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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING: Users of the GreenLight XPS™ Laser System should read this manual thoroughly before attempting surgical procedure. Pay attention to all warnings, contraindications, precautions, and adverse events in this manual 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.

1 DEVICE DESCRIPTION

The GreenLight XPS Laser System is designed for the vaporization and coagulation of soft tissue using light. One example procedure is the endoscopic (transurethral) resection of the prostate for the treatment of Benign Prostatic Hyperplasia (BPH). The laser system consists of a console, which generates the green laser light and a fiber optic delivery device that transmits laser light from the console to the patient. This laser system is not intended to treat prostate cancer.

1.1 Console

The console is a diode-pumped solid-state laser utilizing Nd:YAG laser gain medium and Acousto-Optic Q Switch. The primary wavelength is 1064 nm. Frequency-doubling crystal is used to generate a 532 nm output beam. Quasi-CW pulse repetition rate is 23.6 kHz. Pulse duration is approximately 100 ns. Pulse energy is approximately 8 mJ at maximum power (180 W). The console generates visible green 532 nm laser light. In vaporization mode, the power settings range from 20 W to a maximum power determined by the fiber delivery device. In coagulation mode, the power settings range from 5 W to 40 W. The console features a plug and play capability that self-adjusts to the facility's supply voltage, eliminating the need for electrical modifications of the operating facility. The console includes internal cooling mechanisms ensuring safe operating temperatures with no external water connection. Laser energy emission and console status changes are activated through a surgeon-controlled, color-coded footswitch or console touchscreen feature.

1.2 FiberLife

The console is equipped with the FiberLife feature. The FiberLife feature continuously monitors the temperature of the tip of the fiber and momentarily stops the laser emission when the fiber gets too hot. In most cases, this will prevent damage to the fiber if tissue or vapor bubbles accumulate on the tip or there is excessive heating of the fiber.

In most cases, the laser will turn back on immediately and the procedure continues without interruption. There will be noticeable blinking of the working beam. If the FiberLife feature is activated continuously, vaporization efficiency will be significantly reduced. In this case, the fiber should be cleaned or replaced. The console will automatically detect this condition, put the laser in Standby mode, and display a message.

The FiberLife feature will stop laser emission if the laser is accidentally fired while inside the cystoscope. Generally, this will prevent serious damage to the cystoscope. Some discoloration of the metal may still occur, which can increase the possibility of corrosion.

1.3 Vaporization

The console uses photo-selective vaporization for the resection of soft tissue. The 532 nm green laser light emitted is strongly absorbed by oxyhemoglobin in red blood cells. Absorption of the laser light energy results in the generation of heat, which bursts cells, effectively vaporizing the targeted tissue. Additionally, the heat can coagulate blood vessels near the resected tissue, allowing for a clear surgical field. If bleeding occurs, the console also has a pulsed coagulation feature.

1.4 Coagulation

The console has a pulsed coagulation feature. In this mode, activated when the coagulation (coag) footswitch is pressed, laser emission is pulsed at a rate of ~12.5 Hz with a duty cycle of ~25 %. This pulse mode improves the coagulative effect.

1.5 User Information

Only persons trained in the use of the laser console and who have sufficient medical knowledge should use the GreenLight XPS Laser System. The user should have a demonstrated understanding of the laser console's operation and the risk associated with improper use.

1.6 Contents

- Laser Console
- Footswitch
- Fiber Pole
- Key Chain
- Laser In-Use Sign
- Physician Protective Eyewear
- Spectator Protective Eyewear

2 INTENDED USE/INDICATIONS FOR USE

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:

- **General Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue as well as in endoscopic (for example, laparoscopic) or open surgeries.

- **Gastroenterology:** Tissue ablation and hemostasis in the gastrointestinal tract; esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma; gastrointestinal hemostasis (including varices, esophagitis, esophageal ulcer, Mallory-Weiss tear, gastric ulcer, angiodysplasia, stomal ulcers, non-bleeding ulcers, gastric erosions); gastrointestinal tissue ablation (benign and malignant neoplasm, angiodysplasia, polyps, ulcers, colitis, hemorrhoids).
- **Gynecology:** Vaporizing, incising, or coagulating tissue associated with treatments of conditions such as endometriosis; cervical, vulvar, and vaginal intraepithelial neoplasia; condyloma acuminata; uterine septum; intrauterine adhesions; submucosal fibroids.
- **Head and Neck/Otorhinolaryngology (ENT):** Tissue incision, excision, ablation, and vessel hemostasis.
- **Neurosurgery:** Incising, excising, coagulating, and vaporizing neurological tumors of the firm textured type.
- **Ophthalmology:** Post-vitrectomy endophotocoagulation of the retina.
- **Plastic Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue in endoscopic and open procedures.
- **Spinal Surgery:** Percutaneous lumbar discectomy.
- **Thoracic Surgery:** Vaporizing, coagulating, incising, excising, debulking, and ablating of soft tissue, including lung tissue in thoracoscopic or open procedures.
- **Urology:** 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).

The GreenLight XPS™ Laser System is intended for the hospital, office, and outpatient surgery center markets.

3 CONTRAINDICATIONS

The laser system is contraindicated for patients with the following conditions:

- General medical condition that 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

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.

4 WARNINGS

- Everyone in the room is required to wear protective eyewear.
- Never use a clamp to secure the laser fiber to a drape. The use of a clamp to secure a fiber may cause the fiber to bend at sharp angles, which can damage the fiber, causing an unsafe condition. The fiber can break and release laser energy, causing a burn in the protective jacket. If undetected, this condition will result in a burn or ignition of flammable materials.
- 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.
- Unauthorized use of internal controls, adjustments to the equipment, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.
- Warning signs are not interchangeable. Select a sign that is appropriate for the wavelengths in use.
- 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.
- Unauthorized modification of this equipment is not allowed. Do not attempt to repair or alter any components/parts of the GreenLight XPS Laser System. All repairs and servicing are to be performed only by Boston Scientific Corporation (BSC) or personnel authorized by BSC.

5 PRECAUTIONS

- Before operating the laser system, surgeons and all staff operating the laser should carefully read and become familiar with the User's Manual.
- Do not attempt to turn on the laser system until it has been installed and tested by a BSC service engineer. Severe damage to the laser system may result.
- Alterations in surgical approach or technique may be required to accommodate laser use.
- The laser system is a surgical device used by surgeons who have been trained in laser surgery through courses, preceptorships, or under the guidance of other surgeons knowledgeable in laser use.
- 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.
- As with non-laser treatments, adverse reactions such as fever, chills, sepsis, edema, and hemorrhage may occur after laser treatment. In extreme cases, death may occur due to procedural complications, concurrent illness, or the application of the laser.
- 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 with patients who had previous esophageal/tracheal fistulae or episodes of aspiration.
- Use caution when treating patients who had difficulty with previous endoscopic/cystoscopic procedures.
- No claim is made that the laser system will cure the medical condition or eliminate the diseased entity. Repeated treatment or alternative therapies may be required.
- BSC has no clinical information or experience concerning the use of the laser system on pregnant women or nursing mothers.
- Before turning the laser system on, operating room personnel and the patient should be wearing protective eyewear suitable for the laser energy.
- A basin of water should be available in case a fire should occur.
- Do not press either footswitch while checking the aiming beam.
- To avoid damage from the treatment beam or its backscatter, it is recommended the fiber be fully visible in the visual field. Do not fire the laser unless the aiming beam is visible and directed at the intended target. Aim and use the laser only on tissues that are in full view.
- Avoid firing the laser if the fiber tip is in an air pocket.
- Do not bury the fiber in tissue. Do not use the fiber as a probe.
- 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 of lower power levels and shorter exposure times are required to prevent thermal damage to underlying structures, for example, to thin-walled structures, such as the bladder.
- Tissue perforation can occur if excessive laser energy is applied. This can occur using excessive laser power or the application of power for excessive periods of time, particularly on diseased tissue. Examples of diseased tissue include tissue that has undergone brachytherapy, tissue that is infected, or tissue that has thinned due to another underlying disease other than BPH.
- Use caution when lasing tissue in close proximity to known arteries, nerves, and veins.
- Use caution to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
- 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 surgeon should schedule follow-up visits in the same manner as for patients undergoing such surgery with other modalities.
- Exercise care for special risks related to the disposal of the device. See End of Useful Life section.
- The laser system must be kept dry during storage and transport with temperatures between:
  - 32 °F to 104 °F (0 °C to 40 °C) with all water drained from system
  - 39 °F to 104 °F (4 °C to 40 °C) with cooling system charged with distilled or deionized water

  Improper storage or transport of the laser system may result in damage to the cooling system, optical resonator, and other critical components.

6 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)
- Fatigue or weakness
- Fever
- Fluid overload/hyponatremia
- Gas over-distension
- Hematospermia
- Hematuria
- Infection
- 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

6.1 Some Adverse Events Further Explained

Bleeding: Patients may experience bleeding at the site of the laser therapy during or after laser therapy. Post-treatment hemoglobin and hematocrit are recommended lab tests to assess the severity of bleeding.

Fever and Leukocytosis: Immediately after laser therapy, the patient may experience fever and leukocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Cultures may be indicated to exclude the possibility of infection.

Pain: Short-lived pain may occur immediately after endoscopic/cystoscopic laser therapy and may persist for 48 hours.

Perforation: Perforation can occur as a result of excessive exposure to laser radiation. Perforation can occur from tumor erosion, or as a result of endoscopic/cystoscopic procedure. To clinically diagnose perforations, patients must be closely monitored post-operatively through physical assessment of clinical symptoms, hematology studies as deemed appropriate, and radiography.

Sepsis: Laser-ablated tissue may become infected after therapy. If a question of sepsis exists, a culture should be taken and other appropriate evaluations made.

As with conventional endoscopic treatments, 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.

6.2 Complications And Risks By Indication

For all indications, see Intended Use/Indications for Use section.

General Surgery

Complications and Risks: See Adverse Events for general information. There is a potential risk of thermal damage at the site of the incision.

For endoscopic/laparoscopic procedures, there are no known complications and risks specific to general surgery other than those associated with laparoscopy procedures in general (that is, over-distension, subcutaneous emphysema).

See Contraindications for general information. There are no known contraindications specific to general surgery at this time. Endoscopic/laparoscopic procedure patients should be treated with alternative methods when laparoscopy is contraindicated.

Gastroenterology

See Adverse Events for general information.

The risk of combustion, perforation and laser-induced hemorrhage, all of which could cause serious or fatal complications, must be fully explained to the patients.

Use caution 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 with patients who had previous esophageal/tracheal fistulae or episodes of aspiration.

Discontinue laser therapy immediately if the patient develops cardiopulmonary problems.

To avoid the potential risk of endoscope ignition or damage from the treatment beam or treatment beam backscatter, it is recommended that the fiber extend 1 to 2 cm beyond the distal port of the endoscope, so it is entirely in the visual field.

After esophageal procedures, swallowing may be paradoxically worsened, rather than immediately improved. This is caused by secondary tissue edema. Explain this potential problem to the patient before therapy.

See Contraindications for general information. There are no known contraindications specific to gastroenterological use at this time.

Gynecology

See Adverse Events for general information. There are no known complications and risks specific to gynecology at this time.

See Contraindications for general information. These procedures may be contraindicated for women who are pregnant or have a suspected pregnancy, and for whom hysteroscopy or laparoscopy, or open abdominal surgery would not be appropriate. These procedures may be contraindicated for women with other medical or surgical conditions that would contraindicate laparoscopic or hysteroscopic surgery.

Head and Neck/Otorhinolaryngology (ENT)

See Adverse Events for general information. For cosmetic purposes, it is recommended that initial incisions be performed with conventional scalpels or that skin edges incised with the laser be cut back by approximately 0.5 mm to 1.0 mm with a scalpel before closing the skin.

Use caution to protect the endotracheal tubes. Contact with the laser beam could result in serious or fatal patient complications. When using the laser for coagulation in ENT applications, it is essential to de-focus the laser beam spot to preclude tissue damage beyond the desired coagulation site. Unintended tissue damage could result from a focused treatment beam. While clinical experience to date has demonstrated that lasers can be safely used for hemostatic in ENT, there have been reports of serious complications when lasers are used inappropriately.

The main risk of laser use is thermal damage to the surrounding vital structures, which is risky for oval window surgery as energy applied directly to the open oval window will pass directly through the perilymph and be absorbed by the inner ear structures. Other complications related to laser surgery include, but are not limited to burns, scarring, hemorrhage, perforations, fires and explosions, eye injury, electrical shock, swelling, and obstruction.

Thermal damage caused by laser treatment has been related to adverse side effects and other risks. For example, where laser tissue welding is used, such as in laser-assisted myringoplasty, a low strength anastomosis or thermal damage to tissue are the main concerns. Delayed post-operative pain and slow healing are both thought to be related to thermal damage caused by the laser during tonsillectomy.

Compared to traditional scalpel cutting surgery, laser treatment has sometimes resulted in slower healing in procedures such as uvulopalatoplasty and tonsillectomy. Tissue necrosis, post-operative edema, or bleeding was rarely seen. Slow healing increases the risk of infection. The presence of necrosis could leave the tonsillar bed more vulnerable to infection.

See Contraindications for general information. There are no known contraindications unique to ENT.

Neurosurgery

Particular care must be exercised in heating the brain stem area. Flushing with cool saline in such areas will reduce heat build-up and related bradycardia.

See Adverse Events for general information. There are no known specific complications and risks to neurosurgery use at this time.

