Transurethral resection of the prostate (TURP) has become the primary choice for the treatment of benign prostatic hyperplasia (BPH) over the past 50 years. BPH, an enlargement of the prostate causing urinary tract obstruction, is a major international health problem, affecting at least 50% of men ages 55 years and older. Several clinical studies have shown that TURP has a success rate of about 75%. Yet, with a morbidity rate of 18%, TURP is not a surgical procedure that is free of risks. This, in addition to the high costs and lengthy healing period associated with TURP, has forced the medical community to seek alternative methods of therapy.

Transurethral microwave thermotherapy (TUMT) is among the many new treatment modalities and minimally invasive techniques that have emerged over the past decade. TUMT treats excess prostate tissue with precisely delivered doses of microwave-induced energy. Heat is applied to the prostate via a catheter containing a microwave antenna, while a cooling system simultaneously circulates water throughout the catheter to protect the urethra and adjacent cells from excessive temperatures. This built-in cooling system also minimizes pain and prevents urethral sloughing. In addition, a fiberoptic thermosensor continuously monitors the treatment temperature for safety, according to EDAP Technomed, Inc., manufacturer of the first Food and Drug Administration (FDA)–approved TUMT system.

The hour-long procedure requires no hospitalization and only calls for local, topical analgesia. However, analgesia decisions are the prerogative of the treating urologist. Most patients begin to feel the benefits of TUMT within six to eight weeks following the procedure as the body steadily absorbs the treated prostate tissue, EDAP Technomed notes.

**Involved specialists**

Urologists.

**Positions of societies and academies**

- **AUA**  The American Urological Association (AUA) does not have a position concerning the delineation of privileges for TUMT. However, in its 1995 statement *Delineation of privileges for staff urologists*, the AUA states that “in an effort to ensure the public’s general welfare by promoting the improvement of urologic patient care, [the AUA] recommends that patients of any age suffering from genitourinary tract disease be cared for primarily by physicians who have met training qualifications and passed the examination of the American Board of Urology [ABU] within four years after completion of their residency training.”
Further, “the AUA has officially advised the American Hospital Association and the JCAHO that incidence of malpractice would be decreased and that patient care would be significantly improved if ABU certification were made a prerequisite for receiving specialty clinical privileges in JCAHO-approved hospitals.”

Positions of other interested parties

**FDA**

In May 1996, the FDA reviewed/approved the Prostatron (P950014) as a nonsurgical treatment alternative to TURP for the treatment of BPH. The device, which is manufactured by EDAP Technomed, Inc., of Burlington, MA, was approved via a pre-market approval (PMA) pathway.

The FDA also approved the Targis System (P970008) by Urologix, Inc., of Minneapolis, MN, in August 1997, and the Urowave MicrowaveThermotherapy System (P970044) by Dornier Medical Systems, Inc., of Kennesaw, GA, in May 1998, for the treatment of BPH. Both were approved via a PMA pathway.

**EDAP Technomed, Inc., Burlington, MA**

EDAP Technomed cites the following as patient contraindications for TUMT:
- Peripheral arterial disease with intermittent claudication or Leriches syndrome (i.e., claudication of the buttocks and perineum)
- Clinical or histological evidence of prostatic cancer
- Severe urethral stricture preventing easy catheterization
- Presence of a cardiac pacemaker, an implantable defibrillator, or a metallic implant in the region of the hip, pelvis, or femur

In addition, EDAP Technomed states that the safety and effectiveness of treatment with the Prostatron have not been established in patients with the following conditions:
- Interest in the preservation of future fertility
- Disorders of coagulation
- Renal implant
- Neurological disorders that might affect the bladder function
- Post-void residual urine volumes greater than 350 ml
- Urinary retention requiring an indwelling catheter
- Large median lobe of the prostate protruding into the bladder
- Active urinary tract infections
- Bacteriological evidence of bacterial prostatitis
- Previous pelvic surgery or pelvic radiotherapy
- Previous rectal surgery (other than hemorrhoidectomy)
“TUMT is a nice middle ground,” says John N. Kabalin, MD, FACS, a urologist with Scottsbluff (NE) Urology Associates, PC. “It fills a niche that is not surgery but is more advantageous than pills or other medication.”

Because the procedure is relatively simple for a urologist trained in the anatomy and diseases of the prostate, Kabalin says the key to success lies in proper patient selection and effective postoperative care. “It’s an easy, safe way to get a good result.”

However, the more sedation involved with TUMT, the higher the morbidity associated with the procedure, Kabalin points out.

