

# Cooled ThermoTherapy (TUMT) Coolwave Operative Note

Patient:

Date of Service:

Pre-Operative Diagnosis: BPH with obstructive symptoms  
Operation: TUMT (Transurethral Microwave ThermoTherapy)  
Anesthesia: p.o. sedation, topical bladder & urethral

Urethra length was \_\_\_\_\_ CM

Physician: \_\_\_\_\_

The patient has been advised of the risks of and benefits of the procedure and an informed consent has been obtained from the patient.

Procedure: After the patient was given appropriate pre-operative medications as described in the nurse's note. The patient was reclined on the procedure table in the supine position. The patient was catheterized and 50 ml of \_\_\_% lidocaine solution was instilled into the bladder and retained. 10ml of lidocaine gel was instilled into the urethra. The Coolwave Microwave catheter was then introduced into the bladder and the retention balloon was filled with 10mo of sterile water. The rectal ThermoSensing unit (RTU) was introduced into the rectum and the retention balloon was filled with air to 70cc. Proper balloon orientation was confirmed via ultrasound. A catheter holder was used to maintain the MDS and RTU in the proper position and these units were connected to the Coolwave systems. The calibration process was satisfactorily completed. The treatment was started and when the treatment parameters were met treatment, timing was started and completed after \_\_\_\_\_ minutes. After 5 minute cool-down period the MDS and the RTU were removed and a \_\_\_\_\_ fr. Foley catheter was introduced in to patient's bladder and retained. A drainage bas was attached. Complete care instructions on the catheter care and removal of the catheter for trail void were given to the patient. Please see the nurse's record's for details.

The patient will return in 5 to 7 days or p.r.n. for an office visit.

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Physician's signature

Date

## MICROWAVE THERMOTHERAPY (TUMT)

- PLEASE MAKE ARRANGEMENTS TO AND FROM PROCEDURE
- WEAR COMFORTABLE, LOOSE FITTING CLOTHES THE DAY OF THE PROCEDURE, YOU WILL BE DISCHARGED WITH A CATHETER
- **AT HOME** YOU MUST ADMINISTER A FLEETS ENEMA 2 HOURS PRIOR TO APPOINTMENT, THE ENEMA MAY BE PURCHASED AT ANY GROCERY STORE OR PHARMACY. PLEASE TAKE THE ANTIBIOTIC (LEVAQUIN OR CIPRO) ONE DAY PRIOR AND THE MORNING OF THE PROCEDURE
- TAKE ONE ATIVAN 1 MG, ONE HOUR PRIOR TO PROCEDURE.
- **BRING THE REST OF THE PRESCRIBED MEDICATIONS TO YOUR APPOINTMENT (VICODIN, LEVINSIN, AND THE OTHER ATIVAN) YOU MUST SIGN A CONSENT FORM BEFORE TAKING THESE MEDICATIONS**
- NOTHING TO EAT OR DRINK. 8 HOURS PRIOR TO THE PROCEDURE. YOU MAY HAVE A SMALL SIP OF WATER IF YOU NEED TO TAKE DAILY MEDICATIONS.
- **IF YOU ARE TAKING ANY ASPIRIN, COUMADIN, PLAVIX, OR ANY OTHER BLOOD THINNING MEDICATIONS, PLEASE DISCONTINUE USE 7 DAYS PRIOR TO PROCEDURE.** RETURN TO NORMAL DOSAGE AFTER PROCEDURE IS COMPLETED.
- IF YOU HAVE A HEART MURMUR, PROSTHESIS, OR ANY OTHER TYPES OF MEDICAL CONDITIONS, PLEASE MAKE YOU SURE YOUR DOCTOR OR NURSE IS AWARE.

APPT. DATE: \_\_\_\_\_

APPT. TIME: \_\_\_\_\_



*The Urology Division of Integrated Medical Services*

**TUMT MICROWAVE THERAPY (IN OFFICE)**

**PT MUST HAVE PROSTATE MEASUREMENTS PRIOR TO SCHEDULING PROCEDURE (PROSTATE ULTRASOUND)**

**MEDICATIONS: ATIVAN 1 MG #2 BRING TO PROCEDURE**

**LEVSIN SL 0.125 MG #2 BRING TO PROCEDURE**

**VICODIN ES #24 BRING TO PROCEDURE**

**LEVAQUIN 500 MG #5 BRING TO PROCEDURE**

**PATIENT WILL BE GIVEN THESE MEDICATIONS AT OUR OFFICE, RIGHT BEFORE THE TUMT IS DONE. GIVE PATIENT 2 ANTIBIOTICS (LEVAQUIN) TO START: ONE THE EVENING PRIOR AND ONE THE MORNING OF THE PROCEDURE**

**PATIENT NEEDS TO TAKE 1 ATIVAN, 1 HOUR PRIOR TO PROCEDURE.**

**PATIENT NEEDS A FLEETS ENEMA 2 HOURS PRIOR TO PROCEDURE.**

**HE WILL NEED SOMEONE TO DRIVE HIM HOME.**

**PATIENT WILL ALSO NEED TO MAKE AN APPOINTMENT WITH A NURSE TO HAVE CATHETER REMOVED IN 5 DAYS.**

**IF YOU HAVE ANY FURTHER QUESTIONS FEEL FREE TO CALL OUR OFFICE. THANK YOU.**

**ARIZONA UROLOGY**

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**Contraindications to TUMT (Transurethral Microwave Therapy)**

Have you undergone a procedure to insert a penile or urinary sphincter implant? Y N

Do you have any clogging of the arteries with intermittent claudication or Leriche's Syndrome? Y N

Have you ever had your prostate removed? Y N

Have you ever been diagnosed with prostate cancer or bladder cancer? Y N

Do you have any metallic hip or leg implants? Y N

Do you have an implanted cardiac pacemaker or defibrillator? Y N

Do you have any desire to have more or any children? Y N

Have you ever had any pelvic radiation therapy? Y N

Do you have any abnormality of your blood that prevents it from clotting? Y N

Have you ever had a catheter before? \_\_\_\_\_ Y N

Patient's Signature \_\_\_\_\_

Print Patient's Name \_\_\_\_\_

Witness \_\_\_\_\_

## 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.<sup>1</sup> 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](http://www.cooledthermotherapy.com) or call us at 1.800.475.1403.

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