

# VersaPulse™ PowerSuite™ Holmium Lasers

Refer to the device directions for use for complete instructions on device use.

## Intended Use/Indications for Use

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 this 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

## 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

## Warnings

- 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.
- Good clinical judgment should be used prior to performing the HoLRP procedure on patients who are taking anticoagulants.
- 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.
- 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 levels in the direct surgical area must not exceed 50 percent. The risks of combustion, perforation, and

laser-induced hemorrhage, any of which could cause death, must be fully explained to the patient.

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

## **General Laser Complications**

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.

## **Cautions**

- 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.

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

Caution: US Federal law restricts this device to sale by or on the order of a physician. Refer to package insert provided with this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

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