Surgical Guide
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Introduction

Welcome to the GreenLight HPS™ laser system Surgical Guide. This handbook is part of AMS’s comprehensive training program for the Photoselective Vaporization of the Prostate (PVP™) Procedure for the treatment of BPH. The GreenLight HPS™ laser system is a high power 532nm laser system designed to efficiently vaporize soft tissue in a hemostatic fashion.

AMS is committed to providing quality training to physicians and health care professionals on the use of its products and accessories. Our commitment is reflected in the GreenLight HPS™ Physician Training Policy (page 5) of this Surgical Guide.

We hope you will find the GreenLight HPS™ Surgical Guide informative. If you have further questions, please contact Customer Service at 1-800-328-3881 in the U.S and Canada, international customers dial 001-952-930-6000.

Disclaimer

AMS provides this Surgical Guide in its commitment to help facilitate consistent positive clinical outcomes, and to reduce patient risk and injury. The guidelines given in this Surgical Guide are not, however, intended to in any way replace or substitute a physician’s duty of care, professional responsibility, or professional judgment, nor are they intended to provide any warranty, promise, guarantee, assumption of risk or duty, release or indemnity. Physicians shall at all times maintain responsibility for patient treatment and outcomes, and AMS further assumes no liability for patient treatment or outcome or for physician’s negligence, breach of duty of care or malpractice.
GreenLight HPS™ Physician Training Policy

Consistent with the commitment to good clinical outcomes, AMS requires that all physicians undergo product and procedural training in the use of the GreenLight HPS™ laser system and performance of the PVP procedure prior to laser acquisition and first cases. A Training Completion Certificate is issued to a physician after attending a didactic session with observation of live cases and/or a wet-lab and completion of his/her first three (3) procedures proctored by an AMS Clinical Educator or AMS-certified HPS trainer. Physicians can present certificates signed by the clinical educator to their health-care facility as evidence for completion of training on the GreenLight HPS™ laser system and the PVP procedure. First cases must be supported by an AMS certified clinical educator or AMS-certified HPS trainer.

The GreenLight HPS laser system training process is composed of the following steps:

1. Physicians are strongly advised to study and review the GreenLight HPS™ Surgical Guide prior to first cases, workshops, or wet-lab training sessions.

2. Physicians must attend an AMS-approved workshop, lecture or one-on-one training performed by an AMS Clinical Educator or AMS certified preceptor on the PVP procedure and the safe and effective use of the GreenLight HPS™ laser system. The workshop/preceptorship may consist of a didactic portion and participation in a wet-lab on an animal model such as a bull prostate.

3. An AMS Clinical Educator or a AMS-certified Trainer will be required to attend your first few cases with GreenLight HPS.
   a. A Certificate of Training Completion will be issued only after the physician has successfully completed a minimum of three cases in the presence of an AMS Clinical Educator or AMS-certified Trainer/Proctor.
   b. A minimum of three patients should be scheduled for the first day of GreenLight HPS procedures.
   c. No other Training Certificates are valid for GreenLight HPS use.
**Training and Fiber Shipping Logistics**

1. First HPS cases must be done with an AMS clinical representative whether a direct, LLC or mobilized account.

2. AMS representative will carry fibers into hospital and be present for all first cases.

3. Once trained, (three cases minimum) the physician will receive an AMS-issued Certificate of Training Completion form.

4. Letter will be sent/hand delivered to hospitals explaining this procedure.

5. Once the physician is trained, the hospital or mobile provider/LLC may stock fibers but only AMS-trained physicians will be authorized to perform the procedure.

6. The responsibility for enforcement of this policy resides with hospital Risk Management and the Department of Surgery, the service provider and AMS.

7. Each month the mobile provider/LLC partner will provide AMS with a report detailing information about the hospital/physician where the fibers are being shipped.
Section One
System Overview
System Overview

**GreenLight HPS™ Laser System**
The GreenLight HPS™ laser system is a diode-pumped, frequency-doubled Nd:YAG solid state laser. The laser system delivers a visible 532nm laser light with a power setting range of 20 to 120W, in 10W increments.

The GreenLight HPS System does not need any special water or electrical connections.

Laser energy emission and system status selection is activated through an “On-demand” surgeon-operated, color-coded footswitch or system touch screen feature located in the laser console.

The system provides audio confirmation of laser status (“READY” or “STANDBY”)

**GreenLight HPS™ Fiber**
The GreenLight HPS™ fiber is side firing; delivering up to 120W of 532nm light to tissue. The fiber is guided to the targeted tissue through the working channel of a continuous flow cystoscope.

The GreenLight HPS fiber is used to cut, coagulate and vaporize tissue at a 70º forward deflection angle to the fiber axis. It can rotate 360-degrees, allowing tissue access in multiple planes; and it is used in surgical applications where lateral delivery of laser energy is desired. GreenLight HPS™ fiber(s) are sterile and designed for single use only. The fiber cannot be re-sterilized.
How HPS™ differs from GreenLight PV™ System

1. **FAST VAPORIZATION** The GreenLight HPS System with a maximum output power of 120W offers rapid tissue vaporization. The HPS System allows the surgeon to titrate the power based upon the individual patient tissue response. The surgeon may choose to use a lower power setting when treating smaller or more fibrous glands. When treating a larger or more fibrous gland, the surgeon may elect to use higher power settings.

2. **SURGEON CONTROL – HANDS FREE MODE/SELECTION STATUS** The HPS System allows the surgeon to control the laser settings: a footswitch enables the user to put the laser into “READY” or “STANDBY” modes: or to rapidly switch from VAPORIZATION to COAGULATION modes. These features are accomplished by the use of an electrosurgical unit (ESU)-type footswitch.

3. **VOICE CONFIRMATION OF MODE** The GreenLight HPS system provides audible voice confirmation of the status of the laser when the footswitch is engaged after the laser status has changed from “READY” to “STANDBY” modes. Additionally, there is an audible tonal difference between the vaporization or coagulation modes, as there currently is with ESU units used in surgical suites daily.

4. **LOW DIVERGENCE PRECISION BEAM** Improved collimation of the beam quality enables rapid tissue vaporization at a wider range of working distances. The delivery fiber design also eliminates scatter out of the back of the fiber, thus protecting vital tissue structures from inadvertent damage.

5. **VAPORIZATION EFFECT ACHIEVED AT GREATER TISSUE DISTANCES** The GreenLight HPS System allows for greater variability in working distance and sweep speed than was possible with the GreenLight PV System. The surgeon can achieve vaporization at distances of 3mm, thus employing a technique that is true “non-contact”. More consistent continuous vaporization can be maintained, resulting in a shortened procedure time, or enabling the surgeon to treat larger glands in less operative time than was possible with the GreenLight PV™ System.
6. **COST EFFECTIVE FIBER CHOICES:** The GreenLight HPS System has 2 delivery fibers to enable the surgeon to choose the most cost-effective fiber for the patient’s clinical needs:

a. The GreenLight HPS BPH fiber (p/n 10-2090) is the best option for treating BPH patients. It has a joule guard limit of 275,000 joules.

b. For patients with urethral strictures or bladder tumors, there is a GreenLight HPS fiber (p/n 10-2092) with a joule guard limit of 20,000 joules, available at a lower cost, thus making the procedure economically viable to perform either in an office or outpatient setting.

7. **NO SPECIAL WATER/ELECTRICAL REQUIREMENTS** The GreenLight HPS system is easily transportable from the OR to an ambulatory surgery center or to your office setting. It uses a standard 208V plug and 30A @50-60Hz. The laser is “self-tapping” and adjusts to the voltage and frequency of any facility.

8. **IMPROVED VISUALIZATION** The GreenLight HPS system has a quasi-continuous pulse-width to virtually eliminate any flashing effect you may previously have seen on video screens. The 80W GreenLight PV laser uses a Star Pulse™ technology, which occasionally causes a flashing effect on some video monitors. This can occur when the image refresh rate of the video equipment is closely in sync with that of the Star Pulse.
GreenLight HPS™ vs. 
PV™ Surgical Laser Systems 

* A Side-by-Side Comparison

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>HPS (High Performance System)</th>
<th>PV (Photoselective Vaporization)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEAM CHARACTERISTICS</td>
<td>The GreenLight HPS Laser System has a tighter beam profile with low beam divergence, thus maintaining efficient vaporization at tissue distances of 3 mm.</td>
<td>The GreenLight PV fiber attains optimal vaporization at 0.5mm tissue distance. Greater tissue distances may result in coagulation of tissue, not vaporization.</td>
</tr>
<tr>
<td></td>
<td>Beam has a 70° forward deflection, like the GreenLight PV ADDStat™ fiber. Exercise caution when lasing near bladder neck to prevent inadvertent lasing of bladder wall or ureteral orifices.</td>
<td>Same.</td>
</tr>
<tr>
<td>WAVELENGTH</td>
<td>532 nm wavelength is highly absorbed by hemoglobin in tissue while not losing energy through irrigation fluid</td>
<td>Same</td>
</tr>
<tr>
<td>FIBER DIFFERENCES</td>
<td>Fiber has highly reflective PhotoShield™ coating on back side (opposite the aiming beam) to prevent damage to non-targeted tissue</td>
<td>The PhotoShield™ coating is not available on the ADDStat™ fiber.</td>
</tr>
<tr>
<td>TOPIC</td>
<td>HPS</td>
<td>PV</td>
</tr>
<tr>
<td>-----------------------</td>
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</tr>
<tr>
<td>PRESERVING FIBER LIFE</td>
<td>Do not operate laser at maximum power settings until a channel is created and you can operate with a true “non-contact” technique.</td>
<td>Avoid tissue contact, which can cause premature fiber degradation and fiber failure, including shattering or cap detachment.</td>
</tr>
</tbody>
</table>

**UTILIZING MAXIMUM LASER POWER SETTINGS WHILE THE TISSUE TO FIBER DISTANCE IS <3 mm** MAY RESULT IN PREMATURE FIBER DEGRADATION, POSSIBLY INCLUDING SHATTERING OR CAP DETACHMENT.

If tissue is adherent to fiber, put the laser in STANDBY; remove the fiber from the cystoscope and clean it away from the tip with a moistened sterile gauze. Do not clean the fiber by rubbing it against tissue or burying it into tissue.

**Entrapment of laser fiber tip by large bubbles of hot vapor increases speed of fiber degradation.**

- **SAME.**
- **NOT APPLICABLE.**

<table>
<thead>
<tr>
<th>POWER SETTINGS</th>
<th>AMS recommends that the physician commences the procedure at lower vaporization settings until the urologist can judge the tissue response to the laser, and adjusts the power accordingly. The default vaporization setting for the HPS System is 80W.</th>
<th>Maintain power settings at 80W for vaporization. To coagulate, change power to 30W or increase distance to tissue.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Separate footswitches are used for vaporization and coagulation (similar to an electrosurgical unit). Default coagulation power setting is 20W; this can be increased if required.</td>
<td>Power settings must be manually adjusted by laser operator at console.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>TOPIC</th>
<th>HPS</th>
<th>PV</th>
</tr>
</thead>
<tbody>
<tr>
<td>POWER SETTINGS</td>
<td>If desired, increase power setting to achieve faster tissue removal. Increase power only after channel has been created so a working distance is available between tissue and fiber.</td>
<td>Does not apply; maximum vaporization setting is 80W.</td>
</tr>
<tr>
<td></td>
<td>To avoid inadvertent damage to sensitive anatomic structures such as the bladder wall, ureteral orifices, or adenomatous apical tissue near or beyond the verumontanum, the surgeon may choose to limit vaporization settings to 80W.</td>
<td>Same.</td>
</tr>
<tr>
<td></td>
<td>When treating very small glands, the surgeon may choose to use power settings less than 80W.</td>
<td></td>
</tr>
</tbody>
</table>

