



PROLIEVE Thermodilatation[®] System

A Transurethral Microwave Therapy Device

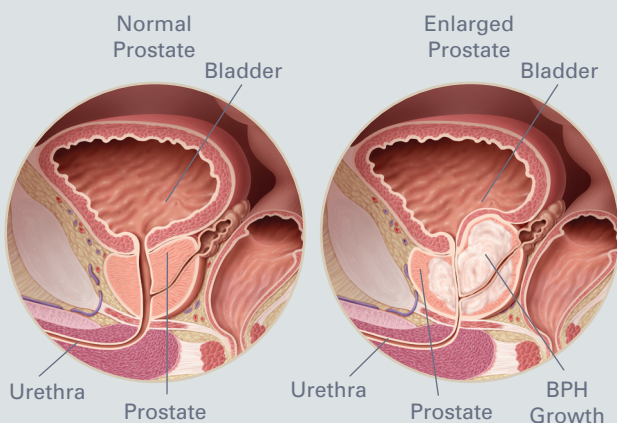
The Prolieve[®] System Patient Information is
Directed to You, the Patient.



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Why am I being treated with the **Prolieve** Thermodilatation® System?



Your physician has determined that you are suffering from symptomatic **benign prostatic hyperplasia (BPH)**. This means that your prostate has become enlarged. The prostate is a walnut-sized gland in men that surrounds the neck of the bladder where it joins the **urethra**. The prostate gland produces a fluid that is part of semen. **BPH** is not life threatening and it is not a type of cancer, but you may have found it to be embarrassing and inconvenient. You are not alone. **BPH** is common in men 50 years of age and older.

The symptoms are:

- Feeling a repeated and instant need to urinate.
- Interrupting your sleep to urinate.
- Waiting for urine to start flowing.
- Having a weak, variable or dribbling stream of urine.
- Feeling pain or burning when urinating.
- Feeling that your bladder does not empty.

The **Prolieve**® System has been successful in treating patients with **BPH** symptoms. Please read the following information and ask your physician if you have any additional questions.



What is the **Prolieve**® System?

The **Prolieve** System is a technology that both heats and dilates the prostate. The purpose of the **Prolieve** System is to treat the symptoms of **BPH** in men with an enlarged prostate who would benefit from drug or surgical therapy.

How does the **Prolieve** System work?

The physician will insert a **catheter** into your **urethra**. When microwave energy is turned on, it will be transmitted from a special antenna inside the **catheter** to provide continuous heat to your prostate. The heat will reduce the enlarged tissue of your prostate. A small balloon that is also part of the **catheter** will inflate within the section of the **urethra** close to where the prostate is located. The inflated balloon will cause the tissue to expand. During the entire 45-minute procedure, warm water will be circulating inside the **catheter** through your **urethra**. For your safety, the Prolieve System's computer monitors the temperature surrounding the treatment area by means of a **rectal temperature monitor**. If the temperature reaches 42°C, the system will shut off automatically.

The **Prolieve** System is FDA approved. The System's design and operating protocol were investigated in clinical studies of other men suffering from **BPH**. The results showed the **Prolieve** System is safe and effective.

The Components of the **Prolieve**



1. Prolieve System



2. Prolieve Catheter

Schematic Illustration of How the Prolieve Thermodilatation® System Works

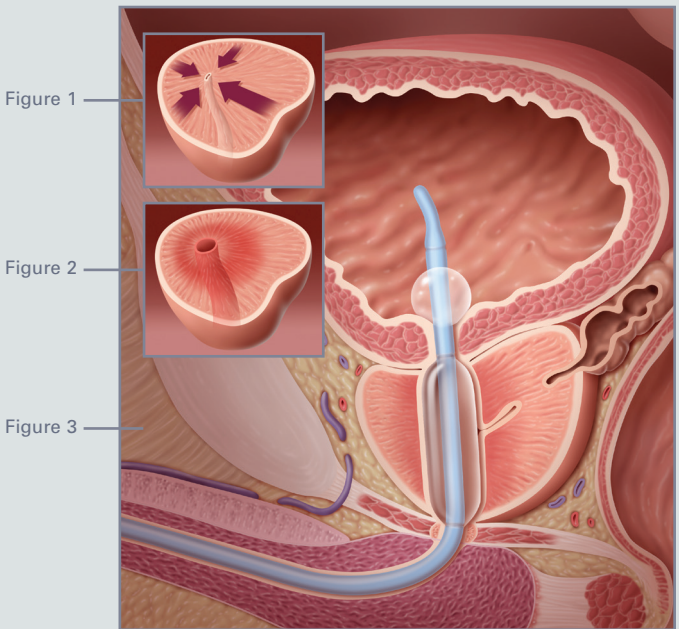


Figure 1: This is a schematic illustration of a cross section of a prostate BEFORE treatment with the Prolieve Thermodilatation System.

