SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

DEVICE GENERIC NAME:	Transurethral Microwave Thermal Therapy System
DEVICE TRADE NAME:	Urologix T3® Targeted Transurethral Microwave Thermo-ablation System: Model 4000
APPLICANT:	Urologix, Inc. 14405 Twenty-First Avenue North Minneapolis, Minnesota 55447
PREMARKET APPROVAL APPLICATION (PMA) NUMBER:	P970008
DATE OF NOTICE OF APPROVAL TO THE APPLICANT:	AUG 22 1997

II. INDICATIONS FOR USE

The Urologix T3® System is a non-surgical device intended to relieve symptoms associated with benign prostatic hyperplasia (BPH) and is indicated for men with prostatic lengths of 30 to 50 mm.

III. DEVICE DESCRIPTION

The T3® Targeted Transurethral Microwave Thermo-ablation System: Model 4000 (T3 System) which includes the T3 System Procedure Kit used in conjunction with the T3 System Control Unit, is an operator controlled device designed to deliver microwave energy to the prostate for the treatment of BPH. This device utilizes a transurethral microwave antenna to heat the prostate, with simultaneous urethral cooling. This heating process is regulated through temperature feedback from one sensor mounted in the urethral catheter at the level of the prostate, and five sensors mounted on the surface of a rectal probe. A complete treatment consists of applying microwave energy at 915 MHz ±13 MHz (60 Watts maximum) to the prostate for 60 minutes at catheter temperatures above 37°C. The device consists of the following four components: 1) a control unit which generates the microwave power and monitors the treatment to allow the operator to deliver appropriate therapy, 2) the Microwave Delivery System (MDS) which consists of a transurethral catheter, 3) the Rectal Thermosensing Unit (RTU), and 4) the Coolant

Bag. (Although not supplied with the device, the T3 System must be used with a legally marketed, free standing, transrectal ultrasound scanner.)

1) The T3 System Control Unit is a portable unit approximately 48 inches high, 16 inches wide and 16 inches deep. It consists of a 486 microprocessor, microwave generator, fiber optic and electronic temperature sensing systems, refrigeration and pumping systems for cooling and circulating water, display screen and printer. The treatment is continuously monitored by the T3 System Control Unit. The power level is controlled by the operator based on pre-defined treatment parameters which have been shown to provide a safe and effective treatment. During each patient's treatment session, treatment parameters (i.e., microwave power administered, urethral and rectal temperatures, mean total energy delivered to prostate, time, etc.) are continuously recorded by the T3 System Control Unit.

2) The MDS consists of a silicone transurethral catheter (21 French), a balloon located near the distal tip which is used to position the catheter within the urethra, the cooling channels, the microwave antenna, a urinary drainage lumen, and a fiber optic thermosensor. The microwave antenna consists of a coil design antenna with a capacitor to enable an impedance match to help ensure efficient energy delivery. The antenna is positioned approximately 5 mm proximal to the balloon to allow alignment with the prostatic tissue. The MDS is designed and manufactured to emit the microwave energy in a preferential pattern with a greater amount of energy delivered to the anterior and lateral portions of the prostate gland and a lesser amount of energy toward the posterior portion (i.e., toward the rectum).

3) The RTU is a silicone rubber balloon with 5 thermosensors mounted on its surface which are positioned in the rectum adjacent to the prostate. The RTU is inflated with air (120 cc) to ensure firm rectal wall contact and secure placement.

4) The Coolant Bag is filled with 100 mL of distilled water and placed in the Control Unit. During the therapy, the water in the Coolant Bag is continuously cooled to 8°C and recirculated through the cooling channels of the MDS catheter to minimize discomfort and urethral trauma.

The MDS, RTU, and Coolant Bag are all sterile, disposable devices which are connected to the Control Unit prior to initiation of therapy. By providing simultaneous heating with conductive cooling, the T3 System maintains the urethral temperature under 44.5°C while prostatic temperatures 5 to 10 mm deep in the prostate are maintained at temperatures above 45.5°C, resulting in tissue necrosis and ablation. The urethral and rectal temperatures are continuously monitored by the system and power is adjusted by the operator as needed. The system automatically discontinues power if the rectal temperatures reach 42.5°C or the urethral temperature sensor reach 44.5°C. After 60 minutes of treatment at therapeutic temperatures ($\geq$ 37°C), microwave energy is discontinued.

IV. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

The labeling for the T3 System contains the following contraindications, warnings and precautions:

CONTRAINDICATIONS FOR T3 SYSTEM THERAPY

- Patients with a prostatic urethra < 3cm in length
- Patients with implanted active pacemakers or defibrillators
- Patients with penile or urinary sphincter implants
- Patients with metallic implants in the region of the pelvis or hip
- Patients with urethral stricture (unable to pass 22F urethroscope with ease)
- Patients with peripheral arterial disease with intermittent claudification or Leriches syndrome (i.e., claudification of the buttocks and perineum)
- Patients with clinical or histological evidence of prostatic cancer or bladder cancer

WARNINGS

The T3 System procedure has inherent associated risks of complications (refer to Adverse Events and Complications). The T3 System should not be used in any way other than the intended and indicated use and according to the Instructions For Use.

PRECAUTIONS

Only those physicians who have been thoroughly trained on the operation of the T3 System and the T3 System procedure should deliver the T3 System procedure.

The T3 System procedure must not be initiated without assurance that the MDS is properly positioned in the patient. The correct positioning of the MDS must always be checked by ultrasound imaging prior to commencing treatment. Improper placement or orientation of the MDS may lead to procedural failures or heating damage of non-target tissues such as the bladder neck, external sphincter or penile urethra.

The treatment must not be initiated until the rectal-thermal probe is properly placed into the patient's rectum and inflated.

All components of the Procedure Kit must be used in a manner consistent with the instructions set forth in the T3 System Instructions For Use Insert and the T3 System User Manual. Failure to do so may result in insufficient therapy or increased risk of injury or infection to the patient.

Use of the T3 System results in the deposition of microwave energy within the patient's prostate and in adjacent regions of the body. Some animal studies in the literature suggest that there may

be as yet unknown health effects from exposure to microwave radiation, including an increased incidence of tumors. Although it is not possible to extrapolate these studies to humans, they suggest that unnecessary microwave radiation exposure should be avoided.

At least 20 cm of ventilation clearance must be provided around the base of the Control Unit.

Equipment that is susceptible to electromagnetic energy could be effected by the emissions of the T3 System if located within 3 meters while treatment is being performed. Other electronic equipment should be operated with caution under these circumstances.

Do not place the equipment near an electronic device or other equipment emitting electromagnetic waves as they may interfere with the operation of the equipment.