<p>| TISSUE DISTANCE       | A true “non-contact” technique should be employed. Fiber-to-tissue distance should BE APPROX. 3 mm. | Must maintain a “near contact” technique and stay 0.5 mm from tissue |
|                       | Do NOT increase power settings until a good working channel has been created so that contact between tissue and fiber can be avoided | Tissue to fiber distance of &gt;0.5 mm will coagulate tissue, resulting in dysuria, sloughing and prolonged catheterization time |
|                       | Fiber to tissue distance and good irrigation flow needs to be maintained to minimize fiber degradation. | Same. |
|                       | Surgeons who perform PVP with the fiber in tissue contact should consider revising their technique to non-contact to avoid fiber failure. | Same. |</p>
<table>
<thead>
<tr>
<th>TOPIC</th>
<th>HPS</th>
<th>PV</th>
</tr>
</thead>
<tbody>
<tr>
<td>COAGULATION OF BLEEDERS</td>
<td>Use the COAG footswitch. Cauterize a bleeder by “painting the neighborhood” surrounding the bleeder using 20W. Power can be increased if needed at the discretion of the treating physician/surgeon).</td>
<td>Adjust laser power to 30W, and maintain tissue distance of 0.5mm while treating the tissue around the bleeder. OR Defocus the beam (increase the distance between the fiber and the tissue) (increase the distance between the fiber and the tissue)</td>
</tr>
<tr>
<td>FIBROUS GLANDS</td>
<td>Vaporization of fibrous tissue can be achieved either by increasing power settings, decreasing sweep speed, or a combination of both.</td>
<td>Slow down sweep speed to speed up vaporization effect on tissue. A slower sweep speed allows the heat from the beam more time to penetrate fibrous tissue and heat the tissue to vaporization temperatures. Decrease fiber-to-tissue working distance.</td>
</tr>
<tr>
<td>IDENTIFICATION OF CAPSULE</td>
<td>The surgeon should identify capsular fibers and consider this anatomical landmark as the natural end point of the procedure.</td>
<td>Same.</td>
</tr>
</tbody>
</table>
First Case Selection and Scheduling

Learning Curve
Skills acquired with other cystoscopic procedures largely apply to GreenLight HPS™. Most urologists find the learning curve for PVP is relatively short, particularly if they are experienced at performing PVP with the GreenLight PV™ Laser System.

The GreenLight HPS™ procedure must be performed using a video camera system. **IF YOU ARE NOT PROFICIENT AT USING A VIDEO CAMERA SYSTEM IT IS STRONGLY SUGGESTED THAT YOU BECOME PRACTICED HANDLING VIDEO CAMERAS WITH PROCEDURES YOU ARE COMFORTABLE PERFORMING** (such as a TURP) prior to scheduling your first PVP procedure.

Patient Selection
If you have never done a PVP procedure before, we recommend selecting patients that fit the following profile for your initial cases:

- Prostate gland size under 40cc **AS MEASURED BY TRUS**
- Patients who are **NOT** on anticoagulants

Patients with large glands, are anti-coagulated, or who have an indwelling Foley catheter due to urinary retention pose a greater surgical challenge. Choosing the proper patients for your first cases will allow you to master fiber handling and vaporization techniques.

Scheduling of First Cases
For your first few cases an AMS Clinical Educator or AMS-certified trainer will be present to support you and answer any technical questions that may arise, as well as remind you about the keys to successful clinical outcomes.

*It is recommended that you schedule 2 or 3 procedures for your first HPS procedures. Clinical educators cover large territories. Accordingly, please coordinate dates with your clinical educator in advance.*
For your first day of GreenLight PVP Procedures with the HPS System, it is recommended that you:

- Schedule two or three (at most) procedures per physician
- Arrange for the procedures at the beginning of your operating schedule, not following major open procedures.
- Plan for an OR time of 90 minutes per case.

**Scheduling of Staff In-Service Education**

If the GreenLight HPS™ laser system is new to your facility, the AMS Clinical Educator will coordinate with the OR supervisor to include time to conduct In-Service training for the key personnel involved with operating the laser or specializing in urology. If you are using the services of a mobile laser provider, the provider will assume responsibility for in-servicing the staff of your facility.

The AMS Clinical Educator will contact you to coordinate dates for In-Service training of key staff members concurrent with your first procedures.

The afternoon before first procedures is an ideal time to conduct training for facility staff. Please make the key staff members available for a 60 minute time slot for the staff In-Service presentation and hands-on introduction to the GreenLight HPS laser system.

**In-Service Education of Facility Staff**

The AMS Clinical Educator will provide the staff copies of a Clinical Competency Validation Checklist (see Section 4: Support Materials) to ensure that key staff members have demonstrated the knowledge and skills required to operate the GreenLight HPS Surgical Laser System.

Subjects covered in the training session include:

- Laser Safety
- Basic understanding of the high-performance 532nm laser and tissue interaction
- Complete front-to-back demonstration of the GreenLight HPS laser system including setup, use, and storage.
- PVP procedure setup

If you do not have the contact information of an AMS Clinical Educator please call AMS Customer Service at 1-800-328-3881 in the U.S and Canada, international customers dial 001-952-930-6000.
Procedure Essentials

Choosing Power Settings
Laser parameters are selected and the system status is changed by using a touch screen. You may also use the button on top of the footswitch to go from “READY” to “STANDBY” laser status. The aiming beam is activated when the system is changed from “STANDBY” to “READY” and the surgical beam is activated by pressing the footswitch. Press the yellow pedal for “VAPOR” and the blue pedal for “COAG”. The laser provides audible voice confirmation of the laser status (“READY” OR “STANDBY”)

Power is set by touching the – or + buttons on the display screen. An audible tone will be heard when maximum or minimum levels are reached.

The default settings for the laser are 80W vaporization and 20W coagulation. AMS recommends that the surgeon consider titrating the laser power according to the tissue response. When treating very small glands, the surgeon may consider using power settings lower than 80W until tissue vaporization effect has been evaluated. If treating bladder tumors or strictures, the surgeon should use lower power settings

![Figure 1: The Touch Screen]

- Indicates Mode of Operation (Vapor/Coag)
- Vaporization Power Indicator
- Power Adjust Buttons
- Ready/Standby Control and Indicators
- Energy Indicator
- Changes the Set-up Screen (adjusting volume, screen brightness, contrast of screen)
- Coagulation Power Indicator
- Power Adjust Buttons
- Resets Energy and Lasing Time
- Total Lasing Time
How To Judge Proper Sweeping Speed:
The GreenLight HPS surgical laser system efficiently vaporizes tissue, as evidenced by the formation of “vapor bubbles”.

Choosing Laser Power Settings

Opening the urethral channel allows increased flow irrigation fluid into the bladder carrying the vaporization bubbles away from the visual field. At start-up, the default setting for vaporization is 80W. For smaller, more vascular glands, the surgeon may choose to remain at 60W throughout the procedure. The higher power is in reserve should you decide it is necessary to use it.

Judge the effectiveness of vaporization by the formation of vapor bubbles as well as the vaporization effect of the tissue. **Always keep the fiber moving to avoid forming deep holes or furrows in the tissue.**
Illuminate the Targeted Tissue

The GreenLight HPS System has a tighter beam profile with low beam divergence, which permits the surgeon to maintain efficient vaporization at fiber to tissue distances of 3 mm. The aiming beam should illuminate the tissue that is planned for removal. The surgeon should visualize the tissue that is targeted for removal prior to beginning vaporization, keeping in mind that the aiming beam exits with a 70° forward deflection. The location of the ureteral orifices must be identified before lasing begins.

The surgeon should exercise caution when treating the bladder neck to ensure that the laser beam does not fire into the bladder and damage the bladder wall or ureteral orifices. The surgeon should stop and evaluate the tissue effect after a few seconds. Following the procedure, the surgeon should again inspect the bladder and ureteral orifices to ensure that the laser beam has not caused unintended damage.

Working Distance

Improved collimation of the laser beam results in a tighter beam profile, resulting in low divergence of the laser beam as it exits the fiber. This feature allows the urologist to use greater fiber-to-tissue distances without sacrificing vaporization efficiency. The GreenLight vaporizes effectively at distances up to 3 mm.

When in “READY” mode the GreenLight HPS™ laser system’s red aiming beam will be visible. Note that the size of the aiming beam (the beam “footprint”) increases as the fiber is moved away from the tissue (see figure 3).
Contact between GreenLight HPS Delivery Fiber and Tissue

Contact between GreenLight HPS™ fiber and tissue should be avoided.

- Contact with tissue also encourages the adherence particles of tissue to the cap (see figure 3)
- Tissue attached to the fiber will absorb laser energy and distort the composition of the cap of the delivery fiber.

If tissue adheres to the quartz cap it must be cleaned off immediately.

Figure 3: Tissue on Fiber

Tissue adhered to delivery fiber can act as a “heat sink” and will accelerate fiber degradation.
Coagulation of Bleeding Vessels

Rarely will bleeding vessels (or “bleeders”) be encountered. However, if a bleeder occurs, the laser can be used to coagulate the vessel.

The GreenLight HPS laser system allows the operator to independently change the power setting of the system “On Demand” from “VAPORIZATION” mode to “COAGULATION” mode by use of the footswitch, in the same fashion surgeons use when operating an electrosurgical unit (ESU). There is no lag time waiting for the laser to adjust wattage settings, which allows the surgeon to immediately change the power settings according to the clinical situation.

Some surgeons have adopted a technique of coagulating superficial blood vessels at the beginning of the PVP procedure, and then proceeding to vaporize the adenoma in the standard manner.

The laser emission can be disabled and the aiming beam turned off at any time by pressing the “STANDBY” button or stepping on the “READY/STANDBY” button located on top of the footswitch housing. The laser provides audible voice confirmation of the laser mode (READY/STANDBY).

Coagulation can be achieved by stepping on the “COAG” footswitch, which decreases the laser power. This lower power will allow the fiber to be placed very near (but not directly on) the tissue surrounding the bleeder.

The HPS laser changes power settings immediately, without any lag time; thus allowing the surgeon to coagulate bleeders without delay.

The goal is to cause the heated tissue to swell and compress the bleeding vessel.

Do not aim the laser directly onto the bleeder. Direct lasing of the open end of a vessel may lead to the formation of vapor bubbles inside the vessel’s bloodstream, thus eroding a deep crater in the tissue and exacerbating the bleeding.
To clean the GreenLight HPS™ fiber:

1. Put the laser on “STANDBY”.
2. Using a wet, sterile gauze gently wipe the fiber from the tip down towards the fiber shaft. Do not wipe up towards the tip as this may result in the accidental removal of the quartz cap.

Caution: Improper cleaning of the fiber tip may cause damage to the fiber
Section Two
Pre- Intra- Post- Procedure
Pre-Procedure Guidelines

Initial Patient Workup

Patients should undergo a standard BPH workup, including a history and physical evaluation and laboratory analysis, as indicated by AHCPR guidelines or the clinical judgment of the urologist. A transrectal ultrasound (TRUS) should be performed on the first few patients you plan on performing the HPS procedure to select patients with smaller glands. Selecting patients with smaller prostate volumes for your first few procedures will shorten your leaning curve.

Pre-Procedure Patient Counseling

Patients should be provided with written instructions regarding changes in medications, NPO status, and what to expect post PVP.

- Have your patients discontinue anticoagulants if medically feasible. This includes, but is not limited to: aspirin, Coumadin®, Plavix®, ibuprofen, and herbal medicines.
- Patients should arrive at the health care facility approximately two hours before their scheduled treatment time.
- Patients must arrange for transportation home with a responsible party. Patients may not drive (or operate dangerous machinery) for 24 to 48 hours after the procedure.
- Give the patient a copy of the GreenLight Patient Information Brochure (p/n 21600087) for specific pre and post-procedure instructions. These guides can be ordered, free of charge, by contacting Customer Service at 1-800-328-3881.

Confirm Anesthesia

PVP procedures may be performed with general, spinal, or under monitored anesthesia care (MAC) with a pudendal block and topical lidocaine gel.

Coumadin is a registered trademark of DuPont Pharmaceuticals Co., Wilmington, DE 19898
Plavix is a registered trademark of Sanofi-Synthelabo, Paris 75013, France
Supplies Needed for PVP

Supplies needed for the PVP procedure are described in the Equipment Checklist. (see “Support Materials“ part of Manual)

Room or body temperature 0.9% normal saline solution should be used for irrigation.

