

Lumenis Pulse™ 50H and Lumenis Pulse™ 100H

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Prescriptive Information

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

Intended Use/Indications for Use

The Lumenis Pulse 50H and 100H System with Delivery Devices and Accessories are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: urology, urinary lithotripsy, arthroscopy, discectomy, endo-nasal surgery, gynecological surgery, pulmonary surgery, gastroenterology surgery, dermatology and plastic surgery, and general surgery.

The Lumenis Pulse 50H or 100H System with delivery devices and accessories are indicated for use in the performance of specific surgical applications as follows.

Urology

- Endoscopic transurethral incision of the prostate (TUIP), bladder neck incision of the prostate (BNI), holmium laser ablation of the prostate (HoLAP), holmium laser enucleation of the prostate (HoLEP), holmium laser resection of the prostate (HoLRP), hemostasis, vaporization and excision for treatment of benign prostatic hypertrophy (BPH).
- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
 - Bladder
 - Superficial and invasive bladder, urethral and ureteral tumors
 - Condylomas
 - Lesions of external genitalia
 - Ureteral and penile hemangioma
 - Ureteral strictures
 - Bladder neck obstructions
- Urinary Lithotripsy including:
 - Endoscopic fragmentation of urinary (urethral, ureteral, bladder and renal) calculi, including cystine, calcium oxalate, monohydrate and calcium oxalate dihydrate stones.
 - Treatment of distal impacted fragments of steinstrasse when guidewires cannot be passed.

Arthroscopy

- Arthroscopy (ablation, excision and coagulation of soft and cartilaginous tissue) in various small and large joints of the body, excluding the spine, including:
 - Meniscectomy
 - Plica removal
 - Ligament and tendon release
 - Contouring and sculpting of articular surfaces
 - Debridement of inflamed synovial tissue (synovectomy)
 - Loose body debridement
 - Chondromalacia and tears
 - Lateral retinacular release
 - Capsulectomy in the knee
 - Chondroplasty in the knee

- Chondromalacia ablation
- Discectomy including:
 - Percutaneous vaporization of the L4-5 and L5-S1 lumbar discs of the vertebral spine; open and arthroscopic spine procedures; foraminotomy.

General Surgery

- Open, laparoscopic, and endoscopic general surgery (vaporization, ablation, incision, and coagulation of soft tissue) including:
 - Cholecystectomy
 - Lysis of adhesions
 - Appendectomy
 - Biopsy, pylorostenotomy, and removal of polyps of the sigmoid colon
 - Skin incision
 - Tissue dissection
 - Excision of external tumors and lesions
 - Complete or partial resection of internal organs, tumors and lesions
 - Mastectomy
 - Hepatectomy
 - Pancreatectomy
 - Splenectomy
 - Thyroidectomy
 - Parathyroidectomy
 - Herniorrhaphy
 - Tonsillectomy
 - Lymphadenectomy
 - Partial nephrectomy
 - Pilonidal cystectomy
 - Resection of lipoma
 - Debridement of decubitus ulcer
 - Hemorrhoids
 - Debridement of stasis ulcer
 - Biopsy

ENT Surgery

- Endoscopic endonasal/sinus surgery (ablation, vaporization, incision, and coagulation of soft tissue and cartilage) including:
 - Partial turbinectomy
 - Ethmoidectomy
 - Polypectomy
 - Maxillary antrostomy
 - Frontal sinusotomy
 - Sphenoidotomy
 - Dacryocystorhinostomy (DCR)
 - Functional endoscopic sinus surgery (FESS)
- Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
 - Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal tissues
 - Tonsillectomy
 - Adenoidectomy

Gynecological Surgery

- Open and laparoscopic gynecological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue).

Gastroenterology Surgery

- Open and endoscopic gastroenterology surgery (ablation, vaporization, incision, excision, resection, coagulation and hemostasis, including:
 - Gall bladder calculi
 - Biliary/bile duct calculi
 - Benign and malignant neoplasm
 - Polyps
 - Colitis
 - Ulcers
 - Angiodysplasia
 - Hemorrhoids
 - Varices
 - Esophagitis
 - Esophageal ulcer
 - Mallory-Weiss tear
 - Gastric ulcer
 - Duodenal ulcer
 - Non-bleeding ulcer
 - Gastric erosions
 - Colorectal cancer
 - Gastritis
 - Bleeding tumors
 - Pancreatitis
 - Vascular malformations
 - Telangiectasias
 - Telangiectasias of the Osler-Weber-Rendu disease

Pulmonary Surgery

- Open and endoscopic pulmonary surgery (cutting, ablation, vaporization, incision, excision and coagulation of soft tissue).

