

# EXCERPT FROM PROSTIVA RF THERAPY GENERATOR MODEL 8930 SYSTEM USER GUIDE

## TUNA Therapy Clinical Overview

**This chapter provides an overview of the TUNA Therapy clinical information.**

### **Overview**

- Indications
- Contraindications
- Warnings
- Precautions
- Clinical Studies
- Study Design
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- Efficacy Data

## Overview

The Medtronic TUNA (Transurethral Needle Ablation) Therapy is a minimally invasive treatment for patients with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The Medtronic PROSTIVA RF System uses precisely focused radio frequency energy to ablate prostate tissue, which helps to reduce the constriction of the urethra and relieve BPH voiding symptoms.

The Medtronic PROSTIVA RF Therapy is clinically equivalent to the Medtronic TUNA (Transurethral Needle Ablation) Therapy. The Medtronic PROSTIVA RF Therapy and System represent a new version of the radio frequency generator and hand piece that are used for the same transurethral needle ablation procedure for treating benign prostatic hyperplasia.

## Indications

The TUNA System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cm<sup>3</sup>.

## Contraindications

- Patients with the following conditions should not be treated:
- Patients with an active urinary tract infection
- Neurogenic, decompensated or atonic bladder (patients with suspect bladder function should undergo a urodynamic evaluation to rule out atonic, decompensated, or neurogenic bladder syndrome)
- Urethral strictures or muscle spasms that prevent insertion of the hand piece sheath

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- Bleeding disorders or patients taking anticoagulation medication unless antiplatelet medication has been discontinued for at least 10 days
- ASA class group V patients
- Clinical or histological evidence of prostatic cancer or bladder cancer
- A prostate gland which is less than 34 mm or greater than 80 mm in transverse diameter
- Presence of any prosthetic device in the region that may interfere with the procedure
- Patients whose prostate has been previously treated with non-pharmacological therapies (such as TUMT, Laser, or TURP)
- Presence of a cardiac pacemaker, implantable defibrillator, or malleable penile implants
- Patients with any component(s) of an implantable neurostimulation system; energy from the TUNA System may be transferred through the implanted system and may damage the patient's tissue in the area of the implanted system components. This applies whether the neurostimulation system is “off” or “on”. The neurostimulation system components may also be damaged.

### Warnings

**Read all Warnings, Precautions, and Instructions for Use carefully prior to use.** Failure to read and follow all instructions, or failure to observe all stated warnings, could cause serious injury or death to the patient.

- **Return electrode-** Failure to properly place the return electrode may result in patient burns or poor electrical performance. Refer to “Attaching Return Electrode (Neutral Electrode)” on page 68, for complete instructions.
- **Return electrode-** The Model 8934 Return Electrode is designed for use only with the Medtronic Model 8930 RF Generator.
- **Patient grounding-** The patient should not come into contact with metal parts that are earthed or that have an appreciable capacitance to earth.
- **Needle placement-** Proper placement of the needles and accurate needle length selections are essential. Improper positioning of the hand piece, misplacement of the needles, or improper needle length selections could result in damage to the external sphincter or urethra, perforation of the prostatic

capsule or bladder neck, incomplete ablation, incontinence, or damage to the rectum.

- **Sterile instrument-** If a sterile instrument is accidentally dropped while connected to the RF generator, it must not be used. If this occurs, take the following steps immediately to avoid risks of using a contaminated hand piece and the possibility of electrical shock:
  - a. Turn **off** the RF generator.
  - b. Disconnect the RF cable from the RF generator.
  - c. Dispose of the hand piece properly according to established facility policy and procedure; be sure to remove telescope.
- **Single-use-only devices-** The hand piece, return electrode, and tubing system are intended for single use only. Do not reuse. Discard according to local environmental regulations.
- **Safety and efficacy-** The safety and efficacy of the treatment in patients with the following conditions has not been established:
  - Patients with a median lobe that grows into the bladder and collapses across the bladder
  - Patients with a transverse diameter of the prostate gland that is greater than 64 mm
  - Patients with prostate size above 50 cm<sup>3</sup>
  - Patients in ASA American Society of Anesthesiologists (ASA) Risk Category Class IV
- **Heart disease-** Patients with cardiac arrhythmia, hypertension uncontrolled by medication, cardiac disease, or congestive heart failure should be cleared by their cardiologist before having a PROSTIVA RF Procedure.
- **Packaging inspection-** Inspect each package prior to use. Do not use if package is opened or damaged.
- **Aseptic technique-** Use aseptic technique in all procedures. In areas where fluid spillage is likely to occur, use plastic sheeting to protect the generator.
- **Flammable agents-** Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before application of radio frequency energy. Because there is a risk of pooling flammable solutions under the

