

VersaPulse™ PowerSuite™

Holmium and Dual Wavelength Surgical Lasers

Prescriptive Information

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

Intended Use/Indications for Use

Indications for Use Specific to the Ho:YAG Wavelength

The Ho:YAG (2.1 μm) wavelength is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision and coagulation of soft tissue in medical specialties including:

- Arthroscopy
- Urology
- Urinary Lithotripsy
- Endonasal surgery
- Gynecological surgery
- General surgery
- Gastroenterological surgery

Indications for Use Specific to the Nd:YAG Wavelength

The Nd:YAG (1.06 μm) wavelength is 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
- General Surgery
- Gastroenterology
- Thoracic and pulmonary surgery
- ENT surgery
- Podiatry
- Gynecology - the use of the Nd:YAG wavelength in Gynecology is limited to specific indications

Arthroscopy Indications

- The following applications are indicated for arthroscopic surgery in various joints of the body, excluding the spine, while using the Ho:YAG wavelength:
 - 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

Urology Indications

- The following applications are indicated for urology while using the Ho:YAG wavelength:
 - 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). The clinical procedure for HoLRP, along with clinical study results is described in Appendix A of the operator manual.

- Open and endoscopic urological surgery (ablation, vaporization, incision, excision and coagulation of soft tissue) including treatment of:
 - Superficial and invasive bladder, urethral and ureteral tumors
 - Condylomata
 - Lesions of external genitalia
 - Urethral and penile hemangiomas
 - Urethral strictures
 - Bladder neck obstructions
- The Nd:YAG wavelength is indicated for ablation, vaporization, incision, excision and coagulation of soft tissue during open and, where applicable, endoscopic procedures in urology. The following applications are indicated for urology while using the Nd:YAG wavelength:
 - Removal of superficial bladder tumors
 - Removal of invasive bladder carcinoma
 - Removal of benign or malignant lesions of the external genitalia, including condyloma
 - Urethral strictures
 - Vascular lesions of the bladder wall
 - Prostatectomy

Urinary Lithotripsy Indications

- The following applications are indicated for urinary lithotripsy while using the Ho:YAG wavelength:
 - 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.

ENT Surgery Indications

- The Ho:YAG wavelength is indicated for endoscopic vaporization, ablation, incision, and coagulation of soft tissue and cartilage during endonasal/sinus surgery procedures including the following applications:
 - Partial turbinectomy
 - Ethmoidectomy
 - Polypectomy
 - Maxillary antrostomy
 - Frontal sinusotomy
 - Sphenoidotomy
 - Dacryocystorhinostomy (DCR)
 - Functional endoscopic sinus surgery (FESS)
- The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in ENT surgery procedures. The surgical method and the method of delivering the laser energy are left to the discretion of the physician.
- The following applications are indicated when using the Nd:YAG wavelength in ENT surgery:
 - Lesions or tumors of the oral, nasal, glossal, pharyngeal, and laryngeal soft tissue
 - Tonsillectomy
 - Adenoidectomy

Gynecology Indications

- The Ho:YAG wavelength is indicated for open and laparoscopic ablation, vaporization, incision, excision, and coagulation of soft tissues.
- The Nd:YAG wavelength is indicated for the following applications in gynecology:
 - Treatment of menorrhagia by the photocoagulation, vaporization, or ablation of the endometrial lining of the uterus under direct hysteroscopic visualization

- Intrauterine treatment of submucous fibroids, benign endometrial polyps, and uterine septum by incision, excision, ablation, and/or vessel coagulation
- Intra-abdominal treatment of endometriosis and/or peritoneal adhesions by laser contact tips
- Soft tissue excisional procedures, such as conization of the cervix

General Surgery Indications

- The following applications are indicated for open, laparoscopic, and endoscopic general surgery while using the Ho:YAG wavelength:
 - Cholecystectomy
 - Lysis of adhesions
 - Appendectomy
 - Pylorostenotomy
 - Removal of rectal 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
- The Nd:YAG wavelength is indicated for ablation, vaporization, incision, excision, and coagulation of soft tissue during general surgery procedures. The surgical method (open or laparoscopic) and the method of delivering the laser energy are left to the discretion of the physician. The following applications are indicated when using the Nd:YAG wavelength in general surgery:
 - Cholecystectomy
 - Hepatectomy
 - Splenectomy
 - Thyroidectomy
 - Herniorrhaphy
 - Appendectomy
 - Partial nephrectomy
 - Resection of lipoma
 - Removal of tumors
 - Debridement of decubitus ulcer
 - Mastectomy
 - Pancreatectomy
 - Hemorrhoidectomy
 - Parathyroidectomy
 - Tonsillectomy
 - Lymphadenectomy

