FiberLase™ CO_2 Fiber

Prescriptive Information

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

Intended Use/Indications for Use
The FiberLase CO_2 laser fiber is indicated for a variety of surgical uses including, but not limited to ablation, coagulation, incision, excision, and vaporization of soft tissue. Refer to Lumenis CO_2 Laser systems operator manuals, Indications for Use section.

Contraindications
See the user manual for your laser 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 this Instructions for Use document and in the operator's manuals provided with Lumenis CO_2 laser systems.
- Use of controls or adjustment, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of CO_2 lasers.
- All personnel in the treatment room, including patients, must wear protective eyewear when the CO_2 laser is in use. Refer to the laser system operator's manual for laser safety eyewear and laser safety information.
- DO NOT ATTEMPT TO CLEAN, RESTERILIZE OR REUSE THE FIBER as it may damage or compromise the performance or durability of the fiber. Cleaning or reuse may expose the patients to the risk of cross-contamination of infectious disease.
- A FiberLase fiber delivery device, such as FiberLase handpiece must be used for all hand-held surgical applications; otherwise the fiber can become too warm to touch.
- Never look directly into any optical lens, scanner, handpiece, probe, laser articulated arm, fiber or laser system aperture while the laser is energized. Severe eye or skin damage could occur. Turn OFF the laser before inspecting any delivery system or laser components.
- 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 this manual and in the Operator Manuals for the relevant Lumenis CO_2 laser system and fiber delivery devices.
- Surgical laser procedures should only be performed by individuals adequately trained in laser surgery and clinical use of CO_2 lasers.
- Do not use if the sterile packaging is torn or punctured.
- Do not use if labeling is incomplete or illegible.
- Do not use if the fiber is not sterile. The use of non-sterile fiber may cause cross-contamination to the patient.
- Do not use if there is evidence of damage or wear that may compromise functionality.
- The first 30 cm (12") of fiber must remain straight during laser use. Failure to do this may diminish power delivery and cause the fiber to overheat and burn, resulting in possible stray laser energy.
- Laser plume may contain viable tissue particulates and can obscure the operative field. The plume presents a possible biologic and pollution hazard and should be effectively evacuated. The use of smoke evacuators is recommended.
- Smoke evacuation of approximately 15 LPS (32 CFM), or more, is highly recommended with the use of this product. When smoke evacuation is not used, laser plume debris may damage the fiber tip, causing decreased energy transmission or unintended, adverse tissue effect.

- Always verify that the diode laser aiming beam spot is acceptable. If it is not, do not use the laser until the problem is corrected by a Lumenis-authorized service representative.
- Never operate the laser unless the red aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
- Never place hands or objects in the direct path of the laser beam. Severe burns could occur.
- Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Patient or clinicians may be burned by diffuse reflections from instruments and other surfaces. Mirrors should not be present in the laser treatment room and reflective items such as reflective jewelry should be avoided. Metal surgical instruments, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid laser reflection, so as not to deflect the beam to a non-target tissue.
- The tip of some accessories or backstops used may become hot during lasing and may cause tissue damage to either the clinicians or patient on contact. After lasing has stopped, allow the tip to cool before touching it.
- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions, and similar substances. An explosion and/or fire could occur.
- The CO_2 laser beam can ignite most non-metallic materials. Use fire-retardant drapes and gowns. Avoid the use of unnecessary flammable instruments and other flammable items.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
- Never substitute appropriate laser safety eyewear with prescription eyewear for the appropriate laser safety eyewear. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high-power density beam, possibly causing severe eye damage.
- For periorbital treatment, always protect the patient with dulled, metal eye shields, as severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam.
- Risk of air embolism:
  - Use of pressurized air which exits the fiber tip during a procedure may increase the risk of air embolism. Use caution when moving the fiber near blood vessels and highly vascular tissues.
  - Monitor vital signs of the patient and blood oxygen level for symptoms of air embolism.
  - The pressurized air from the fiber tip may also cause subcutaneous emphysema.
- Never use oxygen as a purge gas. When used with lasers, combustible gases, such as oxygen, increase the potential fire hazard, and may cause patient injury.
- When procedures are performed in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
- Laser treatment of adipose tissue may cause cellular fat to liquefy and accumulate into lipid pools. Pooled lipids are flammable and can be ignited by laser radiation, resulting in fire and potential patient injury.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in Ready mode.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration or power application. The lowest energy, repetition rate, exposure duration or power settings that are effective for the intended application should be used until familiar with the instrument's capabilities.

Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.

