

# Trans-Urethral Microwave Thermotherapy (TUMT)



**TUMT** is a proven nonsurgical alternative for treating symptomatic and obstructive benign prostatic hyperplasia (BPH), as an outpatient treatment.

It has been found that temperatures in excess of 45°C destroy benign prostate tissue. Through the principle of conductive cooling with radiative heating the treatment known as transurethral microwave thermotherapy (**TUMT**) was developed which has allowed an effective alternative treatment for BPH without the need for surgery or ongoing medication.

## The Prostatron System

The Prostatron is designed to reduce the symptoms and obstruction due to BPH by delivering a controlled dose of microwave energy to the prostate without damaging the urethra or other surrounding structures. The Prostatron delivers microwave energy to the prostate transurethally through a specially designed treatment catheter that encases a tiny microwave antenna. While heat is being delivered into the enlarged prostate, cool water circulates throughout the length of the catheter, protecting adjacent urethral tissues from excessive temperatures. This cooling mechanism minimizes patient discomfort and protects the urinary tract from heat during treatment. By preserving the urethra, the patient does not experience the serious side effects that can result from surgery.

In the weeks following treatment, the resulting tissue elimination and reabsorption by the body leads to a decrease in the urethral pressure and an improvement in patient voiding and BPH symptoms. The Prostatron's TUMT technology aims to offer rapid, pronounced and sustained relief of BPH in a **30 minute to one-hour, minimally invasive outpatient therapy session that minimizes the cost and risk associated with TURP, making TUMT an attractive alternative for more patients.**

## Established Worldwide

Since 1991, when EDAP Technomed launched the Prostatron device in Europe, physicians have been treating patients with Prostatron TUMT. The Prostatron TUMT system received FDA approval for use in the US in May 1996 following an extensive Pre Market Approval (PMA) process. Randomised clinical trials in the United States, Europe and Japan demonstrated that the Prostatron is safe and effective in treating symptomatic BPH. Prostatron's higher-energy treatment, ProstaSoft 2.5 and its specific bladder neck catheter received FDA approval in November 1997 for the treatment of obstructive BPH. The 30 Minute TUMT treatment with the bladder neck catheter received FDA approval in April 2000.

## Clinical study results submitted to the FDA showed that Prostatron TUMT<sub>2</sub>:

- Produced significant improvements in BPH symptoms and urine flow.
- Is nearly as successful as TURP in improving BPH symptoms
- Is not associated with any major complications
- Preserves sexual function
- Maintains durable outcomes

The Prostatron TUMT system delivers temperatures in excess of 45°C to the prostate, selectively destroying prostatic cells, while a patented cooling system maintains non-destructive temperatures in the urethra. The result is a safe and effective treatment alternative for BPH patients.

### Three Treatments

Prostatron is equipped with three treatment protocols – software versions 2.0 and 2.5, and 30 Minute TUMT – allowing physicians to treat both symptomatic and obstructive BPH conditions with Thermotherapy.

#### Prostasoft 2.0 Thermotherapy for Symptomatic BPH

The 2.0 treatment is considered the gold standard for symptomatic treatment. 2.0 treatment provides an effective alternative to patients failing (or unhappy with) drug therapy.

#### Prostasoft 2.5 and 30 Minute TUMT Thermotherapy for Symptomatic and Obstructive BPH\*

The 2.5 treatment and 30 Minute TUMT are the only approved thermotherapy procedures to treat the Bladder Neck. \* Prostatron 2.5 and 30 Minute TUMT restore TURP-equivalent flow rates without the serious TURP morbidity.

- **This high-energy treatment is indicated when the benefits of obstructive improvement outweigh the attendant risks.**

### Why Might You Need TUMT?

The Prostatron provides relief from urinary frequency without surgery or drugs. The Prostatron is an alternative to surgery and drug therapy. It is the first microwave therapy approved as being safe and effective. The Prostatron is truly minimally invasive. It works with gentle; precisely controlled heating of the prostate while the sensitive urinary tract is cooled. In most cases, the Prostatron provides long-term relief from symptoms and restoration of urinary flow typical of people in your age group.

### What are some common symptoms of BPH?

- Frequency of urination
- Hesitancy of difficult start
- Urgency of incomplete voiding
- Waking to urinate

### **What is the prostate gland?**

The prostate gland is part of the male reproductive system. The adult prostate is about the size and shape of a walnut. Its primary function is to produce semen, the fluid that carries sperm. It surrounds the urethra, the tube that carries urine from the bladder.

