

Waterlase®



Introduction

The Waterlase® Fractional Handpiece is designed to work exclusively with a Fractional-ready Waterlase iPlus All-Tissue Laser. It utilizes Waterlase advanced laser technology to atomize water and ablate skin and/or reshape soft tissue with minimal trauma and leverages the absorption properties of the Er,Cr:YSGG 2780nm laser wavelength in skin, generating 10 microbeams in a single line per laser pulse. Treatment is always performed in contact mode; the Disposable Applicator (attached to the distal end of the Fractional Handpiece) is in contact with the skin when the laser is activated.

BIOLASE

Waterlase Fractional Handpiece

Instructions for Use

Section 1: Indications for Use

This Fractional Handpiece is indicated for skin resurfacing, scar revision, including acne scarring, and treatment of wrinkles.

Section 2: Contraindications, Warnings, and Precautions

Contraindications, Warnings, and Precautions related to the use of the Waterlase iPlus laser are provided in the Waterlase iPlus User Manual.

- **Do not use the Fractional Handpiece on patients who are pregnant**
- **Do not use the Fractional Handpiece on patients undergoing treatment for skin cancer**

The laser emits both visible and invisible laser radiation which could cause eye damage if proper safety measures are not taken. Doctor, patient, assistant, and all others inside or entering the operatory must always wear appropriate laser protection eyewear for the laser wavelength (2780nm, OD 3+) whenever the laser is in use. Patient-specific goggles (Biolase p/n 2201293) are included and must be worn by the patient at all times during treatment. Prior to use, inspect eyewear for pitting and cracking; do not use if damaged.



CAUTION: Always check the eyewear specifications as etched on the glasses to ensure they offer the protection required for the laser wavelength.

- **Do not look directly into the beam or at specular reflections while the laser is operational**
- **Do not point the laser beam towards reflective surfaces, including jewelry or protective goggles**



CAUTION: Laser plume may contain viable tissue particulates; special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue when using minimal water spray. Ensure that all appropriate protective equipment, including filtration masks, is used at all times during procedures performed with this laser device.

Use caution when treating patients who have the following conditions:

- History of keloids or hypertrophic scarring
- History of herpes
- Isotretinoin (Accutaine/Raccutane) use
- History of vitiligo

Only licensed professionals who have reviewed and understood this Instruction for Use should use this device. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc. BIOLASE assumes no responsibility for parameters, techniques, methods, or results.

Section 3: Overview

Fractional Handpiece and Disposable Applicator

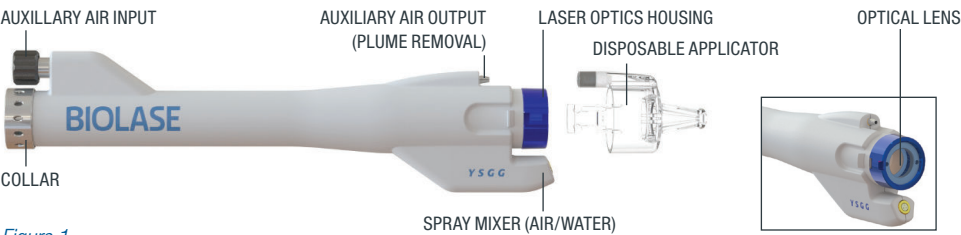


Figure 1

Specifications

Total power output:	Up to 9 W at 15 Hz	Spot spacing:	0.9 mm
Total energy/pulse:	100 - 400 mJ	Fluence per spot:	20 – 120 J/cm ²
Energy per spot:	10 - 40 mJ	Depth of one crater	Up to 0.5 mm
Spot Diameter:	200 - 300 µm	Surface coverage	5 - 8% (single pass)

The Fractional Handpiece Assembly includes:

- (1) Fractional Handpiece
- (5) Single-use disposable applicators
- (1) Auxiliary air hose assembly with fastener clips
- (1) Handpiece holder attachment
- (1) Patient safety goggles
- Instructions for Use

