

## T3® Targeted Transurethral Thermo-ablation System: MODEL 4000

### **Instructions For Use**

#### T3 System Control Unit

#### T3 System Procedure Kit Components:

- T3 System Microwave Delivery System (MDS)
- T3 System Rectal Thermosensing Unit (RTU)
- T3 System Coolant Bag

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program.

**CAREFULLY READ AND UNDERSTAND ALL INSTRUCTIONS, INDICATIONS, WARNINGS, PRECAUTIONS, AND DIRECTIONS FOR USE PRIOR TO USING ANY PROCEDURE KIT COMPONENT OR THE CONTROL UNIT. FAILURE TO DO SO COULD RESULT IN COMPROMISED PATIENT SAFETY, PATIENT COMPLICATIONS AND/OR INSUFFICIENT THERAPY.**

#### 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 urethra lengths of 30 to 50 mm.

#### T3 SYSTEM DESCRIPTION

The T3 System is comprised of a Control Unit which produces the microwave energy and monitors all aspects of the T3 System procedure, an MDS (treatment catheter) which delivers the microwave energy to the targeted prostatic tissue, an RTU which measures rectal temperatures during the T3 System procedure and a Coolant Bag which provides a reservoir of sterile coolant water to the MDS.

#### CONTRAINDICATIONS FOR T3 SYSTEM THERAPY

- Patients with a prostatic urethra < 3 cm 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 22 F urethroscope)
- Patients with peripheral arterial disease with intermittent claudication or Leriche's syndrome (i.e. claudication of the buttocks or 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 and components 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 procedure 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 this 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 affected 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 electrical 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.

The electrical equipment inside the T3 System uses voltages which are capable of causing serious injury or death from electric shock. To avoid this hazard, operators must never remove the cabinet covers.

#### 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 the T3 System procedure has not been established in patients with the following conditions:

- Interest in the preservation of future fertility
- Post Void Residual (PVR) >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:

Neurologic bladder disorders  
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 5 days (median 3 days) following the procedure.

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

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

## ADVERSE EVENTS AND COMPLICATIONS

Most complications occurred shortly after treatment and were transient.

In the United States, multi-center prospective studies of the T3 System procedure, 206 patients were treated and followed for complications, complaints and observations. The following table shows the clinical adverse events and complications that were possibly, probably and definitely related to the T3 System treatment procedure. An asterisk (\*) denotes events which were temporary or minor, requiring minimal or no medical intervention.

Post-treatment catheterization (2-5 days)	98.0%*
Dysuria	38.8%*
Pain or discomfort during sexual activity	13.6%*
Urgency	13.1%*
Frequency	12.1%*
Short term urinary retention (> 7 days following treatment)	11.7%
Irritative symptoms due to catheterization	8.7%*
Nocturia	6.8%*
Hematuria	5.9%*
Urinary tract infection	5.3%
Loss of ejaculate	3.9%
Obstructive urinary symptoms	3.9%*
Prostatic urethra damage	3.4%*
Pain or irritation in groin or penis	3.4%*
Sensation of not emptying bladder	3.4%*
Epididymitis	2.9%
Temporary Acute Incontinence	2.4%*
Flu like symptoms	2.4%*
Symptoms of UTI, non-specific	2.4%*
Rectal irritation	2.4%*
Hemospermia	2.4%*
Severe pain during treatment	1.9%
Hospitalization related in general to the treatment	1.9%
Urethritis	1.5%*
Urethral strictures not requiring treatment	1.0%*
Flank pain	1.0%*
Blood pressure changes during treatment	1.0%*
Urethral stricture (requiring treatment)	0.5%

Study Investigators were required to notify Urologix Inc. of any complications which may have developed as a direct result of the T3 System procedure.

## CLINICAL SUMMARY

Follow-up on patients treated with the T3 System demonstrated that this device is associated with significant improvements in BPH symptoms and urine flow rates. The multiple U.S. Clinical studies, which include 152 patients at 6 month follow up, show that 79% of the T3 System treated patients experienced symptom improvement greater than 25% and that 59% experienced improvement greater than 50%. The mean improvement in AUA Symptom Score was 51%. With regard to uroflowmetry, 66% of the patients demonstrated improvements in Peak Flow Rate of greater than 25%. The mean change in Peak Flow Rate was 4.1 mL/s, a 53% increase over baseline.

In a randomized and blinded study, patients who received an active treatment exhibited significantly greater improvements in symptom score than sham treated patients ( $p=0.011$ ). Patients who received an active treatment also exhibited significantly greater improvements in peak flow than sham treated patients ( $p=0.002$ ).

