

AcuPulse™ DUO Carbon Dioxide Laser

Prescriptive Information

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

Intended Use/Indications for Use

The intended use of the AcuPulse DUO system is for the vaporization, incision, excision, ablation, or photocoagulation of soft tissue in the surgical specialties of:

- Podiatry
- ENT
- Gynecology
- Laparoscopic Surgery including GYN Laparoscopy
- Dental and Oral Surgery
- Neurosurgery
- Orthopedics
- General Surgery

The carbon dioxide laser wavelength is indicated for use in specific surgical applications, as detailed in this chapter. Read and comprehend all of the following general contraindications, warnings, precautions, and recommendations, as well as indications and safety considerations for appropriate specialties.

The physician is also advised to consult medical publications for clinical parameters, techniques, and other current information on carbon dioxide laser treatment in a particular specialty.

Podiatry Indications:

The AcuPulse DUO laser is indicated for use in podiatry for the following applications:

- Laser ablation, vaporization and/or excision of soft tissue for the reduction, removal, and/or treatment of:
 - Verrucae vulgares/plantar (warts), including paronychia, periungual, and subungual warts
 - Fungal nail treatment
 - Porokeratoma ablation
 - Ingrown nail treatment
 - Neuromas/fibromas, including Morton's neuroma
 - Debridement of ulcers
- Other soft tissue lesions
 - Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy

ENT Indications

The AcuPulse DUO laser is indicated for laser incision, excision, ablation, and/or vaporization of soft tissue in otolaryngology for the treatment of:

- Choanal atresia
- Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue
- Nasal obstruction
- Adult and juvenile papillomatosis polyps
- Polypectomy of nose and nasal passages
- Lymphangioma removal
- Removal of vocal cord/fold nodules, polyps and cysts
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue
- Zenker's diverticulum/ pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)]

- Stenosis, including subglottic stenosis
- Tonsillectomy (including tonsillar cryptolysis and neoplasia) and tonsil ablation/tonsillotomy
- Pulmonary bronchial and tracheal lesion removal
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial)
- Benign and malignant lesions and fibromas (nose and nasal passages)
- Benign and malignant tumors and fibromas (oral)
- Acoustic neuroma in the ear
- Stapedectomy, Stapedotomy
- Superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease
- Telangiectasia/hemangioma of larynx, pharynx, and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue)
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx, and trachea
- Myringotomy/tympanostomy (tympanic membrane fenestration)
- Uvulopalatoplasty (LAUP, laser UPPP)
- Turbinectomy and turbinate reduction/ablation
- Septal spur ablation/reduction and septoplasty
- Partial glossectomy
- Tumor resection of oral, subfacial and neck tissues
- Rhinophyma
- Verruca vulgaris (warts)
- Gingivoplasty/gingivectomy

Gynecology and GYN Laparoscopy Indications

The AcuPulse DUO laser is indicated for use in gynecology for the following applications:

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
 - Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN)
 - Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowenoid papulosa (BP) lesions
 - Leukoplakia (vulvar dystrophies)
 - Incision and drainage (I&D) of Bartholin's and Nabothian cysts
 - Herpes vaporization
 - Urethral caruncle vaporization
 - Cervical dysplasia
 - Benign and malignant tumors
 - Hemangiomas
- Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:
 - Endometrial lesions, including ablation of endometriosis
 - Excision/lysis of adhesions
 - Salpingostomy
 - Oophorectomy
 - Fimbrioplasty
 - Metroplasty
 - Microsurgery (tubal)
 - Uterine myomas and fibroids
 - Ovarian fibromas and follicle cysts
 - Uterosacral ligament ablation
 - Hysterectomy

Neurosurgery Indications

The AcuPulse DUO laser is indicated for incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of the following indications:

- Cranial
 - Posterior fossa tumors
 - Peripheral neurectomy
 - Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors
 - Arteriovenous malformation
 - Pituitary gland tumors (transsphenoidal approach)
- Spinal Cord
 - Incision/excision and vaporization of benign and malignant tumors and cysts
 - Intra-and extradural lesions
 - Laminectomy/laminotomy/microdiscectomy

Orthopedic Indications

The AcuPulse DUO laser is indicated for incision, excision and vaporization of soft tissue in orthopedic surgery. Applications include the following:

- Arthroscopy
- Meniscectomy
- Chondromalacia
- Chondroplasty
- Ligament release (lateral and other)
- Excision of plica
- Partial synovectomy
- General
 - Debridement of traumatic wounds
 - Debridement of decubitus and diabetic ulcers
 - Microsurgery
 - Artificial joint revision
 - PMMA removal

General and Thoracic Surgery Indications

The AcuPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in general and thoracic surgery, including endoscopic and open procedures. Applications include the following:

- Debridement of decubitus ulcers, stasis, diabetic, and other ulcers
- Mastectomy
- Debridement of burns
- Rectal and anal hemorrhoidectomy
- Breast biopsy
- Reduction mammoplasty
- Cytoreduction for metastatic disease
- Laparotomy and laparoscopic applications
- Mediastinal and thoracic lesions and abnormalities
- Skin tag vaporization
- Atheroma
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

Dental and Oral Surgery Indications

The AcuPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in dentistry and oral surgery. Applications include the following:

- Gingivectomy/removal of hyperplasias
- Gingivoplasty
- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- Operculectomy
- Crown lengthening
- Removal of soft tissue, cysts, and tumors
- Oral cavity tumors and hemangiomas
- Abscesses
- Extraction site hemostasis
- Salivary gland pathologies
- Preprosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

Contraindications

- Unless specifically indicated, do not use the CO₂ laser on hard tissues, such as bone or teeth.
- Unless otherwise specifically indicated, do not use the CO₂ laser for cutting or ablating dense, healthy bone or bone marrow (for example, hard palate and mandible).
- Do not use the CO₂ laser on vessels greater than 0.5 mm in diameter, as hemostasis may not be effective
- Do not use the CO₂ laser where a clinical procedure is precluded by anesthesia requirements, site access, or other general operative considerations.

ENT Contraindications

- LAUP for palatal snoring is contraindicated without demonstrated obstruction by uvulopalatal tissue.
- LAUP for palatal snoring is contraindicated in pediatric patients (less than 16 years) because the upper airway is not fully developed.
- When used as the only form of treatment for palatal snoring, LAUP may not be effective in obese patients, patients with severe tonsillar hyperplasia, patients with macroglossia or patients with disproportionably short necks. Therefore the physician is advised to consult current relevant published medical information.

Gynecology and GYN Laparoscopy Contraindications

- The CO₂ laser is contraindicated for patients who are not candidates for general and thoracic surgery, where local or spinal epidural anesthesia is inappropriate.
- Use of the CO₂ laser is contraindicated for laparoscopic applications where laparoscopy is contraindicated.

General and Thoracic Surgery Contraindications

Use of the CO₂ laser is contraindicated for laparoscopic procedures where laparoscopy is contraindicated.

Neurosurgery Contraindications

Do not use the laser on tumors that are inoperable or inaccessible with the laser beam.

Dental and Oral Surgery Contraindications

Use of the CO₂ laser is contraindicated for hard tissue applications.

Warnings and Precautions

General Laser Warnings and Precautions

- Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
- No one should use the AcuPulse DUO, or any other medical laser, without specific training in both medical laser use and laser safety.
- 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.
- The AcuPulse DUO system contains a Class IV, CO₂ laser which produces an invisible beam of high energy infrared radiation. Improper use could result in serious personal injury. Observe all safety precautions for Class IV lasers.
- 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, scanner, handpiece, probe, laser articulated arm 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.
- When operating with the CO₂ fiber, always ensure that purge air is flowing through the fiber port and fiber prior to laser beam emission.
 - Scan shape & size or spot size and laser energy are independently controlled. If the user changes to a delivery system with a smaller spot size during a procedure, the user must remember that the energy or power density may increase.
- 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 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.

