

Patient Pamphlet for TMx-2000™ BPH ThermoTherapy System

| Table of Contents | Page No. |
|--|----------|
| Glossary of terms | 2-5 |
| What is the prostate? | 6 |
| What is BPH? | 6 |
| What are the symptoms of BPH? | 7 |
| How severe are my symptoms? | 7 |
| AUA BPH symptom score questionnaire | 8 |
| What are my BPH treatment options? | 9 |
| When the Device Should Not be Used | 10 |
| What is the TMx-2000? | 11 |
| What medical tests will be needed prior to treatment? | 12 |
| How do I prepare for a TMx-2000 treatment? | 13 |
| What happens to me just before the TMx-2000 treatment? | 13 |
| What will I feel during the TMx-2000 treatment? | 14 |
| What can I expect after the treatment? | 15 |
| What are the risks of a TMx-2000 BPH treatment? | 15 |
| You should contact your doctor immediately if: | 16 |
| What are the advantages of a TMx-2000 BPH treatment? | 16 |
| Index | 17 |

Manufacturer:

TherMatrix, Inc.
3675 Commercial Ave.
Northbrook, IL 60062

GLOSSARY

Words that are included in the Glossary are designated by an asterisk when used in the text throughout the patient information.

A

Anesthesia:

(See General Anesthesia or Local Anesthetic)

Antenna:

A wire used to emit high frequency electrical energy.

Antibiotic:

A medicine used to treat or prevent infection.

B

Bladder spasm:

bladder: The organ that collects and holds urine produced by the kidneys

spasm: An involuntary and abnormal muscle contraction.

BPH: (*Benign Prostatic Hyperplasia*)

A non-cancerous enlargement of the prostate that can cause pressure on the urethra and thus narrowing or closure of the urethra.

C

Coaxial cable:

An insulated braided cable, through which an electrical conductor runs, used to transmit high-frequency electrical energy.

Conductive energy:

Transfer of heat energy from one object to another by means of direct contact.

E

Ejaculation:

A sudden release of semen from the urethra during orgasm.

F

Fertility:

The ability to produce offspring

G

General Anesthesia:

Total loss of body awareness. Unconsciousness or sleep caused by medicine.

Genital:

All parts of the reproductive system. The visible body parts are commonly referred to as "genitals".

Gland:

An organ or group of cells that producing secretions.

I

Incision:

A surgical cut into skin or an organ of the body.

Incontinence:

Uncontrollable urination.

Intermittent claudication:

(See Leriche's Syndrome).

Impotence:

An inability to attain or sustain an erection of the penis.

L

Local Anesthesia:

Numbing a part of the body without causing loss of consciousness.

Laser energy:

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

Leriche's Syndrome:

Reduced circulation usually resulting in reduced blood to the penis - necessary for erection - and/or weakness and numbness in the legs.

M

Microwave energy:

High frequency electrical energy, generally above 900 MHz.

O

Open prostatectomy:

The prostate gland is removed through a surgical cut in the abdomen.

P

Pelvic:

Having to do with the lower trunk of the body

Peripheral:

Having to do with the outside edge or portion of a region or area.

R

Radiation therapy:

Medical treatments using x-rays or radioactive materials to kill cancerous or diseased tissues.

Radiofrequency energy:

Low frequency electrical energy generally in the 100 to 900 MHz range.

Resection:

Surgical removal of a part of an organ or body part with repair of the cut end, ends or portion.

Retrograde ejaculation:

A condition where the semen travels into the bladder rather than expelled through the penis.

S

Sedative:

Medicine that calms.

Stricture:

An abnormal narrowing of a passage in the body.

Supine:

Lying on the back, facing up.

Symptom:

A physical condition or indication of a disease or disorder.

T

Thermotherapy:

Treatment using temperatures above normal body temperature.

Transrectal:

Passed through, or placed in, the rectum.

Transurethral:

Passed through, or placed in, the urethra.

U

Ultrasound:

Sound energy that is higher infrequency than can be heard by human ears.

Urethra:

The passage whereby urine is passed from the body.

Urinary:

Pertaining to the organs that produce and remove urine from the body.

Uroflowmetry:

A device used to determine the rate that urine can be emptied from the bladder.

TMx-2000 BPH treatment patient information

This pamphlet is for patients who are considering treatment for Benign Prostatic Hyperplasia (BPH*) using the TherMatrix TMx-2000 ThermoTherapy* System. You will find the symptoms* of BPH* and possible treatment options in this pamphlet. The TMx-2000 ThermoTherapy System is one option for the treatment of BPH*. (Words that are defined in the Glossary located on pages 2 through 5 are designated by an asterisk.)

