

GreenLight™ Laser Therapy

Advanced Treatment for Benign Prostatic Hyperplasia

Patient Information

Introduction

You are receiving this brochure because you have been diagnosed with benign prostatic hyperplasia (BPH), commonly known as an enlarged prostate and may be a candidate for GreenLight™ Laser Therapy.

An enlarged prostate can mean frequent trips to the bathroom and interrupted sleep. Medicines for this condition may not work that well, can be expensive, and may have unpleasant side effects.

If this sounds like you, it's time to take action. There are more treatment options today than ever before.

GreenLight Laser Therapy has helped hundreds of thousands of men similar to you gain relief from frustrating BPH symptoms affecting their lives and the people closest to them.

We hope you find this brochure informative and that it helps you find the right treatment option for your condition. If you have additional questions, please be sure to ask your doctor.

With GreenLight Laser Therapy, you can get help with your BPH symptoms, to help you quickly get back to the things you like to do.

What is GreenLight™ Laser Therapy?

GreenLight™ Laser Therapy
has helped over
700,000 men worldwide.¹



Lasers are now used in many areas of medicine including eye² and cosmetic surgery.³ They are also used to treat an enlarged prostate.⁴

During the GreenLight procedure, the tissue blocking your prostate is rapidly heated and vaporized. Natural urine flow is rapidly restored in most patients.

Typically, the procedure is performed as a same-day surgery. Many patients can go home without a urinary catheter. An overnight stay may be recommended for some patients.

When Medicine Isn't Enough

Alternative Treatment Options

Typically medicines are first used to treat an enlarged prostate. However, sometimes drugs don't provide enough symptom relief. Or the side effects can be bothersome. Drugs can be expensive. Or there may be other reasons medical therapy for BPH isn't right for you.

Fortunately, there are alternatives. Surgical methods to treat an enlarged prostate include:

Transurethral resection of the prostate (TURP) – This procedure involves use of a heated wire to cut tissue from the prostate and has been used to treat an enlarged prostate for years.

Open surgery – This procedure involves removal of the inner part of the prostate through an incision made in the abdomen.

Other types of lasers – In addition to GreenLight™ Laser Therapy, other systems remove enlarged prostate tissue through the use of high-energy lasers. Clinically documented laser therapies have become a viable treatment option.⁵

Transurethral microwave therapies (TUMT) – In this therapy, a microwave antennae mounted on a catheter is used to heat the prostate and open up the blockage.

Advantages of GreenLight™ Laser Therapy

Compared with traditional surgical options, GreenLight™ Laser Therapy is associated with:

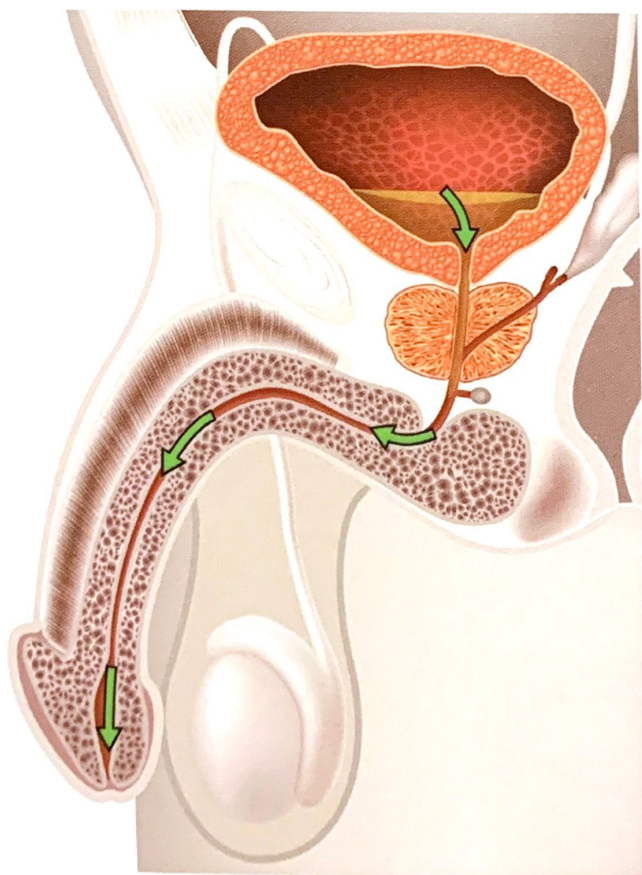
- Significantly less chance of severe blood loss⁶
- Same-day surgery in most cases⁷
- Significantly, faster recovery in typical cases for the following:^{6, 8-11}
 - Shorter hospital stay
 - Shorter catheterization time
 - Less bleeding
- Comparable risks and outcomes

Hospital length of stay and time with a urinary catheter are typically shorter with the GreenLight procedure than TURP.^{6, 8-11}

What Happens during the GreenLight™ Procedure?