- To prevent unintended laser discharge, always set the system to Standby mode before connecting a delivery system.
- 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.
- 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.
- Unintended tissue damage can occur due to incorrect energy, repetition rate, exposure duration, or power application. The lowest energy, repetition rate, 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 Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Only the person directing the laser beam towards the target tissue 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.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- Backstops exposed to continuous CO₂ 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.
- Dirty optical components degrade laser energy transmission. Cleaning the device optics may eliminate this problem; however, this may also effectively increase the laser energy delivered to the treatment site, causing an unintended tissue effect and possible serious tissue damage. Therefore, it is important that after cleaning the device optics, and prior to surgical use, the surgeon test the system and device to verify the lowest effective settings for the specific procedure. The lowest effective treatment settings should be used until the biological interaction and surgical effect are verified. Settings can then be increased in appropriate increments until the optimum treatment settings are obtained.
- 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.
- Never open the laser console 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 service the system.
- To avoid electrical shock, the area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cables are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis' recommendations and institutional standards.
- Avoid using the equipment in adjacent or stacked with other equipment.
- Using accessories and cables other than those specified or provided by manufacturer may result in increased electromagnetic emission or decreased immunity.
- Portable RF communications equipment should be no closer than 30cm to any part of the equipment.
- Use the system only when it is properly grounded via the ground wire lead in the power cable supplied with the AcuPulse DUO system.

- Fire—keep a bottle of sterile saline and a fire extinguisher in the same room where a laser procedure is being performed.
- Training—do not use the AcuPulse DUO in clinical, office or surgical procedures unless you have been trained: In general laser safety, Including operator and patient protection. By a qualified mentor in hands-on situations.
 - On the AcuPulse DUO system.
- Before Performing Procedures—read this manual before performing any patient procedures. The information in this manual should be used in conjunction with, not as a substitute for, formal training.
- Power Settings—Lumenis suggests that you begin new or unfamiliar procedures at the lowest recommended power settings and gradually increase the setting until you see the desired effect
- Accessory Cleaning—To avoid losing efficiency of any non-electronic accessory, always rinse thoroughly after cleaning and dry thoroughly before use.
- Disassemble and clean the accessories over a white cloth so that small dropped parts are easier to find.
 - Clean each accessory type according to the instructions in the individual accessories' operator manuals or directions for use (DFU).
- Handpiece Sterilization—Sterilize each accessory type according to the instructions in the individual accessories' operator manuals or directions for use (DFU). If a liquid or steam sterilant is used, make sure that all parts in the laser beam path are completely dry before use.
 - After sterilization, handpieces with internal mirrors must be completely dry before use.
- Smoke Evacuation—always evacuate smoke. If the smoke evacuator on the system you are using shuts off during the procedure, use another smoke evacuator.
- Console Cleaning—when cleaning the console, use a dampened cloth. Avoid saturating the exterior panel areas and electrical input area.
- Static-Sensitive Components—electronic components in laser systems may be sensitive to damage. Use proper grounding techniques.
- Warranty Void—internal maintenance by unqualified service technicians may cause system damage. This damage is not covered under warranty.
- CO₂ Laser—the AcuPulse DUO system contains a Class IV, CO₂ laser which produces an invisible beam of high energy infrared radiation. Improper use could result in serious personal injury. Observe all safety precautions for Class IV devices.
- To Avoid Injury or Fire—observe all warning and other labels on the equipment. Failure to do so could result in injury or fire.
- Inadvertent Lasing—when not actively lasing, set the system to Standby mode.
- Backstop Lasing—avoid lasing on the backstop.
- Accessory Sterilization—sterilize accessories before each use.
- Sterility—wear sterile gloves and use aseptic technique when handling the accessories to maintain their sterility.
- Infection Control—with all accessories, always use good infection control practices, including barrier products and sterile components when appropriate.
- Risk of Embolism—During intrauterine laser surgery, do not use air for purging the laser accessory or for insufflation. This may cause a life-threatening air embolism.
 - Pressurized purge air exits accessory aperture tip during lasing. To reduce the risk of an air embolism, do not bring the aperture into contact with a blood vessel or vascular tissue.
- Laser Emission—in Ready mode laser light will be emitted through the laser aperture when the footswitch is pressed. Handling of Compressed Gas Tanks—for safe gas tank handling: Gas tank must be secured in position prior to use. Review proper procedures for handling compressed gasses before assembling yoke or CGA valve to tank. Check with your Biomedical Engineer if you are unfamiliar with this procedure.
- The articulated arm is a precision component; carefully handle and position the arm:
 - Avoid arm collision with other objects or the ceiling to reduce risk of misalignment. An improperly oriented or misaligned articulated arm can reduce the quality or intensity of the laser beam and may result in unintended tissue effect.