- The CO_2 laser fiber is designed to be used in non-contact mode. Keep inadvertent contact between the fiber tip and tissue to a minimum. Firing the laser when the fiber is in contact with the tissue will damage the tip and may cause it to break off.
- Firing the laser when the fiber tip and/or aiming beam is not in clear view may result in damage to non-target tissue and may cause inadvertent damage to the fiber, endoscope or patient.
- The CO_2 laser is used in many different clinical procedures for incision, excision and vaporization of soft tissue. For efficient vaporization to occur, adequate laser energy must be applied. The FiberLase fiber is a unique CO_2 laser energy delivery device and has some usage requirements which must be followed.
- To ensure safe and optimum energy delivery through the fiber, follow these general guidelines.
    - To avoid damage to the optical fiber and fiber delivery device, do not use the fiber when the bend radius is less than 40 mm. If the bend radius is less than 40 mm fiber the following may occur:
        - Energy from the fiber tip may suddenly drop.
        - The fiber may break to due heat buildup at the bending spot.
    - Energy transmission decreases with increased angle and number of bends, causing heat buildup inside the fiber. Whenever possible, position the laser console so that the fiber is as straight as possible.
    - When possible, use SINGLE or REPEAT timed exposure modes (short Time OFF intervals permit time for the fiber to cool).
    - The internal purge air system is sufficient for cooling the fiber when the laser power is 20 Watts or less.
    - An external pressurized air source must be used to cool the fiber when the laser power is greater than 20 Watts. The external air supply must be set to deliver air pressure of 60 PSI/4.14 Bar. Refer to the Operator Manual for your laser system for a complete discussion of the air management system.
    - 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 User Manual 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.

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FiberLase™ ENDURE™ CO_2 Fiber

Prescriptive Information

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

Intended Use/Indications for Use

The FiberLase ENDURE CO_2 laser fiber is intended for use in surgical procedures that could require ablation, vaporization, excision, incision, and coagulation of soft tissue. The fiber is indicated for use in open surgical procedures such as ENT surgery, laparoscopy, and endoscopic procedures.

Contraindications

See the user manual for your laser 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 this Instructions for Use document and in the operator's manuals provided with Lumenis CO_2 laser systems.
- Use of controls or adjustment, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of CO_2 lasers.
- All personnel in the treatment room, including patients, must wear protective eyewear when the CO_2 laser is in use. Refer to the laser system operator's manual for laser safety eyewear and laser safety information.
- A FiberLase fiber delivery device, such as FiberLase handpiece must be used for all hand-held surgical applications; otherwise the fiber can become too warm to touch.
- Do not use if the sterile packaging is torn or punctured.
- Do not use if labeling is incomplete or illegible.
- Do not use if the fiber is not sterile. The use of non-sterile fiber may cause cross-contamination to the patient.
- Do not use if there is evidence of damage or wear that may compromise functionality.
- The first 30 cm (12") of fiber must remain straight during laser use. Failure to do this may diminish power delivery and cause the fiber to overheat and burn, resulting in possible stray laser energy.
- Allow the purge air to flow for 60 seconds, as directed above. Residual moisture in the hollow fiber will absorb the CO_2 laser energy, may result in reduced power output and may cause the fiber to overheat and burn.
- Always verify that the diode laser aiming beam spot is acceptable. If it is not, do not use the laser until the problem is corrected by a Lumenis-authorized service representative.
- Never operate the laser unless the red aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
- Never place hands or objects in the direct path of the laser beam. Severe burns could occur.
- Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Patient or clinicians may be burned by diffuse reflections from instruments and other surfaces. Mirrors should not be present in the laser treatment room and reflective items such as reflective jewelry should be avoided. Metal surgical instruments, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid laser reflection, so as not to deflect the beam to a non-target tissue.
- The tip of some accessories or backstops used may become hot during lasing and may cause tissue damage to either the clinicians or patient on contact. After lasing has stopped, allow the tip to cool before touching it.

- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions, and similar substances. An explosion and/or fire could occur.
- The CO_2 laser beam can ignite most non-metallic materials. Use fire-retardant drapes and gowns. Avoid the use of unnecessary flammable instruments and other flammable items.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
- Never substitute appropriate laser safety eyewear with prescription eyewear for the appropriate laser safety eyewear. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high-power density beam, possibly causing severe eye damage.
- For periorbital treatment, always protect the patient with dulled, metal eye shields, as severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam.
- Risk of air embolism:
  - Use of pressurized air which exits the fiber tip during a procedure may increase the risk of air embolism. Use caution when moving the fiber near blood vessels and highly vascular tissues.
  - Monitor vital signs of the patient and blood oxygen level for symptoms of air embolism.
  - The pressurized air from the fiber tip may also cause subcutaneous emphysema.
- Never use oxygen as a purge gas. When used with lasers, combustible gases, such as oxygen, increase the potential fire hazard, and may cause patient injury.
- When procedures are performed in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
- Laser treatment of adipose tissue may cause cellular fat to liquefy and accumulate into lipid pools. Pooled lipids are flammable and can be ignited by laser radiation, resulting in fire and potential patient injury.
- The optical coating on the internal lumen provides the vital function of CO_2 laser beam transmission. Damage to the coating will reduce energy transmission, thereby causing greater buildup of heat inside the fiber and reduced energy to the tissue site.
- To prevent damage to the internal optical coating, do not submerse or flush the fiber with any solution.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in Ready mode.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration or power application. The lowest energy, repetition rate, exposure duration or power settings that are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- The CO_2 laser fiber is designed to be used in non-contact mode. Keep inadvertent contact between the fiber tip and tissue to a minimum. Firing the laser when the fiber is in contact with the tissue will damage the tip and may cause it to break off.
- Firing the laser when the fiber tip and/or aiming beam is not in clear view may result in damage to non-target tissue and may cause inadvertent damage to the fiber, endoscope or patient.
- To ensure safe and optimum energy delivery through the fiber, follow these general guidelines.