### **What is benign prostatic hyperplasia (BPH)?**

BPH is a non-cancerous condition in which prostate cells grow, enlarging the gland and causing it to squeeze the urethra. A variety of symptoms may result, including difficult, frequent, or urgent urination.

### **Is BPH a rare condition?**

No, it is very common. In fact, by the time a man is 70 years of age more than 70% suffer from BPH.

### **When should I seek treatment for BPH?**

If the symptoms of BPH are affecting the quality of your life, it is time to seek treatment. For instance, if you are losing sleep because you need to urinate during the night, you may want to seek treatment.

### **What treatments are available?**

Until now, the two standard treatments of BPH were medication and surgery. However, the medications available for BPH are not always effective, cost hundreds of dollars per year, and may cause side effects. The surgery commonly used to treat BPH, called transurethral resection of the prostate ("TURP"), removes tissue from the inside of the prostate. TURP is associated with potential side effects such as incontinence (rare) and impotence. Thermotherapy, the newest treatment option for BPH, is a non-surgical, outpatient alternative that improves symptoms and urine flow with no serious side effects.

### **Patient Selection for Prostatron Treatment**

To properly determine whether a patient is an ideal candidate for thermotherapy your Urologist may perform some or all of the following:

- Medical history including medications
- Physical Examination, including Digital Rectal Exam (DRE)
- Blood Analysis – PSA, BUN, Creatinine (consider INR if patient is anti-coagulated)
- Urinalysis
- Symptom Score
- Uroflowmetry
- Cystoscopy to rule out presence of protruding median lobe length of prostatic urethra via transrectal ultrasound

## **STUDY RESULTS**

### **Effectiveness of Prostatron TUMT**

In all TUMT clinical studies performed, the primary endpoints used to assess effectiveness were improvements in Madsen Symptom Score (MSS) and peak urine flow rates. All of the study results show that the improvements in these efficacy variables were highly significant across all clinical sites for TUMT 2.0, TUMT 2.5 and 30 Minute TUMT. Improvement in MSS was similar following each type of treatment. Peak flow rate was significantly more improved following either 30 Minute TUMT or TUMT 2.5 than following TUMT 2.0.

### **The TUMT Procedure**

TUMT is often a “day only” procedure. Upon arrival on your appointment day, you should check in with the registration desk. A nurse will then compile and review your pre-test results, have you sign a consent form, and have you change into a patient gown. Medication may be given by injection to aid in preventing future discomfort.

Depending upon your exact treatment the type of anaesthetic you are given will vary, however the basic procedure remains the same. First, your urethra will be locally anaesthetized with lidocaine gel. Then, your bladder may be emptied by a disposable urethral catheter. Next, a treatment catheter will be positioned in your urethra and checked by performing an ultrasound of your bladder. Next, a small probe will be introduced into your rectum. This probe will be equipped with temperature sensors that will continuously monitor rectal temperature.

After initiation of the treatment, you may experience an urge to void. This is not caused by a full bladder but is instead due to heat in the prostate. If this intense urge is causing too much discomfort, some relieving medication can be administered. The treatment itself takes 30 - 60 minutes (depending on the exact type you require). Including preparation and machine start-up time, the whole procedure can take a total of 1.5 to 2 hours. After treatment and removal of the treatment catheter, your prostate may swell and cause a temporary deterioration in your voiding. In approximately 30% of cases, this can lead to urinary retention. If you are not able to void, a transurethral catheter will need to be inserted. In most cases, this catheter can be removed within a week.

Following treatment, you can experience increased symptoms for 2 to 3 days, including increased frequency, urgency, or pain upon urination. Approximately 50% of patients may experience blood in their urine or ejaculate or urethral bleeding. Urinary retention may occur in 30 to 60% of patients, requiring a catheter temporarily. The improvement in urination and consequent alleviation of your symptoms will occur gradually and may continue to improve for 4 to 6 months. Irritative symptoms may occur for weeks prior to improvement of your symptoms.

# REQUEST FOR TRANS URETHRAL MICROWAVE THERMOTHERAPY

I, ....., aged ..... years, of  
(NAME)

.....  
(ADDRESS)

would like to request treatment of my prostate condition using the Prostatron system of Transurethral Microwave Thermotherapy (TUMT).

I have read and understood the information given to me concerning this treatment and understand the risks associated it.

I understand that this therapy is not re-imbursed at this stage in Australia and take responsibility for the cost of the treatment provided by the Sydney Prostate Clinic

.....  
(Signature)

.....  
(Witness Signature)

.....  
(Print NAME)

.....  
(Print NAME)

.....  
DATE