UltraPulse™ DUO Carbon Dioxide Laser

Prescriptive Information

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

Intended Use/Indications for Use

The UltraPulse DUO CO_2 laser system is intended for use in surgical applications requiring the ablation, vaporization, excision, incision and coagulation of soft tissue in medical specialties including:

- Aesthetic (Dermatology and plastic surgery)
- Podiatry
- Otolaryngology (ENT)
- Gynecology (including laparoscopy)
- Neurosurgery
- Orthopedics (soft tissue, including arthroscopy)
- General and thoracic surgery (including open and endoscopic)
- Dental and oral surgery
- Genitourinary surgery

The UltraPulse DUO CO_2 system is indicated for use in specific surgical applications, as detailed in this chapter. Read and comprehend all of the following contraindications, warnings, precautions, and recommendations, as well as indications and safety considerations for the appropriate specialties.

<u>Aesthetic (Dermatology/Plastic Surgery) Indications:</u>

The UltraPulse DUO Laser is indicated for use in dermatology and plastic surgery for the following applications:

- Ablation, vaporization, excision, incision, and coagulation of soft tissue in the performance of:
    - laser skin resurfacing
    - laser dermabrasion
    - laser burn debridement
- Laser skin resurfacing (ablation and/or vaporization) for the treatment of:
    - wrinkles, rhytids, and furrows (including fine lines and texture irregularities)
- Laser skin resurfacing (ablation, and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:
    - Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart and verruca seborrheica
    - Vermilionectomy of the lip
    - Cutaneous horns
    - Solar/actinic elastosis
    - Cheilitis, including actinic cheilitis
    - Lentigines, including lentigomaligna or Hutchinson's malignant freckle
    - Uneven pigmentation/dyschromia
    - Acne scars
    - Surgical scars
    - Keloids including acne keloidalis nuchae
    - Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum)
    - Tattoos
    - Telangiectasia
    - Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
    - Superficial pigmented lesions
    - Adenosebaceous hypertrophy or sebaceous hyperplasia
    - Rhinophyma reduction

    - Cutaneous papilloma (skin tags)
    - Milia
    - Debridement of eczematous or infected skin
    - Basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
    - Nevi, including spider, epidermal and protruding
    - Neurofibromas
    - Laser de-epithelialization
    - Trichoepithelioma
    - Xanthelasma palpebrarum
    - Syringoma
- Laser ablation, vaporization, and/or excision for complete and partial nail matrixectomy
- Vaporization/coagulation of:
    - Benign/malignant vascular/avascular skin lesions
    - Mohs surgery
    - Lipectomy
    - Verrucae and seborrhoecae vulgares, including paronychial, periungual, and subungual warts
- Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty
- Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

<u>Podiatry Indications:</u>
The UltraPulse 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 paronychial, periungual, and subungual warts
    - Porokeratoma ablation
    - Ingrown nail treatment
    - Neuromas/fibromas, including Morton's neuroma
    - Debridement of ulcer
- Other soft tissue lesions
    - Laser ablation, vaporization, and/or excision for complete and partial (nail) matrixectomy

<u>ENT Indications</u>
The UltraPulse 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 esophagodivertuculostomy(ELAED)]
- Stenosis, including subglottic stenosis
- Tonsillectomy (including tonsillar cryptolysis and neoplasma) 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
- Superficial lesions of the ear, including chondrodermatitis nodularis chronica helicis/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
- Verrucae vulgaris (warts)
- Gingivoplasty/gingivectomy

Gynecology and GYN Laparoscopy Indications

The UltraPulse 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 UltraPulse DUO laser is indicated for incision, excision 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 UltraPulse 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 UltraPulse 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 UltraPulse 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

Genitourinary Indications
The UltraPulse DUO laser is indicated for incision, excision, and vaporization of soft tissue in genitourinary procedures. Applications include the following:
- Benign and malignant lesions of external genitalia
- Condyloma
- Phimosis
- Erythroplasia

Contraindications
- Do not use the UltraPulse DUO on hard tissues, such as bone or teeth.
- Do not use the UltraPulse DUO for cutting or ablating dense, healthy bone or bone marrow (for example, hard palate and mandible).
- Do not use the UltraPulse DUO on vessels greater than 0.5 mm in diameter, as hemostasis may not be effective and ensure the immediate availability of other surgical instruments for coagulation (i.e., electrocautery, graspers, sutures, etc.) to control hemostasis is strongly recommended.
- Do not use the UltraPulse DUO where a clinical procedure is precluded by anesthesia requirements, site access, or other general operative considerations.