Operate the Control Unit and connected devices only in clinical environments where the installation is in accordance with international standard DIN VDE 0107; and the national standard ANSI/NFPA 70. The equipment must be connected to a fully tested, hospital grade power outlet with adequate grounding.

The Control Unit must be plugged into the appropriate voltage outlet.

Power Requirements:

Supply: 220/240 V [±10%](8 A) Single phase 50 or 60 Hz or
110/120 V [±10%](15 A) Single phase 50 or 60 Hz or
100 V [±10%](15 A) Single phase 50 or 60 Hz

Connections: Hospital Grade plug

For further safety information, refer to the T3 System User Manual

The safety and effectiveness of T3 System treatment has not been established in patients with the following conditions:

- Interest in the preservation of future fertility
- Post-Void Residual (PVR) volume ≥ 350 mL
- Previous pelvic surgery or pelvic radiotherapy
- Previous rectal surgery (other than hemorrhoidectomy)
- Enlarged obstructing median lobe of the prostate
- Active urinary tract infection
- Urinary retention requiring an indwelling catheter
- Prostatic urethra > 5 cm in length
- Gross hematuria not due to BPH

- Prior prostatic surgery (excluding balloon dilatation)
- Coexisting illness or specific obstructive symptoms found to be caused by any of the following conditions:
  - Neurological disorders which might affect bladder function
  - Prostate volume greater than 100 cc
  - Bladder neck contracture
  - Urinary sphincter abnormalities
  - Bladder stones
  - Evidence of bacterial prostatitis
  - Renal impairment
  - Coagulation disorders

A thorough physical exam should be performed on patients prior to initiation of the T3 System procedure.

Patients who have received treatment with the T3 System should be followed on an annual basis since the treatment does not result in complete destruction of the prostate.

The prostate specific antigen (PSA) levels will increase significantly following treatment. This increase can be up to 10 times (1000 percent) higher at 1 week and will decrease back to approximate normal levels by 6 weeks following the T3 System treatment. The use of PSA testing during this period will be unreliable. Physicians are cautioned to measure the serum PSA level before treatment for future comparisons. PSA levels should return to baseline by 3 months following T3 System treatment and may once again be used as a diagnostic test.

Attention by a qualified physician is required during the use of the T3 System. The Control Unit display must be monitored and controlled during the course of a therapy session to make sure that the MDS and rectal temperatures are within prescribed treatment parameters. Failure to monitor and deliver the T3 System procedure per recommendations by Urologix may lead to decreased patient safety and/or reduced clinical effectiveness.

All components of the Procedure Kit are intended for one time use only. DO NOT resterilize and/or reuse them as this will likely result in compromised device performance and increased risk of injury or infection to a patient. The Procedure Kit components must not be used with any other system.

Do not use a treatment catheter if it appears to be damaged.

Use all components of a Procedure Kit prior to the "use before" date specified on the package.

Use ONLY sterile water when filling the Coolant Bag. DO NOT use saline or non-sterile water.

Care should be taken in handling all components of the Procedure Kit to avoid damage that may lead to subsequent failure of the component or procedure.

Because the T3 System procedure elevates intraprostatic tissue temperature causing tissue damage that may result in acute urinary retention, it is advisable for the patient to be catheterized for 2 to five days (median 3 days) following the procedure.

As patient responses to the T3 System are variable, the patient should be evaluated by their physician following treatment.

Failure to maintain the equipment may result in exposure of the patient an/or the operator to excessive microwave energy.

V. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

A total of 206 patients were evaluated for adverse events or complications in the U.S. clinical investigation of the T3 System in the U.S. IDE studies. These studies recorded the following complications: (1) urinary retention less than 7 days (98.0%), (2) dysuria (includes those patients who reported pain/discomfort during urination) (38.8%), (3) pain/discomfort during sexual activity (13.6%), (4) urgency (13.1%), (5) frequency (12.1%), (6) urinary retention requiring catheterization longer than 7 days (11.7%), (7) irritative symptoms due to catheterization (8.7%), (8) nocturia (6.8%), (9) hematuria (5.9%), (10) urinary tract infection (5.3%), (11) loss of or retrograde ejaculation (3.9%), (12) obstructive urinary symptoms (3.9%), (13) prostatic urethra damage (3.4%), (14) sensation of not emptying bladder (3.4%), (15) pain or irritation in groin of penis (3.4%), (16) epididymitis (2.9%), (17) temporary acute urinary incontinence (2.4%), (18) flu like symptoms (2.4%), (19) symptoms of UTI, non-specific (2.4%), (20) rectal irritation (2.4%), (21) hemospermia (2.4%), (22) severe pain during treatment (1.9%), (23) hospitalization related in general to the treatment (1.9%), (24) urethritis (1.5%), (25) urethral strictures not requiring treatment (1.0%), (26) flank pain (1.0%), (27) blood pressure changes during treatment (1.0%), and (28) urethral stricture requiring transurethral surgical intervention (0.5%).

VI. ALTERNATE PRACTICES OR PROCEDURES

The treatment of BPH has been based predominantly on patient symptomatology and degree of associated urinary obstruction. The following are the currently available BPH treatment options, listed in order from least to most invasive: watchful waiting, alpha blocker therapy, finesteride therapy, balloon dilation, heat therapy (i.e., using laser, radiofrequency, or microwave energy), transurethral incision of the prostate, transurethral resection of the prostate, and open prostatectomy.

VII. MARKETING HISTORY

Eight sites in the United Kingdom and Germany have used the T3 System. The T3 System has not been withdrawn from marketing for any reason relating to its safety or effectiveness.

VIII. SUMMARY OF PRECLINICAL STUDIES

A. Biocompatibility/Sterility Testing

There are three disposable, patient or indirect patient contacting components used with the T3 System: the MDS-a silicone transurethral catheter; the RTU-a silicone rubber balloon (with 5 thermosensors on the surface); and the polymer coolant bag. Biocompatibility testing was performed on all of these components and included: Cytotoxicity (MEM, L-929 mouse fibroblast cells), Mutagenicity (Ames Salmonella), Hemolysis, Implantation (7 day intramuscular, rabbit, macro/microscopic examination), Intracutaneous Toxicity (saline and cottonseed oil in rabbits), Pyrogen (saline in rabbit), Sensitization (dermal, saline and cottonseed oil in guinea pig), Subchronic Toxicity (90 day in rabbit, macro/microscopic examination), and Systemic Injection (mice). Sterility testing included: Bacteriostatis/Fungistatis, Bioburden, Biological Indicator, Packaging (including Microbial Aerosal Challenge and Sterility), Population Verification, Product Inoculation (USP XXIII), and Sterility (USP XXIII). All testing indicated that the T3 System is non-toxic, biocompatible, sterile, and safe for its intended use.