DO NOT USE Glycine or Sorbitol during a PVP procedure as the heated sugar components will adhere to the tip of the fiber and damage the fiber.

Patient Preparation

Follow hospital protocols. Some surgeons choose to administer an antibiotic of choice 30 to 60 minutes before the procedure begins. Prep and drape the patient as for a standard cystoscopic procedure.
Continuous Flow Cystoscope

To perform the PVP procedure (see figure 1) we recommend the use of a continuous flow cystoscope which includes:

- A **22 to 24Fr outer sheath**.
- A **30-degree telescope** should be used as it allows inspection of the ureteral orifices as well as good visualization of the prostatic urethra.
- An **inner sheath** with a 7Fr working channel to stabilize the position of the distal end of the fiber (fiber bridge).
- The use of **visual obturator** provides a non-traumatic direct visualization of the insertion of the scope into the prostatic urethra.

![Figure 1: Components of the continuous flow cystoscope set used with the PVP Procedure.](image)

Inspect the outer sheath for scratches or burrs that may cause trauma to the urethra. Make sure that the 30 degree telescope is clear and dry, and that the fiberoptic cable is in good working order. Replace the light cable if more than 25% of the light bundles are broken.

Defogging agents may be used at the physician’s discretion.
Place Camera Insert

The camera filter insert is a small optical disc that is placed between the telescope and the camera. The insert protects the CCD chip in the camera from being damaged by the high-intensity laser light.

Caution – The video camera insert will not protect the eyesight of the patient, the operating room staff, or the physician.

There are two sizes of video camera inserts available (see figure 2).

- The larger camera insert is compatible with most camera systems.
- If the larger camera insert does not allow the telescope to securely couple onto the camera head, the smaller camera insert may needed instead.

Figure 2: Video camera inserts (pictured at actual size).

The inserts protect the video camera from intense laser light. Most camera systems will use the larger filter pictured at left. If the larger insert does not allow the camera head to securely couple to the telescope eyepiece, a smaller camera insert is included.
Inspect the video camera insert for cracks or damage prior to use.

The video camera insert may be sterilized either by steam sterilization or disinfected by immersion in 70% isopropyl alcohol prior to use.

Be sure to thoroughly dry the camera insert before placing it in the video camera. Do NOT immerse the camera filter in glutaraldehyde or Steris, as doing so will damage the protective coating of the filter.
To place the large camera insert (see figure 3):

1. Hold the camera so that the camera head is pointing towards the ceiling.
2. Place the camera insert so that the writing on the insert is facing the camera lens or that the “top hat” portion of the insert is on top. The camera insert will drop into place when the camera head coupler is depressed, as if you were connecting it to the cystoscope eye-piece.
3. Place the telescope on top of the insert so that the camera insert is held in place between the camera lens and the telescope.

![Figure 3: Placing video camera insert](image)

Figure 3: Placing video camera insert - Place the camera insert so that the writing on the insert faces the lens of the video camera and that the raised portion of the insert fits into the curved eyepiece of the telescope.

To place the small camera filter insert:

1. Hold the telescope portion of the cystoscope with the eyepiece facing up.
2. Place the video camera insert in the eyepiece so that the “top hat” portion of the insert faces down into the curve of the eyepiece and the writing faces up.
3. Place the video camera on top of the telescope and camera insert.

White Balance Camera
The video camera insert should be placed between the camera and the telescope before white balancing the camera system. White balancing the camera system against a sterile white (disposable) towel may be more effective than using a white gauze. It may be helpful to focus the camera on a distant object (infinity); such as a clock on the wall.
Procedural Steps

Introduction of Cystoscope

Assemble the continuous flow cystoscope with the visual obturator (see figure 1). Blind insertion of the cystoscope (without the visual obturator) can cause trauma to the prostatic urethra that may result in bleeding.

DO NOT open the GreenLight HPS™ fiber until after the cystoscope has been inserted and a preliminary cystoscopic exam has been performed. The GreenLight HPS fiber is intended for one-time use and cannot be re-sterilized or returned to AMS for re-sterilization.

![Continuous Flow Cystoscope with a visual obturator](image)

Figure 1: Continuous Flow Cystoscope with a visual obturator.
Inserting the Inner Sheath:
1. Remove the telescope and visual obturator from the outer sheath of the cystoscope.

2. Remove the visual obturator. Insert the camera and telescope into the inner sheath. Insert the inner sheath into the outer sheath of the cystoscope.
   **Note:** Make sure that the video camera filter insert has been placed between the telescope and camera.

Ask the circulating nurse to open the sterile package containing the GreenLight HPS fiber. Remove the fiber from the sterile packaging and carefully fold back the restraining tabs prior to removing it from its packaging nest. Inspect the tip of the fiber prior to inserting it into the working channel of the cystoscope.

Hand the coupling end of the fiber to the laser operator. The laser operator will insert the **Fiber Card** and then attach the fiber to the GreenLight HPS laser system.

**Insert GreenLight HPS™ Fiber**

To insert the GreenLight HPS fiber:

1. Advance the assembled cystoscope into the bladder.

2. Open the irrigation in-flow valve and allow the bladder to adequately distend.

3. Advance the GreenLight HPS 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 to the drainage drawer of the cysto table.
Identify Fiber Markings

Rotate the control knob of the fiber to examine the fiber markings.

Observe the **blue triangle** (see figure 3) on the quartz cap of the fiber (this may appear green to those personnel wearing the amber colored laser safety goggles).

- The blue triangle on the cap is contralateral to where the laser beam fires.
- **A portion of this blue triangle must be visible at all times to avoid damaging the cystoscope sheath and telescope** (see figure 3).

![Figure 3: Blue arrow (left) and red “Stop Sign” markings on the GreenLight HPS fiber.](image)

Rotate the fiber and take note of the **red stop sign** marking on the opposite side of the fiber (see figure 3).

- This stop sign is aligned with the aiming beam of the fiber.
- Visualization of this red stop sign while firing the laser may result in damage to the beak or the telescope portion of the cystoscope (see figure 4).

![Figure 3: Visualization of Fiber Markings](image)

-- Keeping the blue triangle of the GreenLight HPS fiber in the visual field will help protect the cystoscope by ensuring that the fiber is extended out of the working channel and is aimed away from the beak of the cystoscope (a). Retraction of the fiber beyond where the blue triangle is visible may cause laser damage to the fiber channel of the inner sheath (b). Visualization of the red “stop sign” marker indicates that the laser is firing in the direction of the cystoscope beak (c).
Check Aiming Beam

Verify that all personnel, including the patient, in the room have laser-wavelength specific eyewear. The correct eyewear for the GreenLight wavelength should state OD 5@ 532µm. Wait for verbal confirmation that all personnel are adequately protected.

Place the GreenLight HPS laser system from “STANDBY” into “READY” mode by depressing the footswitch. This will activate the laser’s aiming beam. The laser will provide an audible voice confirmation of the status of the laser by stating “READY” or “STANDBY” each time the footswitch is activated following a change of mode status.

- The red aiming beam is aligned in the same direction as the 532 532µm laser beam.

- Note how the beam’s footprint enlarges slightly as the working distance between the laser fiber and the prostate tissue increases beyond 3mm away from the tissue.

Before firing the laser, the laser aiming beam and fiber cap must be clearly visible through the cystoscope and the aiming beam is directed towards the targeted tissue.

Illuminate the tissue you wish to treat with the aiming beam. Never fire the laser unless you can see the aiming beam on the targeted tissue.

Note: The following procedural steps are only suggestions. For purposes of this training it is presumed that you are treating a moderately sized prostate (30 – 40mL total volume)
Removal of Median Lobe Adenoma

Orient the video camera so that it is level. Rotate the cystoscope so that the telescope is oriented at the default 6 o’clock position. It is important to note that the cystoscope remains quiet; only the fiber is moving. The cystoscope moves in a horizontal or vertical plane.

Begin the procedure by lasing the median lobe of the prostate.

**ILLUMINATE THE TARGETED TISSUE WITH THE AIMING BEAM.**
Remember that the aiming beam exits at a 70º forward deflection angle to the fiber axis. Use caution when treating tissue at the bladder neck to avoid incidental injury to the bladder wall and/or ureteral orifices.

Steadily rotate (or “sweep”) the delivery fiber across the tissue. Keep the fiber moving at all times.

Maintain a working distance of 3mm from the targeted tissue. Adjust your sweeping speed to maximize vaporization efficiency.

Consider titrating the laser power until desired tissue effect is achieved. The default setting of the laser is 80W vaporization and 20W coagulation. The laser can be adjusted in 10W increments. For smaller or vascular glands, it is recommended to be lasing at powers less than 80W and evaluate the tissue effect. Do not adjust the power of the laser until the effect of the laser on the tissue has been evaluated.

- Sweep the fiber so that it delivers laser energy between the 5 and 7 o’clock positions.
- Continue lasing tissue at the bladder neck until capsular fibers are visualized.

**TO PREVENT PERFORATION OF THE SURGICAL CAPSULE, IT IS IMPORTANT TO REMEMBER THAT FASTER VAPORIZATION OF FIBROUS TISSUE IS ACHIEVED WHEN USING THE HPS SYSTEM.**

**FAILURE TO RECOGNIZE THE CAPSULAR FIBERS MAY RESULT IN CAPSULAR PERFORATION.**
• Continue tissue removal by retracting the cystoscope gradually towards the verumontanum and sweep the fiber again to the level of the capsular fibers between the 5 and 7 o’clock position on the prostate floor. Part of the lateral lobes near the floor tissue may also be reduced at the same time.

• Continue to retract the cystoscope and reduce the floor tissue until the verumontanum has been reached.

If enlargement of the lateral lobes makes visualization of the floor difficult you may start lasing the lateral lobes to achieve better visualization of the tissue on the floor.

Removal of Lateral Lobe Tissue

Rotate the cystoscope 90 degrees while keeping the video camera on a fixed vertical plane.

1. Begin lasing tissue at the bladder neck by using a “sweep down technique”, which is to sweep the fiber in a downward motion between the 2 to 4 o’clock positions.

2. Systematically lase down to the capsular fibers from the bladder neck to the verumontanum.

3. Return the cystoscope to the bladder neck and repeat the same technique with the tissue at the 4 to 6 o’clock position. Once the entire lobe has been reduced rotate the scope to the contra-lateral lobe while keeping the video camera on the same fixed vertical plane.

4. Begin lasing at the bladder neck and this time sweep the delivery fiber between the 10 to 8 o’clock positions.

5. Systematically lase the tissue down to the capsular fibers from the bladder neck to the verumontanum.

6. Return the cystoscope to the bladder neck and repeat the same technique with the tissue at the 8 to 6 o’clock position.
Treating Anterior Tissue

The decision regarding the necessity of removal of anterior tissue is left to the judgment of the urologist. Some urologists do not believe that obstruction arises from the anterior tissue, and do not remove it when performing a TURP, while others believe it should be treated.

Turn the cystoscope upside down so that the telescope is looking at the 12 o’clock position. Keep the video camera at its original fixed vertical plane.

Begin lasing at the bladder neck by sweeping the delivery fiber between the 11 to 1 o’clock positions. Lase carefully down towards the apical tissue.

**Caution:** It is important to protect the verumontanum and the external sphincter from backward scatter or direct contact with the laser beam.

Confirm End Point

Retract the cystoscope to the verumontanum and look towards the bladder neck. Confirm a TURP-like cavity.

- This prostatic fossa will appear somewhat “ragged” as small strands of glandular tissue project loosely from the walls of the cavity (see figure 5). These miniscule remnants do not have to be removed as they will gradually slough over the course of several weeks and should not cause the patient to experience any negative symptoms.

![Figure 5. Procedure End Point](image)

*Figure 5. Procedure End Point* – Keeping the blue triangle of the GreenLight HPS fiber in the visual field will help protect the At procedure end-point the fossa may have small strands of prostatic tissue that will slough over a matter of weeks.
Check for Bleeders
Turn off the inflow and outflow valves of the cystoscope. Check the prostate carefully for bleeders in the same manner as you would do following a TURP. If bleeders are found, turn the inflow back on and coagulate the tissue surrounding the bleeders.

