

Epic Deep Tissue Handpiece

Introduction

An Epic™ diode laser is designed to provide near-infrared laser energy to a tissue surface for the purpose of temporary pain relief when applied with the Epic Deep Tissue Handpiece.

The pain therapy procedure is the process by which tissue temperature is elevated for the temporary relief of minor pain, the temporary increase in local blood circulation, and the temporary relaxation of muscle, as stated in the Indications for Use found in the appropriate BIOLASE diode laser user manual.

Affected muscles and/or joints have to be exposed to an adequate level of therapeutic energy over a short period of time to provide effective therapeutic effects. Some patients may require more than one laser application or a series of treatments before significant improvement is reported. Repeat the therapy as necessary and monitor the progress of the patient's condition throughout the treatment.



Section 1: Deep Tissue Handpiece Description

The Epic Deep Tissue Handpiece is intended for use with the Epic therapeutic diode laser system. The Epic diode laser is a prescription device intended for use by a licensed medical practitioner. The Handpiece may also be used with BIOLASE legacy diode laser brands, including ezLase and Diolase 10.

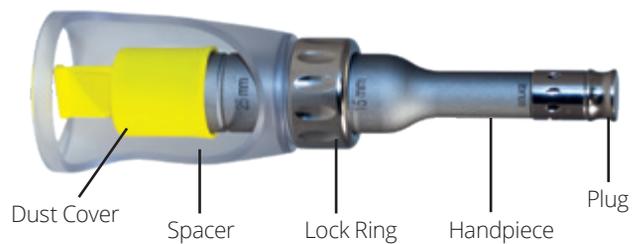


Figure 1

Section 2: Installation

- 1) Remove the plug and dust cover from Handpiece.
- 2) Slide the Handpiece over the monocoil shaft until it clicks into place. *[Figure 2.1]*
- 3) Place protective cover over the adjustable spacer. *[Figure 2.2]*
- 4) Loosen the lock ring and set the spacer at the 30 mm spot size detent location. Tighten the lock ring. *[Figure 2.3]*
- 5) Place the Handpiece into the Handpiece holder. To remove the Handpiece from the Fiber Optic Cable, press and hold the buttons on the side of the shaft and pull Handpiece away from the shaft.



Figure 2.1

Section 3: Operation

Safety and operating instructions of the Epic diode laser are provided with the User Manual. The same instructions apply to the Epic Deep Tissue Handpiece. The Epic Deep Tissue Handpiece is indicated for use at the 30 mm spot size.

- 1) Set the spot size to 30 mm:
 - Loosen the lock ring and slide spacer to the 30 mm spot size detent location. Tighten the lock ring to prevent spacer from moving during treatment.
- 2) Select appropriate laser parameters:
 - To select power and exposure time, refer to Section 6 - Clinical Settings. Adjust power as necessary to maintain patient comfort during treatment.
- 3) Perform treatment:
 - A) Set the system into Ready mode, by pressing the READY button.
 - B) Place Handpiece with protective cover in contact to the treatment area.
 - C) Use the red laser beam as reference for center of the treatment location to position the Handpiece.
 - D) Press the footpedal to activate the infrared laser. A beeping sound is produced to alert the user that the laser is firing.
 - E) Treat the area for the duration needed.
 - G) Check with the patient periodically to ensure comfort during use. Reduce power when patient is reporting discomfort.



Figure 2.2



Figure 2.3

Section 4: Recommended Use

There are four main variables that impact the safety and effectiveness of pain therapy procedures:

- 1) Power output
- 2) Distance from the skin surface
- 3) Range of movement of the Handpiece
- 4) Patient skin type

Safety and effectiveness are described by elevating the skin temperature in the treatment area utilizing the settings recommended in this manual. Use personal clinical judgment with consideration of the Fitzpatrick Skin Type Scale when selecting procedure parameters; monitor the patient and adjust the settings as necessary for effectiveness and patient comfort.

