

## **Section X. Device Labeling**

### **Part 3: Patient Labeling**

# Prolieve™

## A Transurethral Microwave Therapy Device Patient Information

Version 2.0



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The **Prolieve™** Patient information is *directed to you, the patient.*

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## Glossary

|                                     |   |
|-------------------------------------|---|
| <b>BPH</b>                          | Benign prostatic hyperplasia  |
| <b>Benign prostatic hyperplasia</b> | Enlargement of the prostate with no cancer  |
| <b>Bladder spasm</b>                | Involuntary contraction of muscles affecting the bladder wall   |
| <b>Catheter</b>                     | 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  |
| <b>Cystourethroscopy</b>            | 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.   |
| <b>Erectile dysfunction</b>         | Unable to have or maintain an erection of the penis   |
| <b>Intermittent Claudication</b>    | Limping or lameness in your legs  |
| <b>Invasive</b>                     | A puncture or incision of the skin or insertion of an instrument or foreign material into the body  |
| <b>Leriches Syndrome</b>            | 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 |
| <b>Parameter</b>                    | 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                      |
| <b>Prolieve™</b>                    | A Transurethral Microwave Therapy Device  |
| <b>Prostatitis</b>                  | Inflammation of the tissue of the prostate  |
| <b>Rectal Temperature Monitor</b>   | A device inserted into the rectum to measure the temperature of the rectal tissue near the prostate gland   |
| <b>Retrograde ejaculation</b>       | Ejaculation backwards into the bladder instead of forward through the urethra   |
| <b>The device</b>                   | Prolieve™   |
| <b>Transurethral</b>                | To the urethral tube through the penis  |
| <b>Ultrasound</b>                   | 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   |
| <b>Urethra</b>                      | The tube through which urine is passed from the bladder. The length of the urethra is about 25 centimeters in men   |
| <b>Urinary incontinence</b>         | The involuntary discharge of urine  |
| <b>Urinary retention</b>            | Unable to empty the bladder   |
| <b>Urinary sphincter</b>            | A muscle that is normally tight, but when relaxed, allows urine to flow from the bladder  |
| <b>Uroflowmetry</b>                 | A procedure used to measure the rate of urine flow  |

## What is the Prostate?

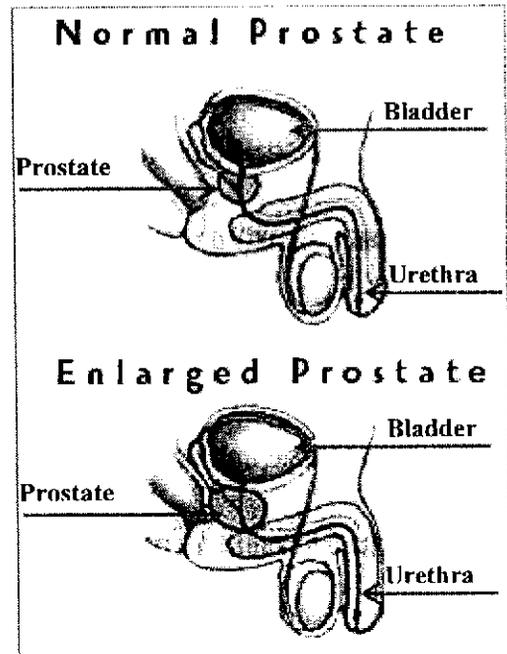
It is a walnut-sized gland in men that surrounds the neck of the bladder where it joins the **urethra**. The prostate gland produces a fluid that is part of semen.

## Why am I being treated with the Prolieve™ System?

Your physician has determined that you are suffering from symptomatic **benign prostatic hyperplasia (BPH)**. This means that your prostate has become enlarged (see images below). **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. The following information has been written *especially for you*. Please read it and ask your physician if you have any additional questions.