Auxiliary Air Hose Assembly

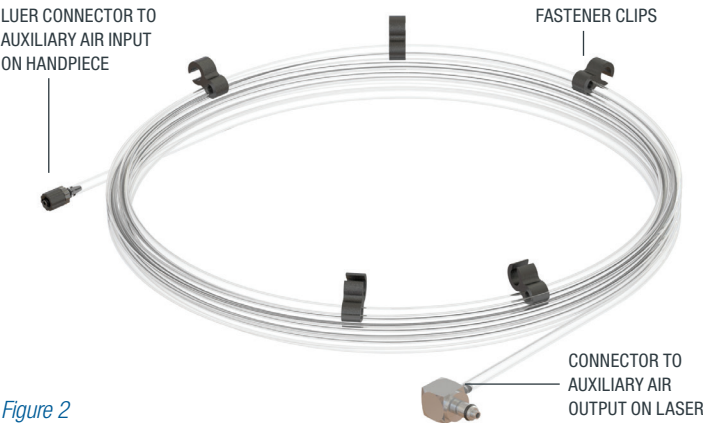


Figure 2

HANDPIECE HOLDER

The Handpiece Holder Attachment is designed to fit over the built-in Waterlase iPlus Handpiece Holder on the laser console and, once in place, will support the Fractional handpiece as well as all other Waterlase iPlus handpieces.

- A** Slide the attachment from the back toward the front onto the existing Handpiece Holder on the laser console.
- B** Clip the back under the edge of the existing holder.
- C** Lower over the existing holder and snap into place.



Figure 3

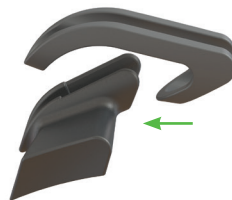


Figure 3A

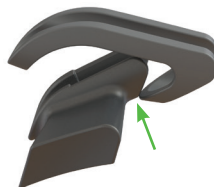


Figure 3B

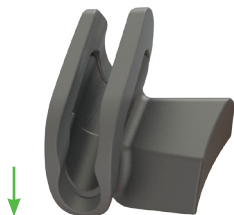
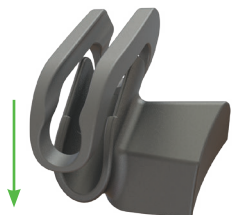


Figure 3C

Section 4: Cleaning and Disinfection



CAUTION: The Waterlase Fractional Handpiece is non-sterile when shipped from the factory. **DO NOT AUTOCLAVE.** Doing so will damage optics. However, the Handpiece must be cleaned and disinfected prior to initial use and between patients to avoid cross-contamination.

The Handpiece

To clean and disinfect the Waterlase Fractional Handpiece, wipe the entire outer surface up to the laser optics housing using a cotton gauze and appropriate disinfecting solution, such as Cavicide™, or a similar quaternary ammonium compound product (containing 20% alcohol or less), and follow the manufacturer's instructions. Avoid getting any liquid or debris on the optical lens inside the laser optics housing.



CAUTION: Always inspect the optical lens for dirt and debris between uses; if any debris is visible on the lens, clean by gently wiping with a cotton swab dampened with isopropyl alcohol. The isopropyl alcohol must be allowed to evaporate before the laser equipment is used.



CAUTION: Check the Handpiece for damage or wear prior to each use. It should be free of nicks, distortion, corrosion, or other signs of mechanical degradation. If damage or wear is observed, discard the Handpiece as required by local recycle/waste disposal regulations.

THE DISPOSABLE APPLICATOR

As with the Fractional Handpiece, the Applicator is sold non-sterile and must be wiped with an appropriate disinfecting solution, such as Cavicide, or a similar quaternary ammonium compound product (containing 20% alcohol or less), prior to assembly. **DO NOT AUTOCLAVE**, as the autoclave process may damage the Applicator and make it unusable.



CAUTION: The disposable Applicator is intended for single-use only to avoid cross-contamination between patients and to ensure the Handpiece performs as indicated; re-using the Applicator will result in a less effective treatment outcome.



DO NOT REUSE. After one-time use, detach it from the Fractional Handpiece and discard in a medical waste sharps container.



CAUTION: High temperatures produced in the normal use of the Waterlase iPlus laser system may ignite some materials (e.g., cotton wool when saturated with oxygen); flammable solutions or solvents used for cleaning and disinfecting must be allowed to evaporate before the laser equipment is used.