- Pilonidal cystectomy
- Pelvic adhesiolysis
- Removal of polyps
- Tumor biopsy

Dermatology and Plastic Surgery Indications

- The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in the following dermatology and plastic surgery procedures. The method of delivering the laser energy is left to the discretion of the physician.
 - Lesions of skin and subcutaneous tissue
 - Telangiectasia
 - Port wine lesions
 - Spider veins
 - Hemangiomas
 - Plantar warts
 - Periungual and subungual warts
 - Removal of tattoos
 - Debridement of decubitus ulcer
 - Keloids

Gastroenterology Surgery Indications

- The following applications are indicated for (Ho:YAG) 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
- The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in gastroenterology surgery. The surgical method and the method of delivering the laser energy are left to the discretion of the physician.
- The following applications are indicated when using the Nd:YAG wavelength in gastroenterology surgery:
 - Partial removal of neoplastic tissue in the management of esophageal obstruction from the symptomatic relief of dysphagia

- Gastrointestinal hemostasis, including:
 - Varices
 - Esophagitis
 - Esophageal ulcer
 - Mallory-Weiss tear
 - Gastric ulcer
 - Angiodysplasia
 - Stomal ulcers
 - Non-bleeding ulcers
 - Gastric erosions
- Gastrointestinal tissue ablation, including:
 - Benign and malignant neoplasm
 - Hemorrhoids
 - Polyps

Podiatry Indications

- The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in podiatry. The method of delivering the laser energy is left to the discretion of the physician.
- The following applications are indicated when using the Nd:YAG wavelength in podiatry:
 - Matricectomy
 - Plantar warts
 - Neuromas
 - Periungual and subungual warts
 - Radical nail excision

Thoracic and Pulmonary Surgery Indications:

- The Nd:YAG wavelength is indicated for ablation, vaporization, excision, incision, and photocoagulation of soft tissue in podiatry. The method of delivering the laser energy is left to the discretion of the physician.
- The following applications are indicated when using the Nd:YAG wavelength in thoracic and pulmonary surgery:
 - Laryngeal lesions
 - Airway obstructions including carcinoma, polyps, and granulomas
 - Palliation of obstruction carcinomas of the tracheobronchial tree

Contraindications

Urology Contraindications

- The Ho:YAG wavelength should not be used for HoLRP for treatment of BPH in patients with:
 - Carcinoma of the prostate
 - Desire for future fertility
- The Ho:YAG wavelength should not be used in patients with the following conditions:
 - Inability to receive endoscopic treatment
 - Intolerance to anesthesia
- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Urinary Lithotripsy Contraindications

- The Ho:YAG wavelength should not be used in patients with the following conditions:
 - Inability to receive endoscopic treatment

- Intolerance to anesthesia

ENT Surgery Contraindications

- The Ho:YAG wavelength should not be used in patients with any of the following conditions:
 - Inappropriate candidates for endoscopic treatment
 - Endonasal malignant neoplasm
- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Gynecology Contraindications

- The Ho:YAG wavelength should not be used in patients with any of the following conditions:
 - Inability to receive laparoscopic treatment
 - Intolerance to anesthesia
 - Septic peritonitis
 - Intestinal obstruction
 - Septic shock
 - Resection or excision of large, highly vascularized organs
- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery
- When treating menorrhagia, the Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Patients who desire child-bearing potential
 - Patients with any medical condition that contraindicates hysteroscopy, such as active pelvic inflammatory disease
 - Patients in which there is an indication of precancerous pathology

Gynecology, General Surgery and Gastroenterology Surgery Relative Contraindications

- The Ho:YAG wavelength should not be used in patients with any of the following conditions:
 - Recent myocardial infraction
 - Multiple previous abdominal surgeries

General Surgery Contraindications

- The Ho:YAG wavelength should not be used in patients with any of the following conditions:
 - Inappropriate candidates for endoscopic or laparoscopic treatment
 - Intolerance to anesthesia
 - Septic peritonitis
 - Intestinal obstruction
 - Septic shock
 - Resection or excision of large, highly vascularized organs (spleen, liver)
- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Dermatology and Plastic Surgery Contraindication

- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Gastroenterology Surgery Contraindications

- The Ho:YAG wavelength should not be used in patients with any of the following conditions:
 - Inappropriate candidates for endoscopic or laparoscopic treatment

- Intolerance to anesthesia
- Intestinal obstruction
- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Podiatry Contraindications

- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Thoracic and Pulmonary Surgery Contraindications

- The Nd:YAG wavelength should not be used in patients with any of the following conditions:
 - Intolerance to anesthesia
 - Inappropriate candidates for laser surgery

Warnings/Precautions

General Warnings/Precautions

This section contains warnings, precautions and complications that apply to all of the wavelengths and surgical specialties described in this user manual. For important information specific to a particular surgical specialty, such as Urology, read the corresponding section later in this chapter.