The following is intended as a general overview. Your experience may differ. Please talk to your doctor about potential risks and questions you may have about the procedure.

Normal Prostate



Enlarged Prostate



- 1 Before treatment begins, you may be asked to empty your bladder.
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- 2 You will then be brought into the procedure room and moved to the treatment bed where you will lie on your back. Your doctor may give you a medication to help you relax.
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- 3 The procedure is typically performed under general anesthesia. This means that you will be asleep during the procedure. A different type of anesthesia may be used, depending on the treatment center.
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- 4 Once the anesthesia takes effect, your doctor will insert a small scope into your urethra. The scope allows your doctor to see the inner surfaces of the urethra, prostate and bladder.
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- 5 After the scope is in place, your doctor will advance the laser device through the scope to the location of the enlarged prostate tissue.
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- 6 Your doctor will then vaporize the prostate tissue that is obstructing urine flow. Dead tissue that is not immediately vaporized will be passed naturally in your urine during the first few days after your surgery.
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- 7 A temporary urinary catheter may be placed at the end of the procedure to let urine drain from your bladder.

After the Procedure

People typically go home within a few hours after the procedure. You should arrange for a ride home.

If a urinary catheter was placed in your bladder at the end of the procedure, it will typically be removed within 24 hours. However, some patients may require a catheter for a longer time.

Most patients experience very rapid relief of symptoms and a dramatic improvement in urine flow. This usually occurs within 24 hours of the procedure. Your experience may differ.

Your doctor will provide you with specific discharge instructions and information on signs and symptoms that may require further medical attention.

You may experience mild discomfort such as slight burning during urination and see small amounts of blood in your urine for a week or so. Also, depending on the condition of your bladder, you may experience greater frequency and urge to urinate. This will likely resolve over time.

Usually, you can return to your everyday activities within a short time after the GreenLight™ procedure. If you have any questions, ask your doctor.

Risks

Every surgical procedure may have complications. The same is true for GreenLight™ Laser Therapy.

The most common complications include:

- Hematuria – Blood in the urine
- Irritation of the bladder – Results in frequent and/or urgent need to urinate
- Irritation of the urethra – Frequent urination, burning sensation
- Retrograde ejaculation – Semen during sexual climax travels backward to the bladder rather than exiting through the penis

At doctor's instruction, some patients taking blood-thinners can be treated with GreenLight without stopping their medicines.¹²

Tried and Tested Technology

GreenLight™ Laser Therapy has been well documented and numerous articles have been published about the therapy in medical literature.

Based on these articles, GreenLight Laser Therapy:

Has low complication rates⁶, and short catheterization^{6, 8-11, 13-14} and hospitalization times.^{6, 8-11, 14}

Can be used if you are taking blood thinners¹², in urinary retention¹⁵, or have a large prostate (> 100 ml).⁸

Can be used if you have an implanted pacemaker, defibrillator, or neurostimulator.¹⁶

Next Steps

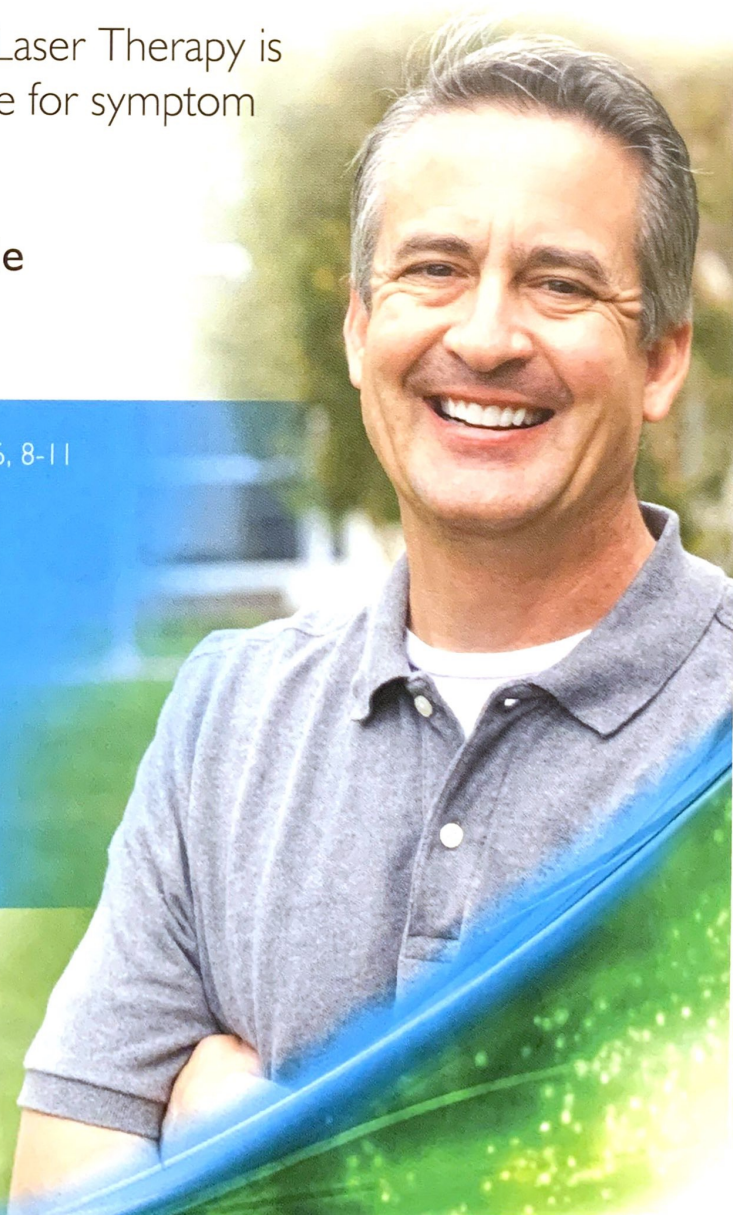
You can get back to your life without the hassles of remembering to take BPH or enlarged prostate pills, dealing with side effects, and paying for prescriptions.