Fill bladder with saline and remove the cystoscope. Drain the bladder and check the flow and the color of the outgoing fluid.

Place Catheter (if necessary)
The surgeon may elect to place a Foley catheter if:

- The patient had a spinal anesthetic
- There is a possibility of the patient having an atonic, decompensated bladder or detrusor instability
- The patient has been catheter dependent or been relying upon intermittent catheterization for a period of time.
- There is a question of adequate hemostasis
- After treating very large glands
- Other factors to consider regarding inserting a catheter overnight may include:
  1. The distance the patient has traveled to the health care facility
  2. The time of day the procedure is performed (late afternoon vs. early morning)
  3. The climate (or time of year) that the procedure is performed (it may be wiser to place a catheter if you live in an area where severe winter weather is common)
  4. Whether the patient's spouse or care-giver drives at night. (many elderly patients do not drive after dark).

Placement of a catheter for all patients is recommended after the surgeon's first few HPS cases. Some physicians prefer to insert a catheter and wait until the patient is fully recovered from anesthesia prior to removing the catheter and attempting a voiding trial. If a catheter is inserted, postoperatively it typically may be removed within 24 hours.
Post-Procedure

Medications

As this is an endourological procedure, a post-op antibiotic is generally recommended.

Urinary analgesics should be considered for those who are experiencing irritative voiding symptoms pre-procedure, or if the surgeon has had to coagulate extensively throughout the procedure.

Systemic analgesics are generally not necessary following a PVP, but may be considered for people with generalized pain or have problems tolerating a catheter.

In addition the following types of medications may be prescribed at the physician’s discretion:

- Anti-spasmodic; anticholinergic medications
- Non-steroidal anti-inflammatory drugs (NSAID's)
- Stool softeners

Post-Op Protocol

Patients should be counseled that BPH does not solely affect the prostate, but affects the bladder function as well, as the bladder works harder to expel urine through the narrowed prostatic urethra. Following removal of the obstructing adenoma, the patient may initially feel as if his urgency has actually become worse until the bladder adjusts to the obstruction being removed. In a study of 160 men with LUTS, 55% of patients were found to have pure bladder outlet obstruction. 45% of these men were diagnosed with outlet obstruction in combination with an overactive bladder. (Knutson T, Edlund C, Fall M, Dahlstrand C (2001) BPH with co-existing oveactive bladder dysfunction- an everyday urological dilemma. Neurourol Urodyn 20: 237-247.)

Advise the patient to avoid strenuous activity (including all sexual activity) and exercise for three weeks after the procedure.

Patients may return to normal, non-strenuous, activities (including driving) within two to three days.
Patients should be advised that they may experience intermittent episodes of initial or terminal hematuria, dysuria, frequency, and urgency for the first several weeks postoperatively. *This is especially true of patients who complained of significant irritative symptoms pre-procedure, or who may have a previously undiagnosed overactive bladder.*

If patients are sent home with a catheter provide them with information regarding proper care of the catheter and (if applicable) instructions for removal.

**Dietary restrictions** as per physician’s routine. This may include limiting the consumption of alcohol, caffeine, spicy food, carbonated beverages, and citrus.

Schedule a post-operative follow up visit.

Have the patient read the [GreenLight Patient Information Brochure](#) for more information.
1. Keep the GreenLight HPS fiber moving over the targeted tissue to ensure even vaporization of the tissue.

2. **Illuminate the targeted tissue** with the aiming beam before firing the laser.

3. Start at default setting of 80W and **titrate** the power settings of the laser or adjust the sweep speed of the fiber across the prostate tissue according to tissue effect. When treating very small glands, the surgeon may choose to use power settings below 80W.

4. To prevent premature fiber failure, do not operate the GreenLight HPS System at settings higher than 80W until a sufficient working channel has been created to allow the surgeon to work in a non-contact mode with the fiber.

5. Entrapment of the laser fiber tip by large bubbles of hot vapor increases the speed of fiber degradation.

6. **Look for vapor bubbles** to confirm efficient vaporization of tissue.
Section Three
Considerations, Safety and Troubleshooting
Complications and Risks

Just as with any surgical procedure, some problems and complications may occur. The following information is provided to help avoid complications.

Difficult or Insufficient Vaporization
Glandular or vascular tissue vaporizes more readily than stromal or fibrous tissue.

Other tissue types include:

- Tissue that is low in hemoglobin content
- Coagulated tissue
- Malignant tissue
- Tissue with prostatic calculi
- Glands that have been treated with other therapies, such as TUR, TUNA, ILC, WIT and/or TUMT of the prostate, may have irregular response to vaporization; some areas may vaporize quite readily, while other areas may be more fibrous and require higher powers, slower sweep-speed, or a combination of both.

Increasing the power of the GreenLight HPS system and/or decreasing the sweep speed until desired tissue effect will improve the vaporization of this tissue type.

Discontinue the procedure if aggressive treatment with the laser does not produce favorable results.

Degradation of the Fiber and Effects upon Vaporization Efficiency
The fiber becomes damaged when the tip becomes too hot.

The main reasons why the tip can become too hot include:

- Decreased Irrigation - If the bladder is full and the irrigation flow is decreased, heat will begin to accumulate at the quartz cap compromising the efficiency and safety of the fiber. In order to avoid this risk always make sure the bladder is regularly drained.

- Tissue Adhesion - Tissue that is adhered to the fiber will act as a “heat sink” and cause heat to build up in the tip of the quartz cap. If tissue adheres to the cap it is important to remove the fiber from the cystoscope and remove the tissue (see Section 1 - Procedure Essentials)
• Entrapment of the laser fiber tip by large bubbles of hot vapor increases the speed of fiber degradation.

• **Operating the HPS System at greater than 80W while in direct contact with tissue.** Do not use the GreenLight HPS fiber at powers greater than 80W if you are in direct tissue contact. Once a sufficient channel has been obtained, the laser power can be adjusted upwards. Operating the HPS System at high powers when in direct tissue contact may result in the cap detaching from the fiber.

Prolonged tissue contact or tissue adhesion to the quartz cap that protects the optical fiber can lead to premature laser beam degradation. This degradation results from either the melting, discoloration, and/or roughening of the quartz cap surface. The HPS fiber was designed to experience less fiber degradation because surgeon operates at greater tissue distances without losing vaporization efficiency, minimizing the time the fiber is in tissue contact.

Degradation of the cap can be judged by visual inspection.

• When degraded, the laser beam gets scattered by the roughened cap surface.

• To check the beam quality (elliptical beam shape and homogeneous light distribution) shine the aiming beam on a piece of cloth or paper (see figure 1).

• To do this, you have to switch the laser to the “READY” mode. **Warning: Do not depress the VAPOR or COAG footswitches while checking the quality of the aiming beam with the fiber outside the cystoscope. Depressing the foot switch will result in high power laser beam emission and may cause damage to any item the beam hits.**
A degraded fiber should be replaced by a new fiber to ensure sufficient vaporization.

**Fiber Failure**
The quartz cap protects the cleaved tip of the fiber-optic portion of the GreenLight HPS fiber from exposure to irrigant. If the cap degrades to the point that holes form in the cap, irrigant may surround the fiber tip. If the tip of the fiber is darkened or charred, laser energy will be reflected back from the tissue to the fiber, and cause the fiber to fail. Internal exposure to irrigant will cause the laser beam to fire straight through the tip of the quartz cap (see Figure 2).
Fiber Breakage
Excessive heat build-up in the quartz cap can occur if tissue is allowed to accumulate on the fiber tip, resulting in fiber failure. Improper cleaning of the fiber by rubbing or burying it in tissue may result in breakage of the fiber.

Do not attempt to change the fiber's position in the cystoscope by twisting or bending the fiber's control knob (see figure 3). This will torque the optical fiber portion of the fiber and may result in breakage.

Use care when removing the fiber from the nest in the sterile package. Inspect the fiber for leaks (of light) and cracks before utilization. Inspect the length of the fiber optic portion of the fiber while in “READY” mode. If you see any red spots on the length of the fiber optic discontinue use and replace it with a new fiber and fiber card. If the fiber is noted to have any defect, please contact the Customer Response Center and request an RMA number (returned material authorization). Return the fiber and the fiber card in its original package.

Figure 3. Fiber Torque – Do not bend the control knob of the fiber in the cystoscope. This will not change the position of the fiber in the cystoscope and may instead result in fiber breakage.
Damage to Cystoscope

The GreenLight HPS or PV laser can cause significant damage to a cystoscope. Damage will occur if the laser is activated while the laser fiber is aimed towards or if the laser is activated while the aiming beam directed towards the inside of the cystoscope.

Damage to the cystoscope's outer sheath may cause rough or sharp spots on the sheath which may be traumatic to tissue. Damage to the scope's inner sheath (see figure 4) can create sharp points or ridges that may damage the GreenLight HPS fiber and result in premature fiber degradation or failure.

To avoid damage to the cystoscope be sure the blue triangle marking on the GreenLight HPS fiber is visible at all times.

Figure 4. Laser Damage to Inner Sheath – Laser activation while the fiber cap is still housed in the working channel may result in the formation of sharp spots or ridges. This image was taken of the inside of a cystoscope's inner sheath after it was noticed that the HPS fibers were “sticking” and failing prematurely.
**Poor Visibility**
Vaporization bubbles can obscure vision. To minimize the chance that vapor bubbles will impair visibility:

- Keep the tip of the fiber cap away from the lens tip
- Maintain adequate irrigation flow rate to allow for proper flushing of particles and vapor bubbles.

**Never activate the laser if the aiming beam is not visible on the targeted tissue.**

If bleeding obscures visibility, the surgeon may choose to defocus the laser energy by increasing the tissue from the fiber or by decreasing the laser power to 20W, or the power of his choice, by depressing the “COAG” switch on the footswitch. Lase around the bleeding site to seal the vessel.

**Fogging of Image**
Fogging or moisture on the telescope eyepiece, video camera insert and video camera can impair visibility.

- After instrument sterilization, allow 5 minutes for the instruments to cool down so that moisture can evaporate.
- If the video camera insert was soaked in alcohol allow 5 minutes for it to dry in air as fluid tends to seep into the filter mount.
- Make sure that irrigant is not leaking from the fiber port seal of the cystoscope and seeping between the camera and telescope.
- Consider the use of an anti-fog agent on telescope eyepiece, video camera insert, and video camera and allow it dry.
External Capsule Perforation

Capsular perforation was not reported during the multicenter patient trial. However, as with any endoscopic prostate procedure that removes tissue, (including TURP, HoLEP, HoLAP, or PVP), the possibility of capsular perforation does exist.

To minimize the possibility of perforation of the surgical capsule, it is important to recognize the end point of the procedure. It is important to keep the fiber moving, and not direct the laser energy at a fixed site for an extended period of time.

**DO NOT START LASING AT MAXIMUM POWER.** Begin the procedure at a lower power (watts) and titrate the power upwards until desired tissue effect is achieved. Vaporization efficiency drops towards the capsule due to the higher tensile strength of the fibrous tissue.

- Do not fire the laser on tissue that will not vaporize.
- Identification of the capsular fibers is important to prevent capsular perforation.

Laser Malfunction

The GreenLight HPS™ laser system will display an error message on the screen in most incidents of laser malfunction.

- System errors that don’t affect the performance of the laser can be reset and are identified by a message that reads **“Press Here To Continue”**.
- To reset the error, touch on the message on the screen and continue with the laser procedure.

If an error message can’t be reset or a laser malfunction is not identified by an error message, shut off the power to the laser and contact **AMS Customer Service at 1-800-328-3881 in the U.S. and Canada, international customers dial 001-952-930-6000**.