- To avoid damage to the optical fiber and fiber delivery device, do not use the fiber when the bend radius is less than 40 mm. If the bend radius is less than 40 mm fiber the following may occur.
    - Energy from the fiber tip may suddenly drop.
    - The fiber may break.
    - The fiber life may be shortened due to poor performance in subsequent procedures.
- Energy transmission decreases with increased angle and number of bends, causing heat buildup inside the fiber. Whenever possible, position the laser console so that the fiber is as straight as possible.
- When possible, use SINGLE or REPEAT timed exposure modes (short Time OFF intervals permit time for the fiber to cool).
- The internal purge air system is sufficient for cooling the fiber when the laser power is 20Watts or less.
- An external pressurized air source must be used to cool the fiber when the laser power is greater than 20Watts. The external air supply must be set to deliver air pressure of 60PSI/4.14 Bar. See the Operator Manual for your laser system for full details about the air management system.
- Risk of Stray Laser Radiation:
    - Improper use of the fiber or use of a damaged fiber may result in severe eye or tissue damage; fire in the treatment room; or accidental laser exposure to the treatment room personnel or patient.
    - Refer to the laser system Operator Manual for detailed safety information.
- Risk of Air Embolism:
    - Use of pressurized air which exits the fiber tip during a procedure may increase the risk of air embolism.
    - Use caution when lasing near blood vessels and highly vascular tissues. Monitor vital signs of the patient and blood oxygen level for symptoms of air embolism.
    - The pressurized air from the fiber tip may also cause subcutaneous emphysema.
- Follow Universal Precautions and wear appropriate Personal Protective Equipment (PPE) when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, goggles, and shoe covers.
- Cleaning solutions should be freshly prepared. The quality of water used for diluting cleaning agents and for rinsing medical devices should be warm (<42°C) and purified/deionized or sterile. The use of hard water should be avoided.
- Personnel should follow institutional protocols to prevent instruments from causing cross-contamination. Universal precautions should be observed by all hospital personnel when working with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- The FiberLase ENDURE CO_2 laser fiber is a unique optical device. These cleaning and sterilization instructions take into consideration the physical properties of the FiberLase ENDURE fiber. The instructions have been validated by Lumenis and should be followed exactly as specified. They must be carried out exactly as stated in this document.
- The healthcare facility should decide how to integrate the procedures into the normal workflow of instrument cleaning, disinfection, sterilization, inspection, care and maintenance.
- For questions, please contact your local Lumenis representative.
- Do not attempt to clean, resterilize or reuse the fiber after five procedures, as it may damage or compromise the performance or safety of the fiber.
- To avoid the use of a contaminated fiber and risk of infection, follow these instructions for cleaning and sterilization.
- Do not use Alkaline detergents (pH >8). Use of alkaline detergents may adversely affect the performance of the device.
- Remove the protective cap prior to sterilization to allow steam to enter the hollow fiber. If not, the fiber will not sterilize properly, possibly harming the next patient.

- Discard the biohazardous fiber according to your institutional protocols immediately after use on any patient with confirmed or suspected Creutzfeldt-Jacob Disease (CJD) or Transmissible Spongiform Encephalopathy (TSE) agents (prions), even if the fiber has remaining uses. There is currently no effective sterilization method for components that are contaminated with the infectious agents that cause CJD or TSE.

Adverse Events/Complications
Refer to the Laser Console User Manual 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.

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FiberLase™ STC CO_2 Fiber

Prescriptive Information

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

Intended Use/Indications for Use

The FiberLase STC CO_2 Fiber is designed for use with the CO_2 Laser systems up to 30W output power, with standard ST Fiber connection ports. The fiber is intended for use in surgical procedures requiring ablation, vaporization, excision, incision, and coagulation of soft tissue. The fiber is indicated for use in open surgical procedures such as ENT surgery, laparoscopy and endoscopic procedures.

Contraindications

Refer to the laser system operator's manual for contra-indications specific to each surgical specialty.