Aesthetic (Dermatology/Plastic Surgery) Contraindications:
Patients should not be considered for laser skin resurfacing procedures if they:
- Have taken isotretinoin (e.g. Accutane®) within the past 12 months
- Have a history of keloid formation
- Have a history of poor wound healing
- Demonstrate excessive or unusually prolonged erythema, hyperpigmentation, or hypopigmentation upon laser test patching

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 UltraPulse DUO is contraindicated for patients who are not candidates for general surgery, where local or spinal epidural anesthesia is inappropriate.

- The UltraPulse DUO is contraindicated for laparoscopic applications where laparoscopy is contraindicated.
- The UltraPulse DUO is contraindicated for uterus laparoscopy or hysteroscopy surgery for pregnant women.

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

Dental and Oral Surgery Contraindications
The UltraPulse DUO is contraindicated for hard tissue such as bone or teeth

Warnings and Precautions
General Laser Warnings and Precautions
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments. No one should use the UltraPulse DUO, or any other medical laser, without specific training in both medical laser use and laser safety.
- Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of CO_2 lasers.
- Do not attempt to open or disassemble the system's cover. Opening the covers exposes personnel to high voltage components, the laser resonator and possibly laser radiation. Only Lumenis authorized technical personal are qualified to service the interior of the system.
- Do not modify the device without explicit approval by the manufacturer. Unauthorized modifications of the device may lead to a serious adverse event, injury or death.
- Using the device after it has been resold and before it has been inspected is a misuse of the device and may result in injuries.
- Read the manual carefully. Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- All personnel in the treatment room, including patients, must wear protective eyewear when the CO_2 laser is in use.
- 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.
- Always verify that all connections between the laser and delivery accessories are properly connected and secure. Stray energy could emit due to an improper connection. Severe eye or tissue damage could occur.
- 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.
- Place a warning sign warning personnel that the laser is in use before they enter the controlled area. To protect passers-by, keep the door closed while the laser is in operation. In addition, appropriate protective eyewear may be placed outside the room for personnel who may enter the treatment room.
- Only Lumenis certified service technicians may open the console covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation.
- Do not place fluid-filled containers on top of the laser console or allow fluid of any kind to leak into the laser console.
- Perform the necessary routine inspections and maintenance procedures on your laser, per Lumenis recommendations and institutional standards.
- Grasp the plug to remove it from the electrical outlet; do not pull the cable.

- To avoid risk of electric shock, this equipment must only be connected to the supply main switch protective earth.
- Avoid using the equipment adjacent to 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.
- Potable RF communications equipment should be no closer than 30cm to any part of the equipment.
- 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.
- Wet towels or gauze sponges can protect the area around the target site. These protective towels and sponges may cause a potential fire hazard if allowed to dry.
- 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.
- During airway laser procedures, oxygen concentrations should be as low as clinically permissible. Anesthetic gases should be least-supportive of combustion and use of laser-safe tracheal tubes is advised.
- When choosing endotracheal tubes consider the complications that may result from by-products of tube combustion. The endotracheal tube can be further protected by placement of wet sponges to absorb accidental or stray laser energy. Ensure that the sponges do not dry, as this increases potential fire hazard.
- When choosing endotracheal tubes, consider the complications that may result from by-products of tube combustion. Use endotracheal tubes that are least hazardous to the patient. Laser-resistant, cuffed, and flexible stainless steel endotracheal tubes are commercially available. Red rubber or silicone endotracheal tubes with FDA-approved, laser-resistant wrapping can also be used.
- 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.
- When using the articulated arm, always verify that the diode laser aiming beam and the CO2laser treatment beam are aligned. If the beams are not aligned, do not use the laser until the problem is corrected by a Lumenis-authorized service representative.
- When using the fiber and treatment is paused, cover the tip of the fiber with a moist sponge when you lay it down or place the fiber handpiece in its dedicated support arm to prevent injury in case of inadvertent lasing.
- 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.
- When using the fiber, never operate the laser unless the fiber tip is in good condition and it is in full view.
- 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.
- 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. Verify the footswitch pressed is the correct one in order to avoid accidental laser exposure.
- 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.

