

Brief Summary Document

Product

Lumenis Pulse 120H Holmium Surgical Laser

IFU #51673473-01A

Rx STATEMENT

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 μm) wavelength.

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

INTENDED USE/INDICATIONS FOR USE

The Lumenis Pulse 120H system with delivery devices and accessories are intended for use in surgical procedures involving endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue and urinary lithotripsy in 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).
- 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.

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.

- Intolerance to anesthesia.
- Resection or excision of large, highly vascularized organs.

Specific Contraindications in Urology

- Carcinoma of the prostate.

WARNINGS

- Always provide eye protection for the patient. Wet thick cloths or wet gauze 4 x 4 cm can be used together with the patient protective eyewear to reduce patient inconvenience. Never use them to replace protective goggles.
- 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.
- When performing procedures in the perianal area, the flammability of methane gas must be considered. Moistened sponges should be inserted into the rectum.
- 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.
- Use extreme care if the aiming beam has been turned off. Operating the laser without the aiming beam may result in laser exposure to non-target tissue and possible injury.

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.

Boston Scientific acquired the global surgical business of Lumenis Ltd. Lumenis Pulse™ 120H is the registered product name. Lumenis Pulse™ 120H is manufactured and sold by Boston Scientific. Lumenis is a registered trademark of Lumenis Be.

©2025 Boston Scientific Corporation or its affiliates. All rights reserved.
URO-1220305-AC MAR 2025