Under no circumstances should anyone other than an AMS representative repair or work on the GreenLight HPS™ laser system.
GreenLight HPS™ Laser Fiber Must Extend from Cystoscope
The laser fiber must extend far enough from the distal end of the cystoscope so reflection from the tissue or off the semi-reflective surface of the scope does not damage the telescope lens or the working channel of the inner sheath (Figure 5). It is recommended that the fiber tip extend 1-2 cm from the distal end of the cystoscope. Keep a portion of the blue triangle in the visual field at all times to prevent instrument damage.

Gravity Outflow vs. Active Suction

Use of a suction pump attached directly to the cystoscope is not generally recommended. However, if one is used, the surgeon must remember to keep the bladder adequately distended throughout the procedure, as with TURP. Contact between the hot or active quartz cap of the delivery fiber and a nearly empty bladder, with its wall collapsed toward the bladder neck, can cause significant damage to the bladder.
“Sweep” Laser for Efficient Tissue Removal

Special attention should be paid to the way the fiber is moved during the procedure.

- The PVP procedure is most efficiently performed by continuously sweeping the fiber over the tissue as if you were “painting” the tissue.

- A control knob is mounted on the fiber to enable fiber rotation. The knob is located near the fiber port of the cystoscope (see figure 6).

- The “paint brush” technique used in the PVP Procedure is in stark contrast to the fiber handling in the VLAP procedure where the fiber is dragged straight along the prostatic urethra. The recommended sweeping technique differs from the motion of the electrosurgical loop used in the TURP procedure.

Figure 6. Control Knob – Use the turning knob to rotate the GreenLight HPS fiber.
Avoid TURP-Like Motion

The GreenLight HPS™ fiber should not be pulled straight from the bladder neck toward the apex; especially when in tissue contact or when lasing at higher powers. (figure 7). This maneuver may create deep furrows in the tissue that may not allow the surgeon to judge the depth of the created defect. It is recommended that the fiber not be held at a fixed stationary point for longer than a few seconds, to avoid an unintended deep gouge or, worse, perforation of the prostatic capsule.

![Figure 7. Sweeping vs. Dragging of Fiber](image)

Figure 7. Sweeping vs. Dragging of Fiber – Tissue effect induced by a high performance 532nm laser applied to the prostate using two different fiber handling techniques. (Schematic cross section of the prostate)  
(a) The fiber is dragged along the urethra leaving deep incisions behind. At the end of the procedure a large volume of tissue remains un-ablated. (b) The laser beam is swept over the urethral wall in a “paint brush” motion quickly creating a wide open cavity with a smooth surface.

Returning to Previously Treated Tissue

Excessive coagulation of glandular tissue may lead to inefficient vaporization. If this type of tissue is encountered it is best to move on to another location in the prostatic urethra and proceed with vaporization and return to treat the coagulated tissue later.

Identification of Prostatic Capsule

To minimize the possibility of perforating the prostatic capsule, it is important for the surgeon to recognize the end point of the procedure. Identification of the capsular fibers should be considered to be the natural end-point of the procedure, as with TURP or the PVP procedure performed with the GreenLight PV™ laser system.
GreenLight HPS™ Laser Safety

The Laser Safety Officer can provide more information on all aspects of laser safety. This portion of the manual summarizes some of the more important features about safety in the operating suite when using 532nm lasers.

**Laser Safety Officer**
One person in the Healthcare Facility should be designated as the **Laser Safety Officer (LSO)**. Specific recommendations for laser safety can be found in AORN Standards and Recommended Practices, as well as the ANSI (American National Standards Institute) Standards. The LSO is responsible for ensuring that the laser safety precautions are met and that members of the surgical team and patient are protected prior to the laser being put into use.

**Laser Protective Eyewear**
The eyes are the most vulnerable part of the body that can be affected by laser energy. The 532nm wavelength is fully transmitted through clear fluids, and attracted to dark chromophores such as melanin or hemoglobin. The lens of the eye is designed to focus light on the retina, and will focus the light from a broken laser fiber onto the retina, resulting in permanent damage. The degree of damage depends upon the duration of exposure, power of the laser, and the area of the retina damaged. Protective eyewear **must** be worn by all personnel, including the patient, at all times when lasers are in operation.

Protective eyewear for different wavelengths of lasers is **not interchangeable**. They are specific for the laser wavelength being used.

- Protective eyewear should be labeled with wavelength and optical density information according to ANSI (American National Standards Institute) standards.

- If the laser wavelength you are using does not match that listed on the eyewear, your eyes will not be protected against exposure. The laser operator should verify this before distributing eyewear.

- The eyewear should be examined often for pitting, cracking or discoloration, and replaced as necessary.
• Eye protection glasses or goggles used with the *GreenLight HPS™ laser system* must be specified with an optical density (OD) of 5 at a wavelength of 532nm. AMS provides appropriate eye protection glasses with each laser system sold.

• For more information regarding eyewear or eye safety, please call AMS Customer Service at 1-800-328-3881 in the U.S. and Canada, international customers dial 001-952-930-6000.

**Who Should Wear Protective Eyewear**

Every person in the operating room including physician, operating room staff, anesthesiologist, observers, and the patient must wear protective eyewear. Extra sets should be hung on all access doors to the operating room to prevent personnel from entering the room without eye protection. The laser should be put into “STANDBY” mode immediately if anyone enters the room without protective eyewear.

Patients **must** also wear appropriate eye protection when the laser is in operation. This may include: moistened sponges or eyewear specific for the wavelength used.

**Operating Room / Equipment Preparation**

All windows in the operating suite with an opaque covering should be covered from the inside of the room.

When using endoscopes or video cameras, **protective safety filters must be used to protect the camera from damage from the laser light.**

**Laser Warning Signs**

Wavelength-specific warning signs should be posted on all access doors. The signs should be removed at the end of the procedure.
Potential Hazards
Lasers have inherent hazards. We will briefly discuss three different potential hazards:

Electrical Shock
Electrical shock can occur anytime you plug a piece of equipment into a power receptacle. Power cables should be handled with dry hands. The foot-switch should be handled by the metal housing, not the cable. Keep all cables in good repair.

Make sure that the circuit breaker on the GreenLight HPS Laser is in the “OFF” position before plugging or unplugging the laser from the wall.

Fire
Two types of fires can be associated with 532 nm lasers:
   1. Electrical fire
   2. Surgical drape ignition

Lasers in general should never be used in the presence of flammable materials, such as anesthetics, wet prep solutions, or alcohol.

Skin Injury
Skin injury with lasers can occur when non-targeted tissue is exposed to laser energy, whether it is the patient or a member of the surgical team. If the laser fiber is over-flexed, the fiber may break at the control knob, potentially resulting in a burn to the surgeon’s hand, the patient, or igniting the surgical drape.

The surgical team should also exercise caution when moving around the laser coupler, where the fiber is connected to the laser. If the fiber is bent, the laser energy can potentially burn through the sheath of the fiber, possibly burning a staff member or surgical drape. The laser should only be placed into “READY” mode after the tissue to be treated has been targeted.
## Trouble Shooting

### Procedural Problems

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<th>Possible Cause</th>
<th>Possible Solution</th>
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<tbody>
<tr>
<td><strong>Possible Cause</strong></td>
<td>Excessive tissue coagulation due to: • Failure to recognize a degraded fiber • VLAP technique used or applied) results in coagulation leading to edema formation</td>
<td>Improve fiber handling technique: • Improved sweeping technique • Remove tissue down to capsular fibers</td>
</tr>
<tr>
<td><strong>Possible overdistention injury of the bladder</strong></td>
<td>The use of a continuous flow cystoscope is recommended. It is recommended that the surgeon be observant of the inflow/outflow ratio of the irrigation fluid to minimize the risk of bladder overdistention.</td>
<td></td>
</tr>
<tr>
<td><strong>Degraded GreenLight HPS™ fiber</strong></td>
<td>Recognize signs of a degraded fiber. If the fiber must be in direct tissue contact due to anatomical limitations imposed by the adenomatous growth, it is recommended that vaporization settings are kept at lower powers. Clean the fiber immediately when tissue adheres to the fiber. Replace HPS™ fiber if necessary</td>
<td></td>
</tr>
<tr>
<td><strong>Insufficient tissue removal acting as a ball-valve.</strong></td>
<td>Systematic vaporization of each segment of prostatic lobe down to capsular fibers to establish tissue plane</td>
<td></td>
</tr>
<tr>
<td><strong>Prolonged irritative symptoms, (urgency, frequency)</strong></td>
<td>Urodynamic evaluation to rule out atonic, neurogenic bladder or detrusor instability if physician has suspicion that patient has co-existing bladder dysfunction. Manage patient expectations properly. The bladder also undergoes physiological changes in response to obstructive BPH, which may result in hypertrophy of the detrusor. As with TURP, improvements in Q-max are immediate. Similarly, patients may initially report increased urgency/frequency symptoms until the bladder adjusts to the fact that the obstruction is gone. Anticholinergic medications may be considered.</td>
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### Persistent Retention, Long Catheterization, Poor Peak Flow Rates

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<th>Potential Cause</th>
<th>Possible Solution</th>
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</thead>
<tbody>
<tr>
<td>Excessive tissue coagulation</td>
<td>Improved fiber handling technique as described above                                                                                                                                }</td>
</tr>
<tr>
<td>Underlying problems such as poor detrusor function, decompensated or neurogenic bladder</td>
<td>Consider urodynamic evaluation if warranted. Advise patients who may have concurrent bladder malfunction that optimal results may not be achieved (as with TURP)</td>
</tr>
</tbody>
</table>

### Persistence of Dysuria or Bothersome Symptoms

<table>
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<tr>
<th>Potential Cause</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underlying problems as listed above</td>
<td>Improve fiber handling technique as described above</td>
</tr>
<tr>
<td>Insufficient tissue removal; especially at bladder neck or apex.</td>
<td>Create a wide channel when vaporizing tissue; check quality of stream after removal of scope by filling bladder with irrigation solution and applying external pressure to dome of bladder</td>
</tr>
<tr>
<td>Excessive tissue coagulation</td>
<td>Scope should be maintained in a relatively “quiet” position throughout the procedure. The only movement of the scope should either be up and down, or from side to side.</td>
</tr>
<tr>
<td>Excessive scope movement in and out of the urethra throughout the procedure</td>
<td>Caution when lasing near bladder neck</td>
</tr>
<tr>
<td>Trigone or bladder floor has been lased (irritative symptoms)</td>
<td>AMS recommends to inspect the bladder floor and trigone region for evidence of incidental lasing prior to removal of the scope. If inspection reveals incidental lasing, prescribe appropriate medication for symptomatic relief. Advise patient that symptoms are temporary, and will decrease with time</td>
</tr>
</tbody>
</table>
### Excessive Treatment Time, Excessive Energy Expenditure

<table>
<thead>
<tr>
<th>Potential Cause</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inefficient tissue vaporization because of improper fiber handling technique, or randomized surgical approach to gland.</td>
<td>Approach the gland with a surgical plan for systematic tissue removal. Establish a working channel then treat one area of the gland at a time.</td>
</tr>
<tr>
<td>Fibrous tissue (less vascular tissue secondary to prolonged medical therapy treatment, prior thermotherapy procedures)</td>
<td>Awareness that fibrous tissue will require additional patience and lasing time. Increase power of laser and/or decrease sweep-speed until adequate tissue effect is achieved.</td>
</tr>
<tr>
<td>Degraded Fiber - Tissue adherent to quartz cap (cap not being cleaned frequently enough).</td>
<td>Cleaning fiber cap more frequently will extend fiber life and increase vaporization efficiency.</td>
</tr>
<tr>
<td>Too much attention paid to cleaning up loose tissue fragments</td>
<td>Loose fragments will slough off within weeks. “Making it look pretty” will increase operative time and increase the potential for coagulation of tissue, while not improving clinical outcomes.</td>
</tr>
</tbody>
</table>