Figure 2: This is a schematic illustration of a cross section of a prostate immediately AFTER treatment with the Prolieve Thermodilatation System.

Figure 3: This is a schematic illustration of the proper internal position of the Prolieve Thermodilatation System balloon catheter in the prostate.

Thermodilatation System are:



3. Sterile Water Bag



4. Heat Exchanger Cartridge



What to expect during your **Prolieve®** System Treatment

First, the physician will evaluate you to see if you are a candidate for this therapy. The following is a list of tests your physician may order: urine analysis, urine culture, blood tests, **uroflowmetry**, **ultrasound**, and **cystourethroscopy**. Your physician will choose which tests you may have.

Then, on the day of your procedure, you will come to the treatment center. You should bring someone to drive you home since this is an outpatient procedure.

Each physician's office is different. Therefore, treatment procedures may vary a bit. In general, here is a recap of the steps of the treatment you can expect:

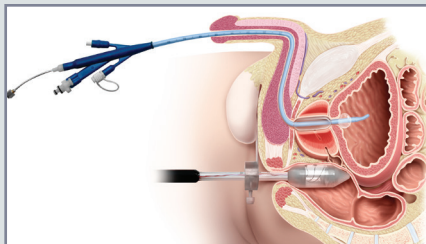
1. At least one hour before treatment, your physician may give you medication to help you relax during the procedure. Other medications that your physician may give you are to help avoid infections.
2. You will be asked to empty your bladder.
3. You will be asked to lie on your back on the treatment bed. Your physician will then apply anesthesia to the tip of your penis. This will help you to not feel pain while the **catheter** is inserted through your **urethra**.
4. To keep you warm and comfortable, you will remain covered throughout the procedure.
5. During the treatment, you may be offered a book, or earphones to listen to music.
6. Before your physician inserts the **catheter**, K-Y® Jelly lubrication will be applied with a large syringe, without a needle, directly into the **urethra**.
7. Your physician will then insert the **catheter** through the **urethra** into the bladder. This is done in the same manner as inserting a regular **catheter**.
8. Your physician will double check that the **catheter** is in place. This may be done by **ultrasound**. When

the **catheter** is in place, your physician will secure it so that it does not move.

When the small balloon of the **catheter** is inflated, you may feel slight pain or discomfort. This is normal. It is also possible that during treatment you may experience bleeding, or some discomfort such as **bladder spasms**, feeling the need to empty your bladder or have a bowel movement. You will feel a warming sensation as the temperature increases during treatment. This is normal. There is water circulating through the **catheter** to keep your **urethral** channel warm, but not hot.

9. Next your physician will prepare the **rectal temperature monitor** for insertion.
 - a. Your physician will place a sterile cover on the monitor.
 - b. The surface of the cover on the monitor will be lubricated with K-Y® Jelly.
10. Your physician will then insert the rectal monitor and secure it so that it does not shift position. During the treatment, the rectal monitor will be checked frequently to ensure proper positioning.

Schematic Illustration of the Prolieve Thermodilatation® System



Treatment will then be initiated. It will last approximately 45 minutes. Your physician will monitor you at all times. If you experience severe pain, please inform your physician right away.



What to expect following your **Prolieve**[®] System Treatment

You will be able to go home right after treatment. You should have someone drive you home after the procedure.

82% of patients leave the doctor's office without a **catheter**. However, there is a chance you may need a **catheter**. There is no need for concern. The **catheter** will let the urine drain from your bladder while the swelling, if any, goes down. In most cases the **catheter** will need to remain for three days or less. Please follow your physician's instructions carefully.

Some patients have experienced side effects following treatment. The most common side effects are:

- Bladder spasm
- Soreness
- Pain
- Blood in the urine

These side effects cleared within a few days. Other side effects reported were urinary frequency, urgency and **urinary retention**. These were most likely symptoms of **BPH** and not caused by the treatment.

