

Embrace Life

without Enlarged Prostate

The logo features a blue circular graphic with a white spiral inside, positioned behind the text.

Cooled
ThermoTherapy™

For the Treatment of BPH

Because results matter.





“After 3 years of paying for drug therapy and letting BPH run my life I decided to take action in the form of a Cooled ThermoTherapy procedure. Cooled ThermoTherapy gave me my life back! I can now go out to dinner and not have to plan my meal around trips to the bathroom. The advice I have to my peers is not to wait. Seek out a urologist and find out if Cooled ThermoTherapy is right for you.”

Tom Hiland, Lakewood, CO

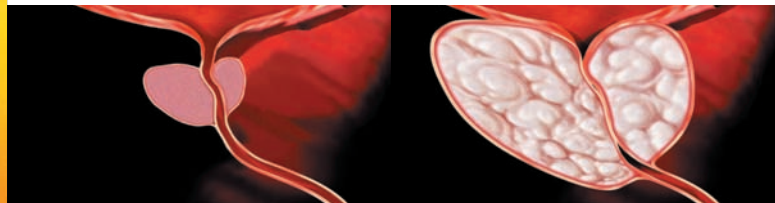
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About Enlarged Prostate or BPH

Benign prostatic hyperplasia (BPH) is the medical term for an enlarged prostate and Cooled ThermoTherapy™, a safe and durable outpatient procedure performed in your urologist’s office, is a leading minimally invasive procedure that is used to treat BPH.

BPH is one of the most common medical conditions among men over 50. It is non-cancerous and occurs naturally during the aging process as the number of prostate cells increases. The progression of BPH causes the prostate gland to become larger and compress the urethra causing frequent and sometimes painful or difficult urination. Interference with sexual activity may also occur. Severe BPH can cause urinary retention, requiring an immediate trip to the emergency room. *To assess your symptoms turn to page 11 of this brochure.*



How do you know if you have BPH? The symptoms include a frequent or urgent need to urinate, difficulty starting and/or sustaining urination or a feeling of being unable to completely empty your bladder.

Millions of men take medication for BPH, which is often prescribed after they discuss their symptoms with a physician. However, drug therapy means taking medication every day for life. Many men find this difficult and expensive. Some experience side effects; for others, the medications’ effectiveness decreases over time and BPH symptoms return.

For all these reasons, urologists often recommend a **minimally invasive procedure** as an alternative in BPH treatment. Cooled ThermoTherapy provides effective and lasting results, allowing men to stop taking BPH medication and avoid surgery.

Management & Treatment Options

There are three main approaches to the treatment of BPH: prescription drugs, **minimally invasive procedures** and surgery.

Drug Therapy

Doctors commonly recommend drug therapy as the initial treatment for BPH. While medicines may relieve your BPH symptoms, at least initially, none of these drugs stops the progression of the disease.

If you have BPH, you may be taking one or a combination of these medications:

- **Avodart®** (dutasteride) and **Proscar®** (finasteride)-**5 Alpha Reductase Inhibitor drugs** interfere with the production of a hormone involved with BPH, shrink the prostate and improve symptoms.
- **Flomax®** (tamsulosin), **Cardura®** (doxazosin), **Hytrin®** (terazosin), and **Uroxatral®** (alfuzosin) are **Alpha Blocker drugs**. They can help to relax the smooth muscle of the prostate and bladder neck, potentially improving urine flow.

Long-Term Effectiveness. While medications provide initial relief from BPH symptoms, some men find that the drugs' effectiveness decreases over time and their symptoms return. When compared to **Cooled ThermoTherapy** at one year, various drug therapies show significantly less improvement in BPH symptoms.¹

¹ Djavan, Heat versus Drugs in the Treatment of BPH, *BJU International*, 91, 131-137: 2003.

Side Effects. For some men, BPH medications cause unwanted side effects, such as dizziness, low blood pressure, loss of sex drive and erectile dysfunction.

Convenience. For many mature men, the hassle of having to take an additional pill when they may be on a variety of medications is burdensome.

Cost. For many men and their families, the cost of BPH medication is an expensive and inconvenient burden. BPH patients can expect to spend thousands of dollars on these medications over a period of five years.