See Contraindications for general information. These procedures are contraindicated for the treatment of necrotic or calcified tumors.

Ophthalmology

See Adverse Events for general information. There are no known specific complications and risks to ophthalmology use at this time.

See Contraindications for general information. These procedures are contraindicated for the treatment of necrotic or calcified tumors.

Spinal Surgery

See Adverse Events for general information. Some patients have reported an inflammatory response four to ten days post-operative at the site of surgery. This has occurred in patients who have reported a successful procedure post-operatively and are otherwise asymptomatic.

The occurrence of this adverse event has reportedly been significantly reduced by the administration of an anti-inflammatory agent, into the surgical site, at the completion of the procedure.

With surgical procedure in the spine, there is the potential risk of infection, inflammation and post-operative pain. The injection of antibiotics, anti-inflammatory drugs, and analgesics into the surgical area at the completion of the procedure has been reported to reduce the occurrence of these adverse events.

See Contraindications for general information. General anesthesia is specifically contraindicated for this procedure.

This procedure is contraindicated, if the following conditions exist:

- Non-contained disc herniation (leakage of dye into epidural space by discogram)
- Radiographic evidence of spinal stenosis > 50 %
- Progressive neurological loss
- Cauda Equina Syndrome
- Tumor
- Infection
- Fracture
- Spondylolisthesis
- Spinal instability
- Free fragments or other significant pathologies
- Significant (> 30 %) narrowing of disc space, possible facet damage
- Patients with previous surgery/chemonucleolysis at the indicated level may be a candidate for laser disc decompression.
- All other factors should be considered.

Plastic Surgery

The laser is not intended for use for skin incision or liposuction. See Adverse Events for general information. Initial skin incision using the laser may result in undesirable scar formation.

See Contraindications for general information. There are no known contraindications unique to plastic surgery.

Thoracic Surgery

The use of contact delivery devices (for example, sculptured fibers) on lung tissue, in conjunction with the wavelength, is considered investigational. When performing thoracoscopic surgery it is vital for the surgeon to appreciate that the view provided is monocular (not binocular) and that depth perception is decreased. Practice on the part of the surgeon to get the feel of operating through a monocular scope is strongly recommended before clinical use.

In surgery of a body cavity that is insufflated, the surgeon and the anesthesiologist must appreciate the risk of embolism, should a blood vessel be opened. Most surgeons prefer CO2 as the pressurizing gas of choice, as it is readily absorbed and does not lead to embolism. The anesthesiologist should monitor the patient for unusually high CO2 absorption, and adjust procedures, as necessary.

See Adverse Events for general information. There are no known specific complications and risks to thoracic surgery use at this time.

See Contraindications for general information. There are no known contraindications unique to thoracic surgery.

Urology

See Adverse Events for general information.

7 HOW SUPPLIED

Do not use if the package is opened or damaged.

Do not use if labeling is incomplete or illegible.

7.1 Handling and Storage

- Storage and transport temperature with all water drained from the system: 32 °F to 104 °F (0 °C to 40 °C)
- Storage and transport temperature with cooling system charged with distilled or deionized water: 39 °F to 104 °F (4 °C to 40 °C)
- Store in a dry place

When in storage or transport outside of the recommended temperature ranges, damage may occur to the cooling system, optical resonator, and other critical components. The console should be drained using the field drain procedure. For complete draining procedure, contact BSC technical support. When the console is drained and in storage, the desiccant pack should be replaced on a six-month interval.

8 SAFETY

8.1 Eye Injury

Visible light laser energy passes through the transparent components of the eye (cornea, lens, aqueous, and vitreous humor), and is focused on the retina. This light can cause an accidental retinal burn. The degree of injury to the eye will depend upon the power of the beam, how focused the beam is, and how long the eye is exposed to the beam.

Protective eyewear for the operating room staff and patient should be provided. Laser eyewear may not be interchangeable between lasers of different wavelength, power, or divergence angle.

WARNING: It is required for everyone in the room to wear protective eyewear.

Eyewear has been designed to protect operating room personnel from the 532 nm laser energy. The eyewear has a minimum optical density (OD) of 6.0 at 532 nm. The eyewear requirements for EU are 532 D L6. These types of laser protective eyewear include:

- Nearly clear physician laser protective eyewear — The essentially clear lens material has high visible light transmission and minimal color distortion.
- Orange protective eyewear — Although it has good visible light transmission, the orange color of the plastic lens causes some color distortion.

8.2 Burns

Personnel using lasers should be knowledgeable of the fire hazards associated with laser use. Accidental irradiation of tissue other than the target tissue may result in a burn or vaporization. Surrounding the target area with moist drapes or saline-soaked sponges will keep it moist and greatly reduce this hazard.

Flammable or combustible items in the laser environment may include flammable liquids or combustible ointments, gases, plastics, paper or gauze materials, adhesive or plastic tapes, and endotracheal tubes.

Laser appropriate fire extinguishers and water should be available where lasers are used. Care and precision in aiming and applying laser energy are important.

WARNING: Never use a clamp to secure the laser fiber to a drape. The use of a clamp to secure a fiber may cause the fiber to bend at sharp angles and damage the fiber. To do so can result in an unsafe condition. The fiber can break and release laser energy causing a burn in the protective jacket. If undetected, this condition will result in a burn or ignition of flammable materials.

8.3 Reflection of the Beam From Instruments

Use caution when aiming the laser beam to prevent reflection of the beam off metallic surgical instruments. Mirror-finish instruments are especially dangerous as they have highly reflective surfaces. The laser light reflected from such instruments is intense and potentially harmful.

Matte, dull, satin-finished, or ebonized instruments have fewer glares, and those with curved surfaces do not reflect light as intensely. While these instruments usually produce a more diffused reflection that is less harmful, this reflection can still be damaging. Protective eyewear should be worn at all times to prevent eye damage.

WARNING: When using anodized, black chrome finished, or ebonized instruments during a surgical procedure, additional caution 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 quickly dissipate heat. When tissue is touched under these conditions, a burn may result.

8.4 Ignition of Flammable Materials

The laser can ignite many materials used during a surgical procedure. Use of non-flammable materials is strongly recommended.

8.5 Electrical

Electrical hazards with the laser are the same with any electrical device. Use caution when plugging the unit into the wall outlet. The area must be free of water and user's hands must be dry.

Always disconnect the laser by grasping the plug and not the power cord. Examine the electrical cord routinely, if signs of wear are noted, contact BSC technical support to have it repaired or replaced.

8.6 Operating Room Environment

This section describes specific safety measures for the operating room to aid in the safe operation of the laser system. Medical Electrical Equipment (MEE) is not intended to be used in an oxygen-rich environment.

Laser Warning Signs

The area where the laser system is operated should be labeled. Warning signs that specify the laser wavelength being used should be posted at all operating room and access door entrances. Figure 1 is an example of a sign suitable for use with the laser system.

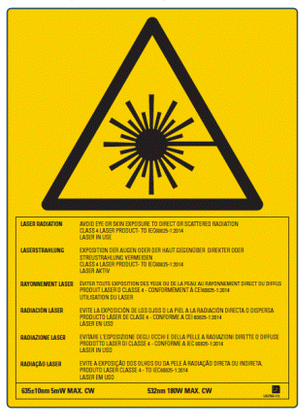


Figure 1. Laser Warning Sign

Remote Door Interlock

Always limit personnel in the operating room to those essential to the procedure. To protect intruding personnel from exposure to the laser beam, an optional remote door interlock can be connected from the console to the operating room entrance door. This interlock will automatically put the console in Standby mode if the door is opened during a procedure. The console will remain in Standby mode until the door is closed and the interlock is reset. Once reset, the user can place the console back in Ready mode and reactivate the surgical beam. The console cannot be placed in Ready mode, unless the interlock is reset.

If the use of the remote door interlock is desired, the biomedical personnel at the user's facility can connect it. The user should test the remote interlock before each use. Access to the console's interlock function is made through a socket located on the back panel of the console (see Figure 3).

Safety Recommendations

The following are general safety recommendations for the operating room and are not specific to the laser system:

- When using accessories, tools, disposables, or materials that were in contact with the patient, take protective measures to prevent cross-contamination.
- Keep drapes and towels moist to prevent their ignition and burning.
- Use non-flammable prepping solutions.
- Prevent combustion of methane gas by packing the rectum during perineal procedures.
- Do not use the laser in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

WARNING: Do not fire the laser unless the aiming beam is visible and directed at the targeted tissue.

8.7 Safety Features of the Laser System

The GreenLight XPS™ Laser System incorporates the following safety features:

- The laser will stop firing when the pressure is removed from either footswitch pedal.
- An automatic circuit breaker shuts the console off in the event of an electrical overload.
- The laser provides an operating room door interlock connection, which must be set up by the biomedical personnel.
- The key can only be removed when the key-switch is in the OFF position.
- An onboard microprocessor continuously monitors the status of the console and displays messages on the screen along with appropriate user prompts.
- Laser energy cannot be emitted from the console unless a fiber has been connected.
- Console will go into ready mode when the Ready button is touched on the touchscreen, or when the button on top of the footswitch is pressed.
- A fiber pole lifts and positions the fiber in a safe and unobtrusive position.
- A continuous audible tone is heard when the surgical beam is activated (that is, foot pedal is pressed). A higher frequency tone is heard for vaporization and a lower tone for coagulation.
- When the laser is fired for the first time after entering Ready mode, and whenever switching between vaporization mode and coagulation mode, a voice will annunciate the current mode.
- A 2-second delay occurs before laser energy is emitted after the laser is placed in Ready mode.
- An Emergency Laser Stop switch is available to disable the console immediately, in the case of an emergency.
- When switching between Ready and Standby mode, a voice will announce the current mode.

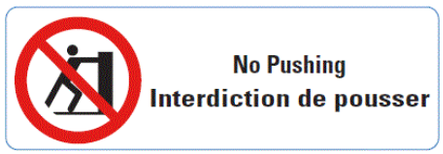
Note: Do not attempt to remove any panel from the console. All panels are fitted with tamper-proof fastenings. Any attempt to remove the panels, unless instructed by authorized BSC personnel, can damage the console and will void the manufacturer's warranty.

Note: The laser system should be protected against unauthorized use. When the console is not in use, remove the key from the key switch and place in a secure location.

WARNING: Unauthorized use of internal controls, adjustments to the equipment, or performance of procedures other than those specified herein, may result in hazardous radiation exposure.

WARNING: No modification of this equipment is allowed.

Tipping Hazard:



During transportation, pull or push the console carefully using the intended handle to prevent tipping.

WARNING: Console may tip if inclined at an angle of greater than 5 degrees.

Rolling Hazard: Secure the console with the wheel locks to prevent the unit from inadvertently rolling.

9 CONSOLE DESCRIPTION

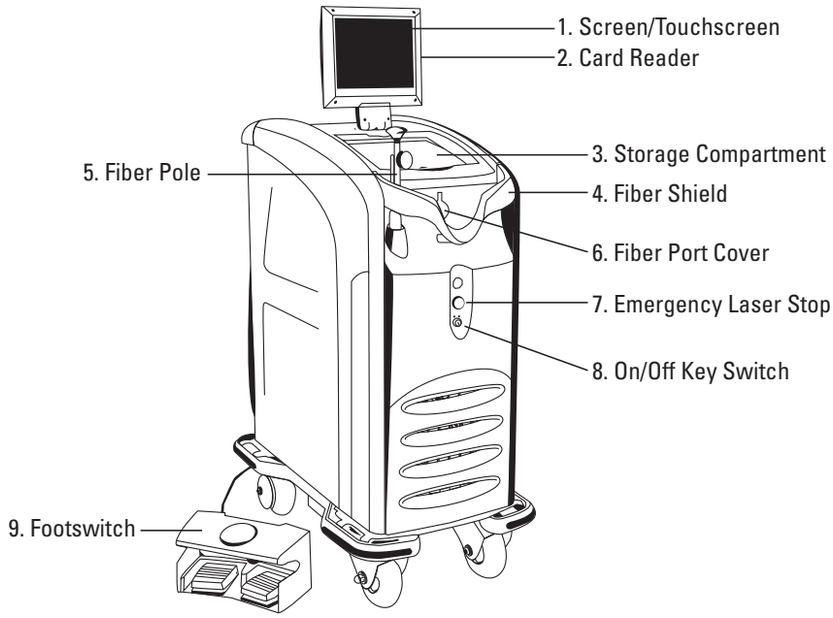


Figure 2. Front View of Console

1. Screen/Touchscreen — Displays user information:
   - Console status (Standby, Ready)
   - Laser output (in watts), separate display for vaporization and coagulation
   - Aiming beam brightness level
   - Energy meter (displays total number of Joules delivered)
   - Exposure time (displays total time light is emitted)
   - Buttons on the screen, when pressed, place the laser in either Ready or Standby mode
   - Error codes and screen prompts
2. Card Reader — Reads fiber card
3. Storage Compartment
4. Fiber Shield — Protects the fiber hub from inadvertent damage
5. Fiber Pole — Secures and protects the fiber (retractable)
6. Fiber Port Cover — Connection for fiber
7. Emergency Laser Stop — Turns console off and terminates laser light emission in case of emergency
8. On/Off Key Switch — Switches the console on and off
9. Footswitch — For control of laser emission

