



Ultralase GYN Handpiece Set Instructions for Use

INDICATIONS FOR USE

The Laser Engineering Fiber Handpiece is indicated for use inconjunction with the Laser Engineering Ultralase Flexible Waveguide to enable the surgeon to perform incision, excision, ablation, vaporatization, and coagulation of body soft tissue including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology and pulmonology.

CAUTIONS

Handpieces are supplied non-sterile. It is recommended you sterilize the product before use.

WARNINGS

Do Not Attempt to 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 the fiber, leading to performance degradation or failure.

Do Not sterilize the handpiece while the rear sealing cap is tightened. Doing so may damage the internal silicone gripper.

LOADING THE FIBER FOR USE

Using aseptic technique, perform the following steps:

1. Loosen the rear sealing cap by turning counterclockwise.
2. Insert the fiber through the rear sealing cap until the distal tip is located between the reference lines of the handpiece.
3. Secure the rear sealing cap by turning clockwise.

UNLOADING THE FIBER AFTER USE

1. Loosen the rear sealing cap by turning counterclockwise
2. Remove the fiber

CLEANING INSTRUCTIONS

The handpiece must be cleaned immediately after use. Charred tissue, blood and debris may clog the lumen if allowed to dry, making it difficult to insert and remove the fiber. It is recommended you perform either the Manual or Autowash Procedure.

MANUAL CLEANING

1. Clean all external surfaces with a solution of enzymatic detergent and water.
Use a 1.78mm (.070"/5 French) brush to clean the lumen.
(e.g. P/N BR24070)

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2. Rinse thoroughly and dry. Use an air gun to remove liquids from the lumen.
3. Unscrew the rear sealing cap and set aside. Remove the silicone gripper using forceps. Clean the seal housing and seal. Ultrasonic cleaning with non-corrosive solutions is recommended.
4. After cleaning, reassemble the silicone gripper. Place a small amount of lubricant (e.g. Instrument Milk) onto the screw threads of the rear sealing cap.

AUTOWASH

1. Remove the rear sealing cap by unscrewing. Remove the silicone gripper using forceps.
2. Prepare enzymatic detergent per manufacturer's instructions.
3. Immerse handpieces into the prepared detergent. Ensure the detergent completely fills the lumen without trapping air.
4. Use a cleaning brush (e.g. 1.78mm (.070"/5 French) brush) to clean the lumen.
5. Leave handpiece, rear sealing cap and silicone gripper in an automatic washer such that all design features can be cleaned and drained easily.
6. Run the automatic wash cycle. (see minimum recommendations below):

PHASE	RECIRCULATION TIME	TEMPERATURE	DETERGENT TYPE
Pre-Wash	2 minutes	Cold tap water	N/A
Enzyme Wash	1 minute	Hot tap water	Enzymatic Solution
Wash 1	2 minutes	66° C	Neutral pH Detergent
Rinse 1	15 seconds	Hot tap water	N/A
Pure water rinse	10 seconds	66° C	N/A
Drying	7 minutes	115° C	N/A

7. Remove handpiece, rear sealing cap and silicone gripper from the washer.
8. Dry interior surfaces of handpiece, seal housings and seals with compressed air.
9. Check instrument for visible soil. Repeat cleaning if needed.
10. Place a small amount of lubricant (e.g. Instrument Milk) onto the screw threads of the rear sealing cap. Reassemble the silicone gripper and rear sealing cap.

INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

1. Carefully inspect device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning and sterilization procedures above.
2. Visually inspect device and threads for cracks, kinks, completeness, damage and /or excessive wear.
3. Place a small amount of lubricant onto the screw threads of the rear sealing cap.

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STERILIZATION

Autoclave sterilization should be performed in accordance with the instructions provided by the manufacturer of the autoclave. When using a sterilization tray, do not place more than 11 handpieces in a tray. Recommended settings for unwrapped or wrapped handpieces are as follows:

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