Talk to your doctor to see if GreenLight™ Laser Therapy is right for you. It just might be the best choice for symptom relief from an enlarged prostate.

It's time to take action and get measurable results – without medications.

GreenLight Typically Delivers^{6, 8-11}

- ✓ Rapid relief
- ✓ Fast recovery time
- ✓ Short hospital stays
- ✓ Short catheterization times



FAQs

Q Is prostate enlargement a type of cancer?

A No. Prostate enlargement occurs naturally as a man ages. It will affect approximately 50 percent of men between the ages of 51 and 60 and up to 90 percent of men over the age of 80.¹⁷ No one knows exactly why the condition occurs.

Q Do I have to stay in the hospital after a GreenLight™ procedure?

A GreenLight is generally performed as a same-day surgical procedure. Typically, an overnight stay in the hospital is not required.

Q What effect does the GreenLight procedure have on sexual function?

A In a recent study, 86% of patients reported improved or unchanged sexual satisfaction; 14% worsened. Similar outcomes were seen for erectile function.⁸

Q How long does it take until symptoms are relieved?

A Most patients experience very rapid relief of symptoms and improvement in urine flow within 24 hours of the procedure. However, medical history, health conditions, and other factors can influence treatment and recovery.

Q Will I continue to need prostate medication after the GreenLight™ procedure?
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A Most patients are able to discontinue taking their prostate medication within a few weeks after the GreenLight procedure. However, as with any medication, consult with your doctor before making any changes to your dosing.

Q How soon can I return to work?
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A Most patients can resume their normal activities within a couple of days. Strenuous activities can be resumed within a short time. Your doctor will discuss any restrictions and your specific condition with you during your visit following your procedure.

Q Is GreenLight Laser Therapy covered by insurance?
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A Yes, GreenLight Laser Therapy is covered by Medicare and most private insurers.

American Medical Systems, Inc. does not guarantee insurance coverage for any procedure or product. It is the responsibility of the patient to contact their insurance provider for specific coverage information.

Resources

We understand how important it is to get answers to questions that you might have about prostate health. The following resources can help you learn more about advances in the diagnosis and treatment of an enlarged prostate.

GreenLight™ Patient Website – You can find a wealth of information about GreenLight Laser Therapy on our website at: www.greenlightforbph.com.

Urology Care Foundation – The Urology Care Foundation is the official foundation of the American Urological Association and provides extensive information on prostate health on its website at: www.urologyhealth.org.

National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC) – This website is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH). In addition to basic information on an enlarged prostate, you will find links to the latest research and statistics on prostate health at: www.kidney.niddk.nih.gov.

Commonly Used Terms

Benign prostatic hyperplasia (BPH): A non-cancerous enlargement of the prostate.

Bladder: Hollow organ in the lower abdomen that stores urine.

Catheter: A flexible tube for withdrawing fluids from (or introducing fluids into) a cavity of the body, especially for inserting into the bladder, through the urethra, to remove urine.

Ejaculation: The release of semen from the male reproductive system.

Erectile dysfunction: Inability to develop or maintain an erection.

Hematuria: Blood in the urine.

Impotence: Inability to maintain an erection and/or the inability to ejaculate.