- 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.
- CO_2 laser energy can be reflected of smooth metallic surfaces. During the procedure, if a clinician makes a change to a delivery system that results in a different spot size, the clinician must remember that the energy or power density may change accordingly.
- 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 familiarity with the instrument's capabilities is achieved. Extreme caution should be employed until you understand the biological interaction between the laser energy and tissue.
- 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 and thermal spread.
- Tissue variability may result in different laser-tissue interaction. During operation, clinicians should carefully observe the procedural results, and amend laser settings according to the desired effect for the targeted area in each specific patient.
- To prevent damage to the system, the external source pressure must never exceed 60 psi.
- Beam alignment checks are extremely important for the safe operation of your laser equipment. If aiming and treatment beams are not coincident do not operate the laser or delivery system; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury. Use caution when performing the laser beam alignment check: follow the procedure as described in this manual. Take care to ensure that the beam alignment procedure is performed when the patient, operating room personnel and flammable materials are not in the beam path.
- In Canada this instrument must be installed and operated according to CAN/CSA-Z386-14: Laser Safety in Health Care Facilities.
- Never use the articulated armor wave guide to move the laser. Moving the laser by the articulated arm may cause irreparable damage.
- Use care when rolling the console in tight spaces and over uneven surfaces and slopes. Any large shock to the system can cause damage to the system, including beam misalignment and/or someone can be injured.
- Once the console is in place, verify that the wheels are locked. If the console moves unexpectedly, the system can be damaged and/or someone can be injured.
- Take appropriate steps to minimize fire hazards, including special precautions for laser surgery in the airway.
- Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the 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.
- Before beginning an operative procedure, always verify that the laser aiming and treatment beams are aligned, as instructed in the delivery system operator manual. If the aiming and treatment beams are not aligned, do not use the laser until alignment is corrected by a Lumenis-certified service technician. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury.
- Always disconnect delivery system components from the laser articulated arm before inspection. Never look directly into a delivery system while it is connected to the laser articulated arm. Never