B. Electromagnetic Compatibility (EMC) Testing

Testing was conducted to assess the potential of the device causing electromagnetic interference (EMI) in other devices, or being susceptible to such interference. This testing demonstrated that the T3 System meets the EMC standards of IEC 601-1-2. Testing was also conducted to characterize the strength of the electromagnetic field being emitted from the T3 System during operation. These measurements indicated that it is safe for medical personnel who are around the equipment or in contact with the patient during the treatment. This is based on the recommendations from the American National Standards Institute (ANSI) standard C95.1-1982.

C. Phantom Studies

In vitro phantom studies were performed to characterize the microwave energy emissions based on the heat generated from the MDS. The phantom material consisted of a gel which has electromagnetic and thermal properties that are similar to those of human tissue. Each of these experiments was conducted using fiber optic thermosensors spaced known distances from the catheter's tip and a thermal sensing material which generated visual color changes with temperature increases. Preferential and lateral projection phantom studies were performed on seven catheters. The temperature pattern measured demonstrated preferential heating, with a difference of approximately 10°C at opposite sides (anterior and posterior) of the catheter

(180° separation) whereas the lateral plane demonstrated a symmetrical pattern. The temperature difference was 4-5°C between the preferential and lateral sides (90° separation). The temperature pattern measured by this method demonstrated that (1) the cooling system lowers temperature at the surface of the catheter, allowing the maximum temperature to be achieved several millimeters radial from the catheter due to the heat reduction at the catheter surface; (2) from this maximum temperature point at 4-5 mm from the catheter surface, the temperature decreases with additional distance from the catheter; and (3) the location of the maximum temperature is centered on the antenna and is symmetrical along the catheter's axis.

D. Animal Studies

Several canine studies were conducted to evaluate the ability of the T3 System to generate temperatures above 45°C in the prostate. These studies included range finding studies, safety evaluations studies, continuation studies, and T3 System testing. Later, the results of the animal studies were compared to the human clinical trials. These studies demonstrated the device's ability to deliver the microwave energy in a preferential pattern and to preserve the urethral tissue. Temperatures in the canine prostate reached over 60° C. These studies also provided valuable information for modifying the device before the clinical trials were initiated. For example, the range finding study showed that continuous monitoring of reflected power is necessary to detect an antenna failure and prevent unpredictable heating and a minimum coolant flow rate of 100 mL/min is required to maintain distention of the catheter lumens and the safety evaluation resulted in a modification of the thermal catheter to reduce the possibility of bladder damage.

IX. SUMMARY OF CLINICAL INVESTIGATIONS

The T3 System clinical studies included four distinct studies conducted at 8 U.S. clinical sites: 1) a T3 System vs. Sham study, 2) a T3 System U.S. General study, 3) a T3 System vs. TURP study, and 4) a feasibility study including interstitial temperature mapping. (Note: There was also an international study which was not part of the IDE study, and is included as supplemental information only.)

The 8 U.S. sites enrolled a total of 276 patients, and all but two received their assigned treatment (i.e., one patient was enrolled and then withdrew; the other patient did not meet the enrollment criteria and that number was never reassigned). Of the 274 patients who received treatment, 221 received the T3 System therapy, 43 received a Sham Treatment and 10 received a TURP. These data were collected between October 1992 and January 1997. Table 1 summarizes each investigational site, as well as the distribution of patients enrolled and treated under each of the four clinical study protocols. The numbers in the table are representative of enrolled and treated patients.

Table 1 - Clinical Studies

INVESTIGATIONAL SITE	Interstitial Feasibility Study	T3 System U.S. General Study	T3 System vs. Sham Study	T3 System vs. TURP Study	Total
Mayo Clinic, Scottsdale, AZ	15	20	30	0	65
Abbott-Northwestern Hospital, Minneapolis, MN	0	14	30*	0	44*
Univ. of Wisconsin, Madison, WI	0	0	30	0	30
Univ. of Rochester Strong Memorial Hospital Rochester, NY	0	3	30	0	33
Mayo Clinic Rochester, Rochester, MN	0	2	50**	0	52**
William Beaumont Hospital, Royal Oak, MI	0	20	0	0	20
Virginia Mason Clinic, Seattle, WA	0	0	0	14	14
The Watson Clinic, Lakeland, FL	0	0	0	18	18
Total Patients Enrolled with T3 System & Control	15	59	170+	32	276+
Total Patients Enrolled with T3 System	15	59	126**	22	222**
Total Patients Enrolled with Sham	0	0	44*	0	44*
Total Patients Enrolled with TURP	0	0	0	10	10

* 1 patient enrolled but not treated, blind broken. ** 1 patient enrolled/not treated, inclusion criteria not met. + see * &**

The design of the clinical investigation of the T3 System is consistent with the recommendations made in the FDA guidance document entitled "Draft Guidance for the Clinical Investigation of Devices used for the Treatment of Benign Prostatic Hyperplasia (BPH), Nov. 1994." Patients with American Urological Association (AUA) Symptom Scores greater than or equal to 9 ml/sec, peak flow rates less than or equal to 12 mL/sec and a prostatic urethra length from 3.0 to 5.0 cm were enrolled in the study.

In all four studies, the primary endpoints for effectiveness were improvements in the AUA Symptom Score (a 0-35 point scale rating the typical urinary symptoms associated with BPH) and in Peak urine Flow Rate (PFR). Other effectiveness endpoints assessed during the studies were improvements in Quality of Life measures; Post-Void Residual urine volume (PVR), Prostate Specific Antigen (PSA) level, Prostate Volume, and global assessments of treatment effect.

The four studies were all performed using the same general protocol developed during the feasibility portion of the study. However, each was designed with different goals to address specific issues regarding the safety and effectiveness of T3 System.

T3 System vs. Sham Study

1. Introduction

The T3 System vs. Sham Study was a randomized study to compare the safety and effectiveness of the T3 System treatment to that of Sham Treatment (i.e., a simulated treatment without microwave delivery). This study was designed to assess the differences in the effects of microwave heating of the prostate from those due to instrumentation alone.

Patients were randomized (3:1) between T3 System Treatment and Sham Treatment. Patients and evaluating physicians were blinded to treatment group assignment (device operators, however, could not be blinded). After the 6-month evaluation the treatment groups were unblinded, at which time Sham Treatment patients were offered an active T3 System Treatment. Although investigators continued to follow patients after the 6-month exam, the primary effectiveness evaluation between the T3 System Treatment patients and the Sham Treatment patients was limited to this 6-month follow-up point. The effectiveness of the blinding was assessed by the Quality of Life questionnaire used at the 6-week, 3-month and 6-month follow-up evaluations which asked which treatment the patient thought they had received. At 6 weeks, over half of the Sham patients questioned (57.9% of 38) thought they had received an active T3 treatment. With time, however, the Sham patients were able to identify their treatment group more accurately; at 3 months 42.1% thought they had received an active T3 treatment; and at 6 months only 25.7% thought they had received an active T3 treatment. The patients actually receiving T3 treatment were consistently (87-89.7%) able to accurately identify their treatment. Most of the Sham Treatment patients (73.8%) chose an active treatment after the blinding was broken after 6 months. As a result, long term data (i.e., >6 months) comparing the T3 System and the Sham Treatment groups are not available.