Surgeons performing TUMT should be board-certified urologists, have participated in a didactic lecture devoted to TUMT, and have had hands-on exposure to the TUMT treatment of two patients, recommends James B. Regan, MD, associate professor of surgery at Georgetown University School of Medicine in Washington, DC, and a trainer in the use of the Prostatron.

“Most urologists have a good feel for the procedure after four or five patient treatments,” he says. “If you follow the guidelines, they’re not too difficult in terms of patient selection and running of the machine.”

In terms of how TUMT measures up overall, Regan says, “There’s very little that TURP can offer that TUMT cannot, except that TUMT does not provide as drastic of an improvement as TURP.”

The JCAHO does not have a position concerning the delineation of privileges for TUMT. In its 1998–1999 Comprehensive Accreditation Manual for Hospitals (CAMH), the JCAHO states (MS.1.1.1) that “each medical staff . . . includes fully licensed physicians and may include other licensed individuals permitted by law and by the hospital to provide patient care services independently in the hospital (both physicians and these other individuals are referred to as ‘licensed independent practitioners’).”

Furthermore, the 1998–1999 CAMH states (MS.5.4) that “professional criteria that are specified in the medical staff bylaws and uniformly applied to all applicants for medical staff membership, medical staff members, or applicants for delineated clinical privileges . . . constitute the basis for granting initial or continuing medical staff membership and for granting initial, renewed, or revised clinical privileges.” The JCAHO further requires (MS.5.4.3) that “the criteria at least pertain to evidence of cur-
rent licensure, relevant training or experience, current competence, and ability to perform the privileges requested.”

While the JCAHO does not require hospitals to use any specific method in delineating clinical privileges, it does require such privileges to be hospital-specific and based on an individual’s demonstrated current competence (MS.5.15).

It further requires (MS.5.15.1–MS.5.15.1.3) “privileges to be related to an individual’s documented experience in categories of treatment areas or procedures, the results of treatment, and the conclusions drawn from organization performance improvement activities when available.”

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

**Minimum threshold criteria for requesting core privileges in TUMT**

- **Basic education:** MD or DO
- **Minimum formal training:** The applicant must be able to demonstrate successful completion of an American College of Graduate Medical Education (ACGME)– or American Osteopathic Association (AOA)–approved residency training program in urology.
- **Required previous experience:** The applicant must be able to demonstrate proven competence in TUMT. It is recommended that a physician who did not receive in-residency training in this area participates in a one-and-a-half day course devoted to TUMT, including a didactic portion and a hands-on session involving the observation of two patient treatments.
- **References:** A letter of reference must come from the individual responsible for formal TUMT training or a physician who is familiar with the applicant’s experience with TUMT.

**Reappointment**

Reappointment should be based on unbiased, objective results of care according to the hospital’s existing quality assurance mechanisms. The applicant must prove that he or she has maintained competence by demonstrating that he or she has met the hospital’s minimum requirement for TUMT privileges.

In addition, continuing medical education relating to TUMT should be required.
Special thanks

Special thanks to Daniel K. Hellerstein, MD, of the Palm Beach Medical Group in West Palm Beach, FL, for his help in making this White Paper possible.

For more information

For more information regarding privileging TUMT, contact:

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EDAP Technomed, Inc.
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Web site: www.edaptechnomed.com

Food and Drug Administration
Office of Device Evaluations
9200 Corporate Boulevard
Rockville, MD 20850
Telephone: 301/594-5072
Fax: 301/480-4224

Joint Commission on Accreditation of Healthcare Organizations
One Renaissance Boulevard
Oakbrook, IL 60181
Telephone: 630/792-5000
Fax: 630/792-5005
Web site: www.jcaho.org
Privilege request form
Transurethral microwave thermotherapy

In order to be eligible to request privileges for transurethral microwave thermotherapy, a physician must meet the following minimum threshold criteria:

• Basic education: MD or DO

• Minimum formal training: The applicant must be able to demonstrate successful completion of an ACGME- or AOA-approved residency training program in urology.

• Required previous experience: The applicant must be able to demonstrate proven competence in TUMT. It is recommended that a physician who did not receive in-residency training in this area participates in a one-and-a-half day course devoted to TUMT, including a didactic portion and a hands-on session involving the observation of two patient treatments.

• References: A letter of reference must come from the individual responsible for formal TUMT training or a physician who is familiar with the applicant’s experience with TUMT.

• Reappointment: Reappointment should be based on unbiased, objective results of care according to the hospital’s existing quality assurance mechanisms. The applicant must prove that he or she has maintained competence by demonstrating that he or she has met the hospital’s minimum requirement for TUMT privileges.

In addition, continuing medical education relating to TUMT should be required.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ______________________________________________________________

Typed or printed name: ____________________________________________________________

Date: __________________________________________________________________________