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patient, any pooled fluid should be removed before using the radio frequency generator. Also, when some materials such as cotton, wool, and gauze are saturated with oxygen, there is a danger of ignition from radio frequency energy.

- **Equipment failure-** The failure of the radio frequency generator could result in an unintended increase of output power.

### Precautions

The safety and effectiveness of treating patients with the following conditions has not been established:

- Patients with an interest in the preservation of future fertility
- Patients with previous rectal surgery other than hemorrhoidectomy, previous radical pelvic surgery or pelvic irradiation
- Patients with PSA > 10 ng/ml. Patients with PSA values between 4-10 ng/ml must have negative core biopsies
- Patients taking any medications that may affect the prostate and bladder, such as 5-alpha reductase inhibitors, antiandrogens, and gonadotropin-releasing hormonal medications within two months of the PROSTIVA RF Therapy Procedure
- Patients taking any medications that may affect the prostate and bladder (alpha and beta blockers, antihistamines, antidepressants, anticonvulsants, antispasmodics, and anticholinergics) within one week of the PROSTIVA RF Therapy Procedure

The treating clinician should be present at all times and the following additional cautions should be observed with respect to the patient's safety:

- The system should only be used by clinicians trained in prostate surgery.
- The PROSTIVA RF Therapy Procedure, unlike transurethral resection of the prostate, does not provide tissue samples for pathological examination. For this reason, it is recommended that patients treated with the system be followed on an annual basis to assess any prostatic changes.
- Interference produced by the operation of the high frequency surgical equipment may adversely influence the operation of other electronic equipment.
- Inspect the outside packaging of the hand piece and tubing system for integrity to ensure sterility.
- Inspect all components prior to use for any obvious signs of damage that may have occurred during transit and/or storage. In particular the return electrode should be checked prior to use.

- The Model 8929 Hand Piece is designed to operate only in conjunction with the Model 8930 Radio Frequency Generator. It is not designed to operate with any other radio frequency generator or electrosurgical power source.
- Excessive risk (leakage) current may result if this equipment is connected to anything other than the manufacturer's recommended power distribution system.
- Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade".
- Use only Medtronic-recommended sterilization techniques outlined in the *Model 8099 Telescope Instructions for Use* to process the telescope.

Additional warnings and precautions applicable to specific procedures can be found at appropriate places in this system user guide.

## **Clinical Studies**

Clinical studies using the TUNA Procedure were performed at multiple medical institutions throughout the United States. Patients with lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH) were enrolled in separate clinical studies to determine the safety and efficacy of the TUNA Therapy.

## **Study Design**

One clinical study included a multicenter, single blind, randomized study comparing the TUNA Therapy to TURP (Transurethral Resection of the Prostate). Of the 167 patients treated in the study, 111 were treated with the TUNA Therapy and 56 were treated with TURP. Safety was measured by the rate and severity of adverse events. Efficacy was evaluated by measuring peak-flow rate and AUA (American Urological Association) symptom score.

Patients 45 years or older with lower urinary tract symptoms secondary to the diagnosis of BPH who have both lateral and median lobe involvement were enrolled in additional two studies (PM1 and P01) to determine safety and efficacy.

The prostate glands were between 30 to 100 grams. Of the 50 patients treated in the studies, 45 were followed up for six months and 24 had up to one-year follow-up data.

## Adverse Events

The clinical trials demonstrated that the TUNA Procedure can be performed without the need for general or regional (spinal) anesthesia; however, sedation is often used. Treatment with the TUNA Procedure is associated with few side effects and adverse events. The following table (Adverse Event) summarizes the safety data of patients from the original TUNA Therapy versus TURP study (lateral lobe only) and that from the two additional studies (P01 and PM1) that included treatment of patients having a degree of median lobe hyperplasia.