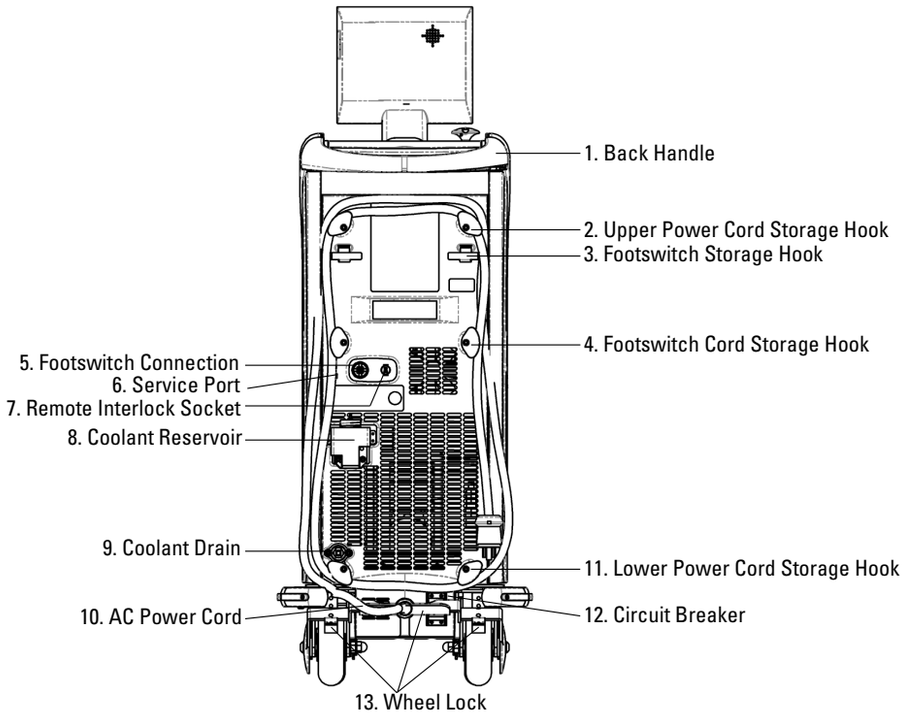


Figure 3. Back View of Console

1. Back Handle
2. Upper Power Cord Storage Hook — 2 upper hooks for coiling footswitch cord
3. Footswitch Storage Hook — 2 hooks for footswitch storage
4. Footswitch Cord Storage Hook — 2 hooks for coiling footswitch cord
5. Footswitch Connection
6. Service Port — USB ports for factory service only
7. Remote Interlock Socket — Can be connected to the room door so the footswitch will be disabled in the event of entry
8. Coolant Reservoir — For refilling the internal cooling liquid (see Coolant Refill Instructions)
9. Coolant Drain — For draining the internal cooling liquid (see Coolant Refill Instructions)
10. AC Power Cord
11. Lower Power Cord Storage Hook — 2 lower hooks for coiling power cord
12. Circuit Breaker — Automatically trips in the event of a power overload, shutting off power to the console
13. Wheel Lock — For locking and unlocking back wheels

10 ACCESSORIES

The operator must use accessories/tools that were cleared by BSC for use with the laser system. BSC assumes no liability and warranty for damage and consequential damage when using the laser system with non-qualified accessories/tools. Contact BSC for an up-to-date list of accessories/tools for the GreenLight XPS™ Laser System.

10.1 Video Camera Insert

A video camera insert must be inserted between the telescope and the camera (unless a comparable camera insert is built into the telescope). The video camera inserts have an optical density (OD) of 5 at a wavelength of 532 nm. This blocks most of the laser light, preventing saturation of the video camera sensor. The optimum transmission at wavelengths other than 532 nm and the video camera insert diameter depends on the video camera and telescope model.

10.2 Laser Protective Eyewear

Eyewear has been designed to protect operating room personnel from the 532 nm laser energy. The eyewear has a minimum optical density (OD) of 6.0 at 532 nm. The eyewear requirements for EU are 532 D L6.

- Physician protective eyewear — The essentially clear lens material has high visible light transmission and minimal color distortion.
- Spectator protective eyewear — Although it has good visible light transmission, the orange color of the plastic lens causes some color distortion.

11 INSTALLATION

This section provides general guidelines for the installation of the laser system. This laser system has specific installation requirements. It is the user's responsibility to fulfill these requirements before the installation of the laser system. Improper installation can result in intermittent operation and even damage to the laser system. Please read the below information carefully.

11.1 Responsibility of BSC

A BSC service representative will install the laser system. Upon arrival at the installation site, the representative will perform the following:

1. Verify appropriate electrical power is available.
2. Remove the console from the crate and inspect for damage.
3. Perform all optical, electronic, and system checks necessary to bring the laser into operation.
4. Inventory all shipped accessories.

11.2 Responsibility of Customer

Provisions for proper power must be made before the receipt and installation of the laser system. Return visits by service personnel for installation will not be covered under warranty. The customer should complete the Installation Checklist and return it to BSC or distributor. Upon completion of the pre-installation site preparation, contact BSC or the distributor to check shipment date and schedule installation of the system.

The laser system uses standard electrical service and has built-in cooling systems; therefore, installation requires minimal site preparation.

11.3 Positioning of the Console

The console must be positioned not more than 5 ft (1.5 m) from the centerline of the treatment table to ensure proper handling of the fiber.

Position the console at least 1 ft (0.3 m) from the wall for proper ventilation during use.

11.4 Power Requirements

The power source for the GreenLight XPS Laser System must be a single-phase service with voltage between 200 to 240 VAC, 50/60 Hz, current ≤ 20 Amp*. The laser will automatically adjust to the voltage and frequency within this range. The laser can function when some voltage change is present in the service line; however, the voltage may not vary by more than ± 10 %.

For BSC to provide the correct electrical plug, the customer must provide information about the installed receptacle in the facility to BSC before installation. Any 250 VAC, current ≤ 20 Amp*, two poles, three wire receptacle can be used if it meets the system's electrical requirements; meets facility, city, county, state, and country ordinances; and complies with EN 60601 for leakage current.

It is recommended the GreenLight XPS Laser System use a dedicated circuit breaker with a minimum rating of 16 Amp or higher to ensure normal operation.

* The 20 Amp rating indicates the current rating that the power source is expected to be capable of supplying to operate the laser at the maximum rated power output of 180 W. The 20 A rating is neither the minimum nor maximum operational main current requirement; it is a current in which internal circuitry protects the GreenLight XPS Laser System in an over-current condition.

12 INSTRUCTIONS FOR USE

12.1 Touchscreen and Footswitch

The touchscreen and footswitch are used to control the console. Laser parameters are selected and the console status is changed by using a touchscreen. Use the button on top of the footswitch to go between Ready and Standby laser status. The aiming beam is activated when the console is in the Ready mode or the surgical beam is activated. The surgical beam is activated by pressing a foot pedal. Press the yellow pedal for VAPOR and the blue pedal for COAG.

Power is set by touching the  or  buttons on the touchscreen. An audible tone will be heard when the buttons are pressed.

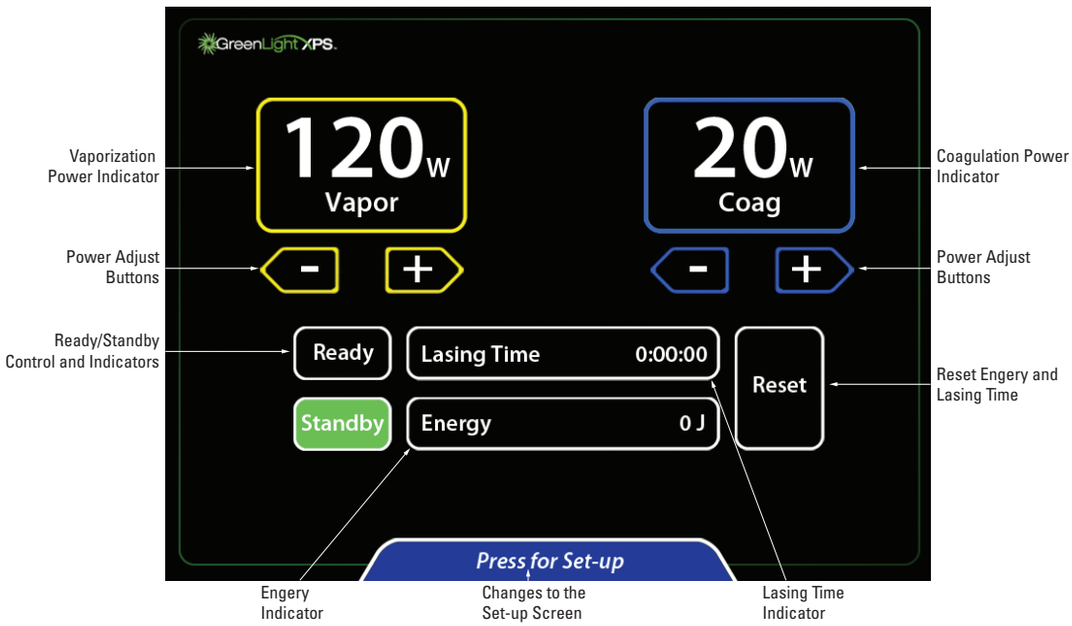


Figure 4. Touchscreen

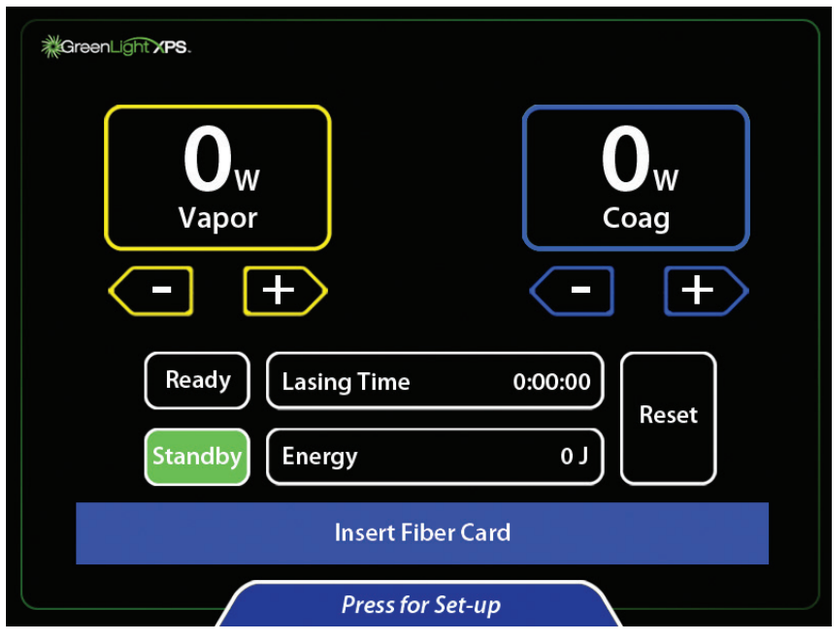
Figure 5. Footswitch

12.2 Preparation

1. Ensure protective eyewear is worn by all personnel including the patient.
2. Ensure the circuit breaker on the back of the console is OFF and connect the power cord to an appropriate electrical outlet.
3. Turn the circuit breaker to ON. On the front of the console, turn the key switch to ON.
4. The console's self-check mechanism detects most problems. A message will appear on the touchscreen to alert the user of problems. Courtesy messages alert the user of problems that the user can correct. Service prompts alert the user of a problem that requires a service call.

Note: It may take time (typically 5 to 15 minutes, but can be up to 40 minutes in rare cases such as extremely cold conditions) for the console to reach the proper operating temperature and pass all internal self-check tests before it is ready for operation.

5. The console will perform self-tests. When the tests are completed, a screen is displayed prompting to insert fiber card.



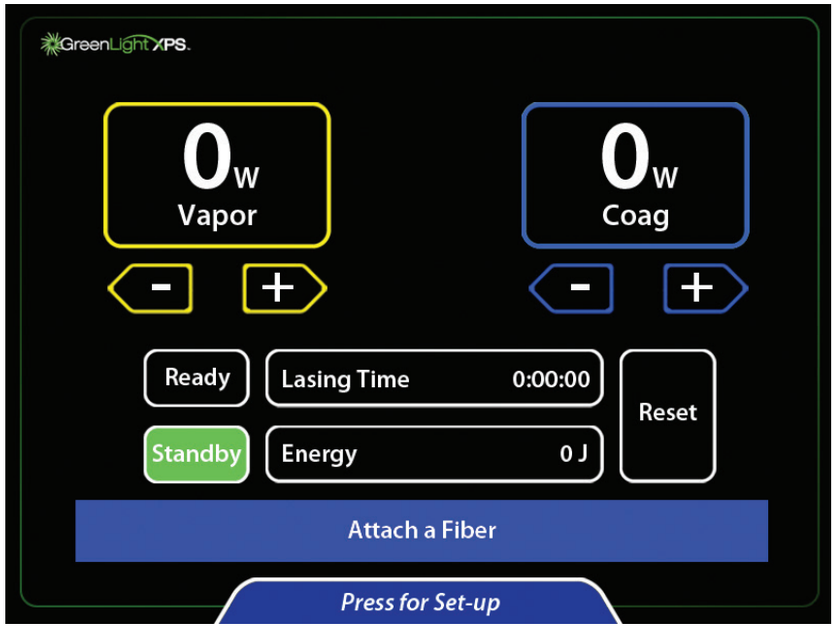
6. Prepare the patient for the procedure.
7. If the telescope does not include a built-in video camera insert, place a small or large video camera insert between the telescope and the camera. The video camera insert protects the camera from the high-intensity light.
   A. To insert the large video camera insert, hold the camera head pointing up. Place the video camera insert (labeled side facing towards camera) onto the camera head and depress the coupler. Attach the telescope to the camera.
   B. To insert the small video camera insert, hold the telescope portion of the cystoscope with the eyepiece pointing up. Place the video camera insert (writing side facing outward) into the eyepiece. Attach the camera to the telescope.

