

Side Firing Tips — Instructions for Use

Introduction

Our patented Side Firing Tip (SFT) is superior to traditional laser tips used for periodontal therapy, featuring a unique design that precisely tapers to the tip. A special feature of the tip is its directional handle, which should be opposite (180°) the direction of the laser energy output. This results in better access to treat the subgingival infected implant surface within the periodontal pocket without opening a flap. In addition, it provides better access for removing plaque on the tooth root surface, especially in the furcation area, without opening a flap.

The SFT is intended for use by dentists in conjunction with a Waterlase Laser System, including Waterlase MD/MDX, Waterlase iPlus and Waterlase Express brands. The SFT is a reusable device which requires cleaning and sterilization between patients. For sterilization parameters, refer to Section 4. Refer to the User Manual for detailed cleaning 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 operator entrances must be marked with an appropriate warning sign.
- Do not operate in the presence of explosive or flammable materials.

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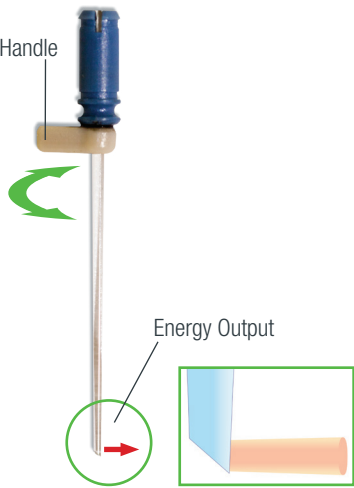
WARNING: All persons present in the operatory must wear protective eyewear, when the laser is in operation.

- 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.

Section 2: Installation

Always inspect the Tip prior to use. Please refer to the appropriate Waterlase User Manual for further instruction. DO NOT use if the tip is damaged. Install the Tip onto the Handpiece by following the directions below:

1. Remove the Tip plug from the Handpiece head.
2. The Tip and handpiece must be sterilized before initial use and between patients. If not sterilized in the Tip Holder or Tip Revolver, remove the Tip from its sterilization pouch and insert it into the Tip Holder by aligning the first groove of the Tip ferrule against the receiving edges of the Holder, then sliding the Tip in; using tweezers facilitates this process.
3. Align the Tip orifice of the Handpiece over the input end of the Tip placed in the Tip Holder/ Tip Revolver. [Figure 2.1-A]
4. Carefully lower the Handpiece and insert a clean/inspected Tip all the way until the shoulder of the Tip ferrule sits against the Handpiece head [Figure 2.1-B]
5. Slide the Handpiece laterally away from the Tip holder or Tip Revolver [Figure 2.1-C]



Section 3: Warnings and Precautions

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WARNING: Never touch the proximal (input) or distal (output) end of the Tip. If the proximal surface is contaminated, it may damage the Tip, Handpiece, and Fiber Optic Cable. Hold the Tip only by the plastic ferrule.

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WARNING: Be careful not to hit the proximal (input) end of the Tip against the Handpiece head and not to break the retaining fingers of the plastic ferrule.

Section 4: Maintenance

Steam Sterilization

Place the SFT 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	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 (EU only)	4 minutes	20 - 30 minutes

Section 5: Tip Guide

1. Use only as specified in this guide.
2. Tip may break if excessive force is applied.
3. Inspect tip before each use using tip inspector from tip inspection kit. Discard if damaged.

Specifications	SFT8-18	Kit Part Number	Description
Tip Diameter:	800µm	7230002	SFT8-18mm (1 Pack)
Tip Length:	18mm	7230003	SFT8-18mm (2 Pack)
Max Power of Operation:	2.4 W (Waterlase Express) 2.25 W (Waterlase iPlus/MDX)		
Calibration Factor	0.95		

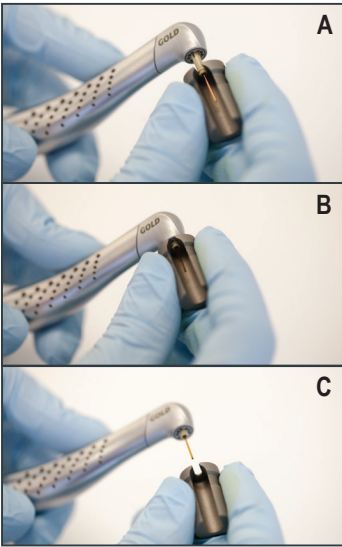
Section 6: Warranty

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 laser system(s) or any BIOLASE materials.



[Figure 2.1] Tip Installation using Tip Holder

Section 7: REPAIR™ Implant Protocol

REPAIR Implant is the first definitive step-by-step protocol for using a Waterlase laser to assist in the management of early, moderate and severe peri-implantitis. It consists of three phases: pre-surgical, surgical and post-surgical.

PHASE I: PRE-SURGICAL PHASE

All patients should have a comprehensive examination/evaluation including data collection of periodontal charting and radiographs, medical and dental history, and risk assessment.

Phase I treatment is implemented for removal of supra- and subgingival biofilm and calculus through scaling and root planing (S/RP) and the initiation and evaluation of oral hygiene compliance. Remove the crown and abutment, when possible, and a healing cap should be placed on the affected implant body. This allows for vertical laser tip access to the implant. Flap reflection may be necessary for complete access to threads in moderate to severe cases.

