures to relieve the frenum will differ for three basic areas: 1) Mandibular frenum – labial or buccal; 2) Mandibular frenum – lingual (tongue-tied relief); 3) Maxillary frenum – labial and buccal.

Mandibular labial frenum attachments:

1. Place tension on the frenum by retracting the lip or cheek.
2. Beginning at the base of the attachment to the gingival tissue, make an incision with the Fiber Optic Tip that is perpendicular to the length of the frenum.
3. If necessary to achieve desired results, increase power level but always use the lowest amount of power necessary to reach the treatment objectives and avoid charring of tissue.
4. Using continued tension, extend the incision until you are nearing the periosteum.

NOTE: Do not cut into or damage the periosteum.

5. The incision may need to extend laterally when there is a wide attachment.
6. Wipe the debris from the hard and soft tissues using hydrogen peroxide or warm saline solution.

NOTE: Sutures are usually not required.

Lingual frenum:

Lingual frenum relief must be approached with caution to ensure that you do not inadvertently rupture or incise the rich vascular beds in the floor of the mouth and the inferior border of the tongue.

- Grasp the frenum with a hemostat near the attachment to the tongue and use a hemostat to protect the vascular complex as the incision is made and the frenum released.

Maxillary labial frenum:

- Grasping the lip, place tension on the frenum and begin to make a perpendicular incision at the most coronal aspect of the attachment to the gingiva.
- With continued tension, release the frenum fibers as you are moving apically.

NOTE: Do not Perforate or incise the periosteum.

Release all fibers down to the frenum attachment to the periosteum.

- A diamond shaped surgical area will indicate that you have released the attachment.
- Use warm saline rinses to clean the area.



Abcess Excision with the Sapphire Plus STM Diode Laser:

Tip: Initiated

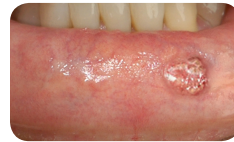
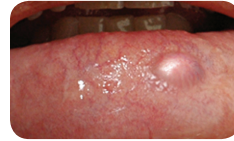
Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Topical or Local, as required

Technique: Contact

1. Determine the status of the lesion, chronic or acute, and select a site to enter the parulis of the infection.
2. Based on the lesion status, enter the lesion by placing the Fiber Optic Tip at the most coronal spot on the parulis and with short strokes, make an incision to establish a drainage path.
3. Using high volume suction, irrigate the area with saline solution as the exudate appears.
4. Insert the Fiber Optic Tip into the incision site without emitting energy and lightly probe the area inside the parulis as you advance the tip apically.
5. Once you have established the base of the parulis, back the Sapphire Plus STM 3W Laser Fiber Optic Tip out approximately 2 mm and activate the Sapphire Plus STM Diode Laser as you slowly withdraw the Fiber Tip.
6. Remove the Fiber Optic Tip briefly and allow any exudate to drain.
7. After the draining is slowed, re-enter the parulis and insert the Fiber Optic Tip just short of the base and then withdraw the tip as the laser is activated.
8. Repeat the process until you have established a clear path for completing the remaining drainage.
9. Administer oral antibiotics as needed and give the patient instructions on using warm saline to cleanse and irrigate the oral environment.
10. If you are not able to complete the drainage procedure without pain, review basic protocols before administering a local anesthetic into the infected area.



Hemostasis with the Sapphire® Plus STM Diode Laser:

Tip: Uninitiated

Mode: Continuous Wave

Power: 1.0 W

Anesthesia: Topical or as required

Technique: Non-Contact

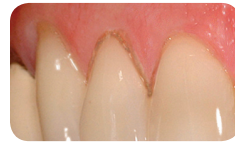
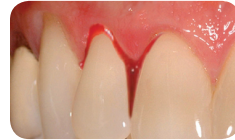
Place the Fiber Optic Tip 2 mm above the gingival sulcus, in non-contact with tissue. Direct energy into sulcus and away from the dentin and cementum.

- Activate the laser as you make a series of 2 – 3 mm strikes while circling the tooth. This should take about 30 – 40 seconds.

NOTE: Do not stop the movement of the Fiber Optic Tip until you have reached the starting point again and do not contact the tissue.

- Examine the sulcus and see if you have hemostasis or if the 'oozing' has slowed.
- Repeat in 30 second intervals if hemorrhage persists.
- If bleeding continues after the second attempt, clean any excessive hemorrhage and lase for a third time. Do not exceed 1½ minutes of lasing care.

NOTE: Continued bleeding indicates that you may have a larger arteriole that requires other hemostatic assistance in order to control.