THE FIBER & AUXILIARY AIR HOSE

Always disinfect the Fiber Optic Cable and Auxiliary Air hose between patients by wiping them completely with an appropriate disinfecting solution such as Cavicide or a similar quaternary ammonium compound product (containing 20% alcohol or less). **DO NOT AUTOCLAVE.** Autoclaving will damage the Fiber and air hose and make them inoperable.

Section 5: Set-Up

Refer to the Waterlase iPlus User Manual for detailed instructions on system set-up, installation and operation.

CONNECTING THE FRACTIONAL HANDPIECE TO THE FIBER OPTIC CABLE

- If switching from a Gold or Turbo Handpiece to the Fractional Handpiece, always purge the Handpiece before disconnecting it from the Fiber Optic Cable.
- Make sure the system is in STANDBY mode, not in READY mode.



Figure 4

A. Gently, but firmly, pull the laser optics protective cap and rear plug from the Fractional Handpiece; be sure to save these, as they will always be required when preparing the Handpiece for cleaning and disinfection, and storage.



Figure 4A

B. Hold the Fiber Optic Cable by the connector; remove the fiber protective cover from the fiber shaft by firmly pulling it. Do not apply excessive force. Be sure to save the cover.

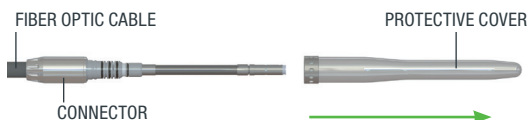


Figure 4B

C. Check the fiber shaft for any moisture and wipe with a dry, lint-free tissue if any is present.



Figure 4C

D. Carefully insert the Fractional Handpiece onto the fiber shaft until it sits firmly against the connector and clicks into place. (To disconnect the Fractional Handpiece, hold the Fiber Optic Cable by the connector and firmly pull on the Handpiece until it comes completely off the shaft. Do not apply excessive force.)

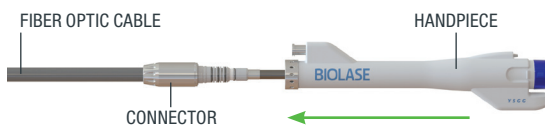


Figure 4D

INSTALLING THE AUXILIARY AIR OUTPUT LINE ON THE WATERLASE IPLUS

- A. Insert the metal connector attached to one end of the auxiliary air hose into the auxiliary air output port on the back of the iPlus laser.
- B. Unscrew the auxiliary air input protective cap from the auxiliary air input port and save; attach the end of the auxiliary air hose with the black luer connector to the auxiliary air input port.
- C. For ease of use, attach the clips threaded on the auxiliary air hose to the Fiber Optic Cable.
- D. To unplug the auxiliary air hose from the Waterlase iPlus laser, press down on the release tab at the top of the of the auxiliary air output port and gently pull on the connector to detach.



Figure 5A



Figure 5B



Figure 5C

ATTACHING THE DISPOSABLE APPLICATOR TO THE FRACTIONAL HANDPIECE

Attach the single-use disposable applicator to the Fractional Handpiece by pushing it onto the distal end of the Handpiece until it snaps into place. To remove the applicator, lift either tab and pull; the tab will break off.



Figure 5D

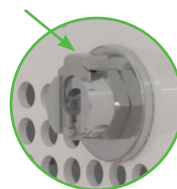


Figure 5F

NOTE: Do not use a disposable applicator if it has been dropped on a hard surface or is cracked or damaged in any way. Sharp edges may cause injury to the patient.

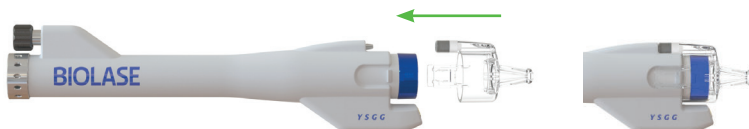


Figure 6

Section 6: Operation

Refer to the Waterlase iPlus User Manual for instructions on how to turn on and activate the Waterlase iPlus All-Tissue Laser.

Make sure the Handpiece is properly connected to the Fiber Optic Cable and the auxiliary air hose to the Waterlase iPlus.