2. Study Population

In this study, 168 males with BPH were randomized and treated. Of the 168 patients randomized in the 3 to 1 ratio, 125 received the T3 System Treatment and 43 received the Sham Treatment. Enrollment was divided among the five sites with each site being assigned a minimum of 30 patients which included 8 randomly selected Sham patients.

By the date of database closure, the majority of patients in this study had completed their 6-month follow-up according to the protocol (i.e., 120/125 T3 System patients, and 34/43 Sham patients). Of the five T3 System Treatment subjects who were not available for the 6-month follow-up, four withdrew from the study and one died due to an unrelated cause. Of the nine Sham Treatment patients who were unavailable, seven presented with unimproved symptoms requiring intervention. All seven of these Sham Treatment patients opted for an active T3 System treatment. Of the other two patients, one patient withdrew for alternative treatment and one Sham Treatment patient was excluded from the analysis since his peak flow rate at 6 months

was over four standard deviations from the mean. Upon a subsequent review of his clinical history, it was found that he had a history of erratic voiding patterns and is suspected to have non-bacterial prostatitis.

3. Baseline Characteristics

The patients had the following baseline characteristics: mean age of 66.0 years for the T3 System Treatment group and 65.1 for the Sham Treatment group; mean duration of BPH symptoms of 6.9 years in the T3 System Treatment group and 5.9 years in the Sham Treatment group; mean PFR of 7.6 mL/sec in the T3 System Treatment group and 7.5 mL/sec in the Sham Treatment group; mean AUA Symptom Score of 20.8 in the T3 System Treatment group and 21.5 in the Sham Treatment group; mean Quality of Life score of 4.2 in the T3 System Treatment group and 4.0 in the Sham Treatment group; and mean Prostate Volume of 40.3 cm^3 in the T3 System Treatment group and 47.2 cm^3 in the Sham Treatment group. Based on an analysis of these comparisons, the T3 System Treatment and Sham Treatment groups were well-matched. Although a statistically significant difference in Prostate Volume was observed at baseline, a co-variate analysis indicated it did not effect the outcome of the study results. A total of 11 patients had deviations from the enrollment inclusion/exclusion criteria. One had a history of diabetic neuropathy, four had initial voided volumes <125 mL and six did not have two of the uroflow measurements within 30 days of enrollment. Of these deviations, only the four patients with voided volume less than 125 mL were considered to have an impact on the data analysis and these four have been excluded from data analysis for urinary flow parameters only.

4. Treatment Parameters

Treatment in the T3 System group was performed according to the study protocol. In 1/125 treatments, the procedure was interrupted prior to the completion of 60 minutes at therapeutic temperatures; this patient was retreated at a later date. None of the 43 Sham Treatment sessions were interrupted. During all treatments, the T3 System safety features functioned as intended.

The mean maximum urethral and rectal temperatures obtained during the 125 T3 System treatment sessions were 42.1°C and 39.6°C, respectively. The urethral cut-off temperature was not reached by any patient in this study; however the rectal cut-off temperature was reached in two patients (1.6%). The average maximum power delivered during these treatments was 37.3 watts, and the mean total energy delivered to the prostate was 133.4 kJ.

All treatments including the Sham Treatments used local Lidocaine gel. In addition, mild analgesics (29.6% T3, 9.5% Sham) or sedatives (44.8% T3, 28.6% Sham) were used on a physician prerogative basis. None of the medications used required the presence of an anesthesiologist or anesthesia services. All treatments were administered on an outpatient basis.

5. Effectiveness Results

The evaluation of effectiveness of treatment with the T3 System was primarily based upon improvements in symptomatology (i.e., AUA Symptom Score) and Peak Flow Rate, as compared between the two treatment arms, at 6 months. Other effectiveness parameters that were measured were Quality of Life, PVR, Prostate Volume, PSA levels, and global patient opinions.

Table 2 presents the effectiveness results including changes in symptomatology and Quality of Life recorded among the two treatment groups at 6 months. The overall AUA Symptom Score decreased from 20.8 to 10.4 (50% improvement) in the T3 System cohort, and from 20.7 to 14.3 (31% improvement) in the Sham cohort. This difference between the two groups was statistically significant ($p=0.011$). In the T3 System group, 74% of the subjects treated had AUA Symptom Score improvements of $\geq$ 30% and 64% had improvements of $\geq$ 8 points. In the Sham group, the corresponding proportions were 49% and 43%, respectively. The differences between the T3 System Treatment and Sham groups were statistically significant when comparing the differences in $\geq$ 30% change ($p=0.010$) and $\geq$ 8 points improvement ($p=0.026$).

The mean improvement of -50% (from 4.2 to 2.1) in the Quality of Life question in the T3 System group was statistically significant both when compared to baseline ($p<0.001$) as well as when compared to the mean change of -23% (3.9 to 3.0) in the Sham group ($p=0.001$).

Table 2
Effectiveness Results at 6 Months Post-Treatment for T3 and Sham Groups
(mean % change from baseline)

	T3 SYSTEM GROUP (n)	SHAM GROUP (n)
AUA Symptom Score (decreased score indicates improvement) Overall Score Obstructive Components Irritative Components % Patients Improved $\geq$ 30% % Patients Improved $\geq$ 8 points	-50% -57% -39% 74% 64% (n=119)	-31% -29% -26% 49% 43% (n=35)
Quality of Life Score (decreased score indicates improvement)	-50% (n=118)	-23% (n=35)
Peak Flow Rate % Patients Improved $\geq$30% % Patients Improved $\geq$3 mL/s	51% 60% 52% (n=101)	17% 26% 16% (n=31)
PVR	-14% (n=100)	-6.0% (n=31)
Prostate Volume	-8% (n=115)	-7% (n=34)

The changes in Peak Flow Rate (PFR) and Post-Void Residual (PVR) volume observed between baseline and 6 months for each treatment arm are also summarized in Table 2. In the T3 System Treatment group, PFR increased from 7.8 mL/sec to 11.8 mL/sec (51%). In the Sham Treatment group, PFR increased from 8.4 mL/sec to 9.8 mL/sec (17%). The difference in PFR for the T3 System Treatment group was statistically significant when compared to baseline ($p<0.001$) and when compared to Sham ($p=0.002$). Sixty percent of the T3 System Treatment patients had increases in PFR of $\geq$ 30% from baseline, and 52% experienced increases of $\geq$ 3 mL/sec. In the Sham Treatment group, 26% of patients had increases in their PFR of $\geq$ 30% and 16% had increases of $\geq$ 3 mL/s. These differences between the T3 System and the Sham Treatment groups were statistically significant when comparing both the percentages of patients with $\geq$ 30% change ($p=0.001$) and $\geq$ 3 mL/sec improvement ($p<0.001$). As seen in Table 2, PVR decreased somewhat from 99.1. mL at baseline to 85.0 mL at 6 months (14%), but is not statistically significant from baseline for the T3 System Treatment ($p=0.121$). The Sham Treatment group baseline PVR was 90.1 mL, which decreased 6.0% to 84.4 mL at 6 months.