### Post-Operative Bleeding

<table>
<thead>
<tr>
<th>Possible Cause</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-coagulated vessels in the operative field</td>
<td>Prior to completion of procedure, turn irrigation off, retract scope towards veru and watch for bleeders. Coagulate bleeders by firing laser with large working distance or at low power (20W)</td>
</tr>
<tr>
<td>Coagulated area may have been dislodged during foley insertion.</td>
<td>Placement of a Foley catheter and over-inflating the balloon will tamponade vessels.</td>
</tr>
<tr>
<td>Capsular perforation should be ruled out, depending upon surgeon’s judgment.</td>
<td></td>
</tr>
<tr>
<td>Urethral bleeding resulting from trauma during insertion of cystoscope.</td>
<td>Use visual obturator during insertion.</td>
</tr>
<tr>
<td>Patient engages in strenuous activity (or sexual activity) during first few weeks of post-op recovery.</td>
<td>Have patient reduce activity level, and increase fluid intake. Patients should be counseled to refrain from ejaculation during the first 2 to 3 weeks following PVP</td>
</tr>
</tbody>
</table>
## Dysuria (Persistent or Severe)

<table>
<thead>
<tr>
<th>Potential Technique</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>VLAP technique employed</td>
<td>Use sweeping technique.</td>
</tr>
<tr>
<td>Incidental lasing of trigone</td>
<td>Careful vaporization of median and lateral lobes, especially near bladder neck. Avoid extending tip of laser fiber into bladder when firing laser near bladder neck.</td>
</tr>
<tr>
<td>Damage to urethra resulting from trauma during insertion of cystoscope or damaged cystoscope</td>
<td>Use visual obturator during insertion. Inspect instruments prior to procedure.</td>
</tr>
</tbody>
</table>

## Incontinence, Stress Incontinence and/or dribbling

<table>
<thead>
<tr>
<th>Possible Cause</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underlying detrusor instability</td>
<td>Pre-procedure urodynamic evaluation as indicated. Manage symptoms with appropriate medications (e.g. oxybutrin).</td>
</tr>
<tr>
<td>Possible damage to external sphincter.</td>
<td>As with TURP, caution should be exercised when treating apical tissue.</td>
</tr>
<tr>
<td>Possible inadequate removal of tissue (remaining obstruction)</td>
<td>Be careful when treating near the verumontanum and apical tissue.</td>
</tr>
</tbody>
</table>
## Trouble Shooting

### Equipment Problems

#### Deteriorating Delivery Fiber Efficiency

<table>
<thead>
<tr>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue is adherent to quartz cap</td>
<td>Avoid tissue contact. Removal of adherent tissue extends fiber life. Use largest tissue to fiber distance possible consistent with maintaining effective vaporization</td>
</tr>
<tr>
<td>Excessive energy (joules) expended due to gland size; composition</td>
<td>Replace fiber as needed to improve vaporization if gland is very large or very fibrous, or if fiber was in tissue contact for prolonged periods to create a working channel</td>
</tr>
<tr>
<td>Tip integrity has been damaged</td>
<td>Inspect integrity of beam/ tip integrity • Remove foot from foot switch • Shine aiming beam against surgical drape to check for clean, concise margins of beam (beam edges should not appear “ragged”) Use proper technique when cleaning fiber tip</td>
</tr>
</tbody>
</table>

DO NOT BURY FIBER TIP IN TISSUE

#### Poor Visualization

<table>
<thead>
<tr>
<th>Cause</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate flow of irrigation fluid</td>
<td>Consider increasing flow of irrigation fluid (raise height of bags) to at least 1 meter above patient.</td>
</tr>
<tr>
<td>Irrigant is bloody.</td>
<td>Use a defocused laser beam or depress “COAG” footswitch and coagulate tissue around bleeding vessel.</td>
</tr>
</tbody>
</table>

#### Tip of Angled Delivery Fiber is “Caramelized”

<table>
<thead>
<tr>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycine (or other sugar-containing medium) is being used as irrigation fluid</td>
<td>Use ONLY 0.9% saline solution for irrigation fluid.</td>
</tr>
</tbody>
</table>
### Burning or Damaging of Sheath and Telescope

<table>
<thead>
<tr>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiber too close to end of scope</td>
<td>Keep blue triangle in visual field at all times</td>
</tr>
<tr>
<td>Sweeping motion too wide (turning indicator knob too far)</td>
<td>Keep “tight” sweeping radius (from 1:00 to 3:00, 3:00 to 5:00, etc.)</td>
</tr>
<tr>
<td>Failure to remove foot from footswitch (laser is activated) while removing fiber for cleaning</td>
<td>Ensure that footswitch is not depressed before beginning to remove fiber, and that laser is in “STANDBY” before removing delivery fiber from the patient.</td>
</tr>
<tr>
<td>Failure to rotate cystoscope &amp; camera</td>
<td>Always rotate cystoscope to keep cystoscope beak contralateral to laser beam</td>
</tr>
</tbody>
</table>

### Green Shadow Visualized on Monitor

<table>
<thead>
<tr>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiber becomes visible to camera chip through the view finder</td>
<td>Put cap on ocular of viewfinder</td>
</tr>
</tbody>
</table>

### White-Out of Visual Field When Laser is Activated

<table>
<thead>
<tr>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to insert video camera filter</td>
<td>Always insert camera filter between telescope eyepiece and camera head to protect camera CCD chip from damage!</td>
</tr>
</tbody>
</table>
Section Four
Support Materials
GreenLight HPS®
Support Materials

To help you and your staff organize the business of the GreenLight HPS® laser system, AMS has developed a package of practice assistance documents. The following forms are included in this chapter:

- **Equipment Check List** (OR equipment needed for the PVP Procedure)
- **Laser Log** (Check list and log for operation of the GreenLight Laser System)
- **Pre-Procedural Patient Instructions**
- **General Post-Procedural Instructions for Patients**
- **OR Readiness Survey**
Supplies Needed

The following is a list of supplies needed to perform a PVP™ Procedure using the GreenLight HPS laser.

**STERILE SUPPLIES**
- Continuous flow laser cystoscope (22-24 Fr) consisting of:
  - Outer sheath with beak
  - Inner sheath (laser bridge)
  - Visual obturator
  - 30º telescope.
- Video camera
- Fiberoptic cable
- De-fogging agent (anti-fog) for telescope, camera, and video camera insert
- GreenLight HPS™ fiber
- 0.9% Saline solution for irrigation (approx. 8-12 units of 3 liter bags at room or body temperature)
- TUR-Y irrigation tubing
- Suction tubing
- Cystoscopy pack
- Cover for back table (instrument trolley)
- Sterile gauze (4” x 4”)
- K-Y Jelly
- Sterile towels (4)
- Sterile gowns
- Prep solution of choice
- Sterile gloves
- Sterile bowl for irrigation (if desired)
- Have available:
  - Van Buren sounds
  - Foley catheter (16 - 20Fr. 5cc 2-way)
  - Urinary drainage bag
  - Catheter Stylet
  - 10 cc syringe
  - Sterile camera drape

**NON-STERILE SUPPLIES**
- GreenLight HPS™ Surgical Laser System
- GreenLight laser card (supplied in fiber package)
- Laserscope video camera insert marked O.D. 5 at 532 nm (diam. 1.25” part no. 10-0721 or diam. 0.95” 10-0722 dependent on video camera and telescope model). Both video camera inserts are delivered with each GreenLight HPS™ Laser System. Soak insert in alcohol or steam sterilize at 270° (30 lb psi) for 3 minutes to clean and let it dry prior to the procedure.
- Eye protection goggles for laser labeled O.D. (optical density) 5 at 532 nm (for everyone in room including the patient). (provided with laser)
- Laser warning signs on all entrance doors to the room
- Opaque window covering for laser safety required for all windows
- Light source
- G.U. Stirrups
- Irrigation Collection bottles (or floor drain)
- Irrigation/suction pump (optional)

If you have any questions, please contact AMS Customer Service at 1-800-328-3881 in the U.S. and Canada, international customers dial 001-952-930-6000.
# Laser Log

**Date:**

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Anesthesiologist</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Pre Op Dx</th>
<th>Anesthesia</th>
<th>General</th>
<th>Spinal:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Op Dx</td>
<td>Pudendal Block</td>
<td>IV Sedation</td>
<td></td>
</tr>
</tbody>
</table>

**Procedure** | Laser s/n |

**Prostate Gland Size:**

**Fiber Lot #**

**Circulating Nurse**

**Fiber Lot #**

If more than one fiber used, please note joules expended per fiber under comments section.

**Scrub Nurse**

**Total # of fibers used**

<table>
<thead>
<tr>
<th>Laser On</th>
<th>AM/PM</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Laser Operator</th>
<th>Laser Off</th>
<th>AM/PM</th>
</tr>
</thead>
</table>

**Lasing Time**

<table>
<thead>
<tr>
<th>watts</th>
<th>time</th>
</tr>
</thead>
</table>

**LASER SAFETY PROCEDURES**

<table>
<thead>
<tr>
<th>Power Settings Used:</th>
<th>watts</th>
<th>time</th>
</tr>
</thead>
</table>

Laser Warning Signs on Access Doors

Access Doors closed

Wavelength-specific eyewear used

Windows covered w/opaque covering

Fire Protection

Fire extinguisher and water basin in room

**COMMENTS:**
Pre-Procedural Patient Instructions

1. Follow any instructions given to you by your personal doctor.
2. Call your doctor if your condition changes, or if you develop a cold, infection or fever.
3. Let your doctor know if you are taking any blood thinners such as aspirin, aspirin-containing medications, ibuprofen, Coumadin® or Plavix®. Your doctor may recommend that you stop taking these medicines several days prior to the GreenLight HPS™ procedure.
4. Take any antibiotics as prescribed by your doctor.
5. Ask your doctor to prescribe medications he/she thinks you will need after your procedure before the day of your scheduled procedure. This will allow you to have those medications “on hand” when you leave the healthcare facility, instead of having to wait for someone else to take them to a pharmacy for you.
6. Write down any questions you have about the procedure and bring them with you. There will be plenty of time to answer your questions before or after your procedure.
7. You may eat and drink as usual the night before. Your urologist or anesthesiologist may allow a clear liquid breakfast, depending upon the time of day your procedure is scheduled. **If you are scheduled to have your procedure before noon, do not take anything by mouth (including water and coffee) after 12:00 midnight the night before.**
8. Wear comfortable, loose-fitting clothing to the healthcare facility on the day of your procedure.
9. Bring a list of all your medications, including over-the-counter medications or herbal remedies with you on the day of the procedure.
10. Ask your doctor if you should take your regularly prescribed medications on the day of the procedure.
11. Plan to arrive at the healthcare facility at least 2 hours prior to your scheduled treatment. Remember that you will also need to spend some time post procedure to recover from anesthesia prior to being discharged to home. If your doctor has indicated that you will need to stay overnight in the facility, please arrange for someone to pick you up the next morning at _____a.m.
12. Arrange for transportation home with a friend or relative. **You may not drive or operate dangerous equipment for 24 – 48 hours after the procedure.** (If you have spent the night in the healthcare facility, you will still need to arrange for a ride home.)
13. If you have any questions, or cannot keep this appointment, please call:

Practice/MD/RN Name

Phone

Coumadin is a registered trademark of DuPont Pharmaceuticals Co., Wilmington, DE 19898
Plavix is a registered trademark of Sanofi-Synthelabo, Paris 75013, France
General Post-Procedure Instructions

1) Follow your doctor’s instructions.
2) You may need to wear a catheter to drain your bladder after the procedure. This catheter is usually removed within 24 hours.
3) Do not drive or operate dangerous equipment for 24 to 48 hours following anesthesia.
4) Avoid beverages containing caffeine because they may cause bladder spasms. Also avoid carbonated beverages, citrus juices, or alcohol.
5) Activity level: Take it easy for 2 to 3 days. Do not engage in activities requiring heavy lifting, gardening, bicycling etc. This will increase the pressure your abdomen puts on the bladder, and may result in blood in your urine.
6) Take all medications as directed. Typical medications may include:
   a) Antibiotic (prevents infection).
   b) Non-steroidal anti-inflammatory drug (reduces inflammation).
   c) A drug to reduce bladder spasms.
   d) Mild over-the-counter pain reliever as needed.
7) Do not engage in any form of sexual activity for 2 weeks.
8) Take a stool softener if needed to avoid becoming constipated for 14 days.
9) Unless you have been advised to limit your fluid intake due to another medical condition, drink one glass (8 oz. or 1/4 liter) of water for every hour you are awake, about 64 oz. (or 2 liters) per day.
10) Please call the office at ___________________________ to schedule a follow-up appointment.
11) Please call the office immediately if any of the following symptoms appear:
   a) Bright red bleeding in urine with a heavy clot.
   b) Fever over 101° F (38°C).
   c) Inability to urinate for more than 4 hours.
   d) Feeling of bladder fullness that does not go away after urinating.

