



<p style="text-align: center;">ULTRALASE ROBOTIC FIBER HANDPIECE INSTRUCTIONS FOR USE</p>
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INDICATIONS FOR USE

The Laser Engineering Robotic Handpiece is indicated for use in conjunction with the Ultralase Fibers to enable the surgeon to perform incision, excision, ablations, vaporization, and coagulation of body soft tissue. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology otorhinolaryngology, gastroenterology, neurosurgery, urology and pulmonology.

WARNINGS

Do Not insert the fiber while the rear sealing cap is tightened.

Do Not over tighten the rear sealing cap after loading the fiber. Doing so may kink or damage the fiber.

Do Not sterilize the Robotic Fiber Handpiece while the rear sealing cap is tightened.

Ensure that the articulating instrument used to grasp the Robotic Handpiece does not interfere with visualizing the tip of the fiber and the surgical field. Fire the laser only when both fiber tip and surgical site are simultaneously in view.

When used for laparoscopic procedures, insert the Robotic Handpiece through an appropriately sized trocar (8mm ID). Ensure that the tip of the handpiece is not snagged by the trocar and neither one is damaged.

LOADING/UNLOADING THE FIBER FOR USE

Using aseptic technique, perform the following steps:

1. Loosen the rear sealing cap by turning counter clockwise.
2. Insert the fiber until its distal tip is aligned with the two reference lines on the Robotic Handpiece tip.
3. Secure the rear cap, by turning clockwise, check that the fiber is secure and does not move.
4. To Upload, perform Step 1 and remove the fiber.

GRASPING THE ROBOTIC HANDPIECE DURING USE

Grasp the Robotic Handpiece with non-energy bearing grasping instruments. The Robotic Handpiece may be used in two configurations either grasped with the tip on the top of the instrument or at a ninety degree, with the tip on the side of the instrument. In order to fit the Robotic Handpiece, the graspers used should be sized smaller than the internal dimensions of this instrument.

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CAUTIONS

The Ultralase Robotic Fiber Handpieces are supplied non-sterile and require sterilization prior to use.

CLEANING PROCEDURE

Immediately after the surgical procedure remove any debris from instrument. Wrap instrument with a towel moistened with sterile distilled water, to prevent soil from drying.

Perform an enzymatic soak with warm water (approximately 40°C) per the instructions of the enzymatic solution manufacturer.

Soak the instrument for a minimum of 15 minutes. Fill a 20cc syringe with detergent and inject it through the lumen to ensure that the instrument lumen has been filled with the detergent solution and no air bubbles are trapped inside.

Change the soak solution often if soiled. While still in the soak solution, use a soft brush or clean cloth to remove all exterior soil.

Use an appropriate size cleaning brush (e.g. 3FR) to thoroughly brush the entire length of the lumen. Run the brush through the entire lumen at least 5 times.

After the enzymatic soak, rinse instrument thoroughly with clean warm water, taking care to flush the lumen, until the water runs clear. Place the instrument in clean warm water and again scrub the instrument, including the lumen, and rinse the instrument again in clean warm running water. A syringe may also be used to flush the lumen with clean water. Repeat until all visible residue has been removed and water runs clear after scrubbing.

Dry the instrument with a clean soft cloth and use clean compressed air or 70% isopropyl to dry the lumen. Perform a visual inspection on the instrument and verify cleanliness and proper working order. Do not use a damaged instrument.

STERILIZATION

Autoclave sterilization should be performed in accordance with the instructions provided by manufacturer of the autoclave. Recommended settings for unwrapped or wrapped instruments are as follows:

CYCLE	STERILIZATION TEMP	STERILIZATION TIME	MINIMUM DRYING TIME
Pre-Vac	270°F (132°C)	5 Minutes	30 Minutes
Pre-Vac	273°F (134°C)	3 Minutes	8 Minutes

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INSTRUMENT INSPECTION AND MAINTENANCE

The instrument is subject to the action of various chemicals present in water, blood and cleaning supplies (Including the detergents used to launder clothes used in the surgical field). This may cause effects such as surface discoloration, which occurs due to interaction between metal and chlorides. Inspect the Ultralase Robotic Fiber Handpiece visually before each use, both before and after cleaning.

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