Note: Some telescopes have a built-in video camera insert to prevent the transmission of green light. In this case, do not insert an additional video camera insert between the telescope and the camera.

CAUTION: Do not touch multiple areas on the touchscreen at one time. Contact in multiple areas of the screen will result in no response from the command buttons. Only touch the desired command button when making adjustments to parameters.

8. Open the laser fiber box. Locate the fiber card attached to the outside of the pouch. Insert the fiber card into the card reader with the chip side facing operator. The touchscreen then prompts for fiber attachment.

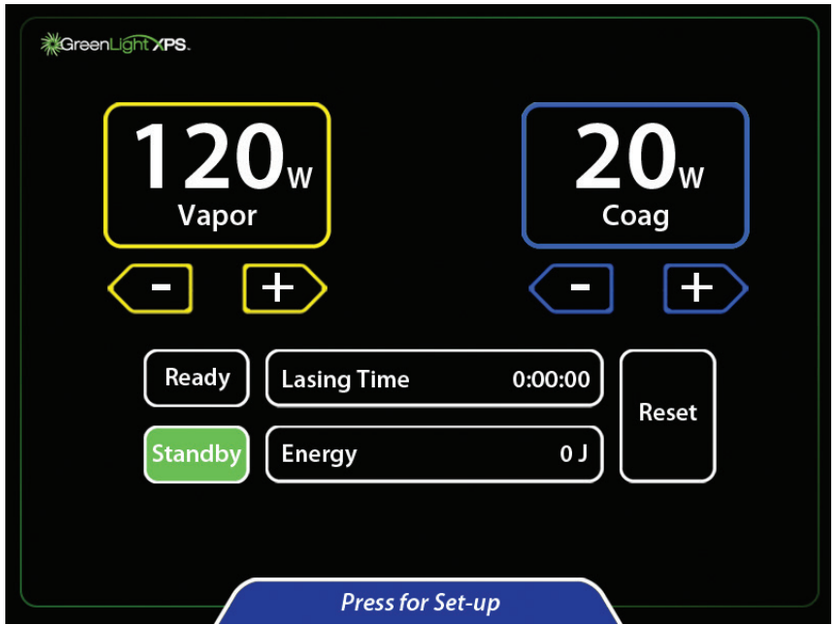
CAUTION: Do not remove the fiber card until procedure is complete.



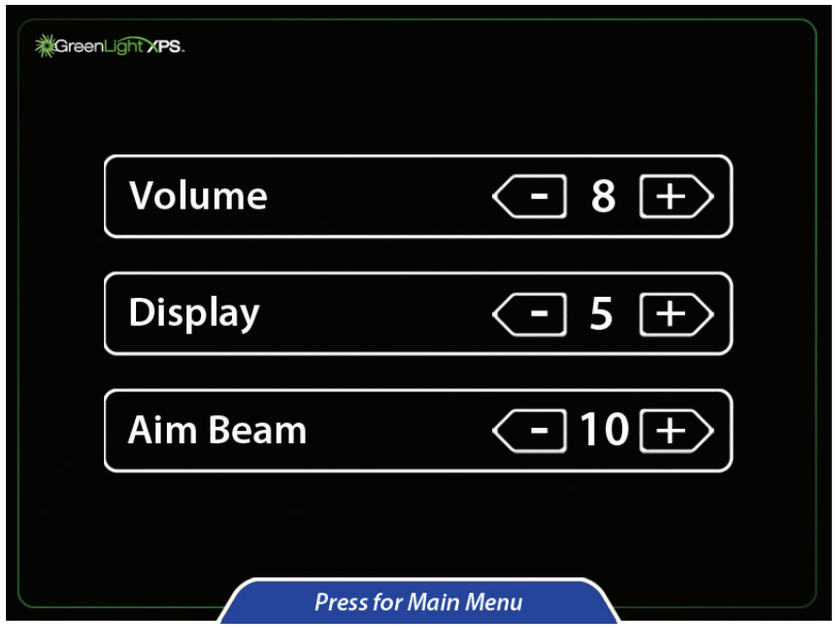
9. Open the fiber pouch and remove the sterile fiber using aseptic technique.

Note: To protect the laser-fiber interface, the fiber connector must be kept free of lubricant, cleaners, and other contaminants.

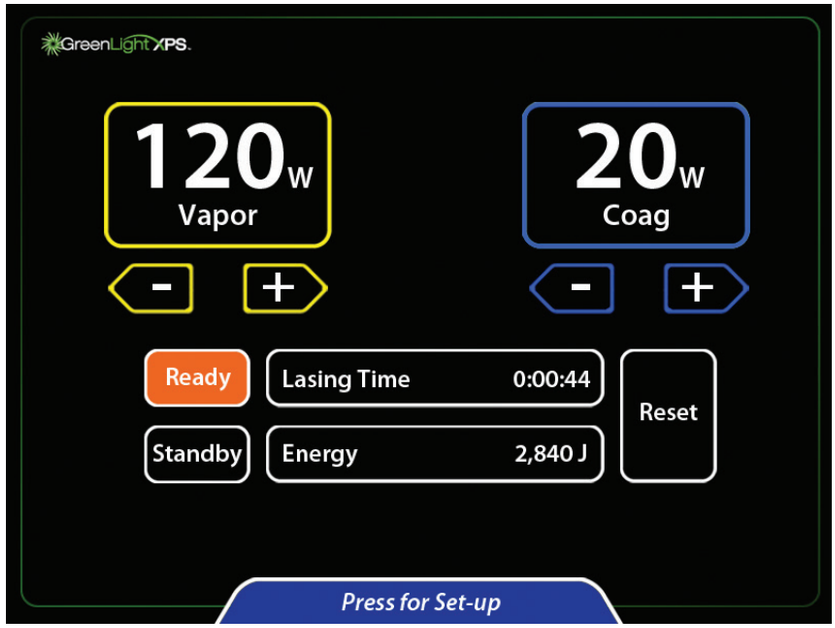
10. Connect the fiber to the fiber port of the console by pushing the connector into the fiber port (arrow on connector facing up) and turning it ¼-turn clockwise until it locks.
11. Follow additional instructions from the fiber package insert.
12. On the console, select the desired vaporization and coagulation setting by pressing the arrow keys.



13. To change the aiming beam intensity, display intensity, or audio volume, touch Press for Set-up at the bottom of the main screen.



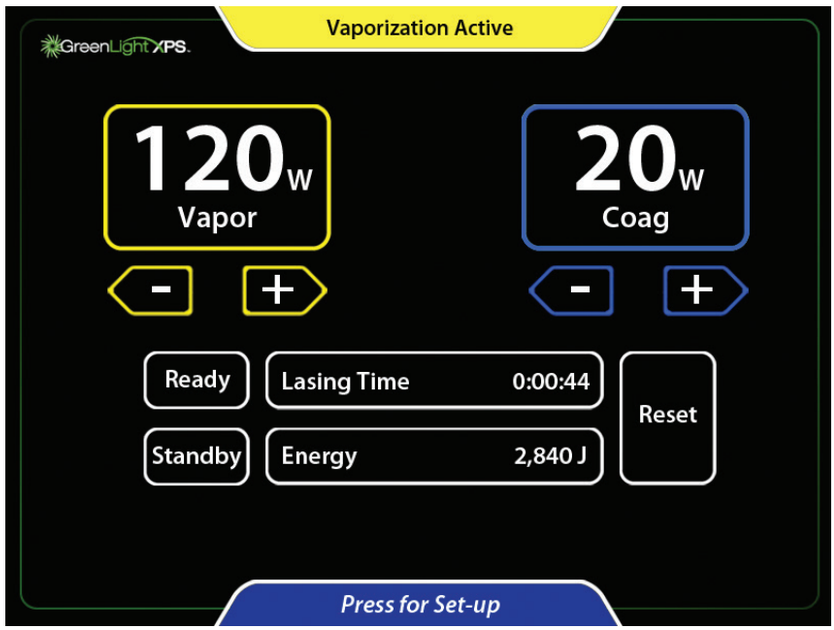
14. Adjust the desired setting by touching the arrow keys.
15. To return to the main screen, touch Press for Main Menu at the bottom of the screen.
16. Press the Ready button to activate the aiming beam. When the Ready button turns orange, the laser system is ready for use in a procedure.



12.3 Procedure

17. Advance the assembled cystoscope with the visual obturator through the urethra into the bladder using standard technique.
18. Advance the fiber through the fiber port and into the visual field of view. A suction tube can be connected to the outflow port of the cystoscope to direct outflow irrigation.
19. Rotate the control knob of the fiber to examine the fiber markings. The triangle is contralateral to where the laser beams fires. The triangle must be visible at all times while firing the beam. The red octagonal stop sign is aligned with the aiming beam of the fiber. Do not activate the working beam if the stop sign is centered in the field of view.
20. Advance the fiber to the treatment site. The tip of the fiber should be in clear view and extended beyond the tip of the cystoscope. The output beam of the fiber is aligned with index of the knob on the distal portion of the fiber.
21. Place the console in Ready mode to enable the footswitch.
22. Observe that the aiming beam is on the tissue targeted for treatment before activating the laser.

23. Laser energy will be emitted when a footswitch is pressed. The Active mode (Vaporization Active or Coagulation Active) is displayed at the top of the screen, depending on the footswitch pressed. Audio tone sounds during emission. The first time a given footswitch is pressed, the word Vapor or Coag will be vocalized, depending on which footswitch is pressed.



24. To go back to Standby, press Standby or step on the black Ready/Standby footswitch.
25. The laser emission can be disabled and the aiming beam can be turned off by pressing the Standby button on the touchscreen or by stepping on the black Ready/Standby footswitch.
26. Begin the procedure. Treatment times may vary based on tissue, power settings, and other factors.
27. Steadily rotate (sweep) the laser beam across a 30 ° to 40 ° arc over the targeted tissue, continually moving the laser beam while maintaining a working distance (fiber-to-tissue distance) between 1 mm and 3 mm. Adjust the sweep speed to achieve the desired tissue effect. Adjusting the power level will affect the rate of tissue removal.
28. Bleeding can often be controlled by sweeping the working beam around (not directly at) the bleeder while pressing the Coag footswitch. In Coag mode the beam is modulated to increase coagulation effectiveness. This causes the beam to pulse (blink on and off). Adjust the sweep speed and Coag power to achieve the most effective coagulation. Do not fire the laser directly at the center of the source of the bleeding.
29. Once the desired tissue has been treated, turn off the inflow and outflow valves of the cystoscope, and check for bleeding. If bleeding is occurring, it may be necessary to treat the bleeding.
30. Once the laser treatment has ended, fill the bladder with saline, and remove the cystoscope. Slowly drain the bladder and check the flow and color of the outgoing fluid. The placement of a Foley catheter may be necessary at physician discretion.
31. Prescribe post-procedure medication at physician discretion.

12.4 After the Procedure

32. When the procedure has ended, place the console in Standby mode.
33. Document the total lasing time and energy appropriately.
34. Remove the fiber from the cystoscope and discard per hospital procedures. Remove the cystoscope from the patient.
35. Remove the fiber card and discard.
36. Turn the key switch to the OFF position.
37. On the back panel, switch the circuit breaker to the OFF position and disconnect the AC power cable from the electric outlet.
38. To protect against unauthorized use, remove the key from the key switch and store in a secure location.
39. The footswitch can be stored on the back of the console.
40. Store the laser system per recommendations in Handling and Storage.

13 TECHNICAL DATA

Table 1. Console Specifications

Laser Type	Solid-state, frequency doubled
Wavelength	532 nm
Maximum Power Output at 532 nm	Limited by fiber delivery device, up to 180 W
Nominal Ocular Hazard Distance (NOHD)	67.1 meters (MPE = 10 W/m^2)
Repetition Rate	Vaporization: Quasi-CW (23.6 kHz) Coagulation: Modulated at ~12.5 Hz, ~25 % duty cycle
Maximum Aiming Beam Power	5 mW
Output Beam Divergence	≥ 0.078 Radians
Electrical Requirements	200 to 240 VAC, 50/60 Hz, ≤ 20 Amp, single-phase
Operating Temperature	50 °F to 86 °F (10 °C to 30 °C)
Operating Humidity	10 % to 90 %, non-condensing
Dimensions	Width: Approximately 22 in (56 cm) Depth: Approximately 36 in (91 cm) Height (screen down): Approximately 48 in (122 cm) Height (screen up): Approximately 55 in (140 cm)
Weight	Approximately 475 lb (215 kg)
AC Power Cable	15 ft (457 cm) maximum length, model 321203 AC power cable is a trademark of OLFLEX.
Footswitch Cable	13 ft (396 cm) maximum length, Cordset #997-G27-1 Footswitch cable is a trademark of LINEMASTER Switch Corporation.
Standards and Regulations	• Safety Regulations conforms with EN/IEC 60825 • EMF output conforms with IEC 60601-1 General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

13.1 Safety Classifications and Electromagnetic Compatibility

Classification: Type of protection against electric shock: Class I equipment

Table 2. Electromagnetic Emissions

Guidance and Manufacturer's Declaration — Electromagnetic Emissions		
The GreenLight XPS™ Laser System is intended for use in the electromagnetic environment specified below. The customer or user of the GreenLight XPS Laser System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment — Guidance**
RF Emissions CISPR 11	Group 1	The GreenLight XPS Laser System uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The GreenLight XPS Laser System is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Section 5 of Standard	

WARNING: This equipment/system are intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the GreenLight XPS Laser System or shielding the location.