One hundred and seven patients have matched data on AUA symptom score from baseline to one year follow-up. The mean symptom improvement in this patient group was 10.2 points (51%). Eighty-nine patients have matched data on peak flow from baseline to one year follow-up. Mean peak flow improvement in this patient group was 3.8 mL/s (49%). Significant improvements were seen in additional measured parameters of Quality of Life, Symptom Problem Index (SPI) and the BPH Impact Index (BII). All improvements remained stable through one-year follow-up. These improvements are consistent with additional data collected from international studies on over 111 patients at one year follow-up.

From the clinical investigations of the T3 System, it was not possible to identify any baseline characteristics that are associated with a favorable response to treatment.

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### INFORMATION FOR PATIENTS

Physicians should inform patients that an inherent risk of complications is associated with the T3 System procedure (refer to Adverse Events and Complications). Physicians should inform patients that loss of ejaculation may occur as a result of the T3 System procedure and thus should be considered by men who may wish to have further offspring. Physicians should inform patients that the volume of ejaculate may be decreased in some men who undergo the T3 System procedure. Temporary acute urinary retention, temporary incontinence, minimal bleeding, pain on urination and intercourse and urinary tract infection may be associated with the T3 System procedure. The patient should be informed that a small risk of urethral stricture may result from the T3 System procedure requiring further intervention (refer to Adverse Events and Complications). Patients may likely be catheterized for a 2 to 5 day (median 3 day) period following the T3 System procedure. Patient should be informed that they may experience discomfort during the procedure that may require the use of analgesics or sedatives to deliver an effective therapy.

### PRODUCT DESCRIPTION

The T3 System utilizes proprietary microwave technology to deliver thermal energy into the anterior and lateral portions of the prostate preferentially and within the axis of the MDS antenna. This allows the T3 System to deliver energy continuously, with minimal concern of treatment limiting shutdowns from rectal and urethral alarms. Thus, the T3 System can selectively generate and maintain peak intraprostatic tissue temperature levels of  $\geq 65^{\circ}\text{C}$  and mean intraprostatic tissue temperature levels of  $\geq 50^{\circ}\text{C}$  with minimal risk of damage to adjacent structures. This allows the T3 System to overcome the heat sink effect of the prostatic blood flow resulting in necrosis of a large volume of diseased hyperplastic tissues.<sup>3</sup>

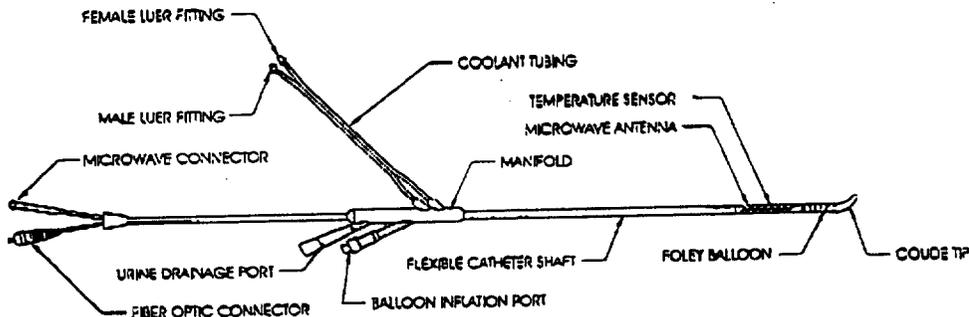
The Procedure Kit is composed of the following individual components:

- Microwave Delivery System (MDS)
- Rectal Thermosensing Unit (RTU)
- Coolant Bag

Each component is a single use disposable designed to be used as a system with the Control Unit intended for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) and its associated voiding difficulties. All components must be in place with the Control Unit to begin a T3 System procedure. The Urologix T3 System is a non-surgical device intended to relieve symptoms associated with BPH and is indicated for men with prostatic urethra lengths of 30 to 50 mm. For complete and detailed instructions, refer to the T3 System User Manual.