Your Contact Person, ________________________________, can answer any needs or concerns you may have.

The Telephone number is: ____________________________.
GreenLight HPS™
Space and Power Requirements

Positioning of the Laser Console
- Power connections must be within a radius of 6 feet from where the laser console will be positioned in the treatment room.
- The laser console, in turn, must be able to be positioned not more than 5 feet from the center line of the treatment table to ensure proper handling of the fiber.

ENVIRONMENTAL REQUIREMENTS
The recommended temperature range for the room where the laser will be operated is 55 to 85°F (13 to 30°C).

The laser unit’s dimensions are:

<table>
<thead>
<tr>
<th></th>
<th>Inches</th>
<th>Centimeters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width:</td>
<td>18.00</td>
<td>45.7</td>
</tr>
<tr>
<td>Depth:</td>
<td>34.00</td>
<td>83.8</td>
</tr>
<tr>
<td>Height:</td>
<td>46.3</td>
<td>117.5</td>
</tr>
</tbody>
</table>
# GreenLight HPS™ Operating Room Readiness Survey

<table>
<thead>
<tr>
<th>Facility Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Urologist Name:</td>
<td></td>
</tr>
<tr>
<td>Site Address:</td>
<td></td>
</tr>
<tr>
<td>City, State, Zip:</td>
<td></td>
</tr>
<tr>
<td>GU Nurse:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
</tr>
</tbody>
</table>

## Operating Room Equipment and Instrumentation

The GreenLight Photoselective Vaporization of the Prostate (PVP) procedure uses instrumentation and equipment common to the Genitourinary (GU) operating room (OR). When performing a PVP procedure, Laserscope recommends utilizing a 22 to 24 French short-beak continuous-flow cystoscope and a video camera. A complete short-beak continuous-flow cystoscope set is required; a complete set includes an outer sheath, inner sheath, telescope, and visual obturator. Smaller French-sized continuous-flow cystoscopes do not provide sufficient irrigation and drainage.

The short-beak continuous-flow cystoscopes used for the PVP procedure should be one of the following brands:

### Continuous Flow Laser Cystoscope

**STRYKER**

- Outer/Inner Sheath  502-880-300  Continuous Flow Laser Cysto Sheath
- Visual Obturator  502-880-301  Visual Obturator, Laser Cystoscope
- Telescope  502-880-030  Autoclavable Telescope, 4mm ; 30°

**ACMI/Circon**

- Sheath System, Short-Beak
  - Outer Sheath  CLS-23 SB  USA Elite System™ II Continuous Flow Laser Cystourethroscope Outer Sheath, short-beak, 23Fr
  - Inner Sheath  CLB8-23 SB  USA Elite System™ II Continuous Flow Laser Cystourethroscope Inner Sheath, short-beak, 23Fr
  - Visual Obturator  CLV-23  USA Elite System™ II Continuous Flow Laser Cystourethroscope Visual Obturator, 23Fr
  - Telescope  M3-30  USA Elite System™ M3™ Series 30° Foroblique Telescope, 4mm
  - or
  - Telescope  M3-30A  USA Elite System™ M3™ Series 30° Autoclavable Foroblique Telescope, 4mm
## Continuous Flow Laser Cystoscope (continued)

### STRYKER

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer Sheath</td>
<td>WA22810A</td>
<td>22.5 Fr Laser Cystoscope Outer Sheath</td>
</tr>
<tr>
<td>Inner Sheath</td>
<td>WA22850A</td>
<td>22.5 Fr Laser Cystoscope Inner Sheath</td>
</tr>
<tr>
<td>Visual Obturator</td>
<td>WA22830A</td>
<td>22.5 Fr Laser Cystoscope Obturator, Visual</td>
</tr>
<tr>
<td>Telescope</td>
<td>A1932A</td>
<td>30° Autoclavable Telescope</td>
</tr>
</tbody>
</table>

### Discontinued Sheath System

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer Sheath</td>
<td>A2296</td>
<td>22.5 Fr Laser Cystoscope Outer Sheath</td>
</tr>
<tr>
<td>Inner Sheath</td>
<td>A2297</td>
<td>22.5 Fr Laser Cystoscope Inner Sheath</td>
</tr>
<tr>
<td>Visual Obturator</td>
<td>A2298</td>
<td>22.5 Fr Laser Cystoscope Obturator, Optical</td>
</tr>
<tr>
<td>Telescope</td>
<td>A1932A</td>
<td>30° Autoclavable Telescope</td>
</tr>
</tbody>
</table>

### Karl Storz

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer Sheath</td>
<td>27026 LO</td>
<td>23 Fr Laser Cystoscope Outer Sheath</td>
</tr>
<tr>
<td>Inner Sheath</td>
<td>27026 LI</td>
<td>23 Fr Laser Cystoscope Inner Sheath</td>
</tr>
<tr>
<td>Visual Obturator</td>
<td>27026 LS</td>
<td>23 Fr Laser Cystoscope Obturator, Visual</td>
</tr>
<tr>
<td>Telescope</td>
<td>27005 BA</td>
<td>30° Autoclavable Telescope</td>
</tr>
</tbody>
</table>

### Richard Wolf

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer Sheath</td>
<td>8632.024</td>
<td>21 Fr Laser Cystoscope Outer Sheath</td>
</tr>
<tr>
<td>Inner Sheath</td>
<td>8632.025</td>
<td>21 Fr Laser Cystoscope Inner Sheath, 7 Fr working channel</td>
</tr>
<tr>
<td>Visual Obturator</td>
<td>8632.724</td>
<td>22.5 Fr Laser Cystoscope Obturator, Optical</td>
</tr>
<tr>
<td>Telescope</td>
<td>8654.402</td>
<td>30° Autoclavable Telescope</td>
</tr>
</tbody>
</table>

### Video Stack

Please indicate the manufacturer of the video camera and light source your facility uses.

#### Video Camera:

- Stryker
- Dyonics
- Olympus
- Karl Storz
- Richard Wolf
- ACMI/Circon

Other (specify): ____________________________________________

#### Light Source:

- Stryker
- Dyonics
- Olympus
- Karl Storz
- Richard Wolf
- ACMI/Circon

Other (specify): ____________________________________________
GreenLight HPS™ Electrical Service Requirements

Prior to installation, please have the facility electrician follow the Electrical Service Requirements.

The power source for the GreenLight HPS™ Surgical Laser System:

Voltage: 200-240 VAC (+/-10%) @50/60Hz
Current: 30 amps
Phase: Single (two wire with ground)

The electrical service must not have an auto-transformer (buck/boost transformer) between the panel and the outlet.

A 250 VAC, 30 Amp, 2 pole, 3 wire plug that complies with the U.S. National Electrical Code 517-61, Section B, Part 6 and NFPA Standard 99, Section C, Part 3, and is acceptable for portable medical equipment of this current rating is recommended. However, any hospital grade plug can be used as long as it meets the system's electrical requirements; meets facility, city, county, state, and country ordinances; complies with UL544 for leakage current; and is ETL certified.

Recommended receptacle and plug: Receptacle: Nema Configuration: L6-30R. The plug sent with the machine is the Hubbell twist lock plug: HBL2621 AMS PN 2120-0028.

GU Nurse Signature
Section Five
Laser Training
GreenLight HPS™
Laser / Tissue Interaction

Characteristics of Laser Light

Laser light can be used as a surgical tool because of its unique physical characteristics of being monochromatic and collimated.

- **Monochromatic light** (light of a single color as defined by its particular wavelength) can be used to selectively target tissue or structures within tissue that specifically absorb light of a certain wavelength.

![Figure 1: Monochromatic versus white light.](image)
• **Collimated light** (light that travels in a parallel beam) can be guided through optical fibers and focused on a small spot. This property allows fiber optic application of endoscopically directed laser-induced heat to destroy the targeted tissue with great precision.

![Collimated Light](image)

**Figure 2: Collimated Light** - Collimated light from a laser all travels in the same direction. White light

**Optical Penetration Depth**

*Optical penetration depth* is the distance that laser light will penetrate into tissue. Laser light directed at tissue is reflected partially by the surface of tissue. The remaining unreflected light enters tissue and is absorbed by a certain component of tissue acting as a chromophore for that particular wavelength, or it is scattered diffusely by in-homogeneities within the tissue. Both of these phenomena, namely absorption and scattering, limit the depth to which laser light can penetrate into tissue.

**Absorption of Laser Light**

Absorption of laser light in prostatic tissue is governed by two main components of tissue: water and hemoglobin. Absorption of laser light by a tissue chromophore leads to generation of heat:

- Vaporization of tissue water or coagulation (denaturation) of tissue protein occurs depending on the temperature reached locally in various parts of the targeted area.

- The patterns of absorption of different laser wavelengths in water and hemoglobin are substantially different.

The GreenLight HPS™ laser system emits visible green light at a wavelength of 532nm, which is absorbed strongly by hemoglobin (chromophore) but poorly by water.
Cystoscopic procedures that use an aqueous irrigant benefit significantly from this characteristic of the 532nm laser as the beam suffers no loss of energy while it travels through the irrigant to the tissue. Nearly all of the 532nm laser energy reaches the targeted tissue. At this point the 532nm laser energy is trapped in the superficial layers of tissue by its affinity for hemoglobin.

**532nm laser energy penetrates only 0.8 mm (optical penetration depth) into the prostatic tissue.**

Consequently, heat is confined to a very small volume of superficial tissue which, at high power settings, is vaporized immediately. Moreover, the high rate of absorption of green light in hemoglobin promotes heat-induced coagulation of the superficial blood vessels. Thus, a nearly bloodless surgical field is produced during the Photoselective Vaporization of the Prostate (PVP) procedure.
**GreenLight HPS™ vs. Other Lasers**

Comparison with modes of action of other laser wavelengths that have been used for the treatment of obstructive BPH demonstrates the uniqueness of the 532nm laser wavelength.

**GreenLight vs. nd:YAG Lasers**

The neodymium:yttrium-aluminum-garnet (Nd:YAG) laser (used in the VLAP procedure) emits an invisible infrared beam with a wavelength of 1064 nm. At this wavelength the Nd:YAG laser is absorbed by hemoglobin approximately 200 times less than 532nm. Therefore, relatively unhindered by its absorption in hemoglobin, the Nd:YAG laser beam is largely free to penetrate deeply (up to 10 mm optical penetration depth) into the prostatic tissue.

![Figure 3. Optical Penetration Depth of the GreenLight HPS 532nm wavelength and Nd:YAG lasers.](image)

1064nm laser energy penetrate up to 10mm in prostatic tissue while 532nm laser energy penetrates only 0.8mm.
Indeed, Nd:YAG laser energy permeates a relatively large volume of tissue. The volume of tissue is heated slowly and heat has time to diffuse into deeper layers of tissue before superficial vaporization ensues. Consequently, **vaporization (removal) of tissue by Nd:YAG laser is superficial and induces deep coagulation of tissue**. These events result in significant postoperative edema of the remaining coagulated prostatic tissue, prolonged urinary retention and significant dysuria during sloughing of the necrotic tissue (See Figure 4).

![Figure 4](image)

**Figure 4.** Diameter of prostatic cavitation defect in comparison with depth of coagulation 2 days after laser prostatectomy. Nd:YAG laser usage results in superficial vaporization with deep tissue coagulation. The GreenLight HPS laser vaporizes more efficiently with only minor coagulation.
GreenLight vs. Ho:YAG Lasers

The holmium:yttrium-aluminum-garnet (Ho:YAG) laser emits a pulsed, invisible infrared beam with a wavelength of 2100 nm which, in contrast to the GreenLight HPS laser, is absorbed much more strongly by water than by hemoglobin. The thulium laser (2,010 nm) operates much like the Holmium laser in reference to tissue effect. It has no clinical advantage regarding speed of vaporization, coagulation of bleeders, or treatment of larger glands. Ho:YAG laser energy preferentially heats the irrigant (water) to create vapor bubbles.