Prostate volume was measured by transrectal ultrasound or hand held scanner at baseline and at 6 months in both the T3 System patients and the Sham patients. Prior to treatment, prostate volume averaged 38.1 cm^3 in the T3 System group and 45.2 cm^3 in the Sham Treatment group. At the 6-month follow-up exam, the mean Prostate Volume was 35.2 cm^3 for the T3 System cohort, and 42.0 cm^3 for the sham cohort. This difference for the T3 System group is statistically significant from baseline ($p<0.001$) but not when compared to sham ($p=.062$).

Serum PSA was evaluated to determine if there was a differential effect on this diagnostic parameter due to microwave heating of the prostate as compared to instrumentation alone. This blood chemistry was measured in the T3 System patients and the Sham patients at baseline, 1-week and subsequent follow-up evaluations. These results demonstrated that the T3 System treated patients had 1-week PSA levels of 26.4 ng/mL compared to 3.4 ng/mL at baseline, a 676% increase. The Sham patients, however, had no increase from baseline. This difference between these two cohorts was highly statistically significant ($p<0.001$). At 6 weeks the PSA level had almost returned to baseline and was below baseline by 6 months follow-up, indicating that the change in PSA is transitory.

Effectiveness Results - 1 year

The T3 System treatment group has been evaluated through 1 year. The follow-up results for the various effectiveness parameters at the 1 year time point are shown in Table 3.

Table 3
One year results
(mean % change from baseline)

	6 MONTH (n)	1 YEAR (n)
AUA Symptom Score % Patients Improved ≥ 30% % Patients Improved ≥ 8 points	-50% 74% 64% (n=119)	-51% 75% 64% (107)
Quality of Life Score	-50% (n=118)	-55% (n=106)
Peak Flow Rate % Patients Improved ≥ 30% % Patients Improved ≥ 3 mL/s	51% 60% 52% (n=101)	49% 56% 48% (n=89)
PVR	-14% (n=100)	-15% (n=87)
Prostate Volume	-8% (n=115)	-6% (n=105)

The 1 year results demonstrate the continued durability through 1 year. Specific changes include:

- AUA Symptom score changed from 20.9 to 10.2, a 51% improvement, ($p< 0.001$);
- Quality of Life changed from 4.1 to 1.9, a 55% improvement, ($p<0.001$);
- Peak Flow rate changed from 7.8 mL/sec to 11.6 mL/sec, a 49% improvement, ($p<0.001$);
- Post Void Residual changed from 99.3 mL to 84.4 mL, a 15% reduction, ($p=0.092$); and
- Prostate volume changed from 37.6 cm^3 to 35.4 cm^3, a 6% reduction, ($p=0.062$).

By the 1-year follow-up visit, 7% of the patients treated with the T3 System sought alternative therapy for BPH. Table 4 lists the alternative treatments pursued by both T3 System and Sham patients.

Table 4
Patients Seeking Alternative Treatments for BPH

	T3 System n=125		Sham n=42	
	n	%	n	%
TURP	2	1.6	1	2.4
Alpha Blockers	5	4.0	2	4.8
TUR Vaportrode	1	0.8	0	0
T3 System treatment/retreatment	1	0.8	31	73.8

6. Safety Results

The evaluation of the safety of the T3 System was primarily based upon the rate of adverse events reported by the patient or found during the follow-up. Additionally, safety was assessed through the following methods: cystoscopy evaluations, laboratory measurements, and questions regarding the incidences of sexual dysfunction and incontinence. The safety evaluation also included the evaluation of the interstitial temperature mapping data which is discussed in a later section. Table 5 summarizes the adverse events or complications which were determined to be related (or possibly related) to treatment for the T3 System and Sham Treatment groups. Some patients experienced more than one event. These complications represent all reported events throughout the 1-year follow-up exam. The adverse events experienced by the T3 patients were transient and not much more severe than those experienced by the Sham patients.

New onset of erectile dysfunction was not reported during the study. Analysis of measurements of hemoglobin, hematocrit, CBC, platelets, creatinine, and BUN indicated no significant associated complications at any of the follow-up exams.

Table 5
Adverse Events or Complications Reported During the T3 System vs. Sham Study

	T3 System n=125		Sham n=42	
	n	%	n	%
Dysuria	54	43	11	26
Frequency	22	18	3	7
Urgency	19	15	4	10
Irritative symptoms attributed to catheterization	16	13	4	10
Pain/Discomfort during sexual activity	15	12	2	4.8
Nocturia	14	11	3	7
Urinary Retention (episode(s) > 1 week post-therapy)	10	8	1	2.4
Urinary Tract Infection (UTI)	8	6.4	2	4.8
Obstructive urinary symptoms at 1 week	8	6.4	1	2.4
Sensation of not emptying bladder completely	7	6	0	0
Hematuria	6	4.8	2	4.8
Damage identified by cystoscopy/TRUS	6	4.8	0	0
Temporary Acute Incontinence	5	4	1	2.4
Loss of Ejaculate	5	4	0	0
Rectal, Perianal findings	5	4	0	0
Flu-like symptoms	5	4	3	7
Symptoms of UTI, non-specific description	5	4	0	0
Prostate changes identified by cystoscopy	5	4	0	0
Transient incontinence	4	3	0	0
Hematospermia	4	3	1	2.4
Therapy-related pain	4	3	0	0
Urethral Stricture	3	2.4	0	0
Epididymitis	3	2.4	0	0
Urethritis	3	2.4	1	2.4
Blood pressure change during therapy	2	2	0	0
Flank pain	2	2	0	0
Hospitalizations related to treatment: UTI Urethral Stricture Back pain and creatinine 2.8	1 1 1	0.8 0.8 0.8	0 0 0	0 0 0
Blood loss (>50 ml)	1	0.8	0	0
Adverse Event Report (mispositioned MDS)	1	0.8	0	0

T3 System U.S. General Study

1. Introduction

The purpose of the T3 System U.S. General Study was to establish the overall safety and effectiveness of the T3 System in support of the data obtained in the randomized study. The data presented from this study were obtained from five U.S. investigational sites.