- **What is the prostate?**

The prostate is a gland* in the male genital*-urinary* tract. The main function of the prostate is to produce fluid that transports sperm during ejaculation. The prostate is located below the bladder* and surrounds the urethra*. The urethra is the tube that carries urine from the bladder through the penis. Another name for the urethra is the "urinary channel".

The figure above may help you understand the location of the genital*-urinary* organs.

- **What is BPH (Benign Prostatic Hyperplasia)?**

BPH* is a non-cancerous (benign) enlargement of the prostate. Your prostate grew to normal size during your teenage years. Usually, the prostate grows to the size of a walnut. The prostate begins to grow again around the age of 50. The reasons for this growth are not fully known. By the age of 80, 80% of men have BPH*. BPH* causes symptoms* in many older men.

- **What are the symptoms of BPH?**

An enlarged prostate presses on the urethra*. The pressure can obstruct the flow of urine through the urethra. Obstruction of the flow of urine can cause problems, including:

- Frequent urination, especially at night (nocturia)
- Weak urine flow
- Sudden urge to urinate (urgency)
- Trouble starting and stopping your urine stream (hesitation)
- Inability to completely empty your bladder*

If you are suffering from the symptoms* of BPH*, you are not alone. Approximately half of all men in the United States, over the age of 50, have BPH*. By age 80, this number has increased to 80% of all men.

- **How severe are my symptoms?**

The American Urological Association (AUA) has developed a questionnaire to help you and your doctor determine the severity of your BPH* symptoms*. This questionnaire is called the AUA Symptom Index.

You may determine the severity of your own symptoms* by completing the AUA Symptom Index below. Circle your score for each question. Add the total of all of the numbers you circled to determine your Total Symptom Score.

• **AUA BPH Symptom Score Questionnaire**

| Item | Question | None | Less than 1 time in 5 | Less than half the time | About half the time | More than half the time | Almost always |
|---|--|------|-----------------------|-------------------------|---------------------|-------------------------|---------------|
| 1. | Over the past month or so, how often have you had to push or strain to begin urination? | 0 | 1 | 2 | 3 | 4 | 5 |
| 2. | Over the past month or so, how often have you had a sensation of not emptying your bladder* completely after you finished urinating? | 0 | 1 | 2 | 3 | 4 | 5 |
| 3. | Over the past month or so, how often have you had to urinate again less than two hours after you finished urinating? | 0 | 1 | 2 | 3 | 4 | 5 |
| 4. | Over the past month or so, how often have you found that you stopped and started again several times when you urinated? | 0 | 1 | 2 | 3 | 4 | 5 |
| 5. | Over the past month or so, how often have you found it difficult to postpone urination? | 0 | 1 | 2 | 3 | 4 | 5 |
| 6. | Over the past month or so, how often have you had a weak urinary* stream? | 0 | 1 | 2 | 3 | 4 | 5 |
| 7. | Over the past month or so, how many times during a single night did you most typically get up to urinate from the time you went to bed until the time you got up in the morning? | 0 | 1 | 2 | 3 | 4 | 5 |
| Symptom Score (total of all the numbers you circled) | | | | | | | |

Courtesy American Urological Association 1992

51

Your AUA Symptom Score will indicate the severity of your BPH* symptoms*.

| Symptom Score | Severity |
|---------------|----------|
| 0 to 7 | Mild |
| 8 to 19 | Moderate |
| 20 to 35 | Severe |

You may choose to receive no treatment if your symptoms* are mild. This is often called "watchful waiting". Under the guidance of a physician you may "wait and see". Most patients look for relief if their symptoms are moderate to severe.

• What are my BPH treatment options?

BPH* treatments vary with the severity of your symptoms*. You may determine the severity of your symptoms by using the score from the above questionnaire. The following table presents the range of treatments for BPH*:

| Treatment Option | Description | Possible Side Effects |
|---|---|--|
| No Treatment | "Watchful waiting", Doctor and patient monitor symptoms* over time | BPH* symptoms* may get worse |
| Medication Proscar (5-alpha reductase inhibitors) | Daily oral pill | Reduced sex drive Problems with erection and ejaculation |
| Medication Hytrin Cardura Flomax (alpha blockers) | Daily oral pill | Orthostatic hypotension (Blood pressure drops when bending over) Dizziness, Tiredness Nasal congestion |
| Surgery TUIP (Transurethral* Incision* of the prostate) | Surgical cuts made from inside the urethra* | Urethral narrowing Incontinence* (Unable to hold urine) |
| Surgery TURP (Transurethral* Resection* of the Prostate) | Surgical removal of prostatic tissue through the urethra* | Impotence* Incontinence* Retrograde ejaculation* |
| Surgery Open Prostatectomy* | Surgical removal of the prostate through the abdomen | Impotence* Incontinence* Retrograde ejaculation* Death (In rare cases) |
| Heat Therapy Laser*, Microwave*, Radiofrequency*, or | Heat is applied to the prostate through a device placed into the urethra* | Blood in urine Inability to urinate (retention) Bladder spasm* |

| | |
|--------------------|---------------------|
| Conductive energy* | Ejaculatory changes |
|--------------------|---------------------|