Dermatology and Plastic Surgery

- Incision, excision, resection, ablation, coagulation, hemostasis and vaporization of soft, mucosal, fatty and cartilaginous tissues, in therapeutic plastic, dermatologic and aesthetic surgical procedures, including:
 - Scars
 - Vascular lesions
 - Port wine stains
 - Hemangioma
 - Telangiectasia of the face and leg
 - Rosacea
 - Corns
 - Papillomas
 - Basal cell carcinomas
 - Lesions of skin and subcutaneous tissue
 - Plantar warts
 - Periungual and subungual warts
 - Debridement of decubitus ulcer
 - Skin tag vaporization

Contraindications

The use of a laser instrument for an application is at the physician's discretion except in cases where the indication has been contraindicated

- Inability to receive endoscopic or laparoscopic treatment.
- Intolerance to anesthesia.
- Resection or excision of large, highly vascularized organs.

Specific Contraindications in Urology

- Carcinoma of the prostate.

Specific Contraindications in Gynecology

- Septic peritonitis
- Intestinal obstruction.
- Septic shock.
- Resection or excision of large, highly vascularized organs.

Warnings and Precautions

This section contains warnings and precautions that are applicable to surgical procedures specifically related to the use of this system

- 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.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.
- Read this operator manual carefully. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- 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 verify that the optical fiber 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 fiber, handpiece, probe or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.
- 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 are qualified to work inside the console.
- 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.

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- 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 non-metallic 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.
- When performing procedures in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
- Smoke evacuation may be required if using the laser in open-air procedures.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Lumenis Pulse 50H/100H, including Lumenis Pulse 50H/100H cables. Otherwise, degradation of the performance of this equipment could result.
- Use of accessories, delivery devices and cables, other than those provided by Lumenis, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Lumenis Pulse 50H/100H is only intended for use in operating rooms, within a professional healthcare facility environment, except for near HF SURGICAL EQUIPMENT, and outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging.
- Lumenis Pulse 50/100H needs special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance, with regard to electromagnetic disturbances for the expected service life of 7 years.
- When using a fiber-optic delivery device, always inspect the fiber-optic cable to ensure that it has not been kinked, punctured, fractured, or otherwise damaged. The fiber-optic cable may be damaged if stepped on, pulled, left lying in a vulnerable position, kinked, or tightly coiled. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable. A damaged fiber-optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Never deliver the treatment beam to the target tissue if the aiming beam integrity has not been verified; the optical fiber may be damaged. A damaged fiber may cause accidental laser exposure to the treatment room personnel or patient, and/or fire in the treatment room.
- 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.
- To prevent accidental laser discharge, always verify that the laser system is in Standby mode before disconnecting the delivery system.
- Never place hands or other objects in the path of the laser beam. Severe burns could occur.
- 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.
- Unauthorized use of this system may expose the operator/patient to potential electrical energy and laser radiation hazards.
- Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 μm) wavelength.
- Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until familiar with the instrument's capabilities. Use extreme caution until the biological interaction between the laser energy and tissue is thoroughly understood.

- Due to interaction between flammable gases in the operating field and the laser energy a flash fire may occur. Therefore, during laser procedures, measures to minimize this potential hazard should be practiced (e.g. avoid administration of inhaled general anesthetics; reduce oxygen levels during mechanical ventilation, use of laser-resistant endotracheal tubes). The flammability of methane gas must also be considered when treating in or near the perianal area.
- The laser system should be used only on tissues that are fully observable. Do not use the laser if the desired target is not visible. All available measures to visualize the target tissue (e.g. copious irrigation, hemostasis) should be taken.
- When using endoscopic equipment confirm that the tip of the fiber-optic delivery device extends at least 6 mm beyond the end of the scope during laser treatment. Activating the laser when the tip of the delivery device is within the scope can result in penetration of holmium laser energy through the scope and destruction of the scope.
- Use of the laser system on anatomical structures in proximity to known critical structures, such as large arteries, veins, bowel, ureter, bladder, nerves, etc., should be performed carefully to avoid inadvertent or unintended damage of such structures. If applicable, maintain irrigation in the treatment area to reduce heat accumulation.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Highly vascularized anatomical structures should be approached with caution, taking into account the limited coagulative properties of the laser. Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding vessel is larger than possible to control with the laser. The risk of bleeding may be higher in patients taking anticoagulants/platelet aggregates.
- Baskets, guidewires, and other surgical accessories may be damaged by direct contact with the laser treatment beam.