2. Study Population

In this study, 59 males with BPH were enrolled and treated at the time of the database closure for this report. The patients had a mean age of 66.9 years, with a range from 50 to 80. The number of patients at each site ranged from 2 to 20. By the date of database closure, 33 of the 59 patients have reached the 3-month follow-up evaluation. No patients have been lost to follow-up or elected an alternative treatment.

3. Baseline Characteristics

The 59 patients had the following baseline characteristics: mean duration of BPH symptoms of 6.2 years; mean PFR of 7.3 mL/sec; mean AUA Symptom Score of 22.4; mean PVR of 117.9 mL; and mean Prostate Volume of 45.0 cm^3.

4. Treatment Parameters

The T3 System treatment was performed according to the standard T3 System protocol. The mean maximum catheter and rectal temperatures obtained during the treatment sessions were 41.9°C and 39.0°C, respectively. Neither the urethral nor the rectal cut-off temperature was reached by any patient in this study. The average maximum power delivered during these treatments was 41.0 watts, and the mean total energy delivered to the prostate was 149.6 kJ.

Other than topical Lidocainé, the only anesthetic medications used during any of the treatment sessions were mild oral or IV sedation (11.9% analgesics, 27.1% sedatives), none of which required the presence of an anesthesiologist or anesthesia services. The use of medications was based upon physician and patient preference. All treatments were performed on an outpatient basis.

5. Effectiveness Results

The effectiveness evaluation of treatment with the T3 System device was primarily based upon symptomatology and PFR. Other effectiveness parameters that were measured were Quality of Life, PVR, and Prostate Volume.

Table 6 presents the effectiveness results among the study subjects between baseline and

3 months. For the 33 patients, the overall AUA Symptom Score decreased from a baseline of 22.4 to 9.0 at 3 months (60% improvement). This difference from baseline was statistically significant ($p<0.001$). Eighty-five (85) percent of the patients had AUA Symptom Score improvements of $\geq$ 30% and 73% had improvements of $\geq$ 8 points. The mean change in the Quality of Life Score was from 4.3 to 2.1; a 51% improvement ($p<0.001$). The PFR increased from 7.3 mL/sec at baseline to 10.7 mL/sec at 3 months (47%, $p<0.001$). Fifty-eight (58%) percent of patients had increases in PFR of $\geq$ 30% at 3 months, and 42% had absolute increases of $\geq$ 3 mL/s. PVR as measured by ultrasound decreased significantly from 117.9 mL at baseline to 70.6 mL at 3 months ($p<0.001$).

Table 6
Effectiveness Results at 3 Months for T3 System U.S. General Study
(mean % change from baseline)

	3 MONTHS n=33
AUA Symptom Score % Patients Improved ≥ 30% % Patients improved ≥ 8 points or more	-60% 85% 73%
Quality of Life Score	-51%
Peak Flow Rate % Patients Improved ≥ 30% % Patients Improved ≥ 3 mL/s	47% 58% 42%
PVR	-40%

6. Safety Results

The evaluation of the safety of the T3 System treatment was primarily based upon the rate of adverse events reported by the patient or found during follow-up. Both the type and severity of complication events were typical of those seen in the other T3 System studies and include urinary discomfort, temporary retention, and urinary tract infection. A list of the complications for the T3 System U.S. General Study are located in Table 7.

Table 7
T3 System U.S. General Study Complications

Complication	n	%
Urinary Retention	7	11.9
Urinary tract infection	2	3.4
Hospitalizations for painful catheterization/retention	1	1.7
Damage identified by cystoscopy/TRUS/RUG	1	1.7

Analysis of measurements of hemoglobin, hematocrit, CBC, platelets, creatinine, and BUN indicated no significant differences between the baseline and any of the follow-up exams.

T3 System vs. TURP Study

1. Introduction

The T3 System vs. TURP Study was a non-randomized study designed to compare the safety and effectiveness of T3 System treatment to that of TURP, which has been the "gold standard" for the treatment of BPH. This study was designed to assess the differences in the outcomes of the these two therapies, primarily focusing on AUA Symptom Score, Quality of Life, Peak Flow rates, and morbidity rates associated with T3 System as compared to surgery. This study was conducted at the Watson Clinic, Lakeland Florida and Virginia Mason Clinic, Seattle, Washington. Treatment selection was based on the decision of the physician and patient. The evaluation of safety and effectiveness in this study is currently limited to a comparison of the short term follow-up results.

2. Study Population

In this study, 32 males with BPH were enrolled as of the date of the data base closure, (22 T3 System patients and 10 TURP patients). Mean patient age was 68.6 years in the T3 System cohort and 71.1 years in the TURP group.

By the date of database closure, 17 patients in the T3 System group and 7 in the TURP group had completed their 3-month follow-up. The remaining patients had not reached the 3-month follow-up evaluation time point. No patients have withdrawn from the study.

3. Baseline Characteristics

The patients had the following baseline characteristics: mean duration of BPH symptoms of 7.9 years in the T3 System group and 5.3 years in the TURP group; mean PFR of 7.9 mL/sec in the T3 System group and 6.6 mL/sec in the TURP group; mean AUA Symptom Score of 22.6 in the T3 System group and 23.0 in the TURP group; and mean Prostate Volume of 41.0 cm^3 in the T3 System group and 53.7 cm^3 in the TURP group. Based on these comparisons, it appears that these two arms were well-matched except for prostate size.

4. Treatment Parameters

Treatment in the T3 System group was performed according to the standard Urologix treatment protocol. The mean maximum catheter and rectal temperatures obtained during the T3 System treatment sessions were 41.9°C and 39.9°C, respectively. The urethral cut-off temperature was not reached by any patient in this study; however the rectal cut-off temperature was reached in

two patients (9%). The average maximum power delivered during these treatments was 40.0 watts, and the mean total energy delivered to the prostate was 146.0 kJ.

All T3 treatments used local Lidocaine gel. In addition, mild analgesics (13%) or sedatives (6%) were used on a physician prerogative basis, none of which required the presence of an anesthesiologist or any anesthesia services. All T3 System patients were treated and released the day of treatment. All TURP surgeries required anesthesia; general anesthesia for two patients and spinal anesthesia for eight patients. All were hospitalized.

5. Effectiveness Results

The effectiveness evaluation was primarily based upon improvements in symptomatology and PFR, and PVR. Based on the small sample sizes, p-values were not calculated.