look directly into the laser articulated arm while the laser is energized. Accidental laser exposure can cause severe eye damage.
- Do not touch any optical lens. Finger oils may damage the delicate coatings.
- Only use the power cable that was provided with the UltraPulse DUO system when connecting the system.
- Damaged fibers may lead to inadvertent laser radiation, therefore verify fiber integrity prior to and during treatment.
- When using an Otolase™ Fiber for Otology procedures the user is instructed to uncheck the Automatic control on air flow in Ready state.
- The UltraPulse DUO system only works with Lumenis-qualified CO_2 fibers. If a non-qualified fiber is connected the laser emission is blocked and a red icon appears on the control display. Any attempt to use incompatible delivery systems may result in unpredictable or unsafe laser operation.
- To prevent unintended laser discharge, always turn OFF the laser before connecting a delivery system.
- Prior to operating with the CO_2 Laser fibers, thoroughly read its complete Instruction for Use document (provided separately with reach fiber).
- In Otology procedures it is not recommended to use an external air flow.
- The articulated arm is a precision component; carefully handle and position the arm. Avoid arm collision with other objects or the ceiling in order 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 the articulated arm storage compartment, with the red protective in place.
- To avoid possible damage to the optical system, use only qualified, compatible Lumenis delivery systems with this laser. Use of incompatible delivery systems may result in unpredictable or unsafe laser operation and will nullify your Lumenis warranty or service contract.
- The quality of the mirrors and focusing lenses need to be inspected and cleaned if necessary. Otherwise the performance will be degraded to prevent unintended laser discharge, always turn OFF the laser before connecting a delivery system.
- To avoid potential damage to the scanner, always connect or disconnect the scanner cable while the laser system is turned OFF, or that it is in the Home Screen if turned ON.
- Prior to using the system, verify that the purge air is operational. Specifically when using the fiber, place the fiber tip in a glass of liquid and activate the purge air flow on the laser system. You should see bubbles that indicate that air is flowing properly through the fiber.
- Once the console is placed, verify that the wheels are locked. If the console moves unexpectedly, the system can be damaged and/or someone can be injured.
- Make sure to select in the graphical user interface, the same accessory that is connected to the articulated arm. Selecting a different accessory may result in unsafe laser operation and danger to the patient and staff.
- Never deliver the treatment beam to the target tissue if the aiming beam integrity has not been verified.
- Avoid eye exposure to the aiming beam.
- Fiber damage can occur when using a laser at a high-power level or at an extreme bending radius for long lasing time periods. To avoid damage to the fiber and delivery accessory, an external pressurized purge air supply must be connected to the system when working with a fiber at a power level greater than 20 watts. The external pressure must be set between 50 psi (3.45 bar) and 60 psi (4.14 bar).
- In Fiber mode when the aiming beam is in its minimum level/value/ intensity, is turned OFF. In Free Beam mode when the aiming beam is in its minimum setting it has minimal light.
- Do not attempt to open or disassemble the system's covers. Opening the covers will expose personnel to high voltage components, the laser resonator and possible laser radiation. Only Lumenis-authorized technical personnel are qualified to service the interior of the system.
- In Canada this instrument must be installed and operated according to CAN/CSA-Z386-14: Laser Safety in Health Care Facilities.

- Beam alignment checks are extremely important for the safe operation of your laser equipment. If aiming and treatment beams are not coincident do not operate the laser or delivery system; call your local Lumenis representative. Misalignment of aiming and treatment beams may result in laser exposure to non-target tissues and possible injury. Use caution when performing the laser beam alignment check: follow the procedure as described in this manual. Take care to ensure that the beam alignment procedure is performed when the patient, operating room personnel and flammable materials are not in the beam path. It may be desirable to place energy-absorbing material behind a target area.
- 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.
- Clean the outer surfaces of the system with alcohol only when system is turned OFF. Verify that the alcohol has evaporated prior to turning system ON.
- Do not spray or pour cleaning agents directly on the laser console or control display. This can damage the console, display and laser system electronics.
- Lack of adequate air flow can damage the fiber and/or the delivery accessory, thus creating laser radiation and/or other injury hazards to the clinicians or patient.
- 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 are risks of excessive thermal injury, ulceration, scarring, edema, excessive bleeding, and infection -associated with any CO_2 laser surgical procedure. These risks may affect the tissue's structure and functionality. Therefore appropriate use of the CO_2 laser, as well as appropriate pre- and post-surgical care should always be practiced.
- Purge gases used with CO_2 delivery accessories and fibers 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.
- Serious tissue damage can occur as a result of incorrect energy settings when using a different accessory than the one selected in the treatment screen.

<u>Dermatology and Plastic Surgery Laser Warnings and Precautions</u>

- The incidence and duration of postoperative hyperpigmentation and postoperative pain may be higher in subjects with darker skin types (III-VI) than in subjects with lighter skin types (I-II). Therefore, careful assessment of the patient skin type and laser test patching is recommended prior to commencement of treatment. Preoperative preparation of skin such as use of sunscreen or retinoic acid may be considered to reduce the likelihood of hyperpigmentation.
- Temperature increase due to laser treatment in patients with previous history of herpes simplex virus (HSV) may increase the like hood of HSV recurrence. Assess the patient's history for HSV and take the necessary preoperative measures such as antiviral therapy to avoid HVS recurrence.
- High energy densities may result in excessive tissue vaporization. Laser test patching should be considered prior to treatment to avoid unexpected results.
- Avoid overlapping of treatment spots as this will cause increased energy density and thermal effect to the treatment area.
- To ensure proper healing of the treated area and the likelihood of hyperpigmentation, subjects should avoid unprotected exposure to sunlight. It is recommended to continue the use of sunscreen during the postoperative period.