Warnings and Precautions

- DO NOT ATTEMPT TO CLEAN, RESTERILIZE OR REUSE THE FIBER as it may damage or compromise the performance or safety of the fiber. Cleaning or reuse may expose the patient to the risk of cross-contamination of infectious disease.
- Do not use if the sterile packaging is torn or punctured.
- Do not use the FiberLase STC CO_2 Fiber without the use of a handpiece or endoscope. Holding onto the fiber directly may result in damage to the fiber or burns to the fingers.
- The FiberLase STC CO_2 fiber is designed to be used in non-contact mode. Keep inadvertent contact between the fiber's tip and tissue to a minimum.
- Acute fiber energy loss or breakage will occur if the fiber is bent into a coil tighter than 4 cm in diameter.
- The FiberLase STC CO_2 fiber is a single use device and cannot be cleaned internally to allow reprocessing/sterilization and repeat use. This repair process is designed only for use during a procedure, in order to maintain adequate energy transmission through the fiber.
- 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 damage resulting from repeated use.
- To avoid damage to the optical fiber and delivery device, an external pressurized purge gas supply must be connected for fiber bending radii smaller than 45 mm, at a pressure setting of 60 PSI / 4.14 Bar.
- Improper use of the fiber or use of a damaged fiber may result in severe eye or tissue damage; fire in the treatment room; or accidental laser exposure to the treatment room personnel or patient. Refer to the laser system operator's manual for detailed safety information.
- Laser Safety
    - Refer to the laser system operator's manual for laser safety information and information on requirements for laser safety eyewear.
    - Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of CO_2 lasers.
    - Avoid using reflective materials near the fiber tip to reduce risk of reflected laser energy.
    - Do not activate the laser if the treatment site and fiber tip are not clearly visible.
    - To avoid fire hazard, anesthesia oxygen concentration should be kept at or below 25% during laser treatment.
    - A special laser resistant endotracheal tube should be used during procedures in the airway to prevent combustion.
    - A fire extinguisher must be available in the operating room when the laser is being utilized.

- Use of Pressurized Gas
  - Use of pressurized gas may increase the risk of gas embolism. Use caution when treating around blood vessels and highly vascular tissues.
  - Monitor vital signs of the patient and blood oxygen level for symptoms of gas embolism.
  - Use of pressurized gas which exits the fiber tip during a procedure may cause subcutaneous emphysema.
- General Precautions Associated with the CO_2 Fiber
  - The fiber is designed to be used in a non-contact mode. Keep inadvertent contact with the tissue and fiber tip to a minimum.
  - Always use the appropriate laser power for a given procedure. Minimize the amount of bending of the fiber assembly to avoid damage to the fiber or handpiece. The tip should always be in line of sight when operating the laser.
  - CO_2 lasers can provide effective hemostasis for vessels up to 0.5 mm in diameter.
  - The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.
  - Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.
  - Laser-ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.
  - The following complications are serious and could result in death:
    - Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrit tests are recommended to identify this potential complication.
    - Sepsis can result from performing any surgical procedure.
    - Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.
    - Patient could experience gas embolism if pressurized gas is used around open blood vessels.

Adverse Events/Complications
- The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment.
- Laser-ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.
- The following complications are serious and could result in death:
  - Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrit tests are recommended to identify this potential complication.
  - Sepsis can result from performing any surgical procedure.
  - Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.
  - Patient could experience gas embolism if pressurized gas is used around open blood vessels.

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.

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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.

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OtoLase™ Flexible CO_2 Fiber Delivery System

Prescriptive Information

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

Intended Use/Indications for Use

The OtoLase Flexible CO_2 Fiber Delivery System is indicated for a variety of surgical uses including ablation, coagulation, incision, excision, and vaporization of soft tissue. Example procedures include stapedotomy or stapedectomy, trans-canal or retro-auricular approaches. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance.

Refer to the Clinical Section in the Operator's Manual for your CO_2 laser for a complete list of indications and contraindications.

Contraindications

See the user manual for your laser 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 this Instructions for Use document and in the operator's manuals provided with CO_2 laser systems.
- Use of controls or adjustment, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of CO_2 lasers.
- All personnel in the treatment room, including patients, must wear protective eyewear when the CO_2 laser is in use. Refer to the laser system operator's manual for laser safety eyewear and laser safety information.
- The OtoLase Handpieces and Tips are intended for use only in conjunction with the OtoLase Fiber, and should be used only with CW mode of operation and up to 10W.
- Do not sterilize the OtoLase Fiber in a steam or gas sterilizer, submerge it or pass any liquids through it; otherwise the fiber performance and/or safety may be compromised.
- The OtoLase fiber is supplied non-sterile. The fiber must be cleaned and, when required, disinfected prior to use. Do not sterilize the OtoLase fiber in a steam or gas sterilizer, submerge it or pass any liquids through it; this may damage or compromise the performance or safety of the fiber.
- The Drapes and OtoLase Tips are supplied ETO-sterilized and are intended for single use only. Do not attempt to clean, resterilize or reuse the Tips or drapes. Such an attempt may damage or compromise the performance or safety of the accessory.
- Cleaning or reuse of single-use components may expose the patient to the risk of cross-contamination of infectious disease. Do not use the Drapes and the OtoLase Tips if the pouch is punctured, torn or if the expiration date has passed.
- The OtoLase Handpieces are supplied non-sterile and must be cleaned and sterilized prior first use.
- The first 30 cm (12") of fiber must remain straight during laser use. Failure to do this may diminish power delivery and cause the fiber to overheat and burn, resulting in possible stray laser energy.
- When the OtoLase Tip is properly installed in the Handpiece, the end of the connector is in direct contact with the non-sterile OtoLase Fiber. Therefore, in order to prevent inadvertent contamination to the sterile field, employ the following measures.
    - Give a gentle tug after installing the Tip to the Handpiece, to ensure it is firmly seated. It is it loose and cannot be tightened, do not use the Tip.
    - If the Tip needs to be exchanged, do not place the used Tip back in the sterile field.

