

Pre-Initiated Tips — Instructions for Use

Introduction

BIOLASE® Pre-initiated tips are intended for use by dentists in conjunction with a BIOLASE Diode Laser for soft-tissue management procedures. Please contact your authorized representative if you have any questions or require assistance.

Tips are single-use, sterilize before use. See Section 5 for instructions.



Section 1: Safety

Precautions

Failure to comply with precautions and warnings described herein may lead to exposure to optical radiation sources. Please comply with all safety instructions and warnings.

General Laser Safety Instructions

Follow these safety instructions before and during treatments:

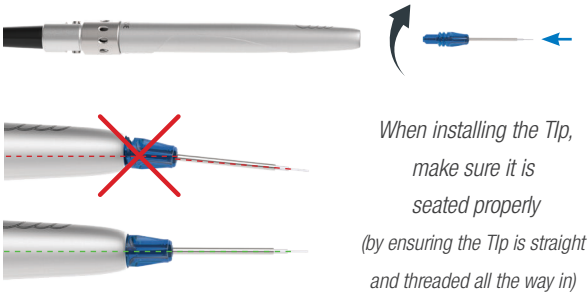
- All operatory entrances must be marked with an appropriate warning sign.
- Do not operate in the presence of explosive or flammable materials.



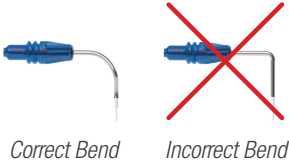
**WARNING:** All persons present in the operatory must wear protective eyewear, when laser is in operation.

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at anyone's eyes.
- Make sure the laser is on STANDBY (Control button) before turning off the unit or removing the handpiece.
- Move the circuit breaker (located on rear panel) to OFF (0) position before leaving the laser unattended.

[Figure 2.1] Tip Assembly



[Figure 2.2] Bending the Metal Cannula



[Figure 2.3] Tip Removal



Section 2: Installation

- 1) To connect the tip, first connect the Handpiece to the fiber, then insert the tip firmly into the distal end of the Handpiece as far as it will go and tighten by turning clockwise (Figure 2.1). Bend the metal cannula according to the specific procedure requirements (Figure 2.2).
- 2) Remove the fiber tip by twisting the tip counterclockwise (Figure 2.3).

Section 3: Operation

For detailed operating instructions please refer to your diode laser user manual.

Settings

- 1) Turn the laser on and select the SOFT-TISSUE procedure category
- 2) Please use the pre-set recommended settings shown on your diode laser system display.

Section 4: Warnings and Precautions



**CAUTION:** Tips are single-use only to avoid cross-contamination and are designed to withstand only a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container.

Always visually inspect the tip prior to use to make sure it is free of debris or damage.



**CAUTION:** Be aware that the metal cannula on the tips may become hot during use. Avoid contact of the cannula with any tissue.

Section 5: Maintenance

Steam Sterilization of Pre-Initiated Tips

Place the Pre-initiated tips in a single-wrap, self-seal autoclave pouch.

- Place on an autoclave tray; do not stack other instruments on top of the pouch .
- Place the tray inside the autoclave chamber and set the appropriate cycle as recommended in Figure 5.1.

Figure 5.1] Tip Sterilization Parameters

| Sterilization                    | Temperature   | Minimum Time | Drying Time     |
|----------------------------------|---------------|--------------|-----------------|
| Gravity displacement             | 121°C (250°F) | 30 minutes   | 15 - 30 minutes |
|                                  | 132°C (270°F) | 15 minutes   | 15 - 30 minutes |
| Dynamic-Air-Removal (Pre-Vacuum) | 132°C (270°F) | 4 minutes    | 20 - 30 minutes |
|                                  | 134°C (273°F) | 3 minutes    | 20 minutes      |

Section 6: Tip Guide

| Tip                                                                                 | Name  | Diameter | Length (mm) | Application | Part Number |
|-------------------------------------------------------------------------------------|-------|----------|-------------|-------------|-------------|
|  | Pi4-4 | 400µm    | 4           | Surgical    | 7400067     |
|  | Pi4-7 | 400µm    | 7           | Perio       | 7400068     |
|  | Pi4-9 | 400µm    | 9           | Perio       | 7400069     |
|  | Pi3-4 | 300µm    | 4           | Surgical    | 7400071     |
|  | Pi3-7 | 300µm    | 7           | Perio       | 7400064     |
|  | Pi3-9 | 300µm    | 9           | Perio       | 7400065     |

Section 7: Warranty

Limited Warranty

For warranty information, refer to separate equipment warranty.

Limited Liability

BIOLASE, Inc. will not be liable for incidental, consequential, indirect or special damages of any kind including, but not limited to, damages for loss of revenue, loss of business or business opportunity or other similar financial loss arising out of or in connection with the performance, use or interrupted use of the BIOLASE diode laser system(s) or any BIOLASE materials.

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