### MDS

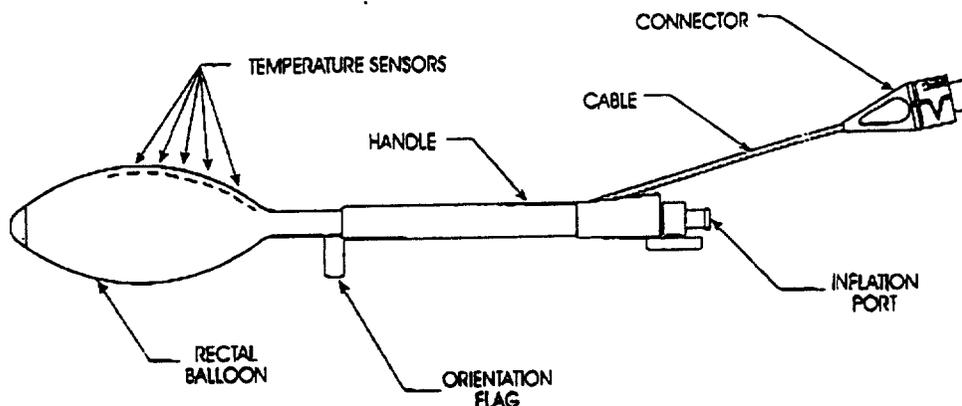
The MDS is a catheter-based system that includes a fiber optic temperature sensor, microwave antenna and cable, coolant channels and connectors, urine drainage channel and a distal balloon for placement. The MDS is designed to deliver microwave energy to the target prostatic tissue, while at the same time cooling and protecting the urethra. The fiber optic sensor in the MDS measures the temperature of the urethra and is used to determine the amount of energy delivered during a procedure. In the event that urethral temperature rises above  $44.5^{\circ}\text{C}$ , the Control Unit will discontinue microwave energy delivery to the MDS. For the T3 System procedure, the MDS is placed in the patient's urethra with the tip and balloon in the bladder and it is anchored into place with the 10 cc balloon. The MDS is oriented with the coolant tubing in the anterior direction. Microwave energy is transmitted from the Control Unit to the MDS antenna and directed into the prostate. The microwave energy generates heat in the prostate that causes tissue necrosis, which, when resolved can improve the patient's symptoms, flow rate and quality of life associated with BPH.



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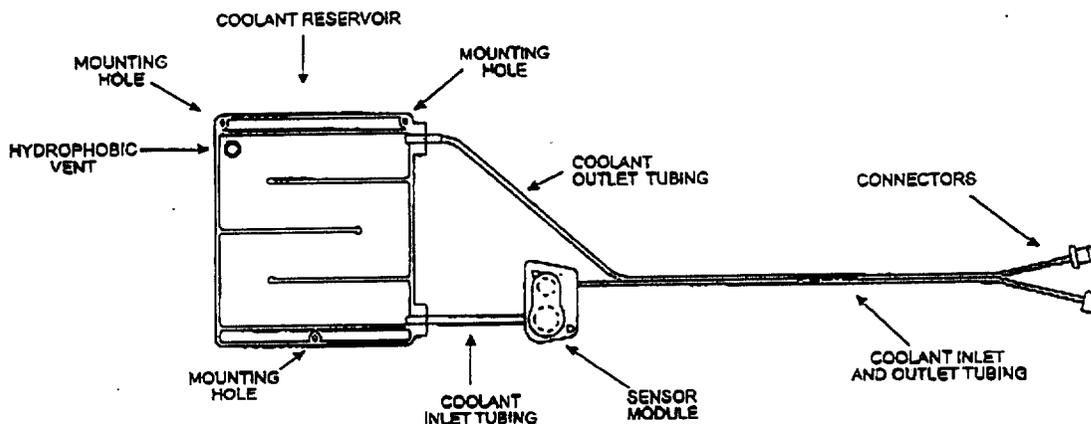
### RTU

The RTU is a catheter-based system that incorporates a compliant balloon and five temperature sensors used to monitor the patient's rectal temperature during a T3 System procedure. The RTU is placed in the patient's rectum prior to a T3 System procedure and left in place for the duration of the procedure. In the event that rectal temperatures are raised above 42.5°C, the RTU will signal the Control Unit to discontinue microwave energy delivery to the MDS.