Adverse Events/Complications

The following is a list of general complications that are related to surgery and within this context, laser surgery. The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic surgery. Refer to updated literature for specific procedure-related complications.

- As with conventional surgery, the possibility of complications and adverse events, such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis, or infection may occur following treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or laser application.
- As with any surgical procedure, there is a possibility of infection or scarring. Therefore, appropriate pre- and post-surgical care should always be practiced.
- As with any conventional surgery, discontinue laser treatment immediately if the patient develops any cardiopulmonary problems.
- As with any conventional surgery, acute pain may occur immediately following laser therapy and may persist for as long as 48 hours.
- Immediately following laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Remnants of destructed tissue may become necrotic or infected. If a question of infection exists, appropriate treatment should be carried out.
- Patients may experience bleeding at the site of laser therapy. Post-treatment hematocrits are recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure. If a question of sepsis exists, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.
- As with any conventional laparoscopic surgery, the use of gas to insufflate the abdomen may lead to a gas embolus. In the extreme case, death may result from an embolus. The use of carbon dioxide

gas for insufflation will minimize patient risk, as it is highly soluble in blood. Insufflation pressure should be set to minimum settings for effective insufflation.

- Verify that all persons in the treatment room are wearing appropriate laser safety eyewear before setting the system to Ready mode.
- Before connecting the Lumenis Pulse 50H or 100H components, inspect the individual components, cables, and electrical connections for dirt, debris, or damage. Verify that the electrical cables are not frayed or split. Contact your local Lumenis service representative if any component appears damaged.
- As with any heavy equipment, use caution when tilting the laser console or moving it up or down an incline. For optimum safety, use a second person when moving up or down a steep incline.
- Carefully inspect the delivery device sterile packaging to ensure that it has not been torn or punctured. If there is any damage to the sterile packaging, do not use the delivery device.
- To avoid possible damage to the optical system, use only qualified Lumenis delivery systems. Using other than Lumenis delivery systems may jeopardize safe operation or damage the laser system and will void your Lumenis warranty or service contract.
- To prevent accidental laser discharge, always verify the laser system is in standby mode before disconnecting the delivery system.
- Always check the expiration date on the delivery device packaging; do not use a delivery device whose expiration date has passed.
- Never inspect the delivery device while it is connected to the laser system. Accidental laser exposure can cause severe eye damage.
- When removing the protective cap on the laser connector, hold the laser connector, not the strain relief or fiber optic cable. Pulling on the strain relief or fiber optic cable may damage the delivery system and result in unintended laser exposure.
- Power on the system and prepare it for operation well in advance of the scheduled surgical procedure, so that there will be sufficient time to troubleshoot any problems without disrupting the surgery schedule.
- If the aiming beam is turned off, ensure that the tip of the optical fiber and the targeted surgical site are both under direct visualization.
- Except during actual treatment, the laser system must always be in Standby mode. Maintaining the laser system in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.
- Do not use the delivery system if the aiming beam is set to high intensity and is still weak or not visible; the fiber optic cable may be damaged. A damaged cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Do not use the laser or delivery system if the aiming beam has not been verified. Verifying the aiming beam integrity is extremely important for the safe operation of your laser equipment.
- Do not use the laser or delivery system if the aiming beam is not visible. Operating the laser without the aiming beam may result in laser exposure to non-target tissue and possible injury.
- Always verify your parameter settings on the screen before setting the system to Ready mode.
- Always set the laser system to Standby mode when it is not in use to avoid unintended laser emission.
- Do not move the laser console rapidly over uneven surfaces; doing so may damage the equipment.
- Do not spray or pour cleaning agents directly on the laser console or control screen. You may damage the console, screen and laser system electronics.
- To avoid contamination, do not touch the surface of the debris shield optic with your fingers.
- The Lumenis Pulse 50H or 100H laser system may be serviced by Lumenis certified field service engineers using an approved service manual.
- These procedures assume 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 Lumenis Certified Service personnel.

- All personnel in the immediate area must wear eye protection rated specifically for the Holmium laser.
- For Canada, the system must be installed and operated according to CAN/CSA-Z386-08: Laser safety in health care facilities.
- Unauthorized use of this system may expose the operator/patient to potential electrical energy and laser radiation hazards.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

Boston Scientific acquired the global surgical business of Lumenis Ltd. Lumenis Pulse™ 100H and Lumenis Pulse™ 50H are the registered product names. Lumenis Pulse™ 100H and Lumenis Pulse™ 50H are manufactured and sold by Boston Scientific. Lumenis is a registered trademark of Lumenis Be.

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URO-1220801-AB APR 2023