- A. From the Home Menu, select Settings.
- B. Press the Purge/Prime icon on the Settings screen, then select Prime. Press and hold Prime until the Fiber Optic Cable and Handpiece are primed with water (water will spray from the end of the Handpiece).
- C. Once the Prime function has completed, press the back arrow and then proceed to the Advanced screen by pressing the Advanced icon (crown).

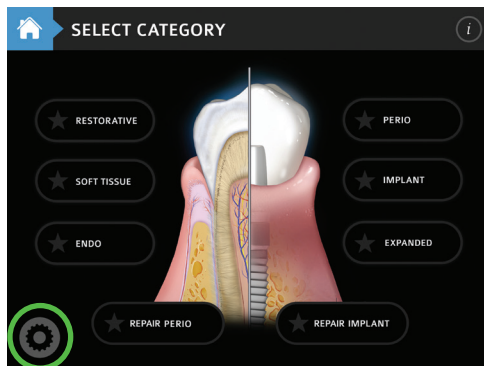


Figure 7A

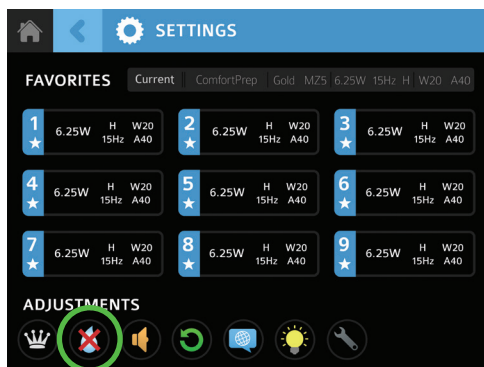


Figure 7B

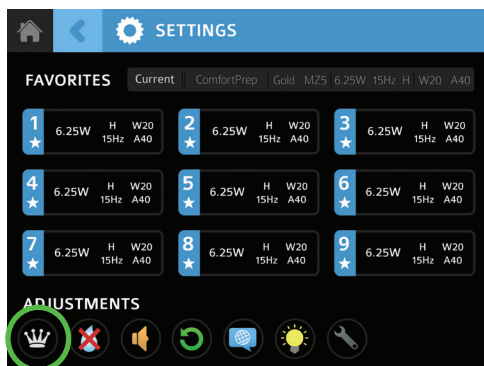


Figure 7C

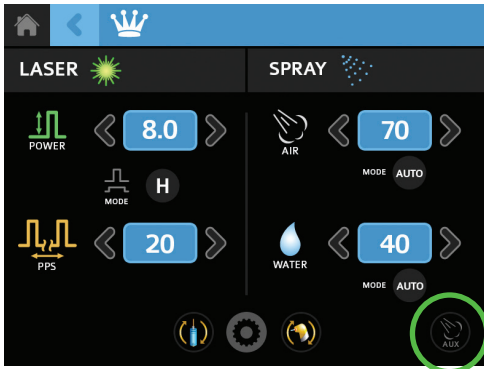


Figure 7D



Figure 7E

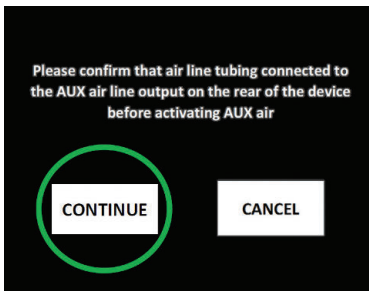


Figure 7F

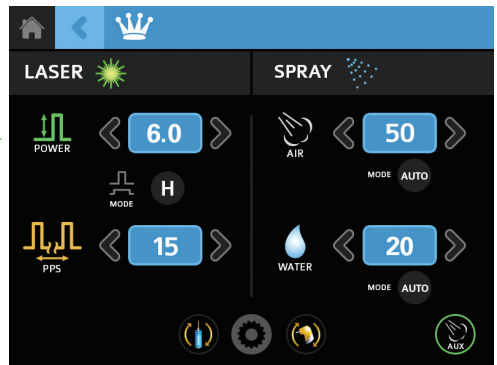


Figure 7G

- D. The Auxiliary Air icon on the bottom right of the screen turns the Fractional function on and off. When it is off, the icon will appear dark.
 - E. Press the Auxiliary Air icon to initiate the Fractional function.
 - F. A screen will appear asking the user to confirm that the Auxiliary Air Output tubing is connected to the Auxiliary Air Output connector; if connected, press “Continue;” the icon will light up. If “Cancel” is selected, the system will not initiate the Fractional function (the icon stays dark).
 - G. Default settings for Fractional will automatically appear on the screen. Place the system in READY mode to activate the Fractional air flow and begin lasing.
- To turn off the Fractional function, press the Auxiliary Air icon again; the icon will go dark.

