FACT SHEET

Medtronic TUNA® Therapy for Benign Prostatic Hyperplasia (BPH)

Overview
TUNA® (Transurethral Needle Ablation) Therapy is a safe, fast and effective minimally invasive treatment for benign prostatic hyperplasia (BPH), or enlarged prostate. The Medtronic Precision™ Plus System delivers low-level radio frequency energy directly into the prostate and destroys the prostate tissue, improving the symptoms of BPH.

Indication
TUNA 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 20 cc and 50 cc.

Benefits
- Safe, fast and effective alternative to a lifetime of BPH medication.
- Provides long-term relief of BPH symptoms in a single treatment.
- Procedure is associated with few side effects and adverse events.¹
- Treatment time is about 15 minutes for most patients, with additional prep time required.
- Treatment can be performed under local anesthesia.
- Treatment is targeted; adjacent tissues and organs are preserved.
- Cost effective – can be performed as an outpatient procedure in a urologist’s office
- Affordable – covered by Medicare and most private health plans.

Medtronic Precision Plus System
- The major components of the Precision Plus System are the Radiofrequency (RF) Generator, the Hand Piece and Telescope.
  ⇒ The Generator is a portable, line-powered, dual channel generator, capable of producing up to 15 watts per channel. The generator produces low power RF energy at 460 kHz.
  ⇒ The Hand Piece consists of two components: the Reusable Handle and the Disposable Cartridge, which contains two insulated needles.
  ⇒ The Telescope allows direct visualization to the physician to view anatomical landmarks and the needle deployment sites.
Procedure and Follow-up

- Treatment time for TUNA Therapy is about 15 minutes total for the average size prostate (20 cc — 50 cc). Total procedure time is less than one hour, with some preparation time required.
- The device is inserted into the urethra and deploys two small needles into the prostate tissue. The needles emit radiofrequency (RF) energy directly and precisely into the prostate, causing thermal ablation of the obstructing tissue.
- Most patients can undergo TUNA Therapy with only minimal anesthesia (a sedative and a local anesthetic).
- Patients are usually able to return to most normal activities within 24-48 hours.
- BPH symptoms begin improving when the body absorbs the treated tissue, usually within one month.

Safety Profile

- Clinical trials demonstrated that the TUNA procedure can be performed without the need for general or regional (spinal) anesthesia; however, sedation is often used.
- TUNA Therapy is associated with few side effects and adverse events, which may include obstruction, bleeding, pain/discomfort, urgency, frequency and urinary tract infection.

History

- Previously, the only BPH treatment options were daily drug therapy or surgery.
- With the development of minimally invasive therapies, patients now have a selection of BPH treatment choices to better meet their lifestyle and health needs.
- RF energy has been used since the 1920s, primarily in cardiac and neurosurgery treatments; RF has been recognized as a safe and effective treatment for many medical conditions.
- Thermotherapy for BPH is based on the principle that heating the prostate tissue to above 45 degrees Celsius will cause tissue necrosis.
- Initial pilot studies of the TUNA Therapy began in 1994, followed by a series of clinical trials to determine safety, efficacy and durability. When comparing side effects and adverse events, TUNA Therapy compared favorably to TURP in a major U.S. clinical trial.\(^1\)
- TUNA Therapy was introduced in the United States in 1996 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 cc and 50 cc.
- In January 2003, the United States Food and Drug Administration (FDA) cleared the TUNA Therapy Precision Plus System.
- TUNA Therapy is included as a recommended treatment option in the 2003 American Urological Association’s BPH Guidelines.
- In a 2003 European study, TUNA Therapy was proven to be effective and to provide good long-term clinical improvement after five years (in this study, more than 75 percent of the patients did not need additional treatment for BPH).\(^2\)
Cost and Coverage

- The cost of TUNA Therapy to patients varies by benefit plan.
- Cost savings are also realized with the limited recovery time and decreased morbidity of TUNA Therapy as compared to TURP.
- TUNA Therapy is covered by Medicare in all 50 states, as well as by many private pay and managed care insurance companies. Most patients will be responsible for a deductible and/or co-payment/co-insurance.
- Effective Jan. 1, 2001, Medicare began to reimburse physicians for performing the TUNA procedure in their offices, where previously the treatment was only performed in the hospital.

References

1 Medtronic Precision Plus System User Guide