Section 5: Adverse Effects, Warnings and Precautions

Adverse Effects

Some reddening of the skin at the treatment site is normal due to increased circulation; however, in very rare cases burning or blistering of the skin may occur. Immediately stop treatment, rinse the area with cool water or place a cold pack to the affected area for at least 5 minutes, then apply a burn ointment or spray. **DO NOT USE ICE.**

Patients should be monitored for discomfort and visual skin changes. Redness has been associated with increased temperature at the site of application and increased absorption properties of the skin. If discomfort or redness of the skin occurs at any time during the treatment, you have the following options:

- Move the Handpiece relative to the affected anatomy
- Defocus the energy by moving the Handpiece further away from the skin
- Decrease the power setting
- Stop treatment

Warnings and Precautions

Eyewear

Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 940±10 nm.



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

Clinical Use

- Scar tissue has been associated with poor circulation and reduced cooling through heat transport by blood; power settings may have to be reduced to avoid overheating.
- Patients with tender or sensitive skin may be hypersensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Patients with swelling and/or inflammation may be sensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Do not treat open wounds.
- Muscle tissue closer to the skin surface may experience a higher absorption of heat; carefully monitor skin temperature and reduce power as necessary.
- Excessive fatty tissue is known to transmit heat without much attenuation; reduce power.
- Different implant materials will respond differently to laser energy and heat; be aware of any implants and their location; avoid direct exposure to laser energy or heat at the site of the implant.
- Avoid treatment of sites that have tattoos.
- Do not apply ointment, creams, lotions or heating lotion patches at, or in close proximity to, the treatment area.
- Do not apply therapies prior to treatment that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches.
- Do not apply treatment over articles of clothing.

Section 6: Clinical Settings

Follow the Fitzpatrick Skin Type Scale below and select the appropriate clinical parameter and reduce power as necessary for patient comfort:

Fitzpatrick Skin Type Scale:

TYPE I: Highly sensitive, always burns, never tans. Example: Red hair with freckles

TYPE II: Very sun sensitive, burns easily, tans minimally. Example: Fair-skinned, fair-haired Caucasians

TYPE III: Sun sensitive skin, sometimes burns, slowly tans to light brown. Example: Darker Caucasians.

TYPE IV: Minimally sun sensitive, burns minimally, always tans to moderate brown. Example: Mediterranean-type Caucasians.

TYPE V: Sun insensitive skin, rarely burns, tans well. Example: Some Hispanics, some Blacks

TYPE VI: Sun insensitive, never burns, deeply pigmented. Example: Darker Blacks

Recommended Clinical Settings: (At 30 mm spot size)

TYPE II: Set Power to 4.0W CW for 2 minutes, followed by Power at 3.25W for 3 minutes and then set Power to 2.75W CW for the remaining 5 minutes

TYPE III: Set Power to 4.5W CW for 2 minutes, reduce Power to 4.0W for the remaining 8 minutes.

TYPE IV: Set Power to 4.0W CW for 2 minutes, reduce Power to 3.5W for the remaining 8 minutes.

TYPE V: Set Power to 3.5W CW for 2 minutes, reduce Power to 3.0W for the remaining 8 minutes.

Type I and VI are less common, settings are not available at this time.

Section 7: Maintenance

Cleaning and Disinfection

- The Epic Deep Tissue Handpiece requires disinfection before and after each patient use.
- To clean and disinfect the Handpiece, wipe the entire surface of the Handpiece with cotton gauze and isopropyl alcohol or a mild chemical disinfectant.
- The Handpiece is equipped with disposable protective covers (sold separately) which are intended for one time use only and therefore cannot be cleaned and reused.



CAUTION: The Handpiece is not autoclavable.

Inspection of the Epic Fiber Optic Cable Shaft

- Visually inspect the optic window located on the Fiber Optic Cable shaft for cleanliness.
- To clean the window, use a lint-free cotton tip and isopropyl alcohol to gently remove contaminants or debris.



CAUTION: Using a BIOLASE diode laser with a dirty or damaged window will damage the Handpiece.

Section 8: Package Contents

Contents of the Epic Deep Tissue Handpiece package:

- Epic Deep Tissue Handpiece
- Epic Deep Tissue Handpiece Protective Covers (pack of 20)
- Epic Deep Tissue Handpiece Instructions for Use

Replenishment Item Numbers

- **6400310** Epic Deep Tissue Handpiece Protective Covers (pack of 20)
- **6400311** Epic Deep Tissue Handpiece

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 Epic diode laser system(s) or any BIOLASE materials.

Rx Only



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