    - Follow all procedural protocols for handing off a contaminated device when handling the detached Tip.
- Do not rotate the fiber inside the Handpiece, as this may damage the fiber.
- Do not bend the OtoLase Tips or the shafts on the OtoLase Handpieces. Bending may reduce transmission of laser energy to the surgical site causing the device to overheat.
- Do not use the OtoLase Tips to manipulate tissue. Manipulating tissue with the OtoLase Tip can damage patient tissue, or alternatively clog the Tip, causing it to overheat.
- The OtoLase delivery system is designed to be used in a non-contact mode. Avoid inadvertent contact between the OtoLase Tip and tissue. Firing the laser when the OtoLase Tip is in contact with the tissue will damage it.
- Firing the laser when the OtoLase Tip is not in clear view may result in damage to non-target tissue and may cause inadvertent damage to the OtoLase Tip or patient.
- Be sure to protect non-target tissue from the possibility of stray energy. Fluid or absorbent material can be used.
- Do not fire the laser at reflective instruments. This may cause reflection that may harm the staff or the patient.
- When unsure of the laser power level to be used, always start low, and increase the power level according to your needs.
- The CO_2 laser is used in many different clinical procedures for vaporization of soft tissue. In order for efficient vaporization to occur, adequate laser energy must be applied. The OtoLase Fiber is a unique CO_2 laser energy delivery device and has some usage requirements which must be respected. To ensure safe and optimum energy delivery through the fiber, follow these general guidelines
    - To avoid damage to the OtoLase Fiber and Fiber delivery device, do not use the OtoLase Fiber when the bend radius is less than 40 mm. If the bend radius is less than 40 mm the following may occur.
        - Energy from the OtoLase Tip may suddenly drop.
        - The OtoLase Fiber may break.
        - The OtoLase Fiber life may be shortened due to poor performance in subsequent procedures.
- Energy transmission decreases with increased angle and number of bends, causing heat buildup inside the fiber. Whenever possible, position the laser console so that the fiber is as straight as possible.
- Risk of Stray Laser Radiation
    - Improper use of the fiber or use of a damaged fiber may result in severe eye or tissue damage; fire in the treatment room; or accidental laser exposure to the treatment room personnel or patient.
    - Refer to the laser system Operator's Manual for detailed safety information.
- Risk of Air Embolism:
    - Use of pressurized air which exits the OtoLase Tip during a procedure may increase the risk of air embolism.
    - Use caution when lasing near blood vessels and highly vascular tissues. Monitor vital signs of the patient and blood oxygen level for symptoms of air embolism.
    - The pressurized air from the OtoLase Tip may also cause subcutaneous emphysema.
- Once connected to the OtoLase Handpiece, the proximal end of the Tip physically contacts the non-sterile OtoLase Fiber. Therefore, if removed from the OtoLase Handpiece, the used Tip must be discarded and NOT be placed back in the operative field. Otherwise, it could contaminate the surgical field.
- Do not use the device if it is not properly cleaned and sterilized as it may expose the patient to cross-contamination.

Adverse Events/Complications

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

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

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MicroLase™ Fiber

Prescriptive Information

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

Intended Use/Indications for Use

The Micro-H and Micro-G handpieces and MicroLase fiber are intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue in the middle and external ear in either trans-canal or retro-auricular approach. Clinical indications include Stapedotomy and Stapedectomy (for example). The handpieces are designed to be used in near-contact mode.

Contraindications

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

Warnings and Precautions

- Never inspect the fiber while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- General Precautions Associated with MicroLase Fiber and Handpieces
  - Always use the appropriate laser power for a given procedure. Minimize the amount of bending of the fiber assembly to avoid damage to the fiber or handpiece. Do not attempt to bend the MicroLase handpiece.
  - CO2 lasers can provide effective hemostasis for vessels up to 0.5 mm in diameter.
  - Laser-ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.
  - The following complications are serious and could result in death:
    - Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrit tests are recommended to identify this potential complication.
    - Sepsis can result from performing any surgical procedure.
    - Patient could experience air embolism if pressurized air is used around open blood vessels.
- Improper use of the fiber and handpieces, or use of a damaged fiber may result in severe eye or tissue damage; fire in the operating room; or accidental laser exposure to the operating room personnel or patient. Refer to the laser system operator's manual for detailed safety information.
- Avoid Damage to the Fiber
  - Do not pull on the fiber when it is connected to the laser.
  - Avoid clamping or clipping any devices such as a hemostat on to the fiber.
  - Avoid any contact of metallic instruments with the fiber tip.
  - Avoid direct laser beam contact with accessories.
  - Ensure laser calibration maintenance was performed according to Lumenis' recommendations. An uncalibrated system may lead to fiber damage.
  - Avoid bending the fiber above the maximum bending radius (refer to the Specifications section of the IFU), as it may lead to energy loss and damage to the endoscope.
  - Do not sterilize the MicroLase fiber in a steam or gas sterilizer; this may damage or compromise the performance or safety of the fiber.
- The fiber must be cleaned and disinfected prior to use. Follow instructions for cleaning and low-level disinfection given later in this Instruction guide.
- If the connector is not properly seated and securely attached into the fiber port, the system's performance will be degraded and possible damage to the fiber may occur.
- The MicroLase fiber should never be used without a MicroLase handpiece connected.