Results based on pivotal clinical trial, 140 patients treated.

Remember you are unique and you may experience other symptoms. Please notify your physician if you experience **bladder spasms**, pain, soreness, or blood in your urine or if you have any other concerns about how you are feeling.

As with any **transurethral** microwave therapy procedure, there are rare cases of serious side effects. Please consult with your physician.

Benefits of the **Prolieve**® System

- Quality of life improvement.
- The side effects reported have been few.
- It is a single 45-minute treatment that is performed at your physician's office.
- It eliminates the need for multiple-office visits for **BPH** medications and the related costs and inconvenience.
- It is not a surgical procedure.





When should the **Prolieve**[®] System not be used?

Please inform your physician if:

- You are not able to feel pain. Microwave treatment is not indicated in patients whose response to pain has been reduced. This reduced pain response may result from surgery, regional or local anesthetic, or other relevant condition that is determined by the physician upon evaluation.
- A **catheter** cannot be passed through your **urethra**.
- You have a urinary infection.
- You have a prostate infection.
- You have undergone a procedure to insert a penile or **urinary sphincter** implant.
- You have clogging of the arteries with **intermittent claudication** or **Leriches Syndrome**.
- You had your prostate removed.
- You have been diagnosed with cancer of the prostate or the bladder.
- You have metallic hip or leg implants.
- You have an implanted cardiac pacemaker, or defibrillator.
- You are interested in having children.
- You have had any history of pelvic radiation.
- You have an abnormality of your blood that prevents it from clotting.
- You have any kidney disease.
- You cannot urinate without help of some kind.
- You have stones in your bladder.

What are the alternative treatments for BPH?

Alternative treatments for **BPH** are:

- Watchful waiting
- Drug therapy
- Surgery
- Other microwave therapies

The microwave therapy takes 45 minutes, but your physician will need additional time to get you prepared for the procedure. Please allow at least 2 hours for the entire treatment visit.

Importance of keeping up with your regimen of care

For your safety and prompt recuperation, it is important that you follow your physician's instructions. Go to all of your follow-up visits. Do not be embarrassed to ask questions. Communicate with your physician and discuss your concerns.



Disadvantages of the Prolieve® System

- Unlike medication, treatments with the **Prolieve** System are performed at a physician's office or at a local hospital in the outpatient unit.
- The patient must be a good candidate for the treatment.
- The procedure requires some exposure and may be a bit embarrassing and or uncomfortable.
- There may be side effects including: anal irritation, **bladder spasms**, bleeding (mild to excessive), bowel irritation, chronic pain at the site, complete **urinary retention**, incomplete **urinary retention**, **erectile dysfunction**, pressure sensation (minimal), **prostatitis**, **retrograde ejaculation**, **urethral** injury (irritation), urinary clot retention, **urinary incontinence**, urinary tract infection, urinary urgency.

Risks of the Prolieve System

There have been serious, but rare, side effects from other **transurethral** microwave therapy **device** treatments.

However, none of these have been experienced by any of the patients treated with the **Prolieve** System. Please consult with your physician.

During the clinical study of the **Prolieve** System, the following events were directly attributed to the procedure: **bladder spasms**, **urethral** irritations, and complete **urinary retention** (requiring catheterization). Other side effects reported were those associated with **BPH**. The majority of the side effects resolved within 2 weeks to 1 month and required little or no medication.

General warnings and precautions

It is very important that you are awake during this procedure. Your doctor will rely on your sensations of pain or heat as a guide during treatment.

Frequently asked questions about Enlarged Prostate (BPH)

Q. Is BPH a type of cancer?

A. No, **BPH** is not a type of cancer.

Q. Who is a good candidate for treatment with the **Prolieve**® System?

A. Men with moderate to severe **BPH** symptoms. Your doctor can discuss with you whether the Prolieve System Treatment is right for you.

Q. Will I continue to need to take my BPH medications after the **Prolieve** System Treatment?

A. As with any medication ask your doctor what regimen is appropriate for you. However, most patients are able to discontinue taking their **BPH** medications within a few weeks after the treatment.

Q. Will the **Prolieve** System Treatment affect my sexual function?

A. 99% of patients treated with the **Prolieve** Thermodilatation® System did *NOT* experience any form of erectile dysfunction following the treatment.