### Coolant Bag

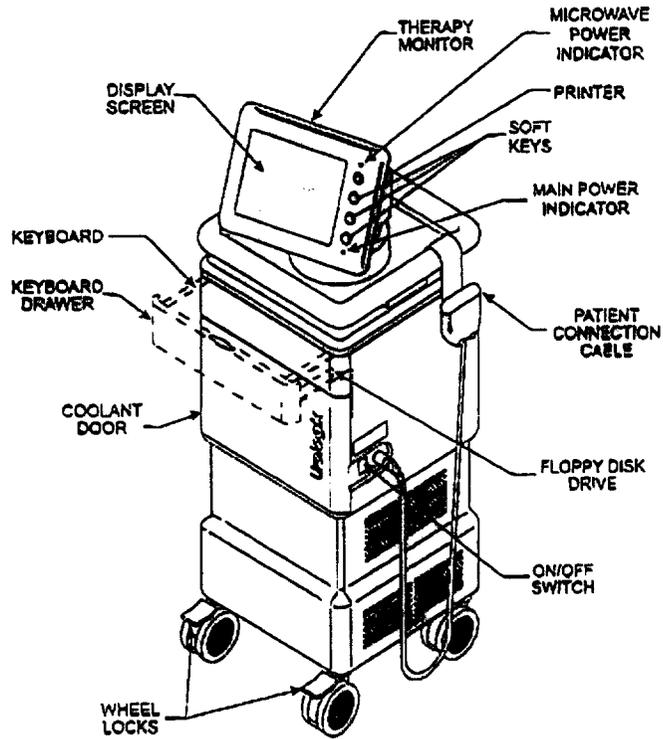
The Coolant Bag is used as a reservoir for sterile water, which, during therapy is chilled and circulated through the MDS by the Control Unit to protect the urethra from heat generated by the MDS. The Coolant Bag is comprised of three (3) main subassemblies; coolant reservoir, sensor module and tubing with connectors. The coolant reservoir is a polymer bag that is filled with sterile water. The coolant reservoir mates with the chill plates of the Control Unit to remove heat generated by the MDS during the T3 System procedure. The sensor module pressure and temperature windows mate with corresponding measurement devices on the Control Unit. The sensor module works in communication with the Control Unit to allow pressure and temperature to be monitored during the T3 System procedure. The Control Unit uses this information to monitor these parameters during the entire T3 System procedure. The inlet and outlet tubing connectors mate with the connectors of the MDS to establish a closed loop coolant system involving the Coolant Bag and the MDS.



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### Control Unit

The Control Unit is used to provide and control energy generation and safety for the T3 System procedure. The Control Unit includes a computer, microwave energy source, coolant system, fiber optic temperature monitoring system and software. These systems are integrated to precisely and continuously monitor all aspects of a T3 System procedure including energy generation and delivery, coolant temperature, and the user interface to provide safety shutdowns when procedural and patient safety issues are detected. The Control Unit also maintains a procedural file on the parameters of treatment for an individual patient and procedure.



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**SUMMARY INSTRUCTIONS FOR A T3 SYSTEM PROCEDURE**

**BEFORE PERFORMING A T3 SYSTEM PROCEDURE, REFER TO THE T3 SYSTEM USER MANUAL FOR SPECIFIC AND COMPLETE INSTRUCTIONS FOR USE FOR THE PROCEDURE KIT COMPONENTS AND CONTROL UNIT.**

**To perform a T3 System procedure the following equipment is required:**

Control Unit	50 cc lubricating gel	200 cc sterile water
Procedure Kit	50 cc Lidocaine Jelly	Leg band or tape
1-Foley catheter	1-60 cc luer tip syringe	Transrectal Ultrasound system
1-straight catheter	1-60 cc catheter tip syringe	Urine drainage bag kit (for outpatient use)
Urine drainage bag	1-10 cc luer syringe	Catheter plug
2 pair sterile gloves		

**PREPARE CONTROL UNIT**

<u>STEP</u>	<u>TROUBLESHOOTING</u>
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At least 20 cm of ventilation clearance must be provided around the base of the Control Unit.

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.

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| <ol style="list-style-type: none"> <li>1. Plug unit in and turn power switch on "I". The unit should be turned on for at least 5 minutes prior to the therapy session.</li> <li>2. Press "MW Off" Soft key</li> <li>3. Verify that screen lights.</li> <li>4. Press "NEXT", access keyboard and enter patient data. Press "Tab" to move between fields. Replace keyboard.</li> <li>5. Press "NEXT".</li> </ol> | <ol style="list-style-type: none"> <li>2. If the system does not come on, turn unit off "O" then on "I"</li> <li>3. Must enter: Patient name, patient ID #, MDS serial #, e.g. AB000123, and RTU Lot # before pressing "NEXT".</li> </ol> |
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**PREPARE COOLANT BAG**

<u>STEP</u>	<u>TROUBLESHOOTING</u>
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Use all components of a Procedure Kit prior to the "use before" date specified on the package.