Table 3. Electromagnetic Interference Resistance

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The GreenLight XPS™ Laser System is intended for use in the electromagnetic environment specified below. The customer or user of the GreenLight XPS Laser System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment — Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line(s) to ground	± 1 kV line(s) to line(s) ±2 kV line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T for 0.5 cycle) 40 % U_T (60 % dip in U_T for 5 cycles) 70 % U_T (30 % dip in U_T for 25 cycles) < 5 % U_T (> 95 % dip in U_T for 5 sec)	< 5 % U_T (> 95 % dip in U_T for 0.5 cycle) 40 % U_T (60 % dip in U_T for 5 cycles) 70 % U_T (30 % dip in U_T for 25 cycles) < 5 % U_T	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GreenLight XPS Laser System requires continued operation during power mains interruptions, it is recommended that the GreenLight XPS Laser System be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	N/A	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The GreenLight XPS™ Laser System is intended for use in the electromagnetic environment specified below. The customer or user of the GreenLight XPS Laser System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment — Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the GreenLight XPS Laser System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.7 * P ½
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = 1.7 * P ½ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 2.3 * P ½ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the GreenLight XPS Laser System is used exceeds the applicable RF compliance level above, the GreenLight XPS Laser System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the GreenLight XPS Laser System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4. Recommended Protective Distances

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system — for equipment and systems that are not life-supporting.

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The GreenLight XPS™ Laser System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GreenLight XPS Laser System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GreenLight XPS Laser System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = [3.5 / V1] * P ½	80 MHz to 800 MHz d = [3.5 / E1] * P ½	800 MHz to 2.5 GHz d = [7 / E1] * P ½
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

14 MAINTENANCE

The console has been designed to provide trouble-free operation with minimal maintenance. This section provides information on the routine maintenance and care required for the console.

The laser, cooling system, and control electronics are enclosed in a tamper-resistant console. The console does not contain user serviceable components.

14.1 Care of the Console

The console may be wiped down periodically with a cloth dampened with a weak solution of water and mild detergent or a mild cleaning agent. When cleaning the console, do not use harsh or abrasive cleansers, especially on the LCD screen panel, and do not pour water or other liquid over the console. If liquid is spilled on the console and it is thought that some may have gone inside, turn the unit off and call BSC technical support.

14.2 Preventative Maintenance

Regular, routine preventive maintenance should be performed by an authorized BSC service representative. Preventive maintenance consists of replacing consumable components such as video camera inserts, adjusting the calibration, and other tasks designed to keep the laser operating reliably and within specification. Preventive maintenance should be scheduled every 6 months unless otherwise determined by the BSC Service organization.

14.3 Coolant Refill Instructions

The console uses a vented internal cooling system that uses distilled or deionized water. Over time, some evaporation can occur resulting in a 'Please fill chiller reservoir with deionized water' courtesy message. The below instructions describe the water filling process for restoring the proper coolant level.

14.4 Instructions How to Refill Coolant

Note: The console holds approximately 1,700 ml of distilled or deionized water.

The below procedure is to be used to top off the water level for the console only if a low water fault occurs.

1. Turn the circuit breaker off and unplug the console.
2. Remove the reservoir cap in the back of the console.
3. Pour water into the filler reservoir until its level stops falling. Fill the reservoir to just above the halfway point, stop, and repeat until the level stops falling.
4. Plug system in, turn on circuit breaker, and turn the laser key switch to on.
5. Make sure that the filler reservoir is still about half full. Add water if necessary. Do not over-fill the reservoir.
6. Replace the cap.
7. Continue with console startup. If a 'Please fill chiller reservoir with deionized water' message is still present, call BSC technical support or the local GreenLight XPS Laser System distributor.

The console's self-check mechanism will detect most problems with the console and alert the operating room staff. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the console will either maintain status or require a solution before reactivating. See Troubleshooting for the types of messages.

14.5 End of Useful Life

When the laser system reaches the end of its useful life, dispose of all products, accessories, tools, and packaging materials in accordance with hospital, administrative, and/or local government policy. Used products should be collected separately and not disposed of as unsorted municipal waste.

15 TROUBLESHOOTING

The console's self-check mechanism will detect most problems with the console and alert the operating room staff. A message will appear on the screen at the time of system malfunction. Depending on the severity of the problem, the console will either maintain status or require a solution before reactivating.

Two types of messages are displayed:

- Courtesy Messages alert the user of problem conditions that the user can correct.
- Service Prompts alert the user of problem conditions that may require a service call.

15.1 Courtesy Messages

When a condition requiring user action is detected, a blue box containing a message describing the condition is displayed on the screen. The messages require that corrective action is taken.

Courtesy messages may display numerical information that may vary depending on the circumstances. In the below table, examples of such additional information are shown in bold.

Table 5. Courtesy Messages

Message	Corrective Action
Attach a Fiber	Attach a fiber.
Insert Fiber Card	A fiber card should be inserted.
Please fill chiller reservoir with deionized water	Restore coolant level (see Coolant Refill Instructions). Turn system off and add distilled or deionized water.
Fiber Approaching Joule Limit Less than **50,000** joules remaining	The number of Joules remaining on the fiber is displayed. If the procedure requires treatment beyond the limit, use a new fiber.
Fiber Expired **400,000** Joules used	The fiber has exceeded its rated Joule limit. The actual number of Joules used is displayed. If the procedure requires treatment beyond the limit, use a new fiber.
Attach a Footswitch	Plug the footswitch into the appropriate socket on the back of the unit. If this fails to resolve the problem, contact BSC technical support.
Release Footswitch Only one footswitch may be pressed at a time	User should reposition his or her foot, to contact only one footswitch.
Vapor footswitch disabled when in Standby	Press the Ready/Standby button on the screen or on the footswitch.
Coag footswitch disabled when in Standby	Press the Ready/Standby button on the screen or on the footswitch.
Fiber Port Overheated, try another fiber. If problem persists, contact Customer Care Center	Wait for device port to cool off. If problem repeats, replace the fiber. Contact BSC technical support if problem persists.
Check Fiber Card Insertion Remove and then re-insert card	Remove and reinsert fiber card. If problem persists, contact BSC technical support.
Invalid Fiber Card **10-2079** not valid for this system	The fiber attached is not a valid GreenLight XPS™ Laser System device. The part number of the invalid fiber is displayed. Replace the fiber with one approved for use with GreenLight XPS Laser System.
Card Read Error Remove and then re-insert card	Remove and reinsert fiber card. If problem persists, contact BSC technical support.
Fiber type does not match card type Try another fiber or card	Fiber ID does not match Fiber ID on fiber card. Make sure that the fiber card being used is the one that was packaged with the fiber.
Fiber Connection Error Check fiber connection or try another fiber	Usually this is caused by a bad fiber connector. If a second fiber gives the same message, the fiber coupler or its cabling may be damaged. If problem persists, contact BSC technical support.
Remote Interlock Opened	If the remote interlock has been connected to the operating room door, make sure the door is closed. Otherwise, make sure the remote interlock bypass connector is inserted into the socket on the back panel of the system.
Excessive FiberLife Activity Please clean and inspect fiber tip	FiberLife can detect if the fiber tip is overheating. Usually this is due to a dirty or damaged fiber. If the problem persists after cleaning or if the fiber is damaged, replace the fiber with a new one.

Message	Corrective Action
Fiber Approaching Time Limit Less than **5:00** minutes remaining	The amount of time remaining on the fiber is displayed. If the procedure requires treatment beyond the limit, use a new fiber.
Fiber Expired Time-out limit reached	The fiber has exceeded one of the time-out limits: Maximum Fiber Time Limit Reached (150 minutes). Inactivity Time-out Surpassed (30 minutes). If the procedure requires treatment beyond the limit, use a new fiber.
Check Footswitch Connection	Double check the footswitch connector: reattach and/or tighten connection. If problem persists, contact BSC technical support.

15.2 Service Prompts

An error code will appear in a yellow box on the screen. When these error codes appear, the user should accurately record the complete problem number and contact BSC technical support or call the local GreenLight XPS™ Laser System distributor.

Error codes are three or four digit numbers. The right two digits identify a specific problem. The remaining digit(s) on the left indicate the error group. These groups are described in the below table.

Table 6. Service Prompts

Error Group	Description
100	Resonator
200	Laser Power Supply
300	Master Control Board
400	Data Log
500	Display Assembly
600	Chiller
700	Q-Switch Driver
800	System
900	Peripherals
1000	Software

Note: Courtesy Messages: Correct the problem as indicated in the Courtesy Message table above and continue the procedure.

Note: Service Prompts: The system can be reset when the message 'Press Here to Continue' is displayed. If the system cannot reset itself, then it will require servicing before it can be used again.

16 WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

If BSC receives timely notice of matters covered under warranty, BSC shall, at its option, either repair or replace instruments or parts that prove to be defective. Instruments or parts shipped under this warranty or used as replacements under this warranty may be either refurbished or new, at BSC option. BSC neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with a BSC instrument.

THE REMEDIES PROVIDED HEREIN ARE BUYER'S SOLE AND EXCLUSIVE REMEDIES. IN NO EVENT SHALL BSC BE LIABLE FOR DIRECT, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, (INCLUDING LOSS OF PROFITS) WHETHER BASED ON CONTRACT, TORT OR OTHER LEGAL THEORY.

Warranty service is performed either on-site or at a BSC facility at BSC option. Where warranty service is provided on-site, the work will be performed at the Buyer's facility or a location that is mutually agreed upon, at no charge. Where warranty work is performed at the Buyer's facility, such work will be performed during normal working hours. If Buyer requests work to be performed outside of normal working hours, then Buyer shall pay for the incremental cost of such work. Where warranty service is provided at BSC, instruments must be returned to a BSC service facility designated by BSC. Parts and labor provided under this Warranty are warranted for 90 days from completion of the service repair or shipment of the replacement instruments/part(s). Instruments may only be returned with the prior approval of BSC. A valid Return Goods Authorization (RGA) number must evidence such approval. Buyer shall prepay shipping charges (and shall pay all duties and taxes) for instruments returned to BSC. BSC shall pay for return of the instrument to Buyer.

Note: The warranty period begins on the date of installation or ninety days after the date of shipment, whichever is first, where installation is included in the purchase price and on the date of shipment where installation is not included in the purchase price. The duration of the warranty period and the extent of the warranty vary depending on the instrument. Every BSC instrument and component is assigned a warranty code that defines the nature and duration of the warranty provided for the particular instrument. Contact BSC for a copy of the Warranty Policy, which defines the warranty codes in detail and assigns a code to each instrument/component.

16.1 Limitation of Warranty

The foregoing warranty shall be voided where in BSC's sole judgment there has been:

1. Improper or inadequate maintenance by Buyer, or service performed by anyone other than BSC or a party authorized by BSC to perform service on the specific item covered under this warranty.
2. Unauthorized modification or misuse.
3. Operation outside of the environmental specifications for the GreenLight XPS™ Laser System.
4. Improper site preparation and maintenance, including but not limited to improper electrical utilities.
5. Use of delivery devices or accessories not manufactured by BSC or approved by BSC for use with the GreenLight XPS Laser System.

16.2 Additional Terms of Warranty for Mobile Systems

Due to the special situations surrounding GreenLight XPS Laser System that are moved to numerous sites of service, the following terms and conditions also apply to mobile systems:

1. Every mobile provider must have a clinical trainer on staff. This person must be certified by BSC to provide clinical support to physicians for their first cases and beyond.
2. Every mobile provider must have qualified technicians (as certified by BSC) on staff to transport, setup, and operate the GreenLight XPS Laser System in all cases. Annual recertification is required.

16.3 Transport of the System

1. Every mobile provider must have suitable transportation for moving the GreenLight XPS Laser System from site to site.
2. The vehicle must have a lift gate or ramp, depending on the height of the vehicle, to load and unload the GreenLight XPS Laser System.
3. Transport the laser system in the original shipping crate or other suitable method designed to absorb road shock (vertical and horizontal loads), to protect the GreenLight XPS Laser System during transport. To absorb vertical shock and vibration, the floater (plywood base supported by foam blocks) can be removed from the original shipping crate and installed in the transport vehicle.
4. The GreenLight XPS Laser System must be protected from temperatures below 32 °F (0 °C). Freezing temperatures can damage the laser system.