Office-Based Procedures

Men who seek long-term relief of their BPH symptoms often choose a minimally invasive office-based procedure over surgery. If you don't want to take medication forever, or your **enlarged prostate** medication stops working, you should consult with your doctor to determine if a minimally invasive option is right for you.

These procedures utilize targeted heat energy and catheter technologies to destroy enlarged prostate tissue and relieve pressure on the urethra. Office-based procedures typically are performed with oral medications in a urologist's office.

Cooled ThermoTherapy is a leading minimally invasive procedure for BPH. Urologists choose it for its proven safety and long-lasting effectiveness, which have been documented in numerous clinical articles and presentations. During the procedure, unique cooling mechanisms protect healthy tissue and enable more BPH tissue to be removed than other office-based procedures.

When compared to various drug therapies one year after treatment is started, Cooled ThermoTherapy shows significantly more improvement in BPH symptoms. Cooled ThermoTherapy studies have shown significant and lasting improvement in BPH symptoms for up to five years following treatment. For precautions associated with Cooled ThermoTherapy, see the brief statement on the back of this brochure.

Surgery

Prior to 1993, surgery was the only therapeutic solution available for men with BPH. Today, it is offered to patients who do not respond to other treatments or who cannot tolerate BPH medication. Surgery provides the most improvement in symptoms but has a higher incidence of complications. If you have prostate surgery, you will need general anesthesia and will have to stay in the hospital, probably for 1 to 3 days.

Transurethral Resection of the Prostate. TURP is a common surgical BPH procedure. The inner portion of the prostate is surgically removed. There is some risk of serious complications. Approximately 10% of TURP patients need another procedure within 5 years. Post-surgical problems can include erectile dysfunction, ejaculation problems and urinary incontinence.

Laser Surgery. A variety of laser procedures have been introduced over the past few years. Short-term improvement in symptoms are similar to TURP, but with fewer complications. However, extensive clinical data confirming the long-term viability of laser surgery is not yet available.

Cooled ThermoTherapy Question and Answers

Below are answers to some of the most frequent questions about the procedure.

Q: Why should I have a minimally invasive procedure?

If you are looking for long-term relief of your **BPH** symptoms, with few side effects, you may choose a minimally invasive procedure over surgery. These procedures are typically performed in a doctor's office or hospital outpatient setting and you won't have to stay overnight in the hospital.

If you don't want to take medication forever, or your **enlarged prostate** medication stops working, you and your doctor should determine if a minimally invasive option is right for you.

Q: What is Cooled ThermoTherapy?

Cooled ThermoTherapy delivers precisely targeted energy to destroy enlarged prostate tissue. Unique cooling mechanisms protect the healthy surrounding urethral tissue. Cooling the urethra reduces the need for anesthesia and provides a more rapid recovery. It allows concentrated energy to be used to destroy enlarged prostate tissue and provides long-lasting reduction in the symptoms associated with BPH.

Q: Why should I choose Cooled ThermoTherapy?

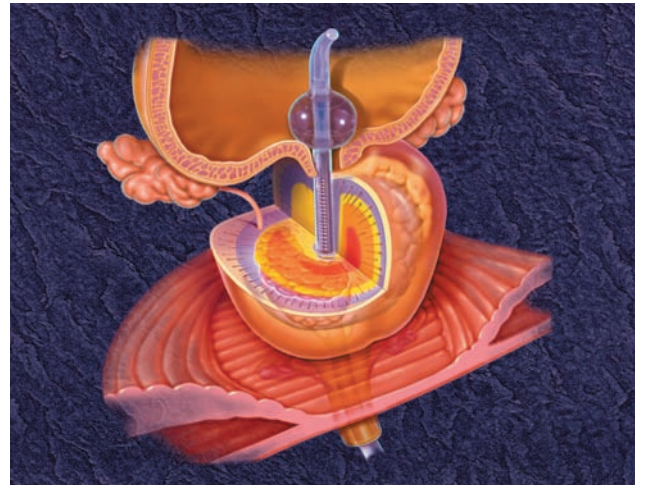
- More than 200,000¹ men have undergone this treatment.
- The procedure's safety and effectiveness have been documented in numerous peer-reviewed clinical articles and presentations.
- Cooled ThermoTherapy is cost-effective and has few side effects.

