FiberLase™ GYN LAP CO_2 Handpieces

Prescriptive Information

Refer to the device user manual for complete instructions on device use.

Intended Use/Indications for Use

The FiberLase GYN LAP Handpieces are designed for use with the FiberLase CO_2 family of fibers. The fiber and handpieces are intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The FiberLase GYN LAP Handpieces are indicated for use in Gynecological procedures such as Endometriosis and Adhesiolysis.

Contraindications

See the user manual for your laser system for a list of contraindications for Gynecological procedures.

Warnings and Precautions

- Do not apply laser energy if the fiber's tip does not protrude from the handpiece tip to avoid damage to the fiber and the handpiece.
- Do not apply laser energy unless the fiber's tip can be seen protruding from the handpiece tip about 2-3mm.
- Only utilize the laser if the handpiece tip protrudes from the distal end of the suction irrigator.
- When utilizing powers above 25W, lasing for more than 60 seconds continuously may cause excessive heating of the GYN LAP-S handpiece. Be sure to allow sufficient cooling time for this handpiece between contiguous extended lasing sessions.
- Do not active fluid suction or aggressively manipulate tissue while handpiece is extended.
- Be sure to disassemble the handpieces prior to cleaning and sterilization.
- These instruments should be cleaned manually and thoroughly after each use. Automated cleaning alone may not be sufficiently effective.
- Alkaline cleaning agents and those with chlorine or chloride as the active ingredient are corrosive to metal and should not be used. End-of-life for reusable instruments is usually necessitated by normal wear resulting from repeated use.
- Always observe universal precautions when handling contaminated/bio-hazardous materials.

Adverse Events/Complications

Refer to the Laser Console User Manual for adverse events/complications specific to Gynecological procedures.

Precautions can be found in the product labeling supplied with each device.

Boston Scientific acquired the global surgical business of Lumenis Ltd.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

URO-1225206-AA JAN 2022

FiberLase™ Robotic Drop-In Guide

Prescriptive Information

Refer to the device user manual for complete instructions on device use.

Intended Use/Indications for Use

See the user manual for your laser console and delivery system for the intended use/indications for use by specialty.

Contraindications

See the user manual for your laser console and delivery system for a list of contraindications by specialty.

Warnings and Precautions

- Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, users should read and comprehend all information provided in the User Manual and Instructions for Use for the laser console and delivery system. Besides operating instructions, users should pay particular attention to the Safety and Regulatory sections.
- DO NOT use a damaged Robotic Drop-In Guide. Damaged guides may cause poor laser performance, unintentional laser exposure, injury to patient or treatment room personnel, and/or fire.
- DO NOT ATTEMPT TO CLEAN, RESTERILIZE OR REUSE THE DROP-IN GUIDE as it may damage or compromise the performance or safety of the FiberLase CO_2 Fiber. Cleaning or reuse may expose the patient to the risk of cross-contamination with infectious disease.
- The FiberLase CO_2 fiber has bend radius and power limitations that must be respected. To avoid damage to the laser fiber when using the Drop-In Guide, read and thoroughly understand the information in the Instructions for Use for the CO_2 fiber, pertaining to minimum bend radius, maximum power and external pressurized purge air use. Be especially mindful of the bends and tension where the Drop-In Guide enters and exits the portal.
- Improper use or adjustment of this system may invalidate the warranty agreement. Please contact your Lumenis representative before attempting to use this device in any manner other than those specified in this manual.

Adverse Events/Complications

Refer to the Laser Console and Delivery System User Manual/IFU for adverse events/complications that may be specific to each surgical specialty.

Precautions can be found in the product labeling supplied with each device.

Boston Scientific acquired the global surgical business of Lumenis Ltd.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

URO-1225508-AA JAN 2022