REF

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
カタログ番号
Katalognummer
Αριθμός καταλόγου
Referência
Katalognummer
Katalógusszám
Katalogové číslo
Numer katalogowy
Katalognummer
目录编号
카탈로그 번호
Katalog Numarası
Número de catálogo
Kataloginumero
Număr de catalog
Номер по каталогу
Katalógové číslo
Каталожен номер
Kataloški broj
Kataloginumber
Vörulistanúmer
Kataloga numurs
Katalogo numeris
Kataloška številka

[blue safety sign]
Follow Instructions For Use
[símbolo azul de seguridad]
Seguir las instrucciones de uso
[symbole de sécurité bleu]
Suivre les instructions du mode d'emploi
[blaues Sicherheitszeichen]
Gebrauchsanweisung befolgen
[simbolo di sicurezza blu]
Attenersi alle Istruzioni per l'uso
[blauw veiligheidsteken]
Volg de instructies voor gebruik
[青の安全標識]
取扱説明書に従うこと。
[blåt sikkerhedsskilt]
Følg brugsanvisningen
[μπλε σήμα ασφαλείας]
Ακολουθήστε τις οδηγίες χρήσης
[sinal de segurança azul]
Siga as Instruções de Utilização
[blå säkerhetssymbol]
Följ bruksanvisningen
[kék biztonsági jel]
Használat során az utasításoknak megfelelően járjon el
[modrý bezpečnostní symbol]
Dodržujte návod k použití.
[niebieski znak bezpieczeństwa]
Postępować zgodnie z instrukcją obsługi
[blått sikkerhetssymbol]
Følg bruksanvisningen
[蓝色安全标志]
请遵照使用说明
[청색 안전 표지]
사용 지침을 따르십시오
[mavi güvenlik işareti]
Kullanım Talimatlarını İzleyin
[símbolo de segurança azul]
Siga as instruções de uso
[sininen turvallisuusmerkintä]
Noudata käyttöohjeita
[simbol de siguranță albastru]
Urmați instrucțiunile de utilizare
[синий знак безопасности]
Соблюдайте инструкции по применению
[modré bezpečnostné označenie]
Dodržiavajte pokyny na používanie
[предупредителен знак в синьо]
Следвайте инструкциите за употреба
[plavi znak sigurnosti] Slijedite upute za upotrebu
[sinine ohutusmärk] Järgige kasutusjuhiseid
[blá öryggismerking] Fylgið notkunarleiðbeiningum
[zilas krāsas drošības simbols] Ievērot lietošanas instrukcijas
[mėlynas saugos ženklas] Vadovaukitės naudojimo instrukcijomis
[Moder varnostni znak] Upoštevajte navodila za uporabo

CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.
PRECAUCIÓN. Atención: consulte los DOCUMENTOS ADJUNTOS.
AVERTISSEMENT. Attention : Lire les documents joints.
VORSICHT. Achtung: BEGLEITDOKUMENTE beachten.
ATTENZIONE. Attenzione: consultare i DOCUMENTI ALLEGATI.
LET OP. Attentie: Raadpleeg BIJGAANDE DOCUMENTEN.
注意．注意：附属の説明書を参照のこと。
FORSIGTIG. Obs! Se MEDFØLGENDE DOKUMENTER.
ΠΡΟΣΟΧΗ. Προσοχή: Συμβουλευτείτε τα ΣΥΝΟΔΕΥΤΙΚΑ ΕΓΓΡΑΦΑ.
CUIDADO. Atenção: Consulte os DOCUMENTOS INCLUSOS.
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FIGYELEM! Figyelem! Nézze át a KÍSÉRŐ DOKUMENTUMOKAT.
UPOZORNĚNÍ. Upozornění: Nahlédněte DO PŘILOŽENÝCH DOKUMENTŮ.
OSTRZEŻENIE. Uwaga: proszę zapoznać się z ZAŁĄCZONĄ DOKUMENTACJĄ.
FORSIKTIG. Viktig! Les MEDFØLGENDE DOKUMENTER.
警示。注意：请参阅随附文档。
조심. 주의: 관련 문서를 참조하십시오.
İKAZ. Dikkat: BİRLİKTE VERİLEN BELGELERE başvurun.
CUIDADO. Atenção: Consulte os DOCUMENTOS INCLUSOS.
VAROITUS. Huomio: tutustu OHEISIIN ASIAKIRJOIHIN.
AVERTIZARE. Atenție: Consultați DOCUMENTAȚIA ÎNSOȚITOARE.
ПРЕДОСТЕРЕЖЕНИЕ. Внимание! Обратитесь к СОПРОВОДИТЕЛЬНОЙ ДОКУМЕНТАЦИИ.
UPOZORNENIE. Pozor: Pozri SPRIEVODNÉ DOKUMENTY.
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OPREZ. Pažnja: pročitajte POPRATNE DOKUMENTE.
ETTEVAATUST. Tähelepanu: vaadake KAASASOLEVAID DOKUMENTE.
VARÚÐ. Athugið: Farið eftir upplýsingum í FYLGISKJÖLUM.
BRĪDINĀJUMS. Uzmanību! Skatīt PAVADDOKUMENTUS!
PERSPĖJIMAS. Dėmesio! Žr. PRIDĖTUS DOKUMENTUS.
POZOR. Pazite: glejte PRILOŽENO DOKUMENTACIJO.

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Innhold
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내용물
İçindekiler
Conteúdo
Sisältö
Conținut
Состав
Obsah
Съдържание
Sadržaj
Sisu
Innihald
Saturs
Turinys
Vsebina

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
法定製造元
Lovmæssig producent
Νόμιμος κατασκευαστής
Fabricante Legal
Laglig tillverkare
Hivatalos gyártó
Oprávněný výrobce
Producent uprawniony
Lovmessig produsent
合法制造商
법적 제조사
Yasal Üretici
Fabricante Legal
Laillinen valmistaja
Producător legal
Законный изготовитель
Výrobca
Официален производител
Zakonski proizvođač
Seaduslik tootja
Löglegur framleiðandi
Likumīgais ražotājs
Teisėtas gamintojas
Zakoniti proizvajalec

EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l'UE
Erkend vertegenwoordiger in EU
EU認定代理店
Autoriseret repræsentant i EU
Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ
Representante Autorizado na U.E.
Auktoriserad EU-representant
Hivatalos képviselet az EU-ban
Autorizovaný zástupce pro EU
Autoryzowany przedstawiciel w UE
Autorisert representant i EU
欧盟授权代表
EU 공인 대리점
AB Yetkili Temsilcisi
Representante Autorizado na UE
EU-valtuutettu edustaja
Reprezentantul Autorizat UE
Уполномоченный представитель в ЕС
Autorizovaný zástupca pre EÚ
Упълномощен представител за ЕС
Ovlašteni predstavnik za EU
ELi autoriseeritud esindaja
Viðurkenndur fulltrúi í ESB
Pilnvarotais pārstāvis ES
Įgaliotasis atstovas ES
Pooblaščeni predstavnik v EU

LOT

Lot
Lote
Lot
Charge
Lotto
Partij
ロット
Parti
Παρτίδα
Lote
Sats
Tételszám
Šarže
Seria
Parti
批号
로트
Parti
Lote
Erä
Lot
Партия
Šarža
Партида
Serija
Partii
Lota
Partija
Serija
Lot

SN

Serial Number
Número de serie
Numéro de série
Seriennummer
Numero di serie
Serienummer
シリアル番号
Serienummer
Σειριακός αριθμός
Número de série
Serienummer
Gyári szám
Sériové číslo
Numer seryjny
Serienummer
序列号
일련 번호
Seri Numarası
Número serial
Sarjanumero
Număr de serie
Серийный номер
Sériové číslo
Сериен номер
Serijski broj
Seerianumber
Raðnúmer
Sērijas numurs
Serijos numeris
Serijska številka

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
リサイクル可能包装
Genanvendelig pakning
Ανακυκλώσιμη συσκευασία
Embalagem Reciclável
Återvinningsbar förpackning
Újrahasznosítható csomagolás
Recyklovatelný obal
Opakowanie przeznaczone do recyklingu
Emballasjen kan resirkuleres
可回收再利用包装
재활용 포장재
Geri Dönüşümlü Ambalaj
Embalagem Reciclável
Kierrätettävä pakkaus
Ambalaj reciclabil
Упаковка, подлежащая вторичной переработке
Recyklovateľný obal
Рециклируема опаковка
Ambalaža za recikliranje
Taaskasutatav pakend
Endurvinnanlegar umbúðir
Atkārtoti pārstrādājams iepakojums
Perdirbama pakuotė
Reciklažna embalaža

Date of Manufacture
Fecha de fabricación
Date de fabrication
Herstellungsdatum
Data di fabbricazione
Fabricagedatum
製造日
Fremstillingsdato
Ημερομηνία κατασκευής
Data de Fabrico
Tillverkningsdatum
A gyártás időpontja
Datum výroby
Data produkcji
Produksjonsdato
生产日期
제조일
Üretim Tarihi
Data de Fabricação
Valmistuspäivämäärä
Data fabricației
Дата изготовления
Dátum výroby
Дата на производство
Datum proizvodnje
Tootmiskuupäev
Framleiðsludagsetning
Ražošanas datums
Pagaminimo data
Datum izdelave

AUS

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australischen Sponsors
Indirizzo sponsor australiano
Adres Australische sponsor
オーストラリア認定代理店住所
Australsk sponsoradresse
Διεύθυνση χορηγού στην Αυστραλία
Endereço do Patrocinador Australiano
Adress till australisk sponsor
Az ausztrál szponzor címe
Adresa australského zadavatele
Adres sponsora australijskiego
Australsk sponsors adresse
澳大利亚赞助商地址
호주 후원인 주소
Avustralyalı Sponsor Adresi
Endereço do Patrocinador Australiano
Australialaisen toimeksiantajan osoite
Adresa sponsorului australian
Адрес австралийского спонсора
Adresa austrálskeho zadávateľa
Адрес на възложителя за Австралия
Adresa sponzora za Australiju
Austraalia sponsori aadress
Heimilisfang ábyrgðaraðila í Ástralíu
Sponsora adrese Austrālijā
Australijos rėmėjo adresas
Naslov avstralskega sponzorja

ARG

Argentina Local Contact
Contacto local en Argentina
Contact local en Argentine
Lokaler Kontakt Argentinien
Contatto locale per l'Argentina
Contactpersoon Argentinië
アルゼンチン現地連絡先
Lokal kontakt i Argentina
Υπεύθυνος επικοινωνίας στην Αργεντινή
Contacto local na Argentina
Lokal kontakt, Argentina
Helyi kapcsolattartó (Argentína)
Místní kontaktní osoba v Argentině
Miejscowy przedstawiciel w Argentynie
Lokal kontakt for Argentina
阿根廷当地联络人
아르헨티나 현지 문의처
Arjantin Yerel İletişim
Contato local na Argentina
Argentiina – paikalliset yhteystiedot
Reprezentant local Argentina
Представительство в Аргентине
Miestny zástupca v Argentíne
Местно лице за контакт за Аржентина
Lokalni kontakt u Argentini
Argentiina kohalik kontakt
Tengiliður í Argentínu
Vietējā pārstāvniecība Argentīnā
Vietos kontaktinis asmuo Argentinoje
Lokalni stik v Argentini

BRA

Brazil Local Contact
Contacto local en Brasil
Contact local au Brésil
Lokaler Kontakt Brasilien
Contatto locale per il Brasile
Contactpersoon Brazilië
ブラジル現地連絡先
Lokal kontakt i Brasilien
Υπεύθυνος επικοινωνίας στη Βραζιλία
Contacto local no Brasil
Lokal kontakt, Brasilien
Helyi kapcsolattartó (Brazília)
Místní kontaktní osoba v Brazilii
Miejscowy przedstawiciel w Brazylii
Lokal kontakt for Brasil
巴西当地联络人
브라질 현지 문의처
Brezilya Yerel İletişim
Contato local no Brasil
Brasilia – paikalliset yhteystiedot
Reprezentant local Brazilia
Представительство в Бразилии
Miestny zástupca v Brazílii
Местно лице за контакт за Бразилия
Lokalni kontakt u Brazilu
Brasiilia kohalik kontakt
Tengiliður í Brasilíu
Vietējā pārstāvniecība Brazilijā
Vietos kontaktinis asmuo Brazilijoje
Lokalni stik v Braziliji

TUR

Turkey Local Contact
Contacto local en Turquía
Contact local en Turquie
Lokaler Kontakt Türkei
Contatto locale per la Turchia
Contactpersoon Turkije
トルコ現地連絡先
Lokal kontakt i Tyrkiet
Υπεύθυνος επικοινωνίας στην Τουρκία
Contacto local na Turquia
Lokal kontakt, Turkiet
Helyi kapcsolattartó (Törökország)
Místní kontaktní osoba v Turecku
Miejscowy przedstawiciel w Turcji
Lokal kontakt for Tyrkia
土耳其当地联络人
터키 현지 문의처
Türkiye Yerel İletişim
Contato local na Turquia
Turkki – paikalliset yhteystiedot
Reprezentant local Turcia
Представительство в Турции
Miestny zástupca v Turecku
Местно лице за контакт за Турция
Lokalni kontakt u Turskoj
Türgi kohalik kontakt
Tengiliður í Tyrklandi
Vietējā pārstāvniecība Turcijā
Vietos kontaktinis asmuo Turkijoje
Lokalni stik v Turčiji

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l'emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
包装が破損している場合は使用しないこと。
Må ikke anvendes, hvis pakken er beskadiget.
Μη χρησιμοποιείτε αν η συσκευασία έχει υποστεί ζημιά.
Não utilize se a embalagem estiver danificada.
Använd inte om förpackningen är skadad.
Ne használja, ha a csomagolás sérült.
Nepoužívejte, pokud je obal poškozen.
Nie używać, jeśli opakowanie jest uszkodzone.
Skal ikke brukes hvis emballasjen er skadet.
包装如有损坏，请勿使用。
패키지가 손상된 경우 사용하지 마십시오.
Eğer paket zarar görmüşse kullanmayın.
Não utilize se a embalagem estiver danificada.
Ei saa käyttää, jos pakkaus on vaurioitunut.
A nu se utiliza dacă ambalajul este deteriorat.
Не использовать, если упаковка повреждена.
Nepoužívajte, ak je balenie poškodené.
Да не се използва, ако опаковката е увредена.
Nemojte upotrebljavati ako je pakiranje oštećeno.
Ärge kasutage, kui pakend on kahjustatud.
Notið ekki ef umbúðir eru skemmdar.
Nelietot, ja iepakojums ir bojāts.
Nenaudoti, jei pakuotė yra pažeista.
Ne uporabite, če je embalaža poškodovana.