• **When the device should not be used**

Your physician will consider many factors before recommending the TMx-2000 microwave* (electrical energy radiated at 915 MHz) thermoTherapy* BPH* treatment for you. ThermoTherapy contraindications (indications against use) are listed below. TMx-2000 therapy should not be done for a patient with any of these conditions. For him, the risks outweigh the benefits. You should understand that the effect of this therapy on your ability to produce sperm has not been determined. Also, the safety and effectiveness of retreatment with the TMx-2000 has not been established.

| Description of Contraindication | Reasons for Contraindication |
|---|---|
| Implanted defibrillator, pacemaker, or active implant | Microwaves* can harm electronic devices. |
| Metallic implant in the pelvis or hip region | Metal can get hot enough to damage surrounding tissue. |
| Prostate size smaller than 30cc or larger than 100cc | The effect of this therapy on small and large prostates has not been determined. |
| Urethral stricture* | A narrow place in the urethra* prevents insertion of the treatment catheter and sensors. |
| Prostate cancer | The effect of this therapy on patients with prostate cancer has not been determined. |
| Peripheral* arterial disease with intermittent claudication* or Leriche's* syndrome | Diseased arteries lower the flow of blood, which may allow too much heating to occur. |
| Bladder* cancer | The effect of this therapy on patients with bladder* cancer has not been determined. |
| Prior radiation therapy* to the pelvic* area | Radiation therapy* causes injury to the tissue that is radiated. The effect of this therapy on radiated tissue has not been determined. |
| Penile or urinary sphincter Implant | The effect of this therapy on patients with penile or urinary sphincter implants has not been determined. Microwaves* may damage the implant. |

- **What is the TMx-2000?**

The TMx-2000 BPH* treatment system uses microwave* energy to heat the prostate tissues that cause your BPH* symptoms*. Heat causes damage to the prostate tissues surrounding the urethra*, which improves your BPH* symptoms*. Heat therapy is also called thermotherapy*.

The TMx-2000 delivers microwaves to your prostate through a disposable catheter. Your physician will place the catheter into the part of your urethra* that is surrounded by your prostate. Your physician will then connect the catheter to the TMx-2000 Treatment System and a urine drainage bag. Your doctor will then thread temperature sensors into two tubes inside the catheter. These sensors are connected to the TMx-2000 and will monitor the temperature in your urethra* throughout your treatment.

TherMatrix BPH Treatment Catheter

Your doctor will also place a probe into your rectum. This probe has a channel through which another temperature sensor is threaded. During the treatment, the temperature sensor in the rectal probe will monitor the temperature in your rectum. The portion of the rectal temperature probe that is inserted into the rectum is a little smaller around and about the same length as most people's index finger.

Rectal Temperature Probe

The function of each part of the treatment catheter is listed below:

| Catheter Part | Function |
|---------------------------|---|
| Microwave antenna* | Delivers microwave energy to the prostate. |
| Microwave* coaxial cable* | Carries the microwave energy from the TMx-2000 to the antenna*. |
| Positioning balloon | The balloon is placed into the bladder* and inflated with water. The balloon will hold the treatment catheter in place during the treatment. At the end of the treatment, the water is removed and the balloon is deflated, allowing removal of the treatment catheter. |
| Balloon fill/drain port | Allows the filling and draining of the balloon. |
| Urine drainage port | Empties urine from your bladder* into a urine drainage bag throughout your treatment. |
| Temperature sensor ports | Two tubes that allow temperature sensors to be inserted to the side of the antenna* to measure the temperature of the prostate. |

• **What medical tests will be needed prior to treatment?**

Before your treatment, you will have an appointment with your doctor. During the appointment, you will be asked to undergo several tests to be sure you are a good candidate for a TMx-2000 microwave* treatment.

