***Chronic Non-Bacterial/Bacterial Prostatitis***

***ThermaspecTM Treatment Protocol***

*(Based Upon Medispec Ltd. Experience in Europe)*

***INTENDED USE****:* ThermaspecTM is intended for use for the treatment of Benign Prostatic Hyperplasia and Chronic Non Bacterial and Bacterial Prostatitis.

1. **INCLUSION CRITERIA:**

* A patient diagnosed as suffering from chronic non-bacterial / bacterial Prostatitis Syndrome.
* The patient has undergone at least one conservative treatment trial which has failed.
* Patient has undergone appropriate Antibiotic treatment with no symptomatic relief.
* Following the antibiotic treatment the patient has undergone a four cup test with a negative culture result – in case of chronic non-bacterial prostatitis, and with positive culture results – in chronic bacterial prostatitis.
* Patient was treated with NSAID for at least 3 weeks with no effect in case of chronic non-bacterial prostatitis.

1. **EXCLUSION CRITERIA:**
   * Metal implant in the urethra
   * Anti-coagulant therapy
   * Prostate cancer
   * Urethral stricture
   * Untreated balanitis or urethritis
   * Previous history of radiation to the prostate
   * Previous history of trans urethral prostatectomy

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

1. **PRE-TREATMENT PROCEDURE**
   1. Room Preparation:

* 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.
* Turn the energy button to low-energy (20 Watt) for the whole treatment duration.

1. **TREATMENT:**

4.1 Medication:

**RECOMMENDATION**

* Analgesic (Dipyrone) should be administered prior to treatment.
* One dose of an oral Quinalone will be given immediately prior to and immediately following the procedure

4.2 Procedure:

* 5-10 ml L of 2% Lidocaine Jelly will be used to lubricate and anesthetize the urethra.
* Insert the catheter containing the applicator (in a similar manner of standard folly catheter insertion) into the urethra.
* Inflate the catheter balloon using a standard syringe with 10-15 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
* Begin treatment at 39°C for at least 3 minutes. Gradually increase temperature according to patient’s tolerance and comfort until it reaches 46-47°C
* Total treatment duration will be 90 minutes.
* Treating catheter may be removed immediately after treatment is completed.
* **Note:** A certain percentage of patients might develop urinary retention post treatment. It is subjected to the physician’s best judgment whether to insert a preventive Foley- catheter for about three days, or to insert a catheter only in case of urinary retention. In such a case the catheter will remain for approximately 3 days.

1. **POST TREATMENT:**

* Patient can be discharged immediately after treatment.
* Patients should be discharged on an oral antibiotic for 5 days
* 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.
  + 2-3 treatments will be performed according to clinical progress.

Treatment Interval: 1 month.