NON STERILE

Non-Sterile
No estéril
Non stérile
Nicht steril
Non sterile
Niet-steriel
未滅菌
Ikke-steril
Μη αποστειρωμένο
Não esterilizado
Icke-steril
Nem steril
Nesterilní
Niejałowy
Ikke-steril
非无菌
비멸균
Steril Değildir
Não estéril
Epästerili
Non-steril
Не стерильно
Nesterilný
Нестерилно
Nesterilno
Mittesteriilne
Ekki Ósæft
Nesterils
Nesterilus
Nesterilno

Separate Collection
Recogida independiente
Élimination séparée
Sonderabfall
Raccolta differenziata
Gescheiden inzameling
別途回収
Indsamles separat
Ξεχωριστή συλλογή
Recolha Separada
Separat avfallshantering
Elkülönített gyűjtés
Shromažďovat odděleně
Usuwać do odpadów segregowanych
Spesialavfall
分类回收
분리 수집
Ayrılması Gereken Atık
Coleta separada
Erilliskeräys
Colectare separată
Раздельный сбор
Separovaný zber
Разделно събиране
Zasebna kolekcija
Eraldi kogumine
Sérstök söfnun
Atsevišķa savākšana
Atskiras rinkinys
Ločeno zbiranje

Type BF Applied Part
Pieza tipo BF aplicada
Pièce appliquée de type BF
Angelegtes Teil vom Typ BF
Parte applicata di tipo BF
Patiëntverbinding type BF
タイプBF装着部
Type BF anvendt del
Εφαρμοζόμενο εξάρτημα τύπου BF
Peça aplicada Tipo BF
Typ BF ansluten enhet
BF típusú alkalmazott alkatrész
Aplikovaný díl typu BF
Zastosowana część typu BF
Anvendt del av type BF
BF类应用部件
유형 BF 적용 부품
Uygulama Parçası Tip BF
Peça aplicada tipo BF
BF-tyypin sovellettu osa
Parte aplicată de tip BF
Рабочая часть типа BF
Aplikovaný diel typu BF
Контактуваща с пациента част от тип BF
Primijenjeni dio tipa BF
BF-tüüpi rakendusosa
Hlutur af BF gerð
BF kategorijas detaļa saskarē ar pacientu
BF tipo su pacientu besiliečianti dalis
Aplicirani del tipa BF

Non-Ionizing Electromagnetic Radiation
Radiación electromagnética no ionizante
Rayonnement électromagnétique non ionisant
Nichtionisierende elektromagnetische Strahlung
Radiazione elettromagnetica non ionizzante
Niet-ioniserende elektromagnetische straling
非電離性電磁放射線
Ikke-ioniserende elektromagnetisk stråling
Μη ιονίζουσα ηλεκτρομαγνητική ακτινοβολία
Radiação Electromagnética Não Ionizante
Icke-joniserande elektromagnetisk strålning
Nem ionizáló elektromágneses sugárzás
Neionizující elektromagnetické záření
Promieniowanie elektromagnetyczne niejonizujące
Ikke-ioniserende elektromagnetisk stråling
非电离电磁辐射
비이온화 전자기 방사선
İyonlaşmayan Elektromanyetik Radyasyon
Radiação eletromagnética não ionizante
Ei-ionisoiva sähkömagneettinen säteily
Radiaţie electromagnetică non-ionizantă
Неионизирующее электромагнитное излучение
Neionizujúce magnetické žiarenie
Нейонизиращо електромагнитно лъчение
Neionizirajuće elektromagnetsko zračenje
Mitteioniseeriv elektromagnetiline kiirgus
Rafsegulgeislun sem er ekki jónandi
Nejonizējošais elektromagnētiskais starojums
Nejonizuojančioji elektromagnetinė radiacija
Neionizirajoče elektromagnetno sevanje

Keep Dry
Mantener seco
Tenir au sec
Trocken halten
Tenere asciutto
Droog houden
湿気厳禁
Holdes tør
Φυλάσσετε σε ξηρό περιβάλλον
Manter seco
Förvara torrt
Tartsa szárazon
Uchovávejte v suchu
Przechowywać w suchym miejscu
Oppbevares tørt
保持干燥
건조한 장소에 보관하십시오
Kuru Yerde Tutun
Mantenha seco
Pidä kuivana
Menţineţi uscat
Хранить в сухом месте
Uchovávajte v suchu
Пазете на сухо
Držite na suhom
Hoida kuivas
Haldið þurru
Glabāt sausumā
Laikyti sausoje vietoje
Pazite, da bo izdelek suh

Fragile
Frágil
Fragile
Zerbrechlich
Fragile
Breekbaar
割れもの注意
Skrøbelig
Εύθραυστο
Frágil
Ömtåligt
Törékeny
Křehké
Produkt delikatny
Skjørt gods
易碎品
깨지기 쉬움
Kırılabilir
Frágil
Herkästi särkyvä
Fragil
Хрупкое изделие
Krehké
Чупливо
Lomljivo
Habras
Brothætt
Trausls
Dužus
Lomljivo

This Way Up
Esta parte hacia arriba
Haut
Diese Seite oben
Alto
Deze kant boven
この面が上
Denne side op
Εδώ επάνω
Este lado para cima
Denna sidan upp
Ez a teteje
Tímto směrem nahoru
Góra
Denne siden opp
此面朝上
이쪽을 위로 향할 것
Yukarı
Este lado para cima
Tämä puoli ylöspäin
A se orienta în sus
Вверх
Touto stranou nahor
Тази страна нагоре
Ova strana prema gore
See pool üleval
Þessi hlið upp
Virziens uz augšu
Šia puse į viršų
Ta stran navzgor

Temperature limitation.
Límite de temperatura.
Limite de température
Temperaturbegrenzung
Limite di temperatura.
Temperatuurgrens
温度制限。
Temperaturgrænse.
Περιορισμός θερμοκρασίας.
Limites de temperatura.
Temperaturgräns.
Hőmérsékleti korlátozás.
Teplotní omezení
Graniczne wartości temperatur.
Temperaturbegrensning.
温度限制。
온도 제한.
Sıcaklık sınırlaması.
Limitação de temperatura.
Lämpötilarajoitus.
Limitare de temperatură.
Ограничение температуры.
Teplotné obmedzenie.
Ограничение на температурата.
Ograničenje temperature.
Temperatuuripiirang.
Hitatakmörk.
Temperatūras ierobežojums.
Temperatūros apribojimas.
Omejitev temperature.

Do Not Stack
No apilar
Ne pas empiler
Nicht stapeln
Non sovrapporre
Niet stapelen
上積厳禁
Må ikke stables
Μην στοιβάζετε
Não empilhar
Får ej staplas
Ne pakoljon rá
Nepokládat na sebe
Nie układać w stos
Må ikke stables
禁止堆叠
적재 금지
Istiflemeyin
Não empilhar
Ei saa pinota
A nu se aşeza în stivă
Не складировать
Neukladať na seba
Да не се поставя едно върху друго
Nemojte stavljati jedno na drugo
Ärge virnastage
Staflið ekki
Nekraut kaudzē
Nedėkite vieno ant kito
Ne nalagajte enega na drugega

Filling
Llenado
Remplissage
Füllen
Rabbocco
Vullen
充填中
Fylder
Πλήρωση
Enchimento
Fyllning
Töltés
Plnění
Napełnianie
Fylling
注入/注满
채우기
Doldurma
Abastecimento
Täyttyminen
Umplere
Наполнение
Plnenie
Пълнене
Punjenje
Täitmine
Fylling
Uzpilde
Pildymas
Polnjenje

Laser Emergency Stop Button
Botón de parada de emergencia del láser
Bouton d'arrêt d'urgence du laser
Laser-Notstopptaste
Pulsante di arresto di emergenza del laser
Lasernoodstopknop
レーザー緊急停止ボタン
Lasernødstopknap
Κουμπί διακοπής Laser λόγω έκτακτης ανάγκης
Botão de paragem de emergência do laser
Laserns nödstoppsknapp
A lézer vészmegállító gombja
Tlačítko nouzového vypnutí laseru
Przycisk awaryjnego wyłączenia lasera
Nødstoppknapp for laser
激光紧急停止按钮
레이저 비상 정지 버튼
Lazer Acil Durdurma Düğmesi
Botão de emergência do laser
Laserin hätäpysäytyspainike
Buton oprire urgență laser
Кнопка аварийного отключения лазера
Tlačidlo núdzového vypnutia lasera
Бутон за аварийно спиране на лазера
Gumb za zaustavljanje lasera u slučaju nužde
Laseri hädaseiskamisnupp
Hnappur fyrir neyðarstöðvun laser-geisla
Lāzera izslēgšanas poga trauksmes gadījumos
Lazerio skubaus sustabdymo mygtukas
Gumb za izklop laserja v nujnih primerih

Mass with Safe Working Load
Masa con carga de trabajo segura
Masse avec charge utile maximale
Masse mit sicherer Arbeitslast
Peso con carico di esercizio sicuro
Massa met veilige werkbelasting
定格荷重での質量
Masse med sikker arbejdsbelastning
Μάζα με ασφαλές φορτίο εργασίας
Massa com carga de trabalho segura
Vikt vid säker arbetsbelastning
A tömeg biztonságos üzemi terheléssel
Hmotnost s bezpečnou pracovní zátěží
Masa z bezpiecznym obciążeniem roboczym
Masse med sikker arbeidsbelastning
带安全工作负载的质量
안전사용하중을 포함한 질량
Güvenli Çalışma Yükü ile Kütle
Massa com carga de trabalho segura
Massa ja turvallinen työkuormitus
Masă cu sarcină de lucru sigură
Масса с безопасной рабочей нагрузкой
Hmotnosť zariadenia s bezpečnou pracovnou záťažou
Тегло с безопасно работно натоварване
Masa sa sigurnim radnim opterećenjem
Mass ohutu töökoormuse juures
Hámarks örugg vinnuþyngd
Masa ar drošu ekspluatācijas slodzi
Masė su saugiu darbiniu krūviu
Masa z varno delovno obremenitvijo

Foot Switch
Pedal
Pédale
Fußschalter
Interruttore a pedale
Voetschakelaar
フットスイッチ
Fodpedal
Ποδοδιακόπτης
Pedal Interruptor
Fotbrytare
Lábkapcsoló
Nožní spínač
Przełącznik nożny
Fotbryter
脚踏开关
발 스위치
Ayak Pedalı
Pedal
Jalkakytkin
Pedalā
Ножная педаль
Nožný spínač
Крачен превключвател
Nožni prekidač
Jalglüliti
Fótrofi
Ar kāju darbināms pedālis
Kojinis jungiklis
Nožno stikalo

Draining
Drenaje
Purge
Entleeren
Scarico
Legen
排液中
Tømmer
Αποστράγγιση
Drenagem
Tömning
Leengedés
Vypouštění
Drenaż
Tømming
排出/排放
배출
Boşaltma
Drenagem
Tyhjeneminen
Scurgere
Слив
Vypúšťanie
Дрениране
Pražnjenje
Äravool
Tæming
Notecināšana
Išleidimas
Drenaža

Power Off
Apagar
Mettre hors tension
Netz AUS
Spegnere
Voeding uit
電源オフ
Slukker
Απενεργοποίηση
Desligar
Ström av
Kikapcsolás
Vypnout
Zasilanie Wył.
Slå av
关闭电源
전원 끄기
Kapat
Desligar
Virta pois päältä
Oprire
Выключение питания
Vypnúť
Изключване на захранването
Napajanje isključeno
Toide väljas
Slökkt
Strāvas padeve atslēgta
Išjungti
Izklop

Power On
Encender
Mettre sous tension
Netz EIN
Accendere
Voeding aan
電源オン
Tænder
Ενεργοποίηση
Ligar
Ström på
Bekapcsolás
Zapnout
Zasilanie Wł.
Slå på
打开电源
전원 켜기
Aç
Ligar
Virta päälle
Pornire
Включение питания
Zapnúť
Включване на захранването
Napajanje uključeno
Toide sees
Kveikt
Strāvas padeve ieslēgta
Įjungti
Vklop

Laser Warning
Advertencia sobre el láser
Mise en garde relative au laser
Laser-Warnhinweis
Avvertenza laser
Laserwaarschuwing
レーザー警告
Laseradvarsel
Προειδοποίηση Laser
Advertência sobre o laser
Laservarning
Lézerfigyelmeztetés
Varování: laser
Ostrzeżenie przed promieniami laserowymi
Laseradvarsel
激光警告
레이저 경고
Lazer Uyarısı
Advertência: Laser
Laservaroitus
Avertisment cu privire la laser
Предупреждение о лазерном излучении
Výstraha: laser
Предупреждение относно лазер
Upozorenje za laser
Laseri hoiatus
Varúð - laser
Brīdinājums par lāzeru
Perspėjimas dėl lazerio
Opozorilo za laser

