

TMX3000™

The TherMatrix® Office Thermo Therapy System is safe and effective thermo therapy designed for in-office use.

Single in-office treatment

- Easily integrated into your office with minimal patient prep and recovery time
- Does not require use of monitoring equipment such as EKG or crash cart
- Non-surgical treatment performed in the comfort and convenience of your office¹

Exceptional Ease of Use

- Three protocol options ranging in treatment time from 38 – 62 minutes.
- Touch-screen monitor provides increased ease of use
- Autocalibration of temperature sensors

Proven Safe and Effective

- 5-year clinical data supports sustained durability and improved quality of life with an exception safety profile²
- No long-term side effects or adverse events reported in clinical study
- Post-treatment side effects like bladder spasms or hematuria were generally transitory, minor and self-resolving¹
- Less than 1% reported cases of erectile dysfunction¹
- 47.1% improvement in AUA symptom score and 58.1% improvement in Peak Flow Rate¹
- UL certified

Exception Patient Tolerance

- Only mild oral medications are needed for excellent patient tolerance and comfort during treatment

¹ TherMatrix-2000 BPH Thermotherapy System. P000043. FDA Approved 6-29-01.

² Data on file at AMS.



The TherMatrix System Description:

The patented TMX3000 System is a computer controlled thermo therapy treatment device that delivers microwave energy to the prostate. The system computer monitors all treatment parameters and automatically adjusts the microwave energy as needed to achieve and maintain thermotherapeutic temperatures for the selected duration of treatment.

Patient Profile:

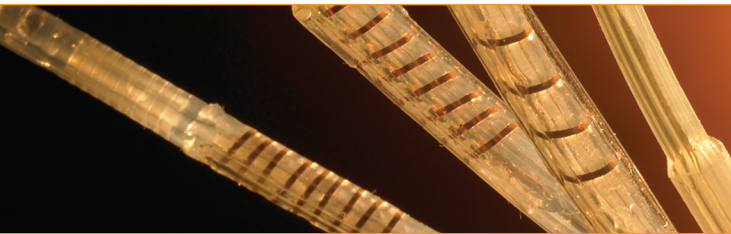
The TherMatrix System is indicated for treatment of symptomatic BPH in men with the following:

- Minimum prostatic urethra length of 25 mm
- Total prostate volume between 30 and 100 cc

Disposables:

Treatment catheter – 4 different lengths

<u>Coil Length</u>	<u>Verumontanum to Bladder Neck</u>
2.0 cm	≥ 2.5 < 3.0 cm
2.5 cm	≥ 3.0 < 4.0 cm
3.5 cm	≥ 4.0 < 5.0 cm
4.5 cm	≥ 5.0 cm



System ordering info:

TMX 3000	72404311
2.0 cm Treatment Catheter Coude Tip	RX20020C
2.5 cm Treatment Catheter Coude Tip	RX20025C
3.5 cm Treatment Catheter Coude Tip	RX20035C
4.5 cm Treatment Catheter Coude Tip	RX20045C

Brief Summary of Warnings, Precautions and Contraindications
the TherMatrix TMX3000™

- This device is contraindicated in patients with intermittent claudication, urethral strictures, active implants, urinary sphincter implants, or metallic implants in the prostatic treatment area, or patients with a minimum prostatic urethra length <25mm and a total prostate volume <30 or >100cc.
- The TMX3000™ System and components should only be used as intended and indicated in the Instructions for Use. Failure to do so could result in compromised patient safety and/or insufficient therapy.
- Failure to properly position the Treatment Catheter could result in heating and severe injuries outside the treatment area. If catheter placement is in question, verify placement by ultrasound imaging after inflating the balloon. Inflation of the balloon with more than 5 cc of sterile water may position the catheter too high in the urinary channel which may result in heating outside of the treatment area.
- The TMX3000™ System procedure has inherent risks of complications, though reported adverse events have been minor and self-resolving.

For a complete list of indications, contraindications, warnings and precautions, refer to the Instructions for Use for the TMX3000™ or contact your AMS representative. This document is written for professional medical audiences. Contact your AMS representative for lay publications. American Medical Systems, Inc. periodically updates product literature. If you have questions regarding the currentness of this information, please contact American Medical Systems.



American Medical Systems, Inc.
World Headquarters
10700 Bren Road West
Minnetonka, MN 55343
USA
Phone: 952 930 6000
Fax: 952 930 6157
www.AmericanMedicalSystems.com
www.thermatrix.com