Table 51. Adverse Events

Adverse Event	Original Tuna Therapy Lateral Lobe Study	P01 Lateral and Median Lobe Study	PM1 Lateral and Median Lobe Study
Obstruction	44%	0%	0%
Catheterization (for urinary retention)	41%	15%	6%
Bleeding	29%	9%	6%
Pain/Discomfort	23%	(included in Dysuria) <sup>a</sup>	(included in Dysuria) <sup>a</sup>
Urgency	8%	(included in Dysuria) <sup>a</sup>	(included in Dysuria) <sup>a</sup>
Frequency	8%	(included in Dysuria) <sup>a</sup>	(included in Dysuria) <sup>a</sup>
Urinary Tract Infection	6%	12%	0%
Dysuria	2%	15% <sup>a</sup> (irritative symptoms)	6% <sup>a</sup> (irritative symptoms)
Scarring/Stricture	<2%	0%	0%
Impotence	<2%	0%	0%

Retrograde Ejaculation	<1%	3% (partial)	0%
Incontinence	0%	0%	0%

<sup>a</sup>In the lateral and median lobe studies, dysuria was described as irritative voiding symptoms, which include pain, discomfort, or frequency.

## Efficacy Data

The original prospective clinical trial (lateral lobe only) was performed at eight (8) medical centers across the United States. One hundred sixty-seven (167) men 50 years of age or older with symptomatic BPH were enrolled in this original trial. One hundred twenty-one (121) of these patients were randomized to either the TUNA Therapy or TURP: sixty-five (65) were treated with the TUNA Therapy and fifty-six (56) underwent TURP. Forty-six (46) additional non-randomized patients were treated with TUNA, making the total TUNA-treated population one hundred eleven (111).

Mean values for AUA (American Urological Association) Symptom Score, Peak Flow Rate, Post Void Residual Volume, and Quality of Life (QOL) score between the TUNA Therapy and TURP groups were measured at baseline, 6 months, and 12 months following the treatment, respectively (Table 52).

**Table 52. Efficacy Data of the TUNA Therapy vs. TURP Study**

<b>Parameter</b>	<b>Baseline</b>	<b>6 Months</b>	<b>12 Months</b>
AUA Symptom			
TUNA Therapy	23.8	10.6	11.9
TURP	24.1	7.9	7.8

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Peak Flow Rate			
TUNA Therapy	8.9	13.4	14.8
TURP	8.9	21.0	21.1
Post-Void Residual Value			
TUNA Therapy	91.4	63.6	65.9
TURP	81.9	45.6	47.1
Quality of Life			
TUNA Therapy	4.7	1.9	1.9
TURP	4.8	1.6	1.4

Similar results were seen from the additional studies (lateral and median lobes). Tables 53 and 54 demonstrated the efficacy results of all the studies.

**Table 53. Total Symptom Score Overview**

<b>Visit</b>	<b>Original TUNA Therapy Lateral Lobe Studies (American Urological Association Symptom Score)</b>	<b>P01 Lateral and Median Lobe Studies (International Prostate Symptom Score)</b>	<b>PM1 Lateral and Median Lobe Studies (International Prostate Symptom Score)</b>
Pretreatment	24.6	21.0	24.0
1 Month	12.5	16.0	13.0

3 Months	9.6	10.0	10.0
6 Months	10.1	10.0	5.0
12 Months	10.6	11.0	N/A

**Table 54. Peak Uroflow Rate (Qmax) Overview**

<b>Visit</b>	<b>Original TUNA Therapy Lateral Lobe Studies (American Urological Association Symptom Score)</b>	<b>P01 Lateral and Median Lobe Studies (International Prostate Symptom Score)</b>	<b>PM1 Lateral and Median Lobe Studies (International Prostate Symptom Score)</b>
Pretreatment	8.306	8.6	6.4
1 Month	16.565	10.2	11.4
3 Months	15.024	12.0	15.1
6 Months	14.748	13.7	11.0
12 Months	13.432	12.7	N/A