<u>ENT Warnings and Precautions</u>

- To prevent airway fires and severe injury to the patient, protect endotracheal tubes from exposure to the CO_2 wavelength, or use CO_2 laser-resistant endotracheal tubes.
- To prevent airway fires and severe injury to the patient, do not direct the CO_2 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.
- 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.
- 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 Warnings and Precautions
- When using a laser laparoscope, maintain an adequate flow of purge gas through the delivery accessory in order to prevent the fiber from over-heating.
- 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.
- Avoid placing the tip of the fiber in direct contact with tissue to prevent reduction of purge flow and to reduce the risk of systemic gas embolism.

Neurosurgery Warnings and Precautions
- Purge air used with CO_2 delivery accessories and fibers 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.
- 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/Expected Sequelae

General Dermatology and Plastic Surgery Adverse Events/Complications/Expected Sequelae

Complications include:
- Scarring
- Ulceration Persistent edema
- Infection
- Persistent erythema

Expected Sequelae include:
- Erythema that resolves over time

- Swelling/edema that resolves over time

In addition to these general complications and sequelae, note the following procedure-specific complications and sequelae:

- Rhinophyma
  - Complications include:
    - Transient pustule formation
    - Alar lift
- Laser Matrixectomy
  - Complications include:
    - Sterile inflammatory condition
- Blepharoplasty
  - Complications include:
    - Ectropion
    - Asymmetry of eyelids
    - Fold release (Asian eyelids)
    - Wound dehiscence
    - Postoperative bleeding
    - Hematoma
    - Keratoconjunctivitis sicca (dry eyes)
    - Suture abscesses that resolve without treatment
    - Allergic reaction to surgical suture material
  - Expected sequelae include:
    - Minimal bruising and swelling (as compared to cold steel)
    - Minimal ecchymosis (as compared to cold steel)
    - Reduced intraoperative and/or postoperative pain (as compared to cold steel)
    - Slightly reduced healing time (as compared to cold steel)
    - Conjunctivitis (usually transient)
    - Ptosis (usually transient)
- Laser Hair Transplantation
  - Complications include:
    - Hypopigmentation at laser-created sites
    - Grafts that do not take (fall out)
  - Expected sequelae include:
    - More crusting (some with de-epithelialization) at laser-created operative sites, as compared to recipient sites created using cold steel
    - Delayed healing of laser-created recipient sites, as compared to recipient sites created using cold steel
    - Removal of hair in laser-created slits in areas bearing hair
- Skin Resurfacing
  - Complications include:
    - Hypopigmentation
    - Scarring that generally resolves over time with steroid treatment
    - Induration that generally resolves over time with steroid treatment
    - Formation of fibrotic tissue that generally resolves over time with steroid treatment
    - Reactivation of herpes simplex
    - Acne flare-up that generally resolves over time by itself or with antiacneic medication if persistent
- Expected sequelae include:
  - Hyperpigmentation that resolves over time
  - Transient pain that is observed immediately postoperatively and generally resolves quickly
  - Transient burning sensation that is observed immediately postoperatively and generally resolves quickly

- Crusting that is observed immediately postoperatively through 2 weeks postoperatively
- Itching that generally resolves within the first 2 weeks postoperatively
- Textural change that is generally observed between 2 and 12 weeks postoperatively and resolves over time
- Sensation of tightness that resolves over time
- Formation of milia that resolves over time
- Contact irritant dermatitis to postoperative topical agents (primarily antibiotics)
- Postauricular skin slough/loss

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:
  - 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
- 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

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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