Section 7: Clinical Applications

The Waterlase Fractional Handpiece generates 10 microbeams in a single line per laser pulse. Treatment is always in contact mode, i.e., the Applicator attached to the distal end of the Fractional Handpiece is applied directly to the skin while the laser is activated.

A uniform, one-dimensional pattern of micro-holes is generated on the tissue surface. For maximum efficacy, the Handpiece needs to be constantly moving across the skin surface at approximately 1.5cm/sec.

**CAUTION:** To avoid damaging the skin, **DO NOT** keep the Handpiece in a fixed position. Always keep the Handpiece constantly moving across the skin surface.

**NOTE:** If the Applicator has not been properly installed, the pattern of micro-holes will not be uniform or will be less than 10. Remove the Applicator and replace it with a new one.


When the Fractional function is activated, the system will default to the following settings:

Power	Frequency	Air	Water	Mode
6W	15Hz	50%	20%	H

However, some parameters may be adjusted by the user, within set boundaries:

Setting	Min.	Max.	Options	Mode
Power	2W	9W	—	H or S
Water	1%	20%	ON/OFF/AUTO	H or S
Air	1%	50%	ON/OFF/AUTO	H or S

It is also possible to switch from H mode (deep penetration in tissue) to S mode (shallow penetration in tissue), as needed, based on the patient’s skin type.

**NOTE:** Water, when combined with air, creates a spray that cools the treatment site and facilitates the effects of the laser energy applied.

Frequency **cannot** be modified, and remains fixed.

Refer to the Fitzpatrick Skin Type Scale before performing Fractional procedures to determine the best settings for use on a patient, as different skin types will react differently to the laser energy. Always monitor patient response: adjust power/water/air settings as needed for patient comfort.

Fitzpatrick Skin Type Scale	
Type I	Highly sensitive, always burns, never tans (pale white skin)
Type II	Very sun-sensitive, burns easily, tans minimally (white skin).
Type III	Sun-sensitive skin, burns moderately, tans uniformly (light brown skin)
Type IV	Minimally sun-sensitive, burns minimally, always tans well (moderate brown skin)
Type V	Sun-insensitive skin, rarely burns, tans profusely (dark brown skin)
Type VI	Sun-insensitive, never burns (deeply pigmented dark brown to black skin)

- Always use a test spot prior to the initial treatment to assess the suitability of the selected settings and effect of the Fractional procedure for the individual patient.
- Adjust power and water settings, and especially treatment duration, as needed, based on the patient's skin type; for example, lighter skin tones require lower settings and treatment time.
- Treatment normally causes minimal pain or discomfort to the patient. However, if the patient does experience pain or discomfort, stop treatment, and/or decrease the power, increase the air setting or the water setting, or both; ice or a topical anesthetic may be applied prior to treatment if necessary.

What to Expect Post-Treatment

- Short-term erythema (redness)
- Short-term edema (swelling)
- Short-term itching
- Scabbing

What to Expect Post-Treatment

If the power level used is too high, or the air and water levels or treatment duration are not optimized for the patient's skin type, the following may occur:

- Hyperpigmentation
- Hypopigmentation
- Blistering
- Erosion

Always monitor the patient for any sign of irritation or infection; if either occur, promptly treat the condition with the appropriate medications to avoid delayed healing, scarring, or the spread of infection.

Section 8: Warranty and Liability

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.

Section 9: Reordering Accessories

To reorder system accessories, contact your authorized BIOLASE representative.

Part No.	Description
6201818	Single-Use Disposable Applicator
6201819	Auxiliary Air Hose Assembly
4201667	Handpiece Holder Attachment
2201293	Patient Safety Goggles

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