Adverse Events/Complications
Refer to the Laser Console User Manual for adverse events/complications that may be specific to Otology procedures.

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AcuSpot™ Micromanipulators- AcuSpot 712, AcuSpot 712-L, AcuSpot 712-Z

Prescriptive Information

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

Intended Use/Indications for Use

This delivery system is indicated for a variety of surgical uses including, but not limited to, ablation, coagulation, incision, excision, and vaporization. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator's manual, Indications for Use section.

Contraindications

See the user manual for your laser 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, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- The AcuSpot's gimbaled mirror (see Figure 4) is very fragile and has a very fine optical coating. Exercise extreme caution when handling the AcuSpot so as not to damage the mirror, its optical coating or its rotating mechanism.
- Remove the plastic window in the drape's plastic connector; otherwise the laser beam will burn a hole through the window.
- Smoke evacuation of approximately 15 lps (32 cfm), or more, is highly recommended with the use of this product. If smoke evacuation is not used, laser plume debris may accumulate on the optical components, causing lens damage, decreased energy transmission, or unintended, adverse tissue effect.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before setting the laser to Ready mode.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, exposure duration, or power settings that are effective for the intended application should be used until familiar with the instrument’s capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- Do not use the laser or delivery system if the aiming and treatment beams are not aligned or if the test burn is unacceptable; contact your local Lumenis service representative. Misalignment may result in laser exposure to non-target tissues and possible injury.
- Do not perform the beam alignment check near or in-line with the patient, operating personnel, or flammable material. Laser energy can penetrate a tongue depressor and ignite underlying flammable material, causing possible injury. It may be desirable to place energy-absorbing material behind a target area.
- Always disconnect the delivery system from the laser before inspection. Never look directly into the device while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- Failure to clean, or improperly cleaning the micro-manipulator, can cause irreversible damage to the micro-manipulator optics, adversely altering the efficiency of the delivery system.

- Irreversible damage could occur if disinfectant comes into contact with any of the micromanipulator's internal surfaces or optics. Therefore do not spray or pour cleaning agents directly on the device, and do not wipe the inside surface.
- Do not soak, steam sterilize, or autoclave the micro-manipulator. The optics will be irreversibly damaged.
- Do not use any solutions other than those specified. Doing so may permanently damage the lens and adversely alter the delivered laser power.
- Isopropyl 70% alcohol contains a large amount of water and therefore should not be used.
- Do not use dry material, such as gauze, to clean the mirror.
- Should the mirror come in contact with water, carefully wipe it dry and clean according to the above instructions.
- Select the appropriate laser safety eyewear for the specific laser in use, by verifying that the above specifications are indicated on the laser safety eyewear that is at your disposal
- Always provide eye protection for the patient. Wet thick cloths or wet gauze 4 x 4's can be used together with the patient's protective eyewear to reduce patient inconvenience. Never use them to replace protective goggles.
- For periorbital treatment, always protect the patient with dulled metal eye shields, as severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam.
- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical lens, optical fiber, handpiece, probe, laser articulated arm, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser and disconnect the delivery system before inspecting any delivery system or laser components.
- Depending on the procedure, the physician must protect the patient’s eyes with either laser safety eyewear or one of the following items moistened with a nonflammable solution: thick cloth, eye pads, or gauze 4 x 4’s.
- Use of the laser in the presence of oxygen increases potential fire hazard. When performing a laser procedure, the surgeon and anesthesiologist should carefully consider airway management. Oxygen concentrations should be as low as clinically permissible during airway laser procedures. Anesthetic gases should be least supportive of combustion.
- When choosing endotracheal tubes, consider the by-product complications of tube combustion, ensuring that it is least hazardous to the patient. Laser-resistant, cuffed, and flexible stainless steel endotracheal tubes are commercially available. Red rubber or silicone endotracheal tubes wrapped with FDA-approved, laser-resistant wrapping are also used. The endotracheal tube cuff may be inflated with saline to protect it from inadvertent penetration and the saline may be dyed with methylene blue so evidence of cuff penetration by the laser will readily appear on surrounding gauze sponges. The endotracheal tube may be further protected by strategic placement of wet sponges to absorb accidental or stray laser energy. Ensure that the sponges do not dry and increase the overall fire hazard.
- Except during actual treatment, the laser must always be in Standby mode. Maintaining the laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.

