



## Proven Clinical Outcomes

# Driven by Superior Technology

#### Not all Lasers for the Treatment of BPH are the Same

The GreenLight HPS® Laser System combines an optimal 532 nm wavelength with advanced laser technology to provide a superior solution for the safe, effective and efficient treatment of BPH and other urologic conditions. Over 600 clinical papers and abstracts supporting GreenLights' safety and efficacy in the widest range of patient profiles provides clinical proof that GreenLight™ is indeed different than other laser technologies.

- Over 500,000 patients treated worldwide
- Used by more urologists worldwide than any other laser for the treatment of BPH
- Proven equally effective as TURP, with fewer complications
- Proven safe and effective for patients on anticoagulation therapy
- Proven safe and effective for the treatment of large prostates
- · Outpatient procedure
- Also used for the treatment of bladder tumors and urethral strictures

Over 600 clinical studies and abstracts support safety and efficacy





Over 500,000 patients worldwide have been treated with GreenLight



# Wavelength is the Primary Factor Influencing

# Procedural Efficiency & Clinical Outcomes

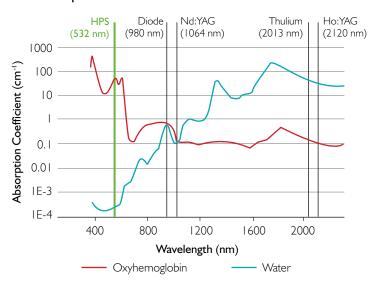
#### Procedural Efficiency

Compared to other lasers for urologic applications, GreenLight's 532 nm wavelength is highly selectively absorbed in tissue hemoglobin and is not impeded by the procedural irrigant. These unique properties allow GreenLight to efficiently and rapidly vaporize prostatic tissue.<sup>6</sup>

#### • GreenLight is absorbed by oxyhemoglobin:

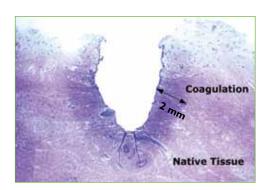
- 40 times greater than Diode
- 100 times greater than Thulium and Ho:YAG

### Absorption



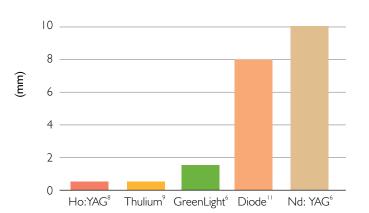
#### Clinical Outcomes

GreenLight's depth of tissue coagulation, irrespective of the power level utilized, does not exceed I - 2 mm because most of the thermal energy is both consumed and carried away by the highly efficient vaporization effect.<sup>6</sup> This means minimal disruption to non-vaporized tissue preventing tissue sloughing which could result in retention.



Histological image of bovine prostatic tissue vaporized at 80 watts showing I-2 mm zone of coagulation utilizing GreenLight HPS.

#### Depth of Coagulation



Deeper coagulation may be a key factor influencing increased dysuria rates and other post-procedural complications.

# Taking Proven Success to a New Level:

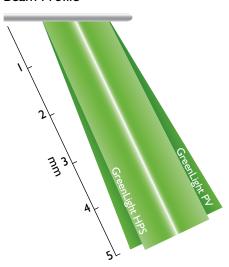
# High Performance

Refinements to the original 80-Watt GreenLight PV technology led to the GreenLight High Performance System (HPS), which boasts significant advantages over its predecessor.

The I 20-Watt HPS unit, with its higher power and more collimated beam, allows more effective energy delivery per unit surface area, providing a more efficient rate of prostatic tissue vaporization.<sup>7</sup>

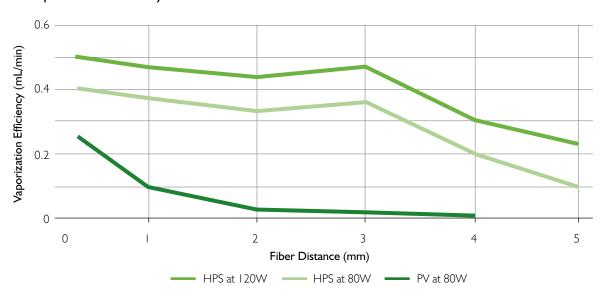
- Minimal loss of vaporization efficiency up to 3 mm from tissue.<sup>7</sup>
- HPS removes up to 100% more tissue than PV over the same period of time at a setting of 80W.<sup>7</sup>

#### Beam Profile



The beam profile of the GreenLight HPS is more collimated than that of the GreenLight PV. This means increased power density at further distances from the tissue.