- Lasers generate a highly concentrated beam of light which may cause injury if improperly used. To protect the patient and operating personnel, the entire laser and the appropriate delivery system operator manuals, including all Safety and Regulatory sections, should be carefully read and comprehended before operation.
- Never inspect the delivery system while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- To avoid risk of electric shock, this equipment must only be connected to a supply-mains with protective earth.
- 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 and will void your Lumenis warranty or service contract.
- Carefully inspect the delivery system and 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 system.
- 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.
- To prevent accidental discharge, always turn off the laser before connecting the delivery system.
- When removing the protective cap, 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.
- Do not remove the protective cap from the laser connector in the sterile field. Removing the protective cap in the sterile field may compromise sterility.
- 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.
- 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 nontarget tissue and possible injury.

- 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.
- When using the delivery system with an endoscopic camera, lower the intensity of the camera light if the aiming beam is weak or not visible. Doing so will not affect visibility at the treatment site, since the camera compensates for the lower level of light.
- Except during actual treatment, the laser must always be in standby mode. Maintaining the laser in standby mode prevents accidental laser exposure if the footswitch is inadvertently depressed.
- Verify that all persons in the treatment room are wearing the appropriate laser safety eyewear before placing the laser in ready mode.
- Always verify that the desired treatment values are displayed on the control screen before initiating treatment. If there is no change in display values when the control screen or remote control selectors are pressed, or if the control screen appears otherwise erratic, do not use the laser. Contact your local Lumenis service representative.
- When using the dual-pedal footswitch for a procedure that requires only one treatment wavelength, it is recommended that you set the unused wavelength energy or power setting to the lowest possible value to avoid unintended delivery of that wavelength.
- Incorrect treatment settings can cause serious tissue damage. Therefore, it is recommended that you use the lowest acceptable treatment settings until you are familiar with the instrument's capabilities. Use extreme caution until you thoroughly understand the biological interaction between the laser energy and tissue.
- Unauthorized servicing or modification of this system, not described in this manual, may expose the surgeon/patient to potential electrical hazards.
- 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.
- 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 4s can be used together with the patient protective eyewear to reduce patient inconvenience. Never use them to replace protective goggles.
- For periorbital treatment, always protect the patient with dulled, metal eye shields, as severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam.
- Always verify that the delivery device is properly connected to the laser. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.
- Never substitute prescription eyewear for the appropriate laser safety eyewear, as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
- Use caution when performing procedures around the eyes. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. In general, visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
- Never look directly into any optical 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.
- Lumenis medical lasers and laser delivery systems are intended solely for physicians trained in the use of these instruments.

- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.
- Smoke evacuation may be required if using the laser in open-air procedures.
- 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 make sure that the footswitch is not being operated while connecting 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.
- 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.
- The area around the laser and footswitch should be kept dry. Do not operate the laser if any of the cords are faulty or frayed. The laser should undergo routine inspection and maintenance per Lumenis manufacturer's recommendations and institutional standards.
- 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.
- Lumenis VersaPulse PowerSuite Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 μm) wavelength. VersaPulse PowerSuite Dual Wavelength lasers are intended solely for use by physicians trained in the use of Ho:YAG (2.1 μm) and Nd:YAG (1.06 μm) wavelengths.
- Refer to warnings specific to each surgical specialty and wavelength within this section.
- As with conventional endoscopic 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.
- Flash fire may occur. Flammable inhalation general anesthetics must not be used. Oxygen leads in the direct surgical area must not exceed 50 percent. The risk of combustion, perforation, and laser-induced hemorrhage, any of which could cause death, must be fully explained to the patient.
- The flammability of methane gas must be considered when treating in or near the perianal area.
- There is a risk of infection scarring associated with any surgical procedure. Therefore, appropriate pre- and post-surgical care should always be practiced.

- The laser 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.
- Use of the laser 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.
- There is an increased risk of back scatter (reflection) and forward scatter (penetration) when using the laser if the laser is in the non-contact mode.
- Refer to the precaution specific to each surgical specialty and wavelength within this section.
- Use caution with patients who have had difficulty with previous endoscopic procedures.
- Blood vessels up to 1 millimeter in diameter can be effectively coagulated with the Ho:YAG wavelength.
- Electrocautery and/or suture (ligature) should be easily accessible in the event that a bleeding artery or vein is larger than possible to control with the laser.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- Discontinue laser treatment immediately if the patient develops any cardiopulmonary problems.
- Lumenis has no clinical information concerning the safety of laser treatment on pregnant or nursing women.
- Refer to the appropriate delivery system instruction guide for use instructions.