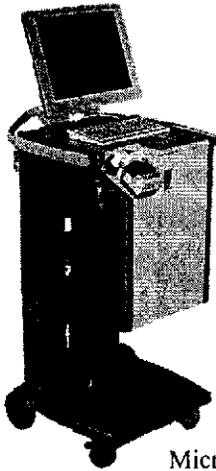
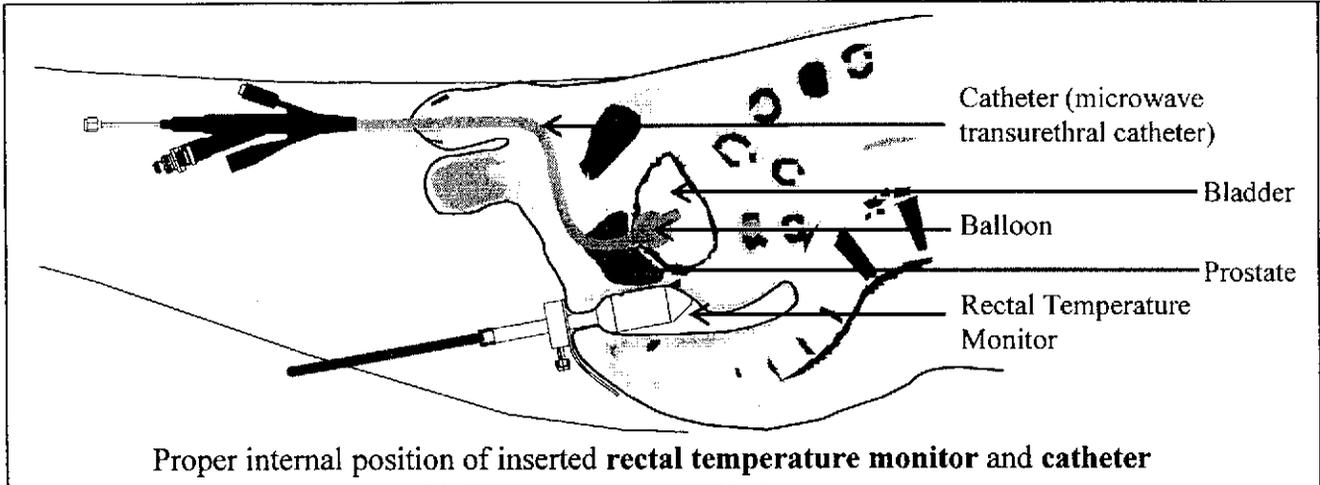
## Purpose of the device (indications for use)

**Prolieve™** is a medical **device** that is used to destroy part of the prostate to treat symptomatic **BPH** in men with an enlarged prostate who would benefit from drug or surgical therapy.

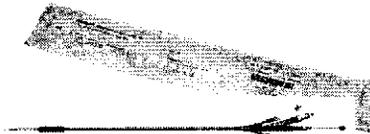
## Description of the device

The **device** is made up of a microwave, computer and a single-use Prolieve™ Procedure Kit. The **device** delivers microwave energy (heat) to the prostate for the treatment of symptomatic **BPH**. The **device** uses a microwave antenna that is inside a **catheter**, which is placed inside the **urethra** to heat the prostate. At the same time, a balloon on the **catheter** inflates and pushes against the wall of the **urethra** to help in the heating process. A heat-exchanger cartridge is responsible for warming the fluid that circulates through the balloon **catheter**. A **rectal temperature monitor** is placed in the rectum near the prostate to monitor temperature. The heating process is controlled by a computer in the machine that reads the temperature measured by the **rectal temperature monitor**.

The heat from the microwave may get high enough to cause tissue damage inside the **prostate**. The tissue that gets damaged will, over time, get reabsorbed by the **prostate** and will relieve the pressure to your prostate which maybe the cause of your symptoms. The water is used to inflate the balloon, which may open the blockage and reduce symptoms.



