Brief Summary Document

Product

GreenLight XPS™ Laser System – IFU 50743154-01

GreenLight HPS™ Laser Fiber – IFU 51513371-01

MoXy™ Liquid Cooled Laser Fiber – IFU 51513372-01

Rx Statement

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

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

GreenLight XPS Laser System

The GreenLight XPS Laser System is intended for the surgical incision, excision, vaporization, ablation, hemostasis, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

Suggested applications include:

> Cutting, coagulating, or vaporizing urologic soft tissues. Open endoscopic minimally invasive urological surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including treatment of bladder, urethral and ureteral tumors; condylomata; lesions of external genitalia; urethral and penile hemangioma; urethral strictures; bladder neck obstructions; and vaporization of prostate tissue for men suffering from Benign Prostatic Hyperplasia (BPH).

GreenLight HPS and MoXy Laser Fibers

Intended Use

The GreenLight HPS and Moxy Laser Fibers are indicated for endoscopic (cystoscopic) 532 nm laser procedures involving surgical incision, excision, vaporization, ablation, hemostasis and coagulation of urological soft tissue.

Indications for Use

- For the treatment of benign prostatic hypertrophy/hyperplasia (BPH).
- Other endoscopic procedures involving surgical incision, excision, vaporization, ablation, hemostasis, and coagulation of urological soft tissue in adults.

CONTRAINDICATIONS

The GreenLight laser system is contraindication for patients with the following conditions:

- General medical condition contraindicates surgical intervention
- When appropriate anesthesia is contraindicated by patient history
- Calcified tissue (especially tumors)
- Hemostasis of vessels over approximately two millimeters in diameter
- When laser therapy is not considered the treatment of choice
- Uncontrolled bleeding disorders and coagulopathy
- Prostate cancer
- Acute Urinary Tract Infection (UTI)
- Severe urethral stricture

WARNINGS

- Everyone in the room is required to wear protective eyewear.
- Do not fire the laser unless the aiming beam is visible and directed at the targeted tissue.
- Never activate the laser energy unless the fiber tip extends visibly beyond the tip of the endoscope.
- Do not use this laser fiber in the presence of flammable anesthetics, combustible materials, or in an oxygen enriched environment due to risk of fire or explosion.

PRECAUTIONS

- Do not bury the fiber in tissue. Do not use the fiber as a probe.
- Do not retract, dissect, or probe tissue with the tip of the fiber. Damage may occur to the fiber tip.
- Firing the working beam continuously at one location (not sweeping the beam) may result in difficult to control bleeding or perforation.
- If extended contact between the fiber tip and tissue is unavoidable, use the lowest power at which acceptable vaporization can be achieved, but no more than 80 W.
- If the working beam or aiming beam exits the fiber in an unusual direction, cease firing immediately, determine if there has been unintended tissue damage and take appropriate action. Replace the fiber before continuing with the procedure.
- The surgeon should carefully assess the target and surrounding tissue, and then begin at the lowest appropriate power, with short duration exposures. Do not adjust the power of the laser

until the effect of the laser on the tissue has been evaluated. Note the surgical effect and adjust the settings and sweeping speed until the desired effect is obtained.
- Use caution when lasing tissue in close proximity to known arteries, nerves, and veins.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following:

- Abdominal bloating (intestinal gas)
- Acute renal failure
- Allergic reaction
- Aspiration
- Bladder neck contracture
- Bladder spasm
- Bleeding
- Burn
- Chills
- Clot retention
- Contamination of the device may lead to injury, illness, or death of the patient
- Deep venous thrombosis
- Delay in healing
- Dysuria
- Edema
- Embolism
- Epididymitis
- Erectile dysfunction (ED)
- Extravasation
- Fatigue or weakness
- Fever
- Fluid overload/hyponatremia
- Gas over-distension
- Hematospermia
- Hematuria
- Infection
- Inflammation
- Leukocytosis
- Malfunction of laser fiber or console resulting in an injury or prolonged procedure
- Nocturia
- Overactive bladder
- Pain:
    - Abdominal pain unresponsive to Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
    - Arm or leg pain
    - Headache
    - Back/low back pain
    - Body aches
    - Pelvic

    - Penile
- Pelvic hematoma
- Penile urethral injury
- Perforation
- Pneumothorax
- Profuse perspiration (not fever-related)
- Prostatitis
- Pulmonary embolus
- Retrograde ejaculation
- Sepsis
- Stricture
- Tissue damage
- Tissue sloughing
- Ulceration
- Unretrieved device fragment
- Ureteral orifice injury
- Urethral stricture
- Urgency
- Urinary frequency
- Urinary incontinence
- Urinary retention
- Urinary tract infection

As with conventional endoscopic treatment, adverse reactions such as fever, chills, sepsis, edema, and hemorrhage are possible after laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or the application of the laser. Use caution when treating patients who had difficulty with previous endoscopic procedures.