- When the laser is not in use, the articulated arm should be stored in its storage compartment, with the red protective cap in place. Two latches secure the arm in the compartment.
- Do not pull the end joint or the shorter arm section to release the arm from its compartment; this result in misalignment of the optical system.
- Laser energy is radiated from the laser accessory when the system is in Ready mode and the footswitch is pressed. Observe laser safety rules –wear safety glasses!
- Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repacking instructions are required.
- The AcuPulse DUO console weighs approximately 53 Kg (117 Lbs.). Use proper lifting techniques. Protect your back!
- To avoid tipping over the laser console, do not lean on the laser console.
- The laser stop button should be activated only in case of an emergency.
- To avoid damage to the CO₂ fiber and delivery device, an external pressurized purge air supply must be connected for fiber bending radii smaller than 45 mm or when at power levels operating above 20 Watts, at a pressure setting of 60 PSI / 4.14 Bar.
- The scanning accessory's software module must be paused when connecting or disconnecting a scanner accessory. Refer to Chapter 5–Utilities Menu screen.
- 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 non-target tissues and possible injury.
- Do not perform the beam alignment check in line with the patient, operating room personnel, or flammable materials. Laser energy can penetrate most non-metallic and non-laser-proof substances and ignite underlying flammable material, resulting in possible injury. If necessary, place energy-absorbing material behind the target area.
- Unauthorized servicing or modification of this system, not described in this manual, may expose the operator/patient to potential electrical energy and laser radiation hazards.
- Improper use or adjustment of this system may invalidate the service warranty agreement.
- Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repackaging instructions are needed.
- These procedures demand specific knowledge, training and use of tools not available to repair personnel outside of Lumenis. Since performing these procedures may expose the user to potential electrical and laser energy hazards, Lumenis requires that these procedures only be performed by trained service personnel.
- All personnel in the immediate area must wear eye protection rated specifically for the CO₂ laser.
- An out-of-calibration power meter will cause power delivery to tissue to be different than that displayed.
- Never use the articulated arm to move the laser. Moving the laser with the articulated arm may irreparably damage the articulated arm.
- Do not ship the system without the factory packaging materials. Doing so may result in damage to the components during shipping and void the warranty. Contact Lumenis if packaging materials or repacking instructions are required.
- When maneuvering the console be careful near stairs, bumps and high slopes. Any serious shock to the system can cause damage to the system and/or someone can be injured.
- The AcuPulse DUO console weighs 53 Kg (117 Lbs.). Use proper lifting techniques. Protect your back!
- Improper use or adjustment of this system may invalidate the service warranty agreement. Please contact your authorized Lumenis distributor before attempting to troubleshoot this system in any manner other than those specified in this manual.
- Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating room 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.

- There is a risk of infection and scarring associated with any surgical procedure. Therefore, appropriate pre-and post-surgical care should always be practiced.
- Purge gases used with CO₂ delivery devices and waveguides may increase the risk of gas embolism where large, open vessels are present. Monitor all patients for gas embolism, which may occur even without the use of the laser.

ENT Warnings and Precautions

- To prevent airway fires and severe injury to the patient, protect endotracheal tubes from exposure to the CO₂ wavelength, or use CO₂ laser-resistant endotracheal tubes.
- To prevent airway fires and severe injury to the patient, do not direct the CO₂ laser at any tracheal tube in any oxygen-enriched environment, or any other environment that supports combustion.
- To prevent airway fires and severe injury to the patient, consideration of the type of anesthesia and ventilation are important.
- To prevent severe injury to the patient, middle ear surgery should be performed with appropriate parameters, considering acoustic and thermal effects.
- Nasal and laryngeal probes (waveguides) produce a divergent beam with a minimum spot size close to the tip of the instrument.
- Avoid placing the tip of the nasal or laryngeal probe or fiber in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.
- Patients undergoing oropharyngeal or laryngeal surgery have to be closely watched in the postoperative period for severe edema which may cause life threatening airway obstruction and for uncontrolled bleeding. The length of close observation depends on the specific procedure and is up to the physician's consideration.
- The physician should take appropriate precautions when evaluating and selecting patients presenting with chronic palatal snoring and other significant symptoms of sleep apnea
- Clinical studies have shown that patency time is directly related to the diameter of the laser fenestration. The average diameter used is 2.0mm. Therefore, clinical judgment and caution should be used when exceeding this diameter.
- Uncooperative pediatric patients should be appropriately restrained during office OtoLAM myringotomy/tympanostomy procedures in order to avoid unexpected movement and risk of affecting non-target tissue. Use appropriate measures to avoid unexpected movement such as local or topical anesthesia.