Microwave, computer, and rectal temperature monitor

Sterile microwave  
transurethral catheter

500 mL sterile water

Heat exchanger  
cartridge system

## How does the device work?

Patient information is entered by a physician into the computer system of the **device**. A sterile microwave **transurethral catheter**, a heat exchanger cartridge system, and a 500 mL bag are hooked to the instrument console. The physician will insert the flexible **catheter** into the **urethra** of the patient. When the microwave energy is turned on, it will be transmitted from a special antenna inside the **catheter** to provide continuous heat to the patient's **prostate**. The heat will reduce the enlarged tissue of the **prostate**. A small balloon that is also part of the **catheter** will inflate within the section of **urethra** close to where the **prostate** is located. The inflated balloon will cause the tissue to expand, which may cause some discomfort to the patient. During the entire 45-minute procedure, warm water will be circulating inside the **catheter** to protect the **urethra** from the heat generated by the microwave energy. For the safety of the patient, the instrument console monitors the temperature surrounding the treatment area by means of a **rectal temperature monitor**. If the patient's rectal temperature reaches 42°C, the system will shut off automatically.

The **Prolieve™** System has been through testing and has been found to comply with all the required conformance standards regarding manufacturing. Moreover, the system design and operating protocol have been investigated in clinical studies of other men suffering from **BPH**. The results show that the **device** is safe and effective and it has obtained approval from the FDA.

## What are the alternative treatments for **BPH**?

You should discuss these with your doctor.

- 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.

## When should the **device** not be used (contraindications)?

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 penile or **urinary sphincter** implants.
- You have clogging of the arteries with **intermittent claudication** or **Leriches Syndrome**.
- You had your prostate removed.
- You have been 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.

## 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.

## What to expect during 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 that the two of you choose, you will come to the treatment center. You should bring a partner to drive you home since this is an outpatient procedure.

You may be given an antibiotic by your physician, but it will be up to your physician to make that decision.

On the day of treatment, you will remain in a comfortable position on the treatment bed. You may be able to listen to music or read a book while the treatment is being done.

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

If you experience severe pain, please inform your physician right away.

Each physician's office and hospital outpatient department is different. Therefore, treatment procedures may vary a bit. In general, here is what you can expect:

1. At least one hour before treatment, your physician may give you medication to help you keep calm 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 table. The physician will then apply anesthesia to the tip of your penis. This will help you to not feel pain while he/she inserts the **catheter** through the **urethra** of the penis.
4. To keep you warm and comfortable, you will remain covered throughout the procedure.
4. Your physician will enter your personal information into the system and will scan the bar codes from the procedure kit.
5. As your physician proceeds with each step, he/she may continue to prepare the system for your treatment.
6. Before your physician inserts the **catheter**, he/she will use a large syringe, without a needle, to apply KY Jelly lubrication directly into the **urethra**.
7. Your physician will then insert the **catheter** through the **urethra** into the bladder. This is the same as inserting a regular **catheter**.

8. Your physician will double check that the **catheter** is in place. The physician may do this by using **ultrasound**. When the **catheter** is in place, your physician will secure it so that it does not move.
9. Next your physician will prepare the **rectal temperature monitor** for insertion.
  - a. Your physician will place a sterile cover on the **rectal temperature monitor**.
  - b. Your physician will lubricate the surface of the cover on the **rectal temperature monitor** with KY 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.

Treatment will then be initiated. It will last approximately 45 minutes. Your physician will continue to monitor you at all times.

### What to expect following treatment?

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

There is a chance that your physician will send you home with a **catheter**. Sixteen percent (16%) of patients that were involved in previous clinical studies were catheterized after treatment. Do not worry; 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 remember it may be different in your situation and that your physician knows best. Please follow his/her instructions carefully.

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

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

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

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.

## Risks of the Prolieve™ System

There have been serious, but rare, side effects with **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.

## Benefits of the Prolieve™ System

- The side effects reported have been few.
- It is a single 45-minute treatment that is performed at your physician's office or at a local hospital in the outpatient department.
- It eliminates the need for multiple-office visits for **BPH** medications and the related costs and inconvenience.
- Quality of life has been shown to improve.
- It is not a surgical procedure.

## 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 are 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.

## 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.

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