Table 8 presents the effectiveness results including changes in symptomatology and Quality of Life recorded among the two treatment groups at 3 months. The improvements observed among both groups were essentially identical at this time. The overall AUA Symptom Score decreased 68% in the T3 System cohort, and 69% in the TURP cohort.

The mean changes in each of the Quality of Life score demonstrated that both groups had significant improvements in their Quality of Life with the T3 System group improving by 56% compared to 62% for the TURP group.

In the T3 System group, the PFR increased from 7.9 mL/sec to 10.8 mL/sec (37%). In the TURP group, however, PFR increased from 6.6 mL/sec to 22.5 mL/sec (241%).

Table 8 also summarizes the PVR results measured by ultrasound. The decreases in PVR were 39% for the T3 System group and 50% for the TURP arm.

Table 8
Effectiveness Results at 3 Months Post-Treatment for T3 System and TURP Groups
(mean % change from baseline)

	T3 SYSTEM GROUP n=17	TURP GROUP n=7
AUA Symptom Score	-68%	-69%
% Patients Improved ≥ 30%	94%	89%
% Patients Improved ≥ 8 points	88%	89%
Quality of Life Score	-56%	-62%
Peak Flow Rate	37%	241%
% Patients Improved ≥ 30%	59%	83%
% Patients Improved ≥ 3 mL/s	29%	83%
PVR	-39%	-50%

6. Safety Results

The evaluation of the safety of the T3 System device was primarily based upon a comparison of the rate of adverse events between the T3 System and TURP treatment arms, as reported by patients or found during follow-up examinations.

A summary of adverse events which were determined to be related (or possibly related) to treatment for the T3 System and TURP groups reveal some differences. One patient in each arm had a urinary tract infection, 4.5% for T3 System and 10.0% for TURP. Temporary urinary retention (>1 week) was reported for six T3 System patients (27.3 %) and no TURP patients. Retrograde ejaculation was reported for four TURP patients (40%) and three T3 System Treatment patients (13.6%). Epididymitis was experienced by three T3 System patients (13.6%) and no TURP patients. In addition, one TURP patient required a T-wave inversion at 1 week post surgery due to urinary retention.

This study did not realize its full potential due to a late start (i.e., 9 months after the T3 System vs. Sham study) and difficulty recruiting patients for the TURP arm.

Interstitial Feasibility Study

1. Introduction

The Interstitial Feasibility Study was conducted (1) to determine that the T3 System achieves its goal of elevating intraprostatic temperatures to levels to cause tissue necrosis, (2) to quantitatively evaluate the temperature distribution in the region of the microwave antenna and the prostatic tissue, and (3) to examine the relationship between intraprostatic temperatures and

therapeutic outcome. This study was conducted at the Mayo Clinic, Scottsdale, AZ.

The 15 patients treated in this study underwent transperineal, needle thermometry with a minimum of 4 probes containing a minimum of 13 temperature sensors. In total, there were 317 sensor probe locations for an average of 21 sensors per patient.

2. Study Population

In this study, 18 males with BPH were enrolled, of which 15 were treated. Three patients withdrew from the study prior to being treated; two due to their own prerogative and one who was found not to meet the inclusion criteria. These 15 patients had a mean age of 68.9 years.

By the date of database closure, all patients in this study had reached the 1-year follow-up time point or were no longer participating in the study. Eleven of the fifteen patients were included in the 1-year follow-up analysis. Of the four patients who did not receive the 1-year follow-up, one withdrew due to lack of improvement, one underwent a TURP due to less than satisfactory results, one withdrew because he could not undergo the invasive follow-up and one patient died of an unrelated event following the 9-month evaluation date.

3. Baseline Characteristics

The 15 treated patients had the following baseline characteristics: mean duration of BPH symptoms of 3.7 years; mean PFR of 8.9 mL/sec; and mean AUA Symptom Score of 20.9. These patients were comparable to those treated in the T3 System vs. Sham study.

4. Treatment Parameters

Treatment in the initial five patients was performed with urethral temperatures similar to the final protocol (40 ±1°C). The next six patients received treatment with lower catheter temperatures in the 30-36°C range. The final four patients received treatment identical to the 40 ±1°C treatment protocol of the patients in the other studies reported here. During the treatment of these 15 patients, device malfunctions caused brief treatment delays in 7 treatments. In all cases the treatment resumed and the treatments were completed at the initial session.

The mean maximum urethral and rectal temperatures obtained during the 15 initial T3 System treatment sessions were 41.7°C and 38.4°C, respectively. The average maximum power delivered during these treatments was 38.7 watts, and the mean total energy delivered to the prostate was 121.5 kJ.

Due to the nature of the perineal insertion of the interstitial probes, these patients were treated with the use of general anesthesia. All treatments were performed on an outpatient basis

5. Effectiveness Results

The effectiveness evaluation in the Interstitial Thermometry Study was based primarily upon symptomatology and PFR at 12 months post-treatment, as compared to baseline values. The effectiveness data for this group are not comparable to the other studies due to the potential effects of the trauma from the interstitial temperature mapping procedure.

The following presents the changes in symptomatology (i.e., AUA Symptom Score), PFR and Quality of Life recorded among the study subjects between baseline and 12 months: the overall AUA Symptom Score decreased from 20.9 to 11.5 (45% improvement); PFR increased from 8.9 mL/sec to 10.8 mL/sec (21%); and the patients' Quality of Life Scores improved from 4.5 to 2.5 (44%).

6. Safety Results

Overall blood loss (mean of 12 cc) was higher in this study compared to the other T3 System studies, due primarily to the trauma of interstitial temperature probe insertion into the prostate. In addition, the rate of retention (33%) was also higher than previously reported, again believed to be related to the additional trauma and inflammation caused by the temperature probes. No other significant adverse events were reported.

7. Interstitial Temperature Measurements

The protocol for this study instructed the physicians to place a minimum of four temperature sensor probes in each patient. The required locations in the prostate were 1 cm lateral to the urethra, 1 cm posterior to the urethra, one near the anterior lateral capsule and one in the rectal serosa tissue. The objective of these thermometry studies was to determine the temperatures reached and maintained in these various regions and their relationship to patient outcome. A total of 317 interstitial temperature measurement locations were monitored with temperatures recorded every 5 seconds during the treatments.

The location of each thermosensor within the prostate was mapped using ultrasound. A three dimensional grid was developed to analyze the temperature data. The data indicated that all patients received therapy which resulted in prostatic tissue temperature exceeding 48°C. All patients who received a treatment within the final protocol parameters of catheter temperatures of 37°C to 41°C reached intraprostatic temperatures of at least 53°C. Statistical analysis (ANOVA) indicated that the temperatures reached were not related to prostate size.