Gynecology and GYN Laparoscopy and General and Thoracic Surgery Warnings and Precautions

- When using a laser laparoscope or waveguide accessory, maintain an adequate flow of purge gas through the delivery device. High purge flows require a specialized purge system or recirculating insufflator/ smoke evacuator to prevent over-pressurization and over-distention of the pneumoperitoneum and resultant complications.
- Ensure that the laser laparoscope is properly aligned and a clear, round aim beam is visible at all times.
- Laparoscopic waveguides produce a divergent beam with a minimum spot size close to the tip of the instrument.
- Avoid placing the tip of the waveguide in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.
- In patients of fertility age, whenever surgery on the uterus is planned either by laparoscopy or hysteroscopy, pregnancy has to be excluded.

Neurosurgery Warnings and Precautions

- Using the laser to open the dura causes shrinkage that may make closure difficult or impossible

Orthopedic Warnings and Precautions

- When performing arthroscopic surgery with fibers where purge air is required, control the purge air with a tourniquet to prevent pressurization of an enclosed space (for example, shoulder), which can result in gas embolism or systemic subcutaneous emphysema.
- Residual carbon by-products of tissue vaporization are believed to increase the risk of postoperative synovitis and other complications. Mechanically scrape observed char from lased tissue surfaces following use of the laser.

Dental and Oral Surgery Warnings and Precautions

- While directing the laser beam near the tooth, shield the tooth from laser energy using either nonreflecting material or an instrument inserted between the tooth and gum, being careful to prevent laser reflection.

Adverse Events/Complications

Podiatry Adverse Events/Complications:

- Infection
- Ulceration of tissue
- Laser matrixectomy complications may also include:
 - Sterile inflammatory condition

ENT Adverse Events/Complications and Expected Sequelae

- General ENT complications include:
 - Unintended thermal injury from combustion of anesthesia or other volatile surgical preparation solutions
 - Excessive bleeding
 - Infection
 - Edema
 - Hearing loss
- Zenker's Diverticulum
 - Transient soft tissue emphysema
 - Mediastinitis
- Tonsil Ablation/Tonsillotomy
 - Transient dysphagia
 - Mucosa lesions
- Cordotomy
 - Formation of granuloma
- Turbinate Reduction/Ablation
 - Transient nasal obstruction associated with postoperative edema and limited nasal crusts
- Stapes surgery complications include:
 - Total sensorineural hearing loss
 - Recurrent conductive hearing loss
 - Dizziness may occur post-operatively
 - Possible facial paralysis/palsy
 - Tinnitus (ringing in the ear)
 - Vertigo
 - Tympanic membrane perforation
 - Temporary change in taste
- LAUP
 - Excessive bleeding
 - Infection
 - Edema
 - Rhinophonia
 - Nasopharyngeal stenosis

- Velopharyngeal incompetence
- Myringotomy/Tympanostomy
 - Scarring
 - Transient otorrhea
 - Infection
 - Recurrence of otitis media

Gynecology and GYN Laparoscopy Adverse Events/Complications

Gynecology and laparoscopic surgery complications include:

- Excessive bleeding
- Infection
- Excessive thermal injury or vaporization of tissue
- Gas embolism
- Subcutaneous emphysema

Neurosurgery Adverse Events/Complications

- Gas embolism
- There are no known complications specific to the use of the CO₂ laser in neurosurgery. However, the physician is advised to consult current literature for any new information on potential neurosurgery complications relating to CO₂ laser treatment.

Orthopedic Adverse Events/Complications

Orthopedics complications include:

- Subcutaneous emphysema.
- Synovitis

General and Thoracic Surgery Adverse Events/Complications

General and thoracic surgery complications include:

- Excessive bleeding
- Infection
- Excessive thermal injury or vaporization of tissue

Dental and Oral Surgery Adverse Events/Complications

Dental and oral surgery complications include:

- Laser damage to teeth through inappropriate use.
- Infection

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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