

Cleaning and Sterilization Guide

INTRODUCTION

The cleaning and sterilization of the Waterlase Handpiece(s) and Fiber Optic Cable is a critical process in the daily maintenance of your Waterlase All Tissue Laser System. This process is intended to destroy infectious microorganisms and pathogens to ensure patient safety. It is also required for proper operation of the Waterlase, as operating the laser with dirty or damaged parts, such as Tips, Handpieces, Handpiece Mirrors, and Fiber Optic Cables can cause damage to the laser.

STEP 1—HANDPIECE AND TIP CLEANING



CAUTION: Handpieces and laser Tips are not sterile when sold and must be sterilized prior to initial use (Step 2); Handpieces, and re-usable Sapphire Tips must be cleaned and sterilized between patients. Disposable, single-use Quartz (glass) Tips, must be disposed of in a biohazard medical waste sharps container. Cleaning must be performed within a maximum of 1 hour after the procedure and prior to sterilization.

Use only the MANUAL cleaning process described below. Avoid getting water or chemicals inside of the Handpiece to prevent laser damage. If the inside of the Handpiece is wet, allow it to fully dry before use.

The cleaning process is intended to remove blood, protein and other potential contaminants, as well as to reduce the quantity of particles, microorganisms and pathogens present from the Handpiece, laser Tip surfaces and crevices. Cleaning should be performed prior to sterilization and must be conducted only by qualified personnel trained in the process who know how to handle the laser Handpiece and Tips, and wearing goggles, masks, gloves, and shields.

1. After each clinical procedure, detach the Handpiece from the Fiber Optic Cable with the Tip still attached. **Do not remove the Tip.**
2. Insert the rear plug into the Handpiece; during the cleaning procedure ensure the cleaning solution and rinse water does not enter the portals of the exhaust ring.
3. Rinse the handpiece with the Tip still installed under lukewarm water (22 – 43°C) for 10 seconds to remove gross soil. (Figure 1.1)
4. Prepare a cleaning solution per the manufacturer's instructions. Use a commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol or similar enzymatic presoak and cleaner. Follow instructions for the disposal of used solution. (Figure 1.2)
5. Soak a piece of gauze large enough to wrap the Handpiece in the cleaning solution. Squeeze out the excess liquid and wrap the Handpiece with the Tip still installed and leave wrapped for a minimum of 10 minutes. (Figure 1.3)



Fig. 1.1



Fig. 1.2



Fig. 1.3

6. Unwrap the Handpiece and Tip. Using a soft-bristled brush dipped in the cleaning solution, gently brush around the Tip ferrule, crevices, and other hard-to-clean areas for 15 seconds. The brush should be wet, but not dripping. (Figure 1.4)

15 SEC



Fig. 1.4

7. Rinse the Handpiece under lukewarm running tap water (22-43°C) for 10 seconds. (Figure 1.1)

8. Dry the Handpiece with a lint-free cloth. (Figure 1.5)



Fig. 1.5

9. Visually inspect the Handpiece for any residual soil. If any is still present, repeat steps 5 through 8 until any residual soil is removed.

10. Using the Tip Remover or Revolving Tip Holder, remove the Tip from the Handpiece:

- Slide the Handpiece laterally toward the Tip Remover or Revolving Tip Holder; (Figure 1.6)
- Place thumb against the selected Tip slot to prevent laser Tip from falling out of the Tip Holder when disconnecting it from the Handpiece;
- Carefully lift the Handpiece to disengage the Tip ferrule from the Handpiece head; (Figure.1.7)
- Use tweezers to slide the Tip out from the Tip Holder or Tip Remover; dispose of the used Tip in a medical waste sharps container.



Fig. 1.6

NOTE: Do not use the Revolving Tip Holder to remove or store SFT8 tips. The SFT8 handle may be damaged by the Revolver. The standard Tip Remover is compatible with SFT8 tips.



Fig. 1.7

11. Gently wipe the orifice of the Handpiece head with a dry lint-free cloth, making sure to remove any soil/debris that may have accumulated in the crevice between the laser tip and the Handpiece.

12. Once removed from the Handpiece, single-use Tips must be disposed of in a biohazard medical waste sharps container; if the Tip is meant to be reusable, rinse with distilled, or de-ionized water for 10 seconds and then dry with a lint-free cloth. Sterilize per the procedure outlined below.

13. Visually inspect the reusable Tip for any residual soil; if any is present, repeat step 13 until all residual soil is removed.

STEP 2—HANDPIECE AND TIP STERILIZATION PROCESS

The steam sterilization process is intended to destroy infectious microorganisms and pathogens.

NOTE: Always perform the procedure immediately after cleaning and prior to use; only use FDA-cleared or CE-marked (Europe) sterilization accessories, i.e., sterilization pouch and autoclave tray. The product packaging is NOT suitable for steam sterilization.

1. Prior to sterilization, remove the Rear and Tip plugs, if installed.

- Place the Handpiece inside a single-wrap, self-sealed pouch. (Figure 2.1)
- The Tips may be autoclaved in the Revolving Tip Holder.** Place the individual Tips or the Revolving Tip Holder loaded with Tips into a separate single-wrap self-sealed pouch. (Figure 2.2)
- Place the pouches on an autoclave tray. Take care when handling the Handpiece and Tip(s).
- DO NOT stack** other instruments on top of the pouches.
- Place the tray into the autoclave chamber and set the autoclave to the appropriate cycle, as noted below.



Fig. 2.1



Fig. 2.2

Type of Sterilizer	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 (273°F)	3 minutes	20 minutes

- Upon completion of the cycle, the Handpiece and Tips must remain in the sterilization pouches prior to use to ensure sterility.
- To reassemble, remove the Tip from the sterilization pouch with tweezers and insert it into the Tip Remover or Tip Holder (if not already in the Tip Holder). Follow the instructions outlined in Section 7 of the User Manual, Installing and Changing the Tip in the Handpiece.

STEP 3—DISINFECTING THE FIBER OPTIC CABLE

Always disinfect the Fiber Cable between patients. Use an appropriate disinfecting solution such as CaviCide or a similar quaternary ammonium compound product (containing 20% alcohol or less) and follow the manufacturer's instructions. Wipe the full length of the Fiber Cable. Remove the Handpiece or Protective Cover and wipe the Fiber Cable flexible neck and metal spindle. **DO NOT wipe the output end**, which includes optical components and the protective window. **DO NOT autoclave.** Make sure the Fiber Cable neck is dry before placing the Handpiece or Protective Cover.



Fig. 3.1

Inspect the O-rings on the distal end of the Fiber Optic Cable (Figure. 3.1) regularly for signs of wear or tear. Replace as needed (PN 6200317).



CAUTION: Check the Handpiece for damage or wear prior to each use. The Handpiece 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 Waste Electrical and Electronic Equipment (WEEE) laws. Follow local and national regulations for disposal.

Prior to disposal, the product and accessories must be appropriately reprocessed and cleaned with a disinfectant. Used or damaged Tips must be disposed of in a biohazard medical waste Sharps container.

Use of damaged or worn Tips may cause damage to the Handpiece or Fiber Optic Cable and will compromise the clinical performance of the Waterlase iPlus Laser System. The Tips must be inspected prior to each use for damage or wear. Please refer to the User Manual for Tip Inspection instructions.

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