Some of the tests you may be asked to complete include the following:

- **Medical questionnaires**
 You must personally complete the questionnaires. Questions on the forms ask about your urinary* symptoms* and their effect on your life. It is important to answer each question accurately and completely. There are no right or wrong answers, only answers that reflect what you are experiencing.
- **Blood tests**
 A needle is used to draw a blood sample from your arm. You may notice minor discomfort and bruising. This blood sample is primarily used to test for prostate cancer. Additional tests may be conducted on your blood sample to evaluate your overall health condition. Your physician will explain and discuss these tests with you. ~~as well as other diseases.~~
- **Uroflowmetry***
 This test measures how quickly you can empty your bladder*. You will need to drink water for this test. You then need to urinate into a container. The container measures the flow rate of urine. The container also measures how much urine you are able to pass.
- **Urinalysis**
 A sample of your urine is tested to measure your overall health.

- **Ultrasound* Imaging (transrectal*)**
You will have to lie on your side so that an imaging probe can be placed into your rectum (transrectal*). The imaging probe is a transrectal ultrasound (high frequency sound energy) probe. You may feel some discomfort and/or pressure during probe placement. On the ultrasound image, your doctor can determine the size of your prostate.
- **Cystoscopy**
You will have to lie on your back so that a viewing scope tube can be inserted into your urethra*. You may feel some discomfort during placement of the scope. By looking through the scope, your doctor can see inside your bladder* and urethra.
- **How do I prepare for a TMx-2000 treatment?**

Prior to arriving at the doctor's office for your treatment, you will be asked to use an enema. An enema is needed because a probe will be placed in your rectum during the treatment. You should remove all jewelry before your treatment. You may eat or drink small quantities before your TMx-2000 treatment.

You will be offered mild pain and sedative* medications before your treatment begins. Your doctor will advise you when to take these medications. No general anesthesia* will be used during the treatment. You will be awake during the entire treatment. It is important to be alert during the treatment so that you may tell the doctor of any pain or discomfort that you feel and the severity.

- **What happens to me just before the TMx-2000 treatment?**

Once you arrive at the doctor's office on the day of your treatment, you undress and put on a gown. You then lie down on the examining table.

You will be placed in a supine* position (on your back) for the treatment. The physician will then apply a local anesthetic jelly in your urethra*. In a few minutes, the lining of your urethra will be numb.

The doctor then places a probe into your rectum. You may feel a mild discomfort or feeling of pressure when he places the rectal probe. This rectal probe is a soft rubber rod that is about the size and length of your index finger. The probe has a channel through which the doctor threads a temperature sensor. The temperature sensor will monitor the temperature in your rectum during the entire treatment.

Your doctor then inserts the treatment catheter into your urethra*. Your doctor will position the balloon, located at the tip of the catheter, inside your bladder*. The doctor will then use a syringe to inflate this small balloon with water. The balloon

holds the catheter in place during your treatment. The doctor then connects the coaxial cable* that carries the microwave* energy to the treatment catheter. The doctor then threads two temperature sensors into the catheter. These sensors will monitor the temperature in your urethra* throughout your treatment.

Your doctor will ensure the correct positioning of all equipment and will then start the thermotherapy*.

It is very important that you remain as still as possible during the treatment. If you need to move, ask one of the staff members to help you. Your movement may cause the treatment catheter to move, which could cause discomfort or harm to you, or could reduce the effectiveness of the treatment.

• **What will I feel during the TMx-2000 treatment?**

The antenna* delivers microwave* energy into the prostate. Microwave* power slowly increases to heat the prostate. Temperature sensors monitor the temperatures in your urethra* and rectum.

You may feel discomfort during the treatment. You may also feel a sensation of warmth or the urge to urinate. The treatment catheter is attached to a urine drainage bag that is emptying your bladder* for you throughout your treatment.

If you have pain or discomfort, tell your doctor or a staff member immediately. Your doctor will want to know how strong your pain or discomfort is. The treatment will be stopped if your pain is severe.

The TMx-2000 has a power reduction button. This button is held by you throughout the treatment. This button allows you to immediately reduce treatment power if you feel pain. However, after pressing the button it may take a few moments until you feel relief. If you feel pain, pressing the power reduction button will allow your prostate more time to adjust to the temperatures. Once you have pressed the power reduction button, the button is disabled for 90 seconds; after 90 seconds, the button will again be functional.

To make the treatment as comfortable as possible for you, the TMx-2000 machine slowly increases the amount of energy being delivered to your prostate until you are at the treatment temperature. This is called the "ramp-up" period. The "ramp-up" period normally takes about 27 minutes, although this will vary from individual to individual and will take longer if you have pressed the power reduction button. Once you reach treatment temperature, your treatment begins. The treatment period normally lasts approximately 40 minutes, although this time may vary, as determined by your doctor's judgment of what is best for you. The total time for the procedure, including the "ramp-up" time and the treatment time, is normally a little over one hour.

