**PROTOCOL FOR THERMASPEC THERMOTHERAPY DEVICE**

**PURPOSE:**

The THERMASPEC™ system is indicated for transurethral microwave high temperature thermotherapy, in the management of male patients with urinary symptoms secondary to Benign Prostatic Hyperplasia. Treatment is performed either as a substitute for, or adjunctive to surgical treatment.

**INCLUSION CRITERIA:**

* Prostatic urethral length ranging between 35mm and 60mm and total prostate volume of 30cm3 to 120 cm3.
* The AUA symptom score greater than 7 total points.
* Peak urine flow rate<12mm/sec on a voided volume >125cc and/or average urine flow rate < 7mm/sec
* PSA < 4 and/or negative prostate biopsy

**EXCLUSION CRITERIA:**

The THERMASPEC™ would be contraindicated for treatment under the following circumstances:

* Suspected or confirmed malignancy of the prostate;
* Previous history of Transurethral Prostatectomy.
* When there has been previous rectal, or radical pelvic surgery (not including herrorrhoidectomy);
* Where there are large metallic implants in the treated area thermotherapy should not be used. This is because electromagnetic radiation from the thermotherapy applicators may excessively, and even preferentially, heat such implants.
* Previous prostatic or pelvic irradiation;
* Neurogenic Bladder
* U.T.I. (recent)
* Untreated Balanitis or Urethritis
* Anti-Coagulant therapy
* Urethral stricture/bladder neck contracture
* Bladder Calculi
* Bladder Tumor
* Urination problems stemming from causes other than benign Prostatic Hyperplasia
* Intravesical Median Lobe
* Post void residual volume>250cc

**WARNING:**

* The physician should seriously consider thermotherapy treatment if the patient is interested in future fertility, because changes in ejaculation have been reported after microwave therapy, and the therapy’s effect on the ability to make sperm is unknown.
* The physician should seriously consider thermotherapy treatment
* If the patient has an implanted defibrillator, pacemaker or any other active (electronic) implant, because the microwave energy of this treatment can harm electronic devices.

If a patient has compromised renal function or upper tract obstructive disease it is recommended that the patient would be discharged with an indwelling catheter according to the physician’s best judgment.

The above criteria shall be established through history and physical examination, blood and urine examination and diagnostic imaging of the prostate.

**PRE-TREATMENT PROCEDURE**

**PRE-TREATMENT MEDICAL EVALUATION:**

* Medical History including AUA Score.
* Physical examination (DRE)
* Ultrasound examination of the urinary system
* Flowmetry
* Residual volume recording
* Urine culture
* Urine analysis
* Total blood count and basic metabolic profile (electrolytes, liver and renal function)
* PSA

**ROOM PREPERATION:**

* Place the THERMASPEC near the patient’s bed.
* Connect the main cord to the system.
* Connect the applicator to the main cord.
* Insert the applicator into the catheter based on the size of the patient’s prostate without taking the catheter out of its sterile wrap.

**TREATMENT:**

**MEDICATION:**

**RECOMMENDATION**

* Proscar (finesteride) should be started 4-6 weeks prior to treatment
* One dose of an oral quinalone should be given immediately prior to and immediately following the procedure
* Administration of oral Cox-2 inhibitor (for both analgesic and anti-inflamatory effects) and anticholenergic (to reduce bladder irritability during treatment) 1-2 hours before treatment (optional).
* In case of pain during treatment, analgsic (Dipyrone) should be administered.

**PROCEDURE:**

* Lubricate the catheter with anesthetic gel.
* Insert the catheter containing the applicator (in a similar manner of standard folly catheter insertion)
* Inflate the catheter balloon using a standard syringe with 20 ml sterile water or saline. Retract the catheter gently until the balloon meets resistance at the bladder neck.
* Fix the catheter with a band-aid to avoid movement of the catheter.
* Turn on the machine
* Gradually raise the treatment temperature from 45ºc -48ºc, according to the patient’s comfort during 5 minutes, than instantly raise the temperature to 60ºc for additional 55 minutes.
* Total treatment duration will be 60 minutes.
* Unless the physician decides otherwise the treating catheter may be removed immediately after treatment is completed.
* **Note**: Approximately 20% of the patients will need catheterization due to urinary retention. The catheter will remain for approximately 3 days.

**RECOVERY:**

* Patient can be discharged immediately after treatment.
* Patients should be discharged on an oral antibiotic for 5 days
* Patients currently on alpha-blockers should continue the medication in the immediate post treatment period
* High- risk patients will remain under supervision in the urology department for a few hours before discharge.

**“HIGH RISK PATIENT”:** Defined by the American Society of Anesthesiologists (ASA). ASA Scale extends from 1-4. For our purpose a high- risk patient is one with an ASA Scale ≥3.

**FOLLOW-UP:**

Current literature and experience suggests that tissue healing following thermotherapy is on the order of 3 months

After 3 months the healing process stabilizes both in the urethra and in the periurethral tissues.

It is recommended that the following shall be done 1 and 3 months post treatment:

* Symptom Score (AUA)
* DRE
* Ultrasound of the urinary system
* Flowmetry: including voided volume, total voiding time, peak flow rate, average flow rate.
* Urine culture and analysis
* Total blood count and basic metabolic profile.
* Residual Volume