- Ho:YAG laser energy has to travel through these vapor bubbles in order to reach the target tissue.
- Because of the loss of energy spent to create a vapor bubble through which the laser beam has to travel to reach the tissue, the Ho:YAG laser energy is consumed significantly by the time it reaches the targeted tissue.

Furthermore, within the time frame of each pulse of the Ho:YAG laser, the aforementioned events rob so much time that the actual duration of direct exposure of tissue to the Ho:YAG laser in near-contact mode becomes rather limited. Therefore, the Ho:YAG laser does not vaporize prostatic tissue efficiently in near-contact mode.

The mechanical impact of sequentially formed vapor bubbles can, however, be used to tear the surface of the tissue on contact. This property allows Ho:YAG laser to be a good cutting tool in contact mode. This also makes Ho:YAG the ideal tool for treating urinary calculi.

Mechanism of GreenLight Laser Vaporization of Tissue

The mechanisms behind GreenLight laser vaporization of tissue at a microscopic level help explain the basis of the PVP technique.

The structure of soft tissue is basically composed of water, blood vessels, and collagen matrix. The collagen matrix acts as the mechanical stabilizer of tissue.

1. The 532nm (GreenLight) laser beam is absorbed strongly within the very superficial layer of tissue by virtue of the fact that blood vessels and hemoglobin (chromophore) contained therein serve as primary absorbers.
2. Heat generated by absorption of the GreenLight laser energy leads to formation of vapor bubbles inside the targeted tissue wherever the temperature of water reaches the boiling point.
3. Continued application of laser energy leads to continued boiling of tissue water.

4. When vapor pressure exceeds the ultimate tensile strength of the matrix the structure of the targeted tissue disintegrates. A volcanic eruption of vapor bubbles results venting water vapor and small fragments of tissue into the irrigant.

5. Continued exposure of the targeted area to GreenLight laser energy leads to progressive vaporization of the newly exposed deeper layers of tissue, accompanied by release of more vapor bubbles and tissue fragments.

**Efficient Vaporization of Tissue Removes Heat**

These events are the hallmark of efficient removal of tissue. *It is important to understand that the very process of vaporization carries away heat from the targeted tissue and, thus, prevents deep coagulation.* Therefore, relatively little heat remains inside the tissue immediately after cessation of laser application.

Consequently, superficial coagulation ensues wherever the local temperature exceeds 65°C and leads to excellent hemostasis. Sealed blood vessels and lymphatics prevent absorption of fluid and resultant dilutional hyponatremia.

| **Photothermal:** |
| Heating of tissue to temperatures < 100°C |
| Tissue coagulation at 65 - 99°C |

| **Photoablation:** |
| Heating of tissue to 100°C |
| Tissue removal by vaporization (PVP) |

*Figure 6.* Photothermal versus Photoablation effects of laser / tissue interaction. Vaporization occurs when tissue is heated to 100°C.
Tissue Composition Affects Vaporization Efficiency
The manner in which the GreenLight laser interacts with tissue at the microscopic level illustrates why glandular tissue vaporizes faster than fibrous tissue.

• **Glandular tissue** possesses a mechanically weak matrix which barely withstands laser-induced buildup of vapor pressure. Glandular tissue will, therefore, disintegrate quickly upon laser application, and may require lower power to achieve optimal vaporization.

• **Fibrous tissue**, on the other hand, is characterized by higher collagen content and, hence, a higher ultimate tensile strength. It requires a much higher vapor pressure to be reached before its matrix bursts. Vaporization of fibrous tissue occurs more slowly. The GreenLight HPS laser system allows the user to use higher power settings and not sacrifice vaporization efficiency.
Instrumentation and Application of the GreenLight HPS™ Laser

The laser energy for PVP is produced by the GreenLight HPS™ high-power 532nm laser system which emits a maximum power of 120 watts (W). The laser operates at a quasi-continuous pulse mode.

GreenLight HPS™ Fiber

The GreenLight HPS™ laser system is equipped with a red aiming diode laser beam that is co-aligned with the treatment beam and, therefore, is an essential guide in targeting the prostatic tissue. Laser energy is applied through a 600 μm side-firing GreenLight HPS laser fiber. The polished end internally deflects the laser beam laterally at an angle of 70 degrees relative to the axis of the fiber. A quartz glass cap with a diameter of 1.8 mm (6Fr) protects the polished end of the fiber optic portion of the delivery fiber. The fiber emits a divergent beam with an opening angle of 15 degrees (See figure 1). The beam diameter (spot size or footprint) at a distance of 1 to 3 mm from the fiber tip is remains virtually consistent.

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Figure 1. Beam characteristic of the GreenLight HPS™ laser fiber. The power density in the divergent laser beam decreases with increasing distance from the fiber tip.
**Distance GreenLight HPS Fiber Must Extend from Cystoscope**

Be certain that the laser fiber extends far enough from the distal end of the cystoscope so that reflection from the tissue or the semi-reflective surface of the scope does not damage the lens tip of the cystoscope or the working channel of the inner sheath (Figure 2). It is recommended that the fiber tip extend 1-2 cm from the distal end of the cystoscope. The distance between fiber tip and lens can be judged by the visibility of the blue triangle printed on the fiber cap.

![Figure 2. HPS Fiber: Extension out of cystoscope - Visualize the blue triangle on the fiber at all times to prevent laser beam damage to the cystoscope, outer sheath, or telescope.](image)

**Gravity Outflow vs. Active Suction**

**Use of a suction pump attached directly to the cystoscope is not generally recommended.** However, if one is used, the surgeon must remember to keep the bladder adequately distended throughout the procedure, as with TURP. Contact between the hot or active quartz cap of the delivery fiber and a nearly empty bladder, with its wall collapsed toward the bladder neck, can cause significant damage to the bladder.
“Sweep” Laser for Efficient Tissue Removal

Special attention should be paid to the way the fiber is moved during the procedure.

- The PVP procedure is most efficiently performed by continuously sweeping the fiber over the tissue as if you were “painting” the tissue.

- A control knob is mounted on the fiber to enable fiber rotation. The knob is located near the fiber port of the cystoscope (see figure 3).

- The “paint brush” technique used in the PVP Procedure is in stark contrast to the fiber handling in the VLAP procedure where the fiber is dragged straight along the prostatic urethra. The recommended sweeping technique differs from the motion of the electrosurgical loop used in the TURP procedure.

Sweeping the fiber across the tissue takes advantage of the high vaporization efficiency of the GreenLight HPS laser system and gives the urologist full control over the tissue effect.

Figure 3. Control Knob – Use the turning knob to rotate the GreenLight HPS fiber.
Avoid TURP-Like Motion

The HPS fiber should not be pulled straight from the bladder neck out toward the prostatic apex (figure 4). This maneuver leads to deep furrows that do not allow sufficient visual control of the depth of the created defect. The fiber should not be held at a fixed stationary near-contact point for longer than a few seconds, to avoid an unintended deep gouge or, worse, perforation of the prostatic capsule.

Figure 4. Sweeping vs. Dragging of Fiber  – Tissue effect induced by a high power 532nm laser applied to the prostate using two different fiber handling techniques. (Schematic cross section of the prostate) (a) The fiber is dragged along the urethra leaving deep incisions behind. At the end of the procedure a large volume of tissue remains un-ablated. (b) The laser beam is swept over the urethral wall in a “paint brush” motion quickly creating a wide open cavity with a smooth surface.

Returning to Previously Treated Tissue

Excessive coagulation of glandular tissue may lead to inefficient vaporization. If this type of tissue is encountered it is best to move on to another location in the prostatic urethra and proceed with vaporization and return to treat the coagulated tissue later.

Identification of Prostatic Capsule

To minimize the likelihood of perforation of the prostatic capsule, it is important to remember that the HPS System provides more rapid vaporization of fibrous tissue. The surgeon should identify the presence of capsular fibers and consider this as the natural end-point of the procedure, as with TURP.
References


GreenLight HPS™
Procedure Training Quiz

1) Surgeons should select patients with which characteristic for their first 10 PVP cases?
   - [ ] Patients on Anticoagulants
   - [ ] Patients who have had previous thermal therapies
   - [ ] Patients with prostates <40mL in volume (as measured by TRUS)

2) What types of anesthesia can be used with the PVP Treatment?
   - [ ] Spinal
   - [ ] General
   - [ ] Prostate Block with light IV Sedation
   - [ ] All

3) Can patients who have undergone previous TURP and minimally invasive therapies be treated with PVP?
   - [ ] Yes
   - [ ] No

4) What is the optimal working distance between the HPS Delivery Fiber fiberoptic and tissue during treatment?
   - [ ] 0.5-1 mm
   - [ ] 1-3 mm
   - [ ] 5-6 mm
   - [ ] 7-8 mm

5) The red aiming beam is in alignment with which part of the HPS Delivery Fiber fiber?
   - [ ] Red “Stop Sign” Marking
   - [ ] Blue Arrow Marking

6) During treatment it is important to continuously move the fiber in an:
   - [ ] Up and Down
   - [ ] Side to Side
   - [ ] Paint brush or Sweeping motion
7) Vaporization efficiency is best measured by:
   - Joules of laser energy delivered per minute
   - Appearance of vapor bubbles in conjunction with tissue removal effect

8) In the event of a bleeding vessel, coagulation can be achieved by:
   - Decreasing the working distance
   - Firing directly onto the bleeding vessel
   - Increasing the working distance or decreasing the laser power to 20 W

9) The visual endpoint of vaporization is achieved when the capsular transverse fibers are observed.
   - True
   - False

10) Can patients be sent home without a urinary catheter?
    - Yes
    - No
Quiz Answers

1) **PATIENTS WITH PROSTATES <40mL AS MEASURED BY TRUS.** Patients with large glands, are anticoagulated, or have failed thermal therapy pose a greater surgical challenge. Choosing the correct patients during the first 10 cases will allow surgeons to master fiber handling and vaporization techniques without risking fatigue.

2) **ALL.** The Anesthesia options for the PVP treatment include:
   - General anesthesia
   - Short acting spinal anesthesia
   - Periprostatic block or prostatic pudendal nerve blockade with Monitored Anesthesia Care (MAC) and urethral topical anesthesia

3) **YES.** All redo-TURP procedures and minimally invasive therapy failures, such as redo-TUMT, redo-TUNA and redo-ILC can be successfully treated with the PVP treatment.

4) **3MM** Although at times it is OK to keep the fiber in contact for 2-3 seconds, the fiber should always remain 1 to 3 mm from the tissue. This protects the delivery fiber from heat damage and allows for efficient vaporization.

5) **THE RED “STOP SIGN” MARKING.** Visualization of the blue triangle, which is located opposite the red stop sign, means that the laser will be firing away from the cystoscope’s telescope.

6) **PAINT BRUSH OR SWEEPING.** It is very important to continuously move the fiber over the tissue as if you were “paint brushing” the tissue in a swinging or sweeping motion. The fiber should not be held at a fixed stationary point for longer than 2-3 seconds.
Quiz Answers

7) APPEARANCE OF VAPOR BUBBLES IN CONJUNCTION WITH TISSUE VAPORIZATION EFFECT The process of vaporization carries away heat from the targeted tissue and, thus, prevents deep coagulation.

8) INCREASING THE WORKING DISTANCE OR DECREASING THE LASER POWER TO 20 W. Coagulating vessels can be easily accomplished by increasing the working distance to more than 2 mm or by decreasing the laser power to 20 W as both techniques reduce the power density on the tissue and cause tissue coagulation without tissue vaporization.

9) TRUE. Once you have observed the capsular fibers the vaporization is complete.

10) YES. The PVP procedure creates superficial vaporization with very little edema.