Q. How soon will my symptoms improve?

A. All patients are different and the response to medical treatments will vary. However, many patients report noticeable **BPH** symptom improvement shortly after the treatment. Many patients showed improvement in their AUA symptom scores within 2 weeks of their **Prolieve** Thermodilatation System Treatment. Ask your doctor about his experience using the **Prolieve** Thermodilatation System.

Q. Is the Prolieve System Treatment covered by Medicare?

A. Yes

Definitions for words in **bold** are located on pages 12-13 of this brochure. 11

Glossary

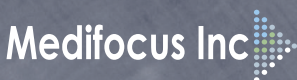
BPH	Benign prostatic hyperplasia
Benign prostatic hyperplasia	Enlargement of the prostate with no cancer
Bladder spasm	Involuntary contraction of muscles affecting the bladder wall
Catheter	A flexible tube for withdrawing fluids from (or introducing fluids into) a cavity of the body, especially one for inserting into the bladder, through the urethra, to remove urine
Cystourethroscopy	A procedure used to look at the inside of the bladder and urethra. A flexible tube with a small camera attached is inserted through the urethra and into the bladder.
Erectile dysfunction	Unable to have or maintain an erection of the penis
Intermittent Claudication	Limping or lameness in your legs
Invasive	A puncture or incision of the skin or insertion of an instrument or foreign material into the body
Leriches Syndrome	A syndrome caused by blocking of the abdominal aorta. It usually occurs in men and is characterized by fatigue in the hips, thighs, or calves during exercise; no pulse in the femoral arteries; impotence; and pale, cold legs
Parameter	A variable whose measure is indicative of a quantity or function that cannot itself be precisely determined by direct methods, for example, blood pressure and pulse rate are parameters of heart function
Prolieve Thermodilatation® System	A transurethral microwave therapy system

Prostatitis	Inflammation of the tissue of the prostate
Rectal Temperature Monitor	A device inserted into the rectum to measure the temperature of the rectal tissue near the prostate gland
Retrograde ejaculation	Ejaculation backwards into the bladder instead of forward through the urethra
The System	Prolieve Thermodilatation® System
Transurethral	To the urethral tube through the penis
Ultrasound	A technique in which high-frequency sound waves are bounced off internal organs and the echo pattern is converted into a 2 dimensional picture of the structures beneath the transducer
Urethra	The tube through which urine is passed from the bladder. The length of the urethra is about 25 centimeters in men
Urinary incontinence	The involuntary discharge of urine
Urinary retention	Unable to empty the bladder
Urinary sphincter	A muscle that is normally tight, but when relaxed, allows urine to flow from the bladder
Uroflowmetry	A procedure used to measure the rate of urine flow

Refer to the Instructions for Use provided with the Prolieve Thermolatilation® System for user information.

INDICATIONS: The Prolieve Thermolatilation System is a transurethral microwave therapy device for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in men with a prostate size of 20 to 80 grams and prostatic urethra length between 1.2 cm and 5.5 cm and in whom drug therapy (Finasteride or Proscar) is typically indicated. **CONTRAINDICATIONS:** Patients who have significantly decreased pain responses, severe urethral stricture prohibiting catheterization, current urinary or prostatic infection, penile or urinary sphincter implants, prostate sizes <20 g to >80 g, peripheral arterial disease with intermittent claudication or Leriche's Syndrome, protruding median lobe with obstruction, metallic implants, implanted cardiac pacemakers or defibrillators, previous transurethral prostatectomy, renal impairment, coagulation disorders, neurological disorders that may affect bladder function, bladder stones, evidence of prostate or bladder cancer or have an interest in the preservation of future fertility. **WARNINGS AND PRECAUTIONS:** The safety and effectiveness of the Prolieve System for men <50 and >80 years old has not been established in clinical studies. **POTENTIAL ADVERSE EFFECTS:** that may occur include but are not limited to bleeding, bowel irritation, urethral injury (irritation), chronic pain at site, bladder spasms, urinary retention (complete or incomplete), urinary incontinence, prostatitis, pressure sensation, urinary urgency, urinary tract infection, urethral tear, anal irritation, urethral stricture, infertility, retrograde ejaculation and erectile dysfunction. **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

K-Y is a trademark of Johnson & Johnson Corporation.



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