An analysis of these data did not reveal an associated between therapeutic outcome and the prostatic temperatures. The temperatures reached in all the patients exceeded the minimum levels required to necrose tissue and a relationship to outcomes could not be identified. Further analysis demonstrated that maximum temperatures were aligned with the center of the antenna

and occurred at a distance of 6-8 mm deep in the prostate (from the urethra surface). The temperature increased with distance from the catheter-urethra interface (due to the cooling of the catheter wall) out to the 6-8 mm point and then fell off as the distance increased from 6-8 mm to the capsule. In addition, the heat was confined to the prostate at both the distal and proximal portions of the prostate which resulted from the combined effect of a coiled antenna design, impedance matching, the coolant temperature (8°C), and the ability to continually deliver heat due to the preferential heating pattern.

Data to support the above conclusions regarding the effect of the T3 System heating were obtained from eight patients studied in Argentina who had previously been scheduled for open surgery for their prostatic condition. Specifically, the temperature analysis was compared to the histological findings that were obtained. This comparison demonstraed that the mean radius of tissue necrosis was approximately 1.6 cm. An analysis of the data also revealed that no tissue outside of the prostate was elevated to temperatures which would cause damage.

T3 SYSTEM INTERNATIONAL STUDY (supplemental data)

An International Study was performed at three study centers: the University of Manitoba, Winnipeg, Canada; the East Surrey Hospital, Surrey, England; and the Royal Liverpool Hospital, Liverpool, England. This was not part of the IDE study used to support the PMA; however, the identical T3 System and similar protocol was used to treat 119 patients at these sites. The study population, baseline characteristics, and treatment parameters were also similar to those in the clinical studies conducted under the IDE. The patients at these sites were followed for up to 2 years post-treatment.

Similar effectiveness results were reported in this study, as shown in Table 9. Also, the complications observed in this study were similar to those previously reported.

Table 9
Effectiveness Results for T3 System International Study
(mean % change from baseline)

	6 MONTHS n=100	1 YEAR n=81	2 YEARS n=41
AUA Symptom Score			
Overall Score	-61%	-57%	-61%
% Patients Improved ≥ 30%	85%	79%	88%
% Patients Improved ≥ 8 points	71%	68%	78%
Quality of Life Score	-60%	-63%	-65%
Peak Flow Rate	62%	53%	40%
% Patients Improved ≥ 30%	67%	66%	67%
% Patients Improved ≥ 3 mL/s	65%	57%	52%
PVR	-20%	0%	0%

PRESSURE FLOW RESULTS

Urodynamic pressure flow results were obtained on 54 patients at 7 different study sites (2 U.S., 5 foreign). The patients were selected from the study population of active T3 System Treatment patients on the basis of their willingness to agree to the pressure flow evaluations both pre- and post-treatment and the study sites' willingness and ability to perform pressure flow analysis. The data were from follow-up exams ranging from 3 to 12 months, with a mean of 6 months. The study was well-controlled (with an established baseline of P(ves), P(abdominal), and Q(max)); the protocol required the follow-up and pre-treatment evaluation be conducted in the same manner and all data were reviewed manually. The results indicated that the mean detrusor pressure drops from 68.1 to 52.8 cm H_2O, a 22% decrease. This decrease is statistically significant ($p<0.001$) The overall change in the Abrams-Griffith Number is from 51.8 (obstructed) to 27.8 (equivocal), a 47% improvement ($p<0.001$).

MRI STUDY RESULTS

A study on nine patients using MRI imaging was performed at the Mayo Clinic, Scottsdale. All patients had pretreatment MRI scans of the prostate. Afterwards, six patients received T3 System Treatment and three patients received Sham Treatment. Within 1 week following the assigned treatment, all patients underwent an additional MRI evaluation.

All six T3 System Treatment patients demonstrated prostatic tissue necrosis based on the post-treatment MRI images. This necrosis was contained inside the capsule of the prostate and the area around the urethra was shown to be preserved. The Sham Treatment patients did not

have necrosis at follow-up.

DEVICE FAILURES

Throughout the U.S. clinical investigations of the T3 System, there were a total of 53 device failures in 248 treatments; 37 occurred prior to treatment or during the calibration of the system prior to the initiation of microwave power, and 16 occurred during treatment (after the initiation of power) where a device malfunction interrupted power and a component was replaced. There was only one occurrence where the device malfunction delayed the treatment requiring a rescheduling. None of the device malfunctions resulted in an injury or a safety concern for the patient or operators. All of these device malfunctions have been addressed through quality system and design improvements. The following summarize the specific device-related problems noted during the study:

1) Microwave Delivery System (catheter) - The MDS failed 22 times. These failures occurred 15 times prior to initiation of power. These failures were due to failure to calibrate (11 times), blockage of the coolant channel (2 times), water leak at balloon inflation hub (1 time), and rough catheter surface (1 time). In 7 of the 22 failures, the MDS failed after the initiation of power, due to reflected power exceeding this value. The device failures were corrected at the time by using a new MDS catheter.

2) Rectal Thermosensing Unit (RTU) - The RTU device failed and needed replacement a total of 17 times. Fourteen of these replacements occurred during calibration and three occurred during treatment. Eleven of the 17 were due to very fine wires in the connector being broken and 4 were due to connector corrosion. The other two were not returned for analysis. The design of the RTU system is such that any interruption of the signal causes the device to fail in a safe mode, discontinuing microwave power delivery until the signal is restored.

3) Coolant Bag - The Coolant Bag was replaced in 13 instances (6 were related to the coolant pressure being outside the specified range, 4 were due to water leakage from the bag, and 3 were due to kinked or twisted tubing). Each was corrected at the time by replacing the coolant bag.

4) Control Unit - One instance occurred where a component in the microwave generator failed to allow the system to calibrate and the component had to be replaced. This was the one instance where the patient treatment was delayed and rescheduled.

X. CONCLUSIONS DRAWN FROM THE STUDIES

The laboratory, animal, and clinical data provide reasonable assurance of the safety and effectiveness of the T3 System for the treatment of BPH, when used as indicated.

XI. PANEL RECOMMENDATION

Pursuant to section 515(c)(2) of the Food, Drug, and Cosmetic Act (the act) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology and Urology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. FDA DECISIONS

An FDA inspection of the Urologix, manufacturing facility was completed on July 1, 1997, and determined that the manufacturer was in compliance with the device Good Manufacturing Practices Regulation.

Based on a review of the data contained in the PMA, CDRH determined that the T3 System is safe and effective for the indication of relief of symptoms associated with BPH in men with prostatic lengths of 30 mm to 50 mm. Furthermore, the applicant agreed to the postapproval requirement that they design a study to collect data on the long-term (5 year) effect of their device.

CDRH issued an approval order for the stated indication for the applicant's PMA for the T3 System on AUG 22 1997.