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|---|--|
| <ol style="list-style-type: none"> <li>1. Open package and inspect Coolant Bag.</li> <li>2. Add 100 ± 5 cc sterile water to the Coolant Bag.</li> </ol> | <ol style="list-style-type: none"> <li>1. Replace if Coolant Bag tray is open or damaged.</li> </ol> |
|---|--|
- Use ONLY sterile water when filling the Coolant Bag.  
DO NOT use saline or non-sterile water.
- |  |  |
|--|--|
| <ol style="list-style-type: none"> <li>3. Open door and place Coolant Bag on pins of chill plate.</li> <li>4. Route inlet tubing through pump mechanism.</li> <li>5. Place sensor module on mounting pins. Close pump tubing clamp, run tubing out the side of the Control Unit and close coolant door.</li> </ol> | <ol style="list-style-type: none"> <li>5. Ensure that tubing is free of door.</li> </ol> |
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**PREPARE MDS**

<u>STEP</u>	<u>TROUBLESHOOTING</u>
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|---|--|
| <ol style="list-style-type: none"> <li>1. Insert 10 cc of lidocaine 2% Jelly into the urethra.</li> <li>2. Insert straight catheter to drain urine, replace with 50 cc sterile water.</li> <li>3. Remove straight catheter.</li> <li>4. Open and inspect MDS.</li> <li>5. Lubricate MDS.</li> <li>6. Attach catheter plug to urine drainage port.</li> <li>7. Insert MDS until the tip and balloon are well into the bladder. Align coolant connector tubing towards patient's anterior.</li> <li>8. Inflate balloon with 10 cc sterile water and pull MDS back to position balloon at the bladder neck.</li> </ol> | <ol style="list-style-type: none"> <li>4. Replace if MDS tray is open or damaged.</li> <li>8. Do not over inflate balloon. If the MDS position is not acceptable, the MDS may be rotated or reinserted.</li> </ol> |
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9. Roll patient onto side. Verify balloon position with transrectal ultrasound. Remove ultrasound.

Care should be taken in the placement and orientation of the MDS. Improper placement or orientation of the MDS may lead to procedural failure or heating and damage of non-target tissues such as the bladder neck, external sphincter or penile urethra. Placement should be confirmed with transrectal ultrasound.

## PREPARE RTU

### TROUBLESHOOTING

#### STEP

1. Open, inspect and deflate RTU.
2. Lubricate RTU and insert into rectum with orientation flag pointed towards patient's posterior.
3. Inflate with 120 cc air, adjust air volume to achieve comfort.
4. Re-position patient. Secure MDS in place.

1. Replace if RTU tray is open or damaged.
3. Retain  $\geq 60$  cc air in RTU.

## CONNECT MDS AND RTU TO CONTROL UNIT

### TROUBLESHOOTING

#### STEP

1. Connect the MDS fiber optic and microwave cable, and RTU connector to patient connection cable. Connect coolant tubing to MDS.
2. Remove catheter plug and fill urine drainage lumen with 4 cc of sterile water. Attach urine drainage bag.
3. Position patient on back with head and shoulders elevated  $<20^\circ$

1. Line fiberoptic connector up with slot in port on patient connection cable.
3. Relieves pressure on RTU and increases patient comfort.

## THERAPY

### TROUBLESHOOTING

#### STEP

1. Equilibrate MDS and RTU to body temp for 1 min.
2. View Therapy Checklist screen to ensure that all steps have been taken.
3. Press "NEXT" to begin calibration.

3. If system will not calibrate, respond to error message and repeat the calibration step by pressing "REPEAT". If a component needs to be replaced, press "REPLACE" to enter new serial #. Resume calibration by pressing "NEXT."

4. When coolant is  $\leq 10^\circ\text{C}$ , press "NEXT" to view power adjustment keys, press "up" to apply 10 W of power.
5. At 2 minute intervals increase power by 5 W.
6. Repeat step 5 until: MDS Temp is  $\geq 35^\circ\text{C}$  or Rectal Temp is  $40^\circ\text{C}$  or Power is 35 W.
7. At 1 minute intervals increase power by 1 W.
8. Therapy begins when MDS sensor is  $\geq 37^\circ\text{C}$  Optimum target MDS temperature is  $40^\circ\text{C} \pm 1^\circ\text{C}$ . Maintain this temperature throughout therapy.

8. Should rectal temperature exceed  $42^\circ\text{C}$  decrease power by 1 watt increments per minute until rectal temp is  $\leq 42^\circ\text{C}$ . If rectal temperature does not respond as quickly as needed to 1 watt decreases, decrease power by 3 watt increments as needed. When rectal temperature begins to decrease, try to increase power to maintain MDS at  $40.0^\circ\text{C} \pm 1^\circ\text{C}$ .

