Brief Summary Document

Overview

Product

GreenLight XPS™ Laser System	IFU 51520079-01
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 physician.

Users of the GreenLight XPS Laser System should read the manual thoroughly before attempting surgical procedure. Pay attention to all warnings, contraindications, precautions, and adverse events and other related material. Failure to thoroughly understand and follow all instructions may result in harm to the patient or the user of the laser system.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

Content

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 urological soft tissue.

Indication for Use:

- Vaporization of prostate tissue for men suffering from Benign Prostatic Hyperplasia.
- Endoscopic urological surgery (ablation, vaporization, incision, excision, coagulation and hemostasis) of soft tissue in adults.

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:

- Acute urinary tract infection (UTI)
- Calcified tissue (especially tumors)

- General medical condition that contraindicates surgical intervention
- Hemostasis of vessels over approximately two millimeters in diameter
- Prostate cancer
- Severe urethral stricture: severe stricture shows visible narrowing on urethrography or ultrasonography, with near total obstruction that makes passage of instruments difficult or dangerous.
- Uncontrolled bleeding disorders and coagulopathy
- When appropriate anesthesia is contraindicated by patient history
- When laser therapy is not considered the treatment of choice

The GreenLight XPS Laser System is contraindicated in the presence of severe urethral strictures; however, the system can be used in the treatment of urethral strictures with proper cautions. A severe stricture shows visible narrowing on urethrography or ultrasonography, with near total obstruction that makes passage of instruments difficult or dangerous. Use caution to avoid injury to urethral tissue.

WARNINGS

Console 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.
- When using anodized, black chrome finished, or ebonized instruments during a surgical procedure, additional care should be taken to prevent burns. These instruments will become extremely hot when they come in contact with a laser beam and are not able to dissipate heat quickly. When tissue is touched under these conditions, a burn may result.

Fiber Warnings:

To avoid fiber damage or breakage:

- Reuse or misuse of the fiber will result in an increased potential for damage to the fiber and ancillary equipment.
- In the unlikely event of a detached tip, it may be visually located through an appropriate scope and removed using forceps. Irrigate the area thoroughly to remove any traces of fiber or other material. If the aim beam or working beam exit the end of the fiber, discontinue use immediately and discard the fiber.

Usage Warnings:

- Do not fire the laser when the red octagon is visible as this may result in damage to the cystoscope or unintended tissue.
- The laser beam is emitted at an angle. Avoid forward deflection of the beam at the bladder neck as damage to the ureteral orifices may occur.
- Do not press the footswitch while checking the aim beam. Pressing the footswitch will activate the laser beam. Inappropriate activation of the laser beam may result in injury to the user, personnel in the room, or the patient.
- Do not use if the red colored aim beam is not visible. Replace the fiber with a new one. Use of a damaged fiber may result in injury to the patient or injury to the user.
- Do not press the footswitch without having the appropriate protective eyewear. Pressing the footswitch may activate the laser beam. Activation of the laser beam when not wearing protective eyewear may result in eye injury to the user, personnel in the room, or the patient. Refer to the laser system's User Manual for requirements concerning eye protection.

Fire Hazard Warnings:

- To prevent drape fires or burns:
    - Do not wrap portion of the fiber in drapes or cloth.
    - Do not attach the fiber directly to surgical drapes with a crushing clamp such as a hemostat.
    - Do not place or drop instrumentation onto the fiber.
    - Do not step on the fiber.
    - Do not bend the fiber where it connects to the laser console.

- 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 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 become fully acquainted with the unique surgical effects produced with the laser system before clinical use. These effects include coagulation, depth of penetration, and cutting intensity.
- The risk of combustion, perforation, and laser-induced hemorrhage, all of which could cause serious or fatal complications, must be fully explained to the patient.
- Caution should be taken when radiation therapy and laser therapy are to be used concurrently, including more stringent post-operative monitoring. Patients who have undergone radiation therapy may present a greater risk of perforation or tissue erosion.
- Use caution when treating patients who had difficulty with previous endoscopic procedures.
- BSC has no clinical information or experience concerning the use of the laser system on pediatric patients or pregnant women or nursing mothers.
- A basin of water should be available in case a fire should occur.
- Avoid firing the laser if the fiber tip is in an air pocket.
- Use of lower power levels and shorter exposure times are required to prevent thermal damage to underlying structures, for example, to thinwalled structures, such as the bladder.
- The laser may not be effective for coagulation in massive hemorrhage situations. The surgeon must be prepared to control hemorrhages with strident alternative non-laser techniques, such as ligature or electrocautery.
- The fiber and GreenLight XPS Laser System can be used in the treatment of urethral strictures with proper cautions. Use caution to avoid injury to urethral tissue. Refer to contraindications regarding severe urethral strictures.
- Do not activate the laser if the blue triangle is not visible. Damage may occur to the fiber or endoscope and require replacement of the damaged devices.

ADVERSE EVENTS

Users should read and understand the specific indications, contraindications, warnings, precautions, and current adverse events included with the fiber used in conjunction with the GreenLight XPS Laser System. Potential adverse events associated with the GreenLight XPS Laser System are, but 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.