TMx-2000™ BPH Thermotherapy System
P000043

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	TMx-2000™ BPH Thermotherapy System
Manufacturer:	TherMatrx, Inc.
Address:	2211-B Lakeside Drive, Bannockburn, Illinois 60015
Approval Date:	June 29, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000043a.pdf

What is it? This medical device is a heat treatment for Benign *Prostatic* Hyperplasia, a non-cancerous enlargement of the prostate gland. (The prostate is the male gland surrounding the lower end of the bladder that mixes with sperm cells from the testicles to produce semen.) The Thermotherapy System destroys some of the prostate tissue by heating it with microwaves.

The system includes:

- A unit that controls how hot the device gets and how long the heat is applied;
- A thin flexible tube (catheter) placed in the urethra, the canal in the penis through which urine and semen leave the body. The catheter is fitted with a thin cable, which carries the heat to the prostate gland and two thin wires that take the temperature of the treatment area.
- A thin rectal tube about three inches long to make other temperature readings in the treatment area.

How does the procedure work? Heat sent through the cable destroys prostate cells, making the prostate smaller. The patient must be awake enough during the procedure to tell the doctor if he feels pain from the heat. Treatment takes about one hour. Healing takes between 6 weeks and 3 months depending on the person.

When is it used? The device is a non-surgical treatment choice for an enlarged prostate.

What will it accomplish? About half of the people in the TherMatrx study had fewer and less severe problems urinating one year after the treatment. The major side effects from the treatment were blood in the urine, bladder contractions (spasm,) and painful urination. Side effects reported less often included a burning feeling after catheter insertion, urgency (sudden, can't-wait desire to urinate,) and blood in the semen.

When should it not be used?

This treatment should not be used in patients who:

- have a prostate size on which TMx-2000 has not been studied
- have a very narrow urethra preventing easy catheter insertion
- have an implanted defibrillator, pacemaker, or any other active (electronic) implant, because the microwave energy of this treatment can harm electronic devices
- have a metal implant in the prostate, pelvis, or hip areas, because the metal could get hot and hurt tissues around the implant
- have a penile implant, because it is unknown if the microwaves could damage the implant
- have prostate or bladder cancer or prior radiation therapy to the pelvic region, because this type of therapy has not been studied on men with these conditions
- want to have children, because changes in ejaculation have been reported after microwave therapy, and the therapy's effect on the ability to make sperm is unknown.

Additional information: The SSED and Labeling are available at:
http://www.fda.gov/cdrh/pdf/p000043.html

(Updated 9/20/2001)