¹ Data on file at Urologix, Inc.

- It does not require hospitalization, general anesthesia or long recovery times.
- The unique cooling mechanism is the key to treating symptoms of BPH safely, effectively and comfortably.
- Cooled ThermoTherapy has been approved by the FDA since 1996 and has been endorsed in BPH treatment guidelines issued by the American Urological Association (AUA), European Association of Urology and the World Health Organization.

Q: How does Cooled ThermoTherapy work?

Cooled ThermoTherapy procedures are typically performed with oral medication. The treatment time is typically 30 minutes. Your urologist will place a catheter in your **urethra** and a small balloon near the tip of the catheter will inflate to anchor the catheter in place. To ensure safety, temperatures are monitored in both the urethra and rectum during the procedure.



The Cooled ThermoTherapy catheter delivers precisely targeted heat energy to destroy enlarged prostate tissue. Cooled water circulates through the catheter during the procedure allowing delivery of the optimal amount of heat while protecting healthy tissue.

Q: Is the procedure painful?

To maximize patient comfort, your urologist may use oral medications during the procedure. Most patients feel some heat during the procedure and some patients experience urgency associated with the need to urinate. Individual responses vary.

Q: What kind of results can I expect after my Cooled ThermoTherapy procedure?

Cooled ThermoTherapy can give you and your loved ones the kind of durable results you are looking for. Studies have shown significant and lasting improvement in several different measures of BPH symptoms up to five years following treatment. These measures include the **AUA Symptom Score** and quality of life scores. As with any medical procedure, individual results will vary. Please consult your urologist for more information.

Q: Is Cooled ThermoTherapy expensive?

Cooled ThermoTherapy is a very cost-effective procedure when compared to drugs and surgery. Most symptom-relieving medications must be taken daily and may cost each patient thousands of dollars annually. Surgery, while effective, is significantly more expensive than Cooled ThermoTherapy.

Q: Is Cooled ThermoTherapy covered by insurance?

Medicare and many commercial insurance plans provide coverage. If your insurance plan needs more information before making a coverage decision, you can ask your doctor's office for assistance.

What to expect *before* the procedure:

- You'll need a physical examination from a urologist trained in performing the procedure. Your urologist will explain the procedure in detail and answer your questions.
- Your urologist will provide specific pre-procedure instructions, such as reducing fluid intake or modifying your diet the day of the procedure.

What to expect *during* the procedure:

- **Cooled ThermoTherapy** is performed in your urologist's office. You will be awake during the procedure, which usually takes 30 minutes. You should allow 2 hours for the entire office visit.
- You will be on an exam table in a comfortable position. You may be able to watch television, read a book or listen to music during the procedure. You may be given medication to help you relax.
- Once the procedure begins you may experience some slight discomfort and sensations in your bladder, bowels or abdomen. The medical staff will make you as comfortable as possible.

What to expect *immediately after* the procedure:

- Arrange in advance for someone to drive you home after the procedure.
- Because the tissue surrounding the **urethra** may be irritated after the procedure, you may go home with a urinary catheter.
- For several weeks after the procedure, you may experience soreness in the lower abdomen or frequent urination, but these will dissipate as you heal.

Healing and results:

- You may not notice any change in your BPH symptoms immediately after Cooled ThermoTherapy. However, your body is actively working to heal itself.
- In the weeks after the procedure, your body will reabsorb the tissue treated with Cooled ThermoTherapy and your **prostate** will shrink, decreasing pressure on your urethra over a period of up to several months.
- Some men start to see an improvement in symptoms as early as 4 weeks, but most men have significant improvement in 6-12 weeks. Individual results vary.



How to Assess Your Symptoms

To check your symptoms of enlarged prostate, complete the following questions based on your experience over the past month or two. (*Circle your answers*)

	not at all	less than one time in five	less than half the time	about half the time	more than half the time	almost always	score
How often have you had to push or strain to begin urination?	0	1	2	3	4	5	
How often have you had the sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5	
How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
How often have you found you stopped and started again several times when you urinate?	0	1	2	3	4	5	
How often do you find it difficult to stop urination?	0	1	2	3	4	5	
How often have you had a weak urination stream?	0	1	2	3	4	5	
How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5	
Total:							

The higher your total score, the more likely you are suffering from an enlarged prostate. No matter what the total of the survey, if you are unhappy with how your urination problems are affecting your life, see a urologist for a complete check-up.