Urology Warnings/Precautions

Ho:YAG:

- Good clinical judgement should be used prior to performing the HoLRP procedure on patient who are taking anticoagulants
- The following precautions are suggested when using the Ho:YAG wavelength in Urology
 - Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distention could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.
- The following precautions are recommended for HoLRP for treatment of BPH
 - Confirm that the tip of the fiber-optic delivery device extends at least 25 centimeters beyond the end of the ureteroscope or endoscope during laser treatment. Activating the laser when the tip of the delivery device is within the ureteroscope or endoscope can result in penetration of holmium laser energy through the scope and destruction of the scope.
 - Use caution during treatment near the verumontanum.
 - The learning curve to obtain proficiency in HoLRP has been described by experienced urologists to be similar to that of learning TURP.

Nd:YAG:

- Care should be exercised so as not to over distend the bladder when using the laser endoscopically. Excessive bladder distention could result in coagulative necrosis of the superficial and inner muscular region of the bladder wall.

Urinary Lithotripsy Warnings and Precautions

Ho:YAG

- Unexpected tissue damage may occur due to excessive power application. Refer to "Urinary Lithotripsy clinical parameters" in this user manual for recommended initial power settings. Use of excessive power may result in inadvertent perforation of the ureter or damage to other urologic structures.
- The laser should be used with an optical fiber delivery system in direct view and in direct contact with the target ureteral stone. To minimize the potential for migration up the ureter, laser energy should be directed to the side of the stone, if possible, rather than the leading edge.

- Be aware of edematous folds of epithelium that may lie between the optical fiber and the stone; however, research suggests such folds are very rare.
- Baskets may be used with larger stone fragments that are relatively hard or tend to escape in a retrograde fashion up the ureter. Use of endoscopes in laser procedures allows excellent viewing and minimal trauma to the ureter during fragmentation.
- The use of irrigation is recommended throughout the lithotripsy procedure to absorb any heat produced, to carry stone fragments out of the urinary system, and to enhance direct visualization. The rate of irrigation should be carefully adjusted to avoid flux of calculi into the kidney.

ENT Surgery Warnings and Precautions

Ho:YAG

- Unexpected or uncontrolled tissue damage can sometimes occur due to excessive power application. Use low power and pulse rate settings until familiar with instrument capabilities. Extreme caution should be employed until the biological interaction of the laser energy with tissue is fully understood by the physician. Use the initial power settings recommended in the operators manual.
- As with conventional endonasal surgery, damage to the orbit may occur, resulting in partial visual loss or blindness
- Perforation of dura may result in leakage of cerebral spinal fluid with meningitis.

General Surgery Warnings and Precautions

Ho:YAG:

- With the use of gas to insufflate the abdomen, there is a possibility of gas embolus. In the extreme case, death may result from an embolus.
- Extreme caution should be used when insufflating the abdomen with gas. 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. The maximum safe intra-abdominal pressure setting is 15 to 20 mmHg.

Nd:YAG:

- Extreme caution should be used when insufflating the abdomen with gas. 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. The maximum safe intra-abdominal pressure setting is 15 to 20 mmHg.

Gynecology Warnings and Precautions

Ho:YAG:

- With the use of gas to insufflate the abdomen, there is a possibility of gas embolus. In the extreme case, death may result from an embolus.
- Extreme caution should be used when insufflating the abdomen with gas. 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. The maximum safe intra-abdominal pressure setting is 15 to 20 mmHg.

Nd:YAG

- It is essential that the physician and attending staff be trained in all aspects of these gynecological procedures. No physician should use this laser without first obtaining detailed instructions in laser use. In addition, this laser should not be used for hysteroscopic procedures until the physician or hysteroscopist also has obtained detailed instructions in hysteroscopy using a fluid distention medium.
- During intrauterine laser surgery, do not use gas or air for cooling the laser delivery system's fiber tip or for insufflation. The use of gas or air may cause a life-threatening gas or air embolism.
- The following precautions are specific to treatment of menorrhagia:
 - Special precautions should be taken to monitor the patient fluid absorption from the hysteroscopic distention media. Excessive fluid absorption may be a problem if the procedure is prolonged. During the procedure, venous channels seem to be open, but bleeding is controlled by

the pressure of the irrigating solution. There is a large, raw surface and a large volume of fluid may be absorbed. Wider dilation of the cervix to allow irrigating fluid to flow more freely around the hysteroscope and reduce intrauterine pressure may reduce the risk. If excessive fluid is absorbed, appropriate therapy, such as diuretic administration should be considered with subsequent electrolyte monitoring.