- **What can I expect after the TMx-2000 treatment?**

You should arrange for someone to bring you to your appointment and to take you home when your treatment is complete. You should not drive until the effects of the pain and/or sedative* medications are gone.

You will be given an antibiotic* to prevent infection following your treatment.

After the treatment, you will go home with a catheter in your urethra*. The catheter is attached to a drainage bag that will keep your bladder* empty. You will be instructed on care of the catheter and urine bag

The catheter will be removed 2-5 days after treatment. Your doctor will discuss with you whether you will return to the office to have this done or provide you with instructions on how to remove the catheter yourself at home. Either way, it is important to check with your doctor during this time.

Once your catheter is removed, you will be free to resume your normal day-to-day activities. A period of 6 weeks to 3 months is required for complete healing. During this time, your symptoms* may get worse before they begin to improve. You will have the opportunity to discuss your symptom* improvement with your doctor at follow-up visits.

- **What are the risks of a TMx-2000 BPH treatment?**

Every medical treatment may have side effects. The same is true for the TMx-2000 therapy. You will want to know the risks before your treatment.

Doctors at hospitals and clinics have studied the TMx-2000 BPH* treatment. The side effects reported from these clinical studies are listed below. If you have questions about the possible side effects of this treatment, discuss them with your doctor.

| Possible Side Effects | Description of Side Effects |
|----------------------------------|--|
| Hematuria | Blood in the urine |
| Hematospermia | Blood in the sperm |
| Urinary* retention | Unable to pass urine from the bladder* |
| Bladder spasm* or urgency | Cramping in the bladder* or a urgent need to urinate |
| Irritation of the urinary* tract | Frequent urination, burning sensation |
| Pain / Discomfort | A feeling of warmth and discomfort in the bladder*, urethra*, or rectum |

Listed below are possible side effects of thermotherapy treatment. However, these side effects were NOT experienced during the clinical study of the TMx-2000 system.

- Rectal damage, possibly including fistula (an abnormal urine passage between the urethra and rectum)
- Urinary infection
- Changes in ejaculation* following treatment (retrograde, painful, or difficult ejaculation; loss of ejaculation; or decreased fluid volume)
- Burns within prostate from the heat treatments, which may lead to bleeding or increased discomfort in the prostate area
- Urethral narrowing from urinary scarring at a later date, leading to restriction of the urinary flow
- Temporary sterility (the therapy's effect on fertility is unknown)

In clinical studies on the TMx-2000 BPH* treatment system, most patients did not experience any side effects. The majority of the side effects were reported within days after the treatment and disappeared shortly thereafter without any treatment. If at any time you are concerned about any side effect you may be experiencing, do not hesitate to contact your doctor.

• **You should contact your doctor immediately if:**

- You see large amounts of blood (a spoonful or more) in your urine or semen
- You see blood that is bright red in color
- Your urine drainage bag is not filling with urine
- There is leaking around the catheter
- You have a temperature above 101° F
- You experience chills or shaking

• **What are the advantages of a TMx-2000 BPH treatment?**

You will want to know the advantages before you consider having a TMx-2000 BPH* treatment. The clinical results of thermotherapy* compare well to other BPH* treatments.

Treatment with the TMx-2000 offers the following benefits:

- An effective BPH* treatment performed in your doctor's office
- An approximate total treatment time of one hour
- No general or spinal anesthesia*, only oral medication is used
- Shorter recovery than hospital procedures
- Minor side effects

Index

B

Bladder spasm, 9, 15
BPH, 6, 7, 9, 16

C

catheter, 12, 13, 14, 15, 16
Conductive energy, 9
Cystoscopy, 13

D

defibrillator, 10

G

genital-urinary tract, 6

H

Hematospermia, 15
Hematuria, 15

I

Impotence, 9
Incontinence, 9
intermittent claudication, 10

L

Leriche's syndrome, 10

M

Microwave energy, 9

O

orthostatic hypotension, 9

P

Penile Implant, 10
Peripheral, 10
Peripheral arterial disease, 10
prostate, 6, 7, 10, 12, 13, 14

R

Radiofrequency, 9
Resection, 9
Retrograde ejaculation, 9

S

supine, 13

T

thermotherapy, 14
TMx-2000, 1, 10, 11, 14, 15, 16
transrectal, 13
Transurethral, 9

U

ultrasound, 13
urethra, 6, 7, 10, 11, 13, 14, 15
Urinary retention, 15
Uroflowmetry, 12