9. Maintain power levels for 60 minutes which meet the above criteria by adjusting the power  $\pm 1$  W per minute.
10. After 60 minutes of therapy, reduce power to 0 W by pressing "NEXT", "NEXT", "MW END."
11. Run  $3^\circ\text{C}$  coolant for  $\geq 10$  minutes.

9. If a system shutdown occurs respond to the error message. Make note of any error message numbers for later reference

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### TERMINATION OF THERAPY

STEP

TROUBLESHOOTING

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1. Press "QUIT".
  2. Press "YES".
  3. Deflate MDS balloon, withdraw and disconnect.
  4. Remove air from RTU, withdraw and disconnect.
  5. Disconnect Coolant Bag and drain.
  6. Press "NEXT".
  7. If desired, copy data file onto pre-formatted disk.
  8. Press "Tab" to reach "Copy File to Diskette." Press enter.
  9. Press "NEXT"
  10. Turn off the T3 Control Unit and unplug.
8. Press "Tab" to reach "Print a File." Press "Enter" to obtain Therapy Summary Information.

### FOLLOWING THERAPY

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1. Urologix recommends that the physician prescribe the use of an antibiotic for 3 to 5 days following the T3 System procedure to minimize the possibility of a urinary tract infection to the patient.
2. Because the T3 System procedure elevates intraprostatic tissue temperature causing tissue damage that may result in acute urinary retention, it may be advisable for the patient to be catheterized for 2 to 5 days following the procedure.

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## REFERENCES

1. Paul D. Miller, Keith Parsons, Ernest Ramsey, Transurethral Microwave Thermoablation (TUMT) for Benign Prostatic Hyperplasia Using a New Device (T3), Presented at the 90th Annual Meeting of the AUA, Las Vegas, NV April, 1995.
2. Ramsey E.W., Miller P.D., Parsons K., A Novel Transurethral Microwave Thermoablation System To Treat Benign Prostatic Hyperplasia: Results of a Prospective Multicenter Clinical Trial. J. Urol. 1997; V. 158: 112-119.
3. Larson T.R., Bostwick D.G., Corica A., Temperature Correlated Histopathologic Changes Following Microwave Thermoablation of Obstructive Tissue in Patients with Benign Prostatic Hyperplasia. Urology. 1996; 47 (4): 463-469.

For complete references, refer to the T3 SYSTEM USER MANUAL.

## HOW SUPPLIED

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 and treating staff. The Procedure Kit components are supplied in sterile double barrier packaging that has been exposed to ethylene oxide. The Procedure Kit and components are placed in shelf boxes with tamper proof labels. DO NOT USE COMPONENTS THAT HAVE EVIDENCE OF A COMPROMISED PACKAGE OR DAMAGE. Store in a cool, dry place.

## RESTRICTED DEVICES

The Procedure Kit, its components and the Control Unit are intended for urological use only in the treatment of patients suffering voiding difficulties secondary to BPH. Candidates for T3 System procedure require careful consideration.

The Procedure Kit components must not be used with any other system.

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.

## WARRANTY AND LIMITATIONS

Urologix, Inc. warrants that each component of this device has been manufactured, packaged and tested with reasonable care and will be free from defects in workmanship and material. Urologix will not be liable for any incidental, special, or consequential loss, damage or expense direct or indirect, from the use of its product. Urologix' sole obligation shall be to repair, replace, at its option, any device that we feel was defective at time of shipment if notice thereof is received within one year of shipment. Buyer assumes all liability, whether arising on warranty, contract, negligence, compliance with all local laws and regulations which govern the use and sale of this device, or otherwise for damages resulting from the handling, possession, use, or misuse of the product. Because Urologix has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over the selection of patients, **THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESSED OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.** If the user is located outside the United States, Urologix invokes all oral or written expressed or implied warranty, limitations legally permissible in that jurisdiction. The remedies set forth in the above Warranty and Limitations shall be the exclusive remedy available to any person. No agent, employee or representative of Urologix has any authority to change any of the foregoing or assume or bind Urologix to any additional liability or responsibility in connection with this device.

T3® System Model 4000 IFU 250021

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U.S. Patents: 5,234,004; 5,300,099; 5,370,677; 5,413,588; 5,464,445; 5,480,417; 5,643,335; 5,645,528.

European Patent Spec: 0 370-890 B1; 0 519-958 B1. French Patents: 2,639,238; 2,659,519.

Japanese Patent: 2,127,932

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