

Informed Consent Form for Cooled ThermoTherapy™ Treatment

Description of Procedure: Cooled ThermoTherapy, or transurethral microwave thermotherapy (TUMT®), is a non-surgical treatment for benign enlargement of the prostate gland (also known as benign prostatic hyperplasia, or BPH). The procedure is delivered through a medical device that uses microwave energy to heat the diseased prostate gland areas in conjunction with a circulating cooling system that cools and protects the urethral tissue. During this procedure, a catheter-like probe will be inserted into my urethra after application of an anesthetic jelly. This probe contains the microwave generating applicator and the cooling system used to treat my prostate gland. In addition, a temperature-sensitive probe will be inserted into my rectum to monitor the temperature during the procedure. The procedure time will be approximately 30 minutes to one hour. Pain medications may be given before, during, and / or after treatment.

Anticipated Benefit: I understand that the anticipated benefit of having a Cooled ThermoTherapy procedure is to relieve my bladder outflow obstruction and associated symptoms.

Risks / Possible Complications: I understand that the risks of this procedure to be: decreased sexual function and/or impotence, temporary or permanent loss of ejaculation (a consideration for men who may wish to have further offspring), post treatment urinary retention which will require catheterization, temporary or permanent incontinence, urethral stricture. I understand that I may have temporary: pain and inflammation in the reproductive tract, post treatment urethral discharge, bleeding from the urethra/penis, urinary tract infection, rectal discomfort. I may likely have to wear a catheter for a 2 to 5 day (median 3 day) period following the procedure.

Alternative to Procedure: I understand there are alternative methods for the treatment of benign prostatic hyperplasia (BPH). These include: 1) a procedure known as transurethral resection of the prostate (TURP), which involves surgical removal of part of the prostate; 2) laser and vaporization therapy; 3) transurethral needle ablation of the prostate (TUNA), using radio frequency waves; 4) drug therapy with specific medications; and 5) insertion of a urethral stent. These therapies may or may not be considered advantageous alternatives based on my particular condition. They may have risks and / or complications that are greater or lesser in nature than the Urologix Cooled ThermoTherapy procedure. My physician has discussed the alternatives with me and answered any questions I have about these alternative treatments.

Consent for Treatment: My physician has discussed with me the contraindications and precautions, along with the above information, concerning this procedure. I certify by my signature below that I have read (or have had read to me) and understand this Informed Consent form. Any questions that I asked have been answered in a language that I understand. I voluntarily consent to this procedure.

Signature of Patient

Date

Printed Name of Patient

Signature of Physician

Date

Signature of Witness

Date

Cooled ThermoTherapy™ is available by prescription only. This therapy is not for everyone. Talk to your physician to see if Cooled ThermoTherapy is right for you. Most medical procedures may have side effects. Possible side effects for Cooled ThermoTherapy include blood in urine, clots in urine, painful or difficult urination, thickened bladder muscle, rectal irritation, temporary inability to control urination, brief inability to achieve or maintain an erection and the inability to discharge semen in orgasm thus should be considered by men who wish to have further offspring. A small risk of urethral stricture may result requiring further intervention. Patients may experience discomfort during the procedure that may require the use of analgesics or sedatives. Patients may be catheterized for a 2 to 5 day period following the treatment.¹ For more complete information about the benefits and risks associated with Cooled ThermoTherapy please refer to the Instructions for Use found on our website at www.cooledthermotherapy.com or call us at 1.800.475.1403.

¹Data taken from the CTC Advance® Instructions for Use, 250348 Rev B 12/08.