- To prevent accidental laser discharge, always turn off the laser before connecting the delivery system.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Never discharge the laser without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.
- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, certain surgical preparation solutions, and similar substances. An explosion and/or fire could occur.
- The treatment beam can ignite most nonmetallic materials. Use fire retardant drapes and gowns. The area around the treatment site can be protected with towels or gauze sponges moistened with sterile saline solution or sterile water. If allowed to dry, protective towels and sponges can increase the potential fire hazard. A UL-approved fire extinguisher and water should be readily available.
- Never open the laser console protective covers. Opening the covers will expose the user to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians shall work inside the console.
- The area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Carbon dioxide light can be reflected off of smooth metallic surfaces, even though they may be blackened
- Laser plume may contain viable tissue particulates.
- The laser plume obscures the operative field and is noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be effectively evacuated.

Adverse Events/Complications
Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

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

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AcuBlade™ D Micromanipulator- Digital AcuBlade™

Prescriptive Information

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

Intended Use/Indications for Use

This delivery system is indicated for a variety of surgical uses including, but not limited to, ablation, coagulation, incision, excision, and vaporization. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator's manual, Indications for Use section.

Contraindications

See the user manual for your laser 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, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- Never look directly into the gimbaled mirror or laser articulated arm while the laser system is energized - severe eye damage could occur. Turn off the laser and close the manual safety shutter, if applicable, before inspecting the micromanipulator lenses.
- Failure to set the microscope eyepieces to the correct refraction will result in a mismatch of visual and laser beam focus, which may cause an abnormally large spot size at the smallest setting on the micromanipulator. In addition, the treatment beam could actually become smaller as the operator uses the focusing knob to enlarge the laser beam, delivering higher energy and power densities than intended, and possibly resulting in over-treatment of tissue. The treatment beam is in optimum focus when the microscope is optimally focused. Do not rely on the size of the aiming beam for focusing purposes.
- To prevent unintentional defocusing of the treatment beam when using Digital AcuBlade, ensure that the preset defocus limiter on the micromanipulator is always set to FOCUS.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- The working distance displayed on the control screen must match the working distance settings of both the microscope and the micromanipulator. Mismatched working distance settings may result in incorrect spot sizes and unintended tissue effect.
- The ablation depth of multiple passes is deeper than that of a single pass. It is recommended that the lowest practical settings be used until thoroughly familiar with the biological interaction of the laser energy with the tissue. The surgeon must clinically assess the depth of ablation throughout the procedure.
- Serious tissue damage can occur as a result of incorrect power settings. Use the lowest acceptable settings until you understand the biological interaction between the laser power and tissue.
- The power shown on the power display indicates the power delivered at the end of the articulated arm, not necessarily the power delivered to the treatment site. See Specifications in the Maintenance chapter of this manual to determine the approximate reduction of laser power at the treatment site.
- Except during actual treatment, the system must always be in Standby mode. Keeping the system in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before setting the laser to Ready mode.

- To avoid unintended tissue effect, pay attention to changes in power settings when toggling between scan and non-scan modes while operating.
- The working distance displayed on the control screen must match the working distance settings of both the microscope and the micromanipulator. Mismatched working distance settings may result in incorrect spot sizes and unintended tissue effect.
- The ablation depth of multiple passes is deeper than that of a single pass. It is recommended that the lowest practical settings be used until thoroughly familiar with the biological interaction of the laser energy with the tissue. The surgeon must clinically assess the depth of ablation throughout the procedure.
- Serious tissue damage can occur as a result of incorrect power settings. Use the lowest acceptable settings until you understand the biological interaction between the laser power and tissue.
- The power shown on the power display indicates the power delivered at the end of the articulated arm, not necessarily the power delivered to the treatment site. See Specifications in the Maintenance chapter of this manual to determine the approximate reduction of laser power at the treatment site.
- To avoid unintended tissue effect, pay attention to changes in power settings when toggling between scan and non-scan modes while operating.
- Verify that all persons in the treatment room are wearing appropriate laser safety eyewear before setting the laser to Ready mode.
- Do not use the micromanipulator until the problem [Troubleshooting 2.1.6- Micromanipulator Slips Out of Place on the Operating Microscope] is corrected.
- Do not use the laser until the problem [Troubleshooting 2.1.8- The Burn Spot Falls Outside of the Area of the Aiming Beam] is corrected, as the laser may be misaligned. Contact your Lumenis representative.
- Do not use the micromanipulator until the problem [Troubleshooting 2.1.15- A Secondary Satellite Burn, in the Shape of a Crescent, Appears near the Treatment Burn] is corrected.
- Beam alignment checks are extremely important for the safe operation of your laser. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call your Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- Do not perform the beam alignment check near or in-line with the patient, operating personnel, or flammable material. Laser energy can penetrate a tongue depressor and ignite underlying flammable material, causing possible injury. It may be desirable to place energy-absorbing material behind a target area.
- Always disconnect the delivery system from the laser before inspection. Never look directly into the device while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- Failure to clean, or improperly cleaning the micro-manipulator, can cause irreversible damage to the micro-manipulator optics, adversely altering the efficiency of the delivery system.
- Do not touch any optical lens; finger oils may damage the delicate optical coatings.
- Irreversible damage could occur if disinfectant comes into contact with any of the micromanipulator's internal surfaces or optics. Therefore do not spray or pour cleaning agents directly on the device, and do not wipe the inside surface.
- Do not soak, steam sterilize, or autoclave the micro-manipulator. The optics will be irreversibly damaged.
- Do not use any solutions other than those specified. Doing so may permanently damage the lens and adversely alter the delivered laser power.
- Do not attempt to clean lenses that are not readily accessible.
- Do not use any solutions other than those specified. Doing so may permanently damage the mirror and adversely alter the delivered laser power.
- Do not touch the mirror top or bottom surface with your fingers. Fingerprints can permanently damage the mirror coating.
- Do not use dry material, such as gauze, to clean the mirror.
- Do not sterilize the micromanipulator, scanner or thread adapter. Sterilization may irreparably damage the optics and internal electronic circuitry.

- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical lens, optical fiber, handpiece, probe, laser articulated arm, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser and disconnect the delivery system before inspecting any delivery system or laser components.
- Spot size and laser energy are independently controlled. If the operator changes to a delivery system with a smaller spot size during a procedure, the operator must remember that the energy or power density will increase.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Incision/excision ideally should be performed with small laser spot sizes and appropriate power/energy densities. At the highest power densities, avoid prolonged exposure to limit depth of incision.
- Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam, possibly resulting in chemical burns or noxious gases. Therefore, use only stainless steel surgical instruments designed specifically for laser use.
- Carbon dioxide light can be reflected off of smooth metallic surfaces, even though they may be blackened.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
- When using carbon dioxide as a purge gas, the treatment room must be adequately ventilated. Uncontrolled carbon dioxide gas flow can cause suffocation in a confined area.
- Do not use this device in the presence of flammables or explosives, such as volatile anesthetics, alcohol, volatile surgical preparation solutions and similar substances. An explosion or fire could occur.
- The area around the target site can be protected with wet towels or gauze sponges. If allowed to dry, these protective towels and sponges can increase the potential fire hazard.
- When procedures are performed in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
- Never use oxygen as a purge gas. When used with lasers, combustible gases, such as oxygen, increase the potential fire hazard, and may cause patient injury.
- Laser treatment of adipose tissue may cause cellular fat to liquefy and accumulate into lipid pools. Pooled lipids are flammable and can be ignited by laser radiation, resulting in fire and potential patient injury.
- Laser plume may contain viable tissue particulates.
- The laser plume obscures the operative field and is noxious to those who come into contact with it. The plume presents a possible biologic and pollution hazard and should be effectively evacuated.
- Care should be taken to prevent the introduction of laser plume into the lungs during the treatment of patients with Recurrent Respiratory Papillomatosis (RRP) to prevent the spread of the papillomas virus to the lungs.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, and exposure duration and power settings that

are effective for the intended application should be used until familiar with the instrument's capabilities. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- Except during actual treatment, the system must always be in Standby mode. Maintaining the system in the Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Only the person directing the aim of the laser beam should have access to the laser footswitch. Use caution pressing the laser footswitch when it is in proximity to footswitches for other equipment. Make sure the footswitch pressed is the correct one to avoid unintended laser exposure.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. Do not use the laser or delivery system if aiming and treatment beams are not coincident; call you local Lumenis service representative. Misalignment of aiming and treatment beams may result in laser exposure to nontarget tissues and possible injury.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Backstops exposed to continuous CO_2 laser energy may become excessively hot. Do not allow a hot backstop to touch tissue or any flammable materials. Doing so may cause possible injury or fire.
- Activate the laser only when the aiming beam is directed at the targeted lesion or structure and there is a clear view of the treatment site.
- Never discharge the laser without a target to absorb it and without consideration given to what lies behind the target. Place energy-absorbing material behind the target tissue when aiming the laser at an oblique target.
- To prevent unintended laser discharge, always turn off the laser before connecting a delivery system.
- Use caution when performing the laser beam alignment check, as instructed in the delivery device operator's manual. Care should be taken to ensure that the alignment procedure is not performed in line with the patient or operating room personnel or materials.
- Metal instruments used behind the area of treatment, such as tongue depressors or laser backstops, must be anodized or ebonized matte-finished to avoid reflection.
- Never open the laser console's protective covers. Opening the covers will expose personnel to high voltage components, the laser resonator, and possible laser radiation. Only Lumenis-certified service technicians are qualified to work inside the console.
- To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.

Adverse Events/Complications
Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

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