Laser Exit Aperture
Apertura de salida del láser
Ouverture de sortie du laser
Laseraustrittsöffnung
Apertura con uscita di radiazioni laser
Laseruitgangsopening
レーザー出射口
Laserudgangsåbning
Άνοιγμα εξόδου Laser
Abertura da saída do laser
Laserns utgångsöppning
A lézer kilépési nyílása
Otvor výstupu laseru
Otwór wyjściowy lasera
Utgangsåpning for laser
激光射出口
레이저 출구 어퍼처
Lazer Çıkış Deliği
Abertura de saída do laser
Laserin lähtöaukko
Apertură ieșire laser
Выходное окно лазерного излучателя
Otvor výstupu lasera
Изходно прозорче на лазерния излъчвател
Izlazni otvor laserske zrake
Laseri väljumisava
Útgangsop laser-geisla
Lāzera izejas apertūra
Lazerio išėjimo anga
Izhodna odprtina laserja

Remote Interlock
Bloqueo a distancia
Verrouillage à distance
Türsicherung
Blocco remoto
Externe interlock
リモート・インターロック
Fjernafbryder
Ενδασφάλεια από απόσταση
Interbloqueio Remoto
Fjärrstyrd förregling
Távoli reteszelés
Dálkový zámek
Blokada zdalna
Fjernsperre
遥控联锁
원격 연동
Uzaktan Kilit
Intertravamento remoto
Etälukitus
Dispozitiv de blocare la distanță
Дистанционная блокировка
Diaľkové blokovanie
Отдалечено блокиране
Daljinsko zaključavanje
Kaugjuhtimisega blokeering
Fjarsamlæsing
Attālais bloķētājs
Nuotolinė blokuotė
Oddaljeni zaklep

Service Port USB Connection
Conexión USB de puerto de servicio
Connexion USB du port de maintenance
Service-Port USB-Anschluss
Connessione USB della porta di servizio
USB-aansluiting onderhoudspoort
サービス・ポート USB接続
USB-tilslutning til serviceport
Σύνδεση USB θύρας σέρβις
Ligação USB na Entrada de Serviço
Serviceport USB-anslutning
Szervizport USB-kapcsolat
USB připojení servisního portu
Złącze USB portu serwisowego
USB-tilkobling for serviceport
服务端口USB连接
서비스 포트 USB 연결
Servis Portu USB Bağlantısı
Conexão USB da porta de serviço
Huoltoportin USB-liitäntä
Conexiune USB port service
USB-соединение сервисного порта
Pripojenie servisného portu USB
Сервизен порт (USB връзка)
USB-priključak servisnog ulaza
Teeninduspordi USB-ühendus
Þjónustugátt USB-tenging
Apkopes USB pieslēgvietas savienojums
Priežiūros prievado USB jungtis
USB-povezava servisnih vrat

[black and red safety sign] No Pushing
[símbolo de seguridad rojo y negro] No empujar
[panneau de sécurité noir et rouge] Interdiction de pousser
[schwarz-rotes Sicherheitszeichen] Schieben verboten
[segnale di sicurezza nero e rosso] Non spingere
[zwart met rood veiligheidssymbool] Niet tegen duwen
[黒と赤の安全標識] 押さないでください
[sort og rødt sikkerhedssymbol] Der må ikke skubbes
[μαύρο και κόκκινο σήμα ασφαλείας] Απαγορεύεται η ώθηση
[sinal de segurança preto e vermelho] Não Empurrar
[svart och röd säkerhetsskylt] Framskjutning förbjuden
[fekete és piros biztonsági jel] Tilos tolni!
[černočervený bezpečnostní symbol] Netlačit
[czarno-czerwony znak ostrzegawczy] Nie popychać
[sort og rødt sikkerhetssymbol] Forbudt å skyve
[黑色和红色安全标识] 禁止推动
[검은색과 빨간색 안전 표지] 밀지 마시오
[siyah ve kırmızı güvenlik işareti] Itmek yasaktır
[sinalização de segurança preto e vermelho] Proibido empurrar
[musta ja punainen turvallisuusmerkintä] Työntäminen kielletty
[simbol de siguranță negru cu roșu] Împingerea interzisă
[черно-красный знак безопасности] Не толкать!
[čierne a červené bezpečnostné označenie] Zákaz tlačiť
[предупредителен знак в червено и черно] Бутането забранено
[crno-crveni znak sigurnosti] Pritiskanje je zabranjeno
[must ja punane ohutusmärk] Mitte lükata
[svart og rautt varúðarmerki] Ekki ýta
[melni sarkana brīdinājuma zīme] Nestumt
[juodas ir raudonas saugos ženklas] Negalima stumti
[rdeče-črn varnostni znak] Potiskanje prepovedano

This product complies with standards set forth in EN 60601-1, 60601-1-2 and 60601-2-22. cTUVus Mark indicates compliance to UL 60601-1 and CAN/CSA 22.2 601.1 M90 covering electrical safety requirements for the US and Canada.
Este producto cumple la normativa establecida en EN 60601-1, 60601-1-2 y 60601-2-22. El símbolo cTUVus indica cumplimiento con las regulaciones UL 60601-1 y CAN/CSA 22.2 601.1 M90 correspondientes a los requisitos de seguridad eléctrica en Estados Unidos y Canadá.
Ce produit est conforme aux normes établies dans les publications EN 60601-1, 60601-1-2 et 60601-2-22. La marque cTUVus indique le respect des normes de sécurité électrique UL 60601-1 et CAN/CSA 22.2 601.1 M90 pour les États-Unis et le Canada.
Dieses Produkt entspricht den Anforderungen der Normen EN 60601-1, 60601-1-2 und 60601-2-22. Das cTUVus-Kennzeichen weist auf Konformität mit den Richtlinien UL 60601-1 und CAN/CSA 22.2 601.1 M90 bezüglich der Anforderungen für elektrische Sicherheit in den USA und in Kanada hin.
Il prodotto è conforme agli standard esposti in EN 60601-1, 60601-1-2 e 60601-2-22. Il marchio cTUVus indica la conformità del prodotto ai requisiti elettrici di sicurezza UL 60601-1 e CAN/CSA 22.2 601.1 M90 per gli Stati Uniti e il Canada.
Dit product voldoet aan de eisen van norm EN 60601-1, 60601-1-2 en 60601-2-22. Het cTUVus-keurmerk geeft aan dat het product voldoet aan UL 60601-1 en CAN/CSA 22.2 601.1 M90 aangaande de vereisten betreffende elektrische veiligheid voor de VS en Canada.
本製品は、 EN 60601-1、60601-1-2 および 60601-2-22に定める基準を遵守しています。cTUVusマークは、米国およびカナダ向け電気安全要件を包含するUL 60601-1およびCAN/CSA 22.2 601.1 M90へ適合していることを示す。
Dette produkt er i overensstemmelse med standarderne i EN 60601-1, 60601-1-2 og 60601-2-22. cTUVus-mærket betyder, at produktet overholder UL 60601-1 og CAN/CSA 22.2 601.1 M90 vedr. sikkerhedskrav til elektrisk udstyr for USA og Canada.
Το προϊόν αυτό συμμορφώνεται με τα πρότυπα EN 60601-1, 60601-1-2 και 60601-2-22. Η σήμανση cTUVus δείχνει συμμόρφωση με τα πρότυπα UL 60601-1 και CAN/CSA 22.2 601.1 M90, τα οποία καλύπτουν τις απαιτήσεις ηλεκτρικής ασφαλείας στις Η.Π.Α. και τον Καναδά.
Este produto cumpre as normas estipuladas em EN 60601-1, 60601-1-2 e 60601-2-22. A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que cobrem os requisitos de segurança elétrica para os EUA e o Canadá.
Denna produkt uppfyller kraven i standarderna SS-EN 60601-1, SS-EN 60601-1-2 och SS-EN 60601-2-22. cTUVus-märkningen indikerar efterlevnad av UL 60601-1 och CAN/CSA 22.2 601.1 M90 som behandlar elektriska säkerhetskrav i USA och Kanada.
Ez a termék megfelel az EN 60601-1, 60601-1-2 és 60601-2-22 szabványok előírásainak. A cTUVus jel az USA és Kanada területén érvényes UL 60601-1 és a CAN/CSA 22.2 601.1 M90 számú elektromos biztonsági követelményeknek való megfelelőséget jelzi.
Tento produkt vyhovuje standardům podle norem EN 60601-1, 60601-1-2 a 60601-2-22. Označení cTUVus tohoto produktu značí soulad s elektrickými bezpečnostními předpisy UL 60601-1 a CAN/CSA 22.2 601.1 M90 pro Spojené státy a Kanadu.
Niniejszy produkt jest zgodny z normami określonymi w EN 60601-1, 60601-1-2 i 60601-2-22. Znak cTUVus jest potwierdzeniem zgodności z normami UL 60601-1 i CAN/CSA 22.2 601.1 M90 określającymi wymagania dotyczące bezpieczeństwa instalacji elektrycznych w USA i Kanadzie.
Dette produktet er i samsvar med standarder i EN 60601-1, 60601-1-2 og 60601-2-22. cTUVus-merket angir at produktet er i samsvar med UL 60601-1 og CAN/CSA C22.2 601.1 M90, som dekker de elektriske sikkerhetskravene for USA og Canada.
此产品符合 EN 60601-1、60601-1-2 和 60601-2-22 中设置的标准。cTUVus 标记表示符合美国及加拿大关于电气安全要求的 UL 60601-1 和 CAN/CSA 22.2 601.1 M90 标准的规定。
이 제품은 EN 60601-1, 60601-1-2, 60601-2-22에 규정된 표준을 준수합니다. cTUVus 마크는 미국 및 캐나다의 전기 안전 요건에 대한 UL 60601-1 및 CAN/CSA 22.2 601.1 M90을 준수함을 나타냅니다.
Bu ürün, EN 60601-1, 60601-1-2 ve 60601-2-22'de ortaya konan standartlarla uyumludur. cTUVus İşareti, ABD ve Kanada için elektrik güvenliği gereklerini kapsayan UL 60601-1 ve CAN/CSA 22.2 601.1 M90 normlarına uygunluğu gösterir.
Este produto está em conformidade com as normas estabelecidas na EN 60601-1, 60601-1-2 e 60601-2-22. A marca cTUVus indica conformidade com as normas UL 60601-1 e CAN/CSA 22.2 601.1 M90 que abrangem os requisitos de segurança elétrica nos EUA e no Canadá.
Tämä tuote noudattaa standardeja EN 60601-1, 60601-1-2 ja 60601-2-22. cTUVus-merkki osoittaa, että laite on yhdenmukainen standardien UL 60601-1 ja CAN/CSA 22.2 601.1 M90 kanssa, jotka kattavat sähköturvallisuusvaatimukset USA:ssa ja Kanadassa.
Acest produs respectă normele stabilite în EN 60601-1, 60601-1-2 şi 60601-2-22. Marca cTUVus atestă conformitatea cu UL 60601-1 şi CAN/CSA 22.2 601.1 M90 privind cerinţele de siguranţă pentru echipamentele electrice în SUA şi Canada.
Изделие отвечает требованиям стандартов EN 60601-1, 60601-1-2 и 60601-2-22. Знак cTUVus указывает на соответствие стандартам UL 60601-1 и CAN/CSA 22.2 601.1 M90, которые содержат требования к электрической безопасности для США и Канады.
Tento produkt je v súlade so štandardmi uvedenými v normách EN 60601-1, 60601-1-2 a 60601-2-22. Označenie cTUVus predstavuje súlad s požiadavkami na elektrickú bezpečnosť podľa normy UL 60601-1 a CAN/CSA 22.2 601.1 M90 pre USA a Kanadu.
Този продукт отговаря на стандартите, посочени в EN 60601-1, 60601-1-2 и 60601-2-22. Обозначението cTUVus указва съответствие със стандартите UL 60601-1 и CAN/CSA 22.2 601.1 M90 относно изискванията за безопасност на електрическото оборудване в САЩ и Канада.
Ovaj je proizvod usklađen s odredbama normi EN 60601-1, 60601-1-2 i 60601-2-22. Oznaka cTUVus označava usklađenost s normama UL 60601-1 i CAN/CSA 22.2 601.1 M90 koje obuhvaćaju zahtjeve električne sigurnosti za SAD i Kanadu.
See toode vastab standarditele EN 60601-1, 60601-1-2 ja 60601-2-22. cTUVus-märk tähistab vastavust USA ja Kanada elektriohutusnõuetele UL 60601-1 ja CAN/CSA 22.2 601.1 M90.
Þessi vara samræmist stöðlum sem settir eru fram í EN 60601-1, 60601-1-2 og 60601-2-22. cTUVus merkið sýnir að fylgt sé UL 60601-1 og CAN/CSA 22.2 601.1 M90 kröfum um rafmagnsöryggi í Bandaríkjunum og Kanada.
Šī ierīce atbilst EN 60601-1, 60601-1-2 un 60601-2-22 noteiktajiem standartiem. cTUVus marķējums apliecina atbilstību standartiem UL 60601-1 un CAN/CSA 22.2 601.1 M90 par elektrodrošību ASV un Kanādā.
Šis gaminys atitinka standartus, išdėstytus EN 60601-1, 60601-1-2 ir 60601-2-22.„cTUVus“ ženklas reiškia, kad prietaisas atitinka UL 60601-1 ir CAN/CSA 22.2 601.1 M90 standartus, JAV ir Kanadoje nustatančius elektrosaugos reikalavimus.
Izdelek je skladen s standardi EN 60601-1, 60601-1-2 in 60601-2-22. Oznaka cTUVus predstavlja skladnost z UL 60601-1 in CAN/CSA 22.2 601.1 M90 na področju zahtev glede električne varnosti za ZDA in Kanado.