#### Vaporization Efficiency



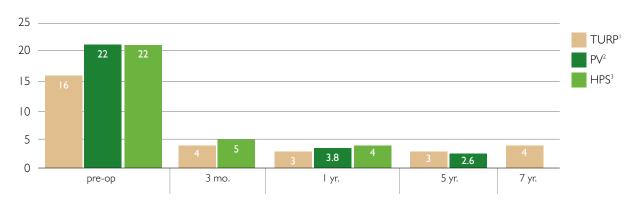
Data on file at AMS has shown that HPS at 120W vaporized tissue 100% faster than PV at 80W in bovine prostatic tissue (ex vivo). $^{7}$ 

## Documented Clinical Outcomes

# Proving Equivalency to TURP with Fewer Complications

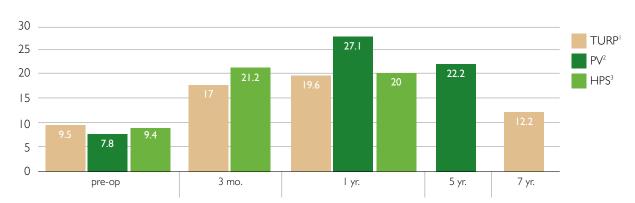
GreenLight™ Laser Therapy offers clinical outcomes equivalent to Transurethral Resection of the Prostate (TURP) for the treatment of BPH, with fewer complications. More than 600 clinical papers and abstracts have proven the safety and efficacy of GreenLight: no significant risk of TUR syndrome, fluid absorption or blood transfusion, and no increase in erectile dysfunction postoperatively. <sup>10</sup>

#### **AUA Symptom Score Improvement**



Five-year observations suggest that GreenLight PV provides significant and sustainable long-term improvements.

## Mean Peak Flow - QMAX (mL/sec)



Many patients obtain symptom relief and a dramatic improvement in urine flow usually within 24 hours of the procedure. GreenLight PV studies show dramatic urine flow improvement of 170%-252% improvement at three years.

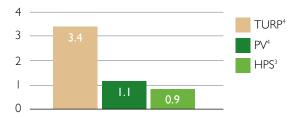
#### Length of Catheterization (Hours)

100% catheter-free by 23 hours.3



Many patients do not require a catheter following the procedure. If one is required, it is typically removed in less than 24 hours.

#### Length of Stay (Days)

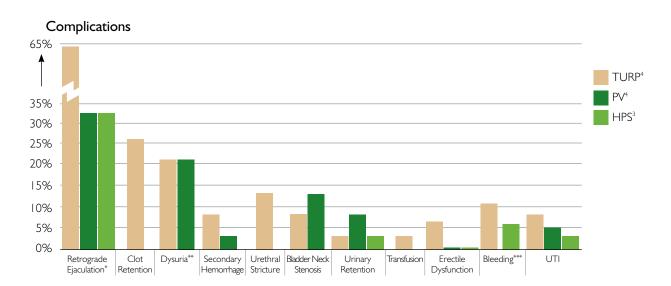


Because GreenLight has minimal risk of blood transfusion most patients return home a few short hours after the PVP procedure and can return to normal, non-strenuous activities within days. TURP requires a hospital stay and a lengthy recovery time.

#### Expected Cost per Patient (\$)



GreenLight ranged from 1.3 - 3.3 times less costly than TURP in a series of comparative studies (including disposables, capital equipment, and hospitalization).



<sup>\*</sup> TURP study showed a retrograde ejaculation range of 53%-75%, \*\* Dysuria was not an end point in the HPS study, \*\*\* Bleeding defined as non-significant hematuria > I week

# The GreenLight HPS® Laser System Specifications\*



Laser Type Diode-pumped solid state laser operating at 532 nm	
Aiming Beam Diode laser, red, 635 nm, < 5 mW adjustable	Operating Temperature 55°F (13°C) - 85°F (30°C)
Output Beam Divergence 0.05 - 0.15 radians full angle at half maximum	Storage Temperature 50°F (10°C) - 104°F (40°C)
Power Settings 20 - 120W in 10W increments - vaporization	Humidity 10% - 90%, non-condensing
	Dimensions 46.3"H x 18" W x 33"D
Requirements 200 - 240 VAC, 30 Amps @ 50/60 Hz, self adjusts to voltage and frequency	(117.5 cm x 45.7 cm x 83.8 cm )
	Weight 335 pounds (152 kg)

**SOLUTIONS FOR LIFE®** For more than 35 years, American Medical Systems® has provided world-class medical devices used for treating pelvic health issues. Over the past decade, our reputation for quality and medical efficacy has broadened to encompass both devices and therapies that restore pelvic health for men and women. The medical conditions our solutions address include male and female urinary incontinence, erectile dysfunction, prostate disorders (including BPH), urethral strictures, pelvic organ prolapse and fecal incontinence.

**Cooling**Air cooled



See the Instructions for Use and the Operator's Manual for the complete directions, contraindications, warnings and risks associated with the device.

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- \* Nominal

