PROSTIVA® RF Therapy

Patient Selection Algorithm

PATIENT EVALUATION

- · History and Physical
- DRE
- Cystoscopy
- TRUS (Optional)
- Flow Rate (Optional)
- PSA Test
- Urinalysis

PATIENT SELECTION

All Patients with symptoms of BPH:

- Prostate size between 20 and 50 cm³
- Over the age of 50

Meets Criteria

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
- 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 nonpharmacological 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.

Does not meet criteria

ALTERNATIVE TREATMENT

Does not meet criteria

PRECAUTIONS1

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
- \bullet 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 gondatropin-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 antichololinergics) within one week of the PROSTIVA RF Therapy Procedure

Meets Criteria

Meets Criteria

PROSTIVA® RF Therapy

UROLOGIX

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¹The safety and effectiveness has not been established in patients with these conditions. Additional warnings and precautions applicable to specific procedures can be found at appropriate places in the System User Guide. Indications: Prostiva RF Therapy 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 20cc and 50cc. Adverse Events: Side effects may include obstruction, bleeding, pain/discomfort, urgency, frequency and urinary tract infection.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions and warnings, please refer to the System User Guide. Prostiva is a registered trademark of Medtronic. Urologix is the exclusive licensed distributer for Prostiva RF Therapy products. © 2011 Urologix, Inc. All rights reserved.