- Because of the risk of possible fluid absorption, patients with cardiovascular disorders should be carefully evaluated as candidates for this procedure.
- Consideration should be given to closing the fallopian tubes prior to the procedure. However, if the physician, after consultation with the patient, determines that sterilization is not indicated, the patient must be advised to utilize a contraceptive technique to avoid pregnancy. Although pregnancy is highly unlikely after this procedure, there is no data regarding potential risks should pregnancy occur.
- Patients are urged to have a pap smear annually. There is a possibility that in a very small percentage of women who develop uterine cancer, their symptoms of bleeding may be hidden as a result of this treatment. And, while other symptoms would still be expected to occur, this precautionary step should be taken to reveal any possible cancerous development.

Dermatology and Plastic Surgery Warnings and Precautions

Nd:YAG:

- Dark-skinned patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit ratio.
- Lesions that have been previously treated with other laser wavelengths or with chemicals should be treated with caution and with the lowest possible power levels in order to avoid burns on the previously thinned skin.
- Treatment should be done in a "dot" fashion in areas where the skin is thin, such as the temple or scalp.

Gastroenterology Surgery Warnings and Precautions

Ho:YAG and Nd:YAG

- Use caution when treating patients who have had previous esophageal-tracheal fistulae or episodes of aspiration.

Thoracic and Pulmonary Surgery Warnings and Precautions

Nd:YAG

- Use caution when treating patients who have had previous esophageal-tracheal fistulae or episodes of aspiration.

Adverse Events/Complications:

General Adverse Events/Complications

- Refer to complication specific to each surgical specialty and wavelength within this section.
- The potential complications encountered in endoscopic laser surgery are the same as those normally encountered in conventional endoscopic 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.
- Laser ablated tissue may become necrotic or infected after treatment. If a question of infection exists, appropriate treatment should be carried out.
- The following complications could be serious and could result in death:
 - 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.

Urinary Lithotripsy Adverse Events/Complications

Ho:YAG:

- As with other endoscopic urologic procedures, there may be urine leakage following the laser procedure.
- The use of flexible endoscopes carries an equivalent incidence of stricture formation; these rates may improve with further advances in ureteroscope design.
- Although rare, loss of a kidney may occur as a result of the procedure or because of the stone, itself.

ENT Surgery Adverse Events/Complications

Ho:YAG:

- Swelling of the nasal membranes may cause nasal airway obstruction for up to one week. Patients should be followed post-treatment to clean debris from the nasal cavity.
- Perforation of the orbit or intracranial cavity may occur as a result of laser treatment. To diagnose perforations, patients must be carefully followed post-treatment with appropriate tests.

General Surgery Adverse Events/Complications

Ho:YAG and Nd:YAG

- Air embolus is usually diagnosed intra-operatively. This condition requires rapid emergency treatment.

Dermatology and Plastic Surgery Adverse Events/Complications

Nd:YAG

- The treatment of colored vascular lesions with the Nd:YAG wavelength may result in no benefit or a decrease in lesion size and/or blanching of color. The lesion may also worsen due to scar formation. Potential complications of the laser treatment include the following:
 - Scarring - hypertrophic and non-hypertrophic
 - Burns - from superficial to full thickness
 - Excessive tissue destruction
 - Ulceration
 - Hyperpigmentation
 - Induced hemorrhage
 - Edema
 - Failure of the procedure - while clinical studies have shown efficacy in treating colored vascular lesions, it is possible that there may be regeneration of some ectatic vessels. Should this happen, further laser treatment may be necessary.

Gastroenterology Surgery Adverse Events/Complications

Ho:YAG and Nd:YAG:

- Patients may experience gastrointestinal distension or pneumothorax during or after therapy
- Swallowing may be worsened, rather than immediately improved, following esophageal procedures due to secondary tissue edema. This potential problem should be explained to the patient prior to therapy.

Gynecology Adverse Events/Complications

Nd:YAG:

- There is no guarantee that treatment with the Nd:YAG wavelength will entirely eliminate that disease entity. Repeat treatments or alternative therapies may be required.

- Formation of air emboli can occur if air or gas are used for cooling the laser fiber tip or for insufflation. Only use fluid coolant when performing hysteroscopic laser surgery.

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.
All trademarks are the property of their respective owners.

©2022 Boston Scientific Corporation or its affiliates. All rights reserved.
URO-237309-AC