Glossary

The first references to the terms defined below can be found in bold type in each section of this brochure.

5 alpha reductase inhibitor drugs – These drugs, often prescribed to men with BPH symptoms, interfere with the production of a hormone involved with BPH, shrink the prostate and improve symptoms.

AUA Symptom Score – The most widely used gauge of the lower urinary tract symptoms associated with the constriction of the urethra caused by an enlarging prostate. Symptoms measured include urgency and frequency of urination, problems with urination, and nocturia (getting up at night to urinate).

Alpha blocker drugs – These drugs can help to relax the smooth muscle of the prostate and bladder neck, potentially improving urine flow and reducing blockage of the bladder.

BPH (benign prostatic hyperplasia) – The medical term for an enlarged prostate. It is one of the most common medical conditions among mature men. BPH is not cancer, but a natural part of the aging process that occurs when the number of prostate cells increases. The progression of BPH causes the prostate gland to compress the urethra.

Cooled ThermoTherapy™ – This is the leading office-based treatment for BPH. Urologists have used it to treat more than 200,000 men. A unique cooling mechanism is the key to Cooled ThermoTherapy's safety, effectiveness and long-lasting results.

Enlarged prostate – Also known as benign prostatic hyperplasia (BPH).

Erectile dysfunction – The inability to have or maintain an erection of the penis.

Laser surgery – A variety of laser procedures have been introduced over the past few years as a replacement for traditional TURP.

Minimally invasive procedures – These procedures utilize targeted heat energy and catheter technologies to destroy enlarged prostate tissue and relieve pressure on the urethra. They are performed with local anesthesia or oral medications in a urologist's office or hospital outpatient setting.

Prostate – A gland that surrounds the neck of the bladder and the urethra in the male. It is partly muscular and partly glandular and consists of a median lobe and two lateral lobes. The gland secretes a fluid that forms part of the seminal fluid.

TURP – Transurethral resection of the prostate is the most common surgical BPH procedure. The inner portion of the prostate is surgically removed.

Urethra – A canal for the discharge of urine extending from the bladder to the outside of the body.

Urinary incontinence – The involuntary discharge of urine.

Urinary retention – Inability to empty the bladder.

CONTRAINDICATIONS

- Patients with a prostatic urethra <2.5 cm in length as measured from the bladder neck to the verumontanum
- Patients with urinary sphincter or any implant (metallic or non-metallic) which is within 1.5 inches (38 mm) of the prostatic urethra
- Patients with urethral stricture (unable to pass 22 F urethroscope)
- Patient with peripheral arterial disease with intermittent claudication or Leriche's Syndrome (i.e. claudication of the buttocks or perineum)
- Patients who have undergone pelvic radiation therapy
- Patients with implanted active devices, including pacemakers or defibrillators within 2.6 inches (6.5 cm) of the prostatic urethra

WARNINGS AND PRECAUTIONS

- This procedure has inherent associated risks of complications.
- Post-treatment catheterization is needed in most cases after treatment.

ADVERSE EVENTS AND COMPLICATIONS

- Men who may wish to have further offspring should note the loss of ejaculation and/or decreased volume of ejaculate in some cases.
- Other associated risks include: temporary acute urinary retention, temporary incontinence, clots in urine, bladder spasms and trabeculation, rectal fistula, minimal bleeding, pain during urination and intercourse, pain or irritation in groin or pelvis, hemospermia, prostatic urethral damage, rectal irritation, interrupted flow, frequency, hesitation, urgency, post-void dribbling, weak stream, urinary tract infection, blood pressure changes during treatment and hospitalization in general related to the treatment.
- There is a minimal risk of urethral stricture post procedure.
- Patients may be prescribed anti-inflammatory and antibiotic medications following the procedure.
- Patients may require use of analgesics or sedatives during the procedure.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program.

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MC1195 Rev C 03/07