PHASE II: SURGICAL PHASE

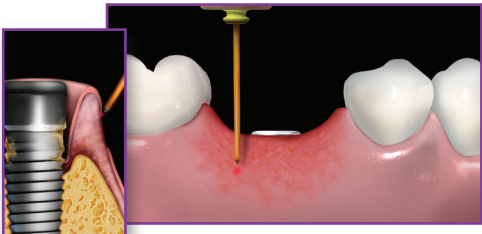
Phase II surgical treatment plan is developed based on the re-evaluation of periodontal inflammation and oral hygiene compliance. The surgical plan can be for a single implant or multiple sites.

STEP-BY-STEP SURGICAL PROCEDURE

1 OUTER DE-EPITHELIALIZATION

Outer pocket gingival epithelium is removed from the free gingival margin down to a width at least equal to the pocket depth.

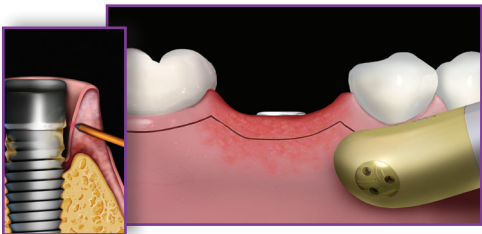
Tip	Power	Air/Water	Pulse rate	Mode
RFPT5	1.5W	40% / 50%	30 Hz	H



2 GINGIVECTOMY

A gingivectomy should only be performed if pseudo-pocketing is present. Ensure you do not compromise adequate attached gingivae.

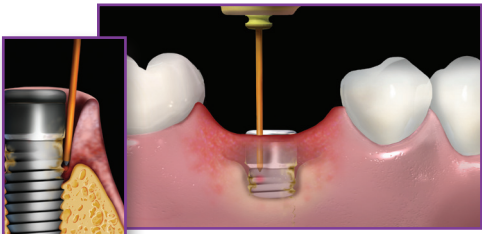
Tip	Power	Air/Water	Pulse rate	Mode
RFPT5	1.5W	40% / 50%	30 Hz	H



3 POCKET DEBRIDEMENT

The epithelium should be removed and should be completed apically, from the free gingival margin down to the osseous level. All granulation tissue is removed. Gingival margin can be retracted as a mini-flap for access.

Tip	Power	Air/Water	Pulse rate	Mode
RFPT5	1.5W	40% / 50%	50 Hz	H

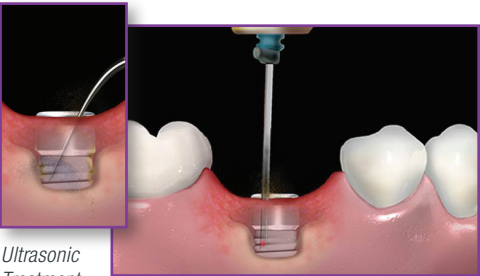


4 IMPLANT DECONTAMINATION

Conventional treatment with ultrasonics to osseous levels. (Use implant-safe tips. Please consult your implant manufacturer for recommended ultrasonic tips.) Upon completion, place a side firing tip circumferentially beginning at the coronal surface of the first thread exposed and move apically.

NOTE: When using the side firing tip, the orientation of the tip handle should be opposite (180°) the direction of the laser energy output.

Tip	Power	Air/Water	Pulse rate	Mode
SFT8	1.5W	40% / 50%	30 Hz	H



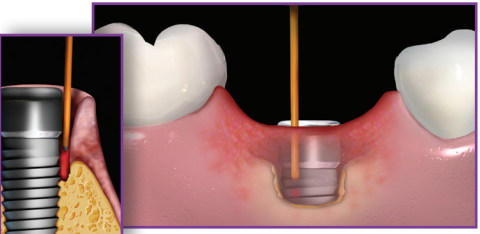
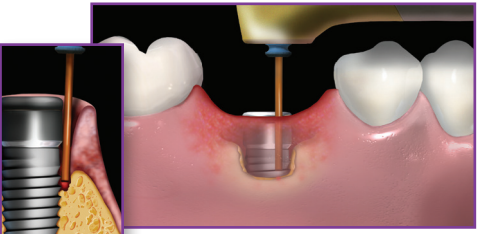
Ultrasonic Treatment

Side-Firing Tip

5 DECORTICATION

Re-contour osseous defects and stimulate bone regeneration. Hold tip parallel to implant surface and gently tap all the way down to and into bone, retracting slightly and repeating all the way around the implant. If necessary, change angle of laser tip and treat into the walls of infrabony defects.

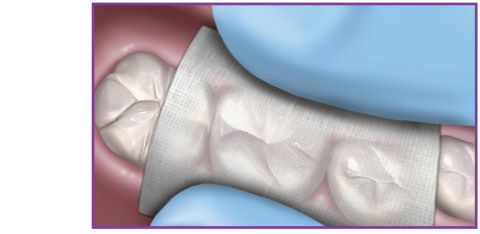
Tip	Power	Air/Water	Pulse rate	Mode
MZ6	2.5W	70% / 80%	30 Hz	H



6 FINAL DEBRIDEMENT

Remove residual debris and induce blood coagulation.

Tip	Power	Air/Water	Pulse rate	Mode
RFPT5	1.5W	10% / 10%	50 Hz	H



7 COMPRESS WITH 2X2 GAUZE

Compress surgical site with wet 2x2 gauze for 3-5 minutes.

PHASE III: POST-SURGICAL PHASE

- Immediate post-operative: Brush teeth lightly with soft brush and use mouth rinse to supplement brushing if discomfort exists.
- One week after laser treatment: Gently clean between teeth using an interproximal brush dipped in mouthwash.
- No probing for at least 3 months, at which time a supragingival scaling is completed.