10. SAPPHIRE PLUS STM DIODE LASER SYSTEM SPECIFICATIONS

SAPPHIRE PLUS STM 3W Diode Laser Unit:

Style:

| | |
|--------------------------|--|
| SAPPHIRE PLUS STM | Plug-In accessory for Sapphire Plus System |
| Laser Classification: | Diode laser Class 4 laser device (per IEC 60825) |
| Working Beam Wavelength: | 808 nm \pm 10 nm |
| Beam Divergence: | 9° \pm 1° |
| Power Range: | 100 mW to 3 W |
| Hertz rate (Pulsed): | fixed 4 Hz |
| Pulse Duration: | fixed 0.125 seconds |
| Duty Cycle: | Pulsed mode 50% Continuous wave 100% |
| Aiming Beam Wavelength: | 640 nm \pm 10 nm |
| Output: | 0 - 2 mW (adjustable) |
| Audible signal: | Yes |
| Visual signal: | Yes |
| Power Supply: | Derived from Sapphire Plus System |
| Auxiliary Power: | 12 VDC supplied from 110 - 120 VAC @ 60 Hz, or 220 - 240 VAC @ 50 Hz Power Adapter |

Complies With:

IEC 60601-2-22, IEC 60825-1, IEC 60601-1 and US Laser Performance Standards compliant with 21 CFR 1040.10 and 1040.11 with permissible deviations pursuant with Laser Notice 50, dated July 26, 2001.

Handpiece:

| | |
|--------------------|--|
| Length: | 6.90 in |
| Diameter: | 0.60 in |
| Tip removal: | Manual friction-fit |
| Activation method: | Electrical contact on handpiece/ Footswitch control (optional) |
| Power cable: | 72 in X 0.26 in |
| Aseptic care: | Wipe with appropriate disinfecting solution |

Tips:

| | |
|-----------|----------------------------------|
| Type: | Removable, Single-Use Disposable |
| Material: | Fused Silica, coated |
| Size: | 400 μ m X 2 inch |
| Style: | Polymer-clad Fiber |

Accessories:

Foot Switch (EN 60529, IP 38 compliant; includes contact guard)
Sanitary, disposable single-use Barrier Sleeve for handpiece

Contact DenMat® Holdings, LLC Sales for information regarding the Foot Switch and Barrier Sleeves.

11. SERVICING THE SAPPHIRE PLUS STM DIODE LASER

In the event that the laser fails to operate correctly and your sales representative is unable to help, the unit will need to be returned to Den-Mat® Holdings, LLC for repair, there are no user-repairable parts found with the device.

It is recommended that lasers be returned in their original shipping box. If not available, one can be requested at the time you discuss your return with your Den-Mat Holdings, LLC Sales Representative.

Send returns to:

Repairs
Den-Mat Holdings, LLC
2727 Skyway Drive
Santa Maria, CA 93455 USA

Tel.: 800-433-6628 or 805-922-8491

12. SYSTEM WARRANTY SAPPHIRE® PLUS STM 3W DIODE LASER

When used under normal operating conditions as described in the Sapphire® Plus STM 3W Diode Laser Owner's Manual, the Sapphire Plus STM Diode Laser system is warranted to be free of defects in materials and workmanship for one (1) year from the date of original shipment.

Within the warranty period, all parts and service charges for repairs to the Sapphire Plus STM Diode Laser system are covered by Den-Mat® Holdings, LLC.

If service is required, the system must be returned to Den-Mat Holdings, LLC for diagnosis and repair. Contact your 1Call Representative for Return Authorization prior to shipping the System to Den-Mat Holdings, LLC. The Return Authorization will include a pick-up notice (Call Tag) for a common carrier to return the unit to DenMat. Freight charges for returns within the warranty period will be paid by Den-Mat Holdings, LLC. Freight charges for returns outside of the warranty period will be paid by the customer. The outside shipping container and any accompanying documents must be clearly marked "Repair Return." Use only the original shipping container or other adequate shipping materials to protect the system in transit. Repairs may be made with new or refurbished parts, at the manufacturer's discretion.

Returned units that are outside the Warranty period will be evaluated for the cause and extent of failure or damage by Den-Mat Holdings, LLC Service Representatives. Subject to the results of this evaluation, Den-Mat Holdings, LLC will contact the customer with a price quotation for the cost of repairs.

This is a limited warranty and the liability of Den-Mat Holdings, LLC is to repair or replace the system with new or refurbished parts. Den-Mat Holdings, LLC has no liability to refund any part of the purchase price and no liability for consequential damages, loss of profits, and damages to person or injury by reasons of any defects in said system from any cause whatsoever. Any buyer who purchases said system acknowledges their familiarity with the terms, conditions, and provisions of this limited warranty and purchases said system agreeing to such terms, conditions, and provisions.

Buyer purchases the Sapphire Plus STM Laser system from Den-Mat Holdings, LLC on the terms, conditions, and provisions of this limited warranty and waives all other rights and claims against Den-Mat Holdings, LLC for any damages or remedies exceeding said limited warranty.

EXTENDED WARRANTY

Within the first thirty (30) days following the date of original shipment of the Sapphire Plus STM Diode Laser, the purchaser is eligible to receive the Sapphire Plus STM 3W Diode Laser Extended Warranty for additional cost. Contact your Den-Mat Holdings, LLC Sales Representative to learn about the System's Extended Warranty.

Den-Mat Holdings, LLC
2727 Skyway Drive
Santa Maria, CA 93455 USA
800-433-6628 · 805-922-8491
www.denmat.com