Incontinence: Loss of control of the bladder. Can range from minor leakage to total inability to control bladder function.

Laser energy: A highly concentrated, very intense beam of light energy that can create high temperatures.

Prostate: Gland in males located in front of the rectum and below the bladder. The main function of the prostate is to transport sperm during ejaculation.

Retrograde ejaculation: Semen travels backward to the bladder during sexual climax rather than exiting through the penis.

TUMT: Treatment for an enlarged prostate that uses heat to treat an enlarged prostate. Stands for transurethral microwave therapies.

TURP: Common surgical treatment for an enlarged prostate. Stands for transurethral resection of the prostate.

Urethra: Tube that connects the urinary bladder to the genitals for the removal of fluids from the body.

Urinary urgency: A sudden, compelling urge to urinate.



All surgical treatments have inherent and associated risks. The most common risks associated with Photoselective Vaporization of the Prostate (PVP) are: hematuria; short term dysuria; and, urinary tract infections. You should talk with your doctor about benefits and risks before moving forward with any treatment option.

References

1. AMS. Data on file.
2. Munnerlyn CR. Lasers in ophthalmology: Past, present and future. *J Mod Opt.* 2003;50:2351-60.
3. Hruza GJ, Dover JS. Laser skin resurfacing. *Arch Dermatol.* 1996;132(4):451-455.
4. McVary KT, Roehrborn CG, Avins AL, et al. Update on AUA guideline on the management of benign prostatic hyperplasia. *J Urol.* 2011;185(5):1793-803.
5. Hueber PA, Zorn KC. Canadian trend in surgical management of benign prostatic hyperplasia and laser therapy from 2007-2008 to 2011-2012. *Can Urol Assoc J.* 2013;7(9-10):E582-6.
6. Bachmann A, Tubaro A, Barber N, et al. 180-W XPS GreenLight laser vaporization versus transurethral resection of the prostate for the treatment of benign prostatic obstruction: 6 month safety and efficacy results of the European multi-centre randomized trial – The GOLIATH Study. *Eur Urol.* November 12, 2013. E pub ahead of press.
7. Garnick MB. 2013 Annual Report on Prostate Diseases. Boston, MA: Harvard Health Publications; 2013.
8. Lukacs B, Loeffler J, Bruyère F, et al. Photoselective vaporization of the prostate with GreenLight 120-W laser compared with monopolar transurethral resection of the prostate: A multicenter randomized controlled trial. *Eur Urol.* 2012;61(6):1165-73.
9. Capitán C, Blázquez C, Martín MD, et al. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia: A randomized clinical trial with 2-year follow-up. *Eur Urol.* 2011 Oct;60(4):734-9.
10. Al-Ansari A, Younes N, Sampige VP, et al. GreenLight HPS 120-W laser vaporization versus transurethral resection of the prostate for treatment of benign prostatic hyperplasia: a randomized clinical trial with midterm follow-up. *Eur Urol.* 2010 Sep;58(3):349-55.
11. Bouchier-Hayes DM, Van Appledorn S, Bugeja P, et al. A randomized trial of photoselective vaporization of the prostate using the 80-W potassium titanylphosphate laser vs transurethral prostatectomy, with a 1-year follow-up. *BJU Int.* 2010 Apr;105(7):964-9.
12. Sohn H, Choi YS, Cho HJ, et al. Effectiveness and safety of photoselective vaporization of the prostate with the 120 W HPS GreenLight laser in benign prostatic hyperplasia patients taking oral anticoagulants. *Korean J Urol.* 2011; 52(3): 178-83.
13. Ahyai SA, Gilling P, Kaplan SA, et al. Meta-analysis of functional outcomes and complications following transurethral procedures for lower urinary tract symptoms resulting from benign prostatic enlargement. *Eur Urol.* 2010 Sep;58(3):384-97.
14. Pereira-Correia JA, de Moraes Sousa KD, Santos JB, et al. GreenLight HPS[™] 120-W laser vaporization vs transurethral resection of the prostate (<60 mL): A 2-year randomized double-blind prospective urodynamic investigation. *BJU Int.* 2012;110(8):1184-9.
15. Woo H, Reich O, Bachmann A, et al. Outcome of GreenLight HPS 120W laser therapy in specific patient populations: those in retention, on anticoagulants, and with large prostates (≥ 80 ml). *Eur Urol.* 2008;7 (suppl):378-383.
16. AMS, Inc. (2010) GreenLight XPS[™] Laser System Operator's Manual, Part No. 0010-0240 Rev. C. November 2010.
17. Barry M, Roehrborn C. Management of benign prostatic hyperplasia. *Annu Rev Med.* 1997;48:77-189.