

Section X. Device Labeling

Part 1: Essential Prescribing Information (EPI)

February 12, 2004

Prolieve™ System

A Transurethral Microwave Therapy Device

Essential Prescribing Information

Version 1.0

CELSION™

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CAUTION: Federal Law restricts this device to sale and use by or on the order of a physician (or properly licensed practitioner).

The Prolieve™ Thermodilatation System (Prolieve™) Essential Prescribing Information (EPI) is directed to the prescribing physician. For details concerning the operation of the device, please see the User Manual for Prolieve™.

DEVICE DESCRIPTION

Prolieve™ is a transurethral microwave therapy device equipped with automated controls designed to deliver microwave energy to the prostate and balloon-administered compression (thermodilatation) for the treatment of symptomatic benign prostatic hyperplasia (BPH). This device utilizes a transurethral microwave antenna to heat the prostate to a temperature between 41°C and 46°C, with simultaneous 46 Fr. prostatic urethral catheter balloon-administered compression over a treatment length of 1.2 to 5.5cm. Warm water is circulated through the transurethral catheter system and compression balloon to protect the wall of the urethra. The microwave heating process is regulated through temperature feedback from three sensors mounted on the surface of a rectal temperature monitor (temperature monitor). The temperature monitor is placed against the rectal mucosa adjacent to the prostatic capsule. A treatment consists of applying microwave energy at 915 MHz \pm 5 MHz (50 Watts maximum) to the prostate for 45 minutes reaching an intraprostatic temperature of 41°C to 46°C, at a rectal control temperature up to 41°C and a maximum rectal temperature of 42°C.

The device consists of a permanent instrument and a single-use Prolieve™ Procedure Kit (Procedure Kit). The permanent instrument generates the microwave power, provides temperature-controlled water circulation, monitors treatment parameters with built in safety alerts, and records treatment data. A monitor screen with graphic user interface (GUI) provides a visual display. The permanent instrument is configured as a single integrated cart unit, which provides computer control, microwave power and temperature measuring capabilities, constant temperature thermoelectric plates, circulatory fluid pump, and rectal temperature monitor. The thermoelectric plates are coupled to the heat exchanger

cartridge, which is part of the Procedure Kit. In this way, the device can maintain the circulating water at a temperature of $34.5^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ at the point of entry into the transurethral catheter system.

The single-use Procedure Kit contains a single sterile 18 Fr diameter 36 cm long microwave transurethral catheter, a heat exchanger cartridge system, and a 500 mL bag of sterile water. The transurethral catheter includes a 5cc retention balloon as well as a 3.7 cm long compression balloon for dilatation that reaches 46 Fr diameter when inflated. The microwave antenna consists of a coaxial cable; the active portion is positioned towards the distal end of the compression balloon.

INDICATIONS FOR USE

Prolieve™ is a transurethral microwave therapy device that provides a non-surgical, minimally invasive procedure for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in men with a prostate size of 20 to 80 grams, a prostatic urethra length between 1.2 cm and 5.5 cm and in whom drug therapy (e.g., Finasteride (Proscar®)) is typically indicated.

CONTRAINDICATIONS

The contraindications for Prolieve™ are:

- Patients whose pain response has been significantly decreased by any means (previous surgery, regional or local anesthetic, or other relevant condition which is determined by the physician upon evaluation) because the patients' ability to detect pain is a treatment safety mechanism.
- Severe urethral stricture preventing catheterization.
- Current urinary or prostatic infection.
- Presence of a penile or urinary sphincter implant.
- Prostate size <20g or >80g.
- Peripheral arterial disease with intermittent claudication or Leriche's Syndrome (i.e., claudication of the buttocks or perineum).
- Protruding median lobe resulting in a "ball-valve" type of obstruction at the bladder neck.
- Evidence of prostatic cancer or bladder cancer.
- Presence of metallic implants, e.g. pelvic, femur, penile prosthesis, etc.
- Presence of implanted cardiac pacemakers, or defibrillators.
- Previous transurethral prostatectomy.
- Patients interested in the preservation of future fertility.
- Patients with a previous history of pelvic radiation.
- Patients with coagulation disorders.
- Patients with renal impairment.
- Patients with neurological disorders that might affect bladder function.
- Patients with bladder stones and large post voiding residual (greater than 250 mL).

WARNINGS

The following is a list of warnings for the safe and effective use of Prolieve™

Warning – Patient Safety

Warning: The physician must monitor patient condition during the treatment. Patient comments regarding pain or excess heat in regions not associated with the expected treatment location should be fully investigated. Failure to monitor adequately and deliver the procedure per recommendations of the labeling may lead to serious patient injury.

Warning: There are unlikely but serious thermal (heat-related) injuries that may occur which include fistula formation and tissue damage to the penis or urethra requiring urostomies, partial amputation of the penis, and/or other therapeutic interventions, and narrowing of the penile urinary tube at any time after the treatment.

Warning: The physician must ensure the careful and correct placement of the catheter and temperature monitor as shown in the User Manual before heating commences. The recommended procedures for catheter and temperature monitor placement will minimize the probability of excessive temperature in normal tissue and non-therapeutic temperature in the treated area.

Warning: The physician must adhere to the recommended applicator placement and sterile field preparation to reduce the likelihood of surface burns and blistering from the subsequent delivery of therapeutic heat.

Warning: The emission of microwave energy must be off during placement and removal of the catheter to avoid stray microwave radiation directed towards the eyes (or testes) of the patient or the operator.

Warning: A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period, may result in temporary or permanent sterility. Elevated temperatures may be expected to affect the pharmacological activity of some drugs, with unpredictable results. Altered vascular perfusion may dramatically affect the local tissue effects of systemic or infused drugs

PRECAUTIONS

Treatment Related

Caution - The safety and effectiveness of Prolieve™ for men <50 and >80 years old has not been established in clinical studies.

Caution - The use of Prolieve™ must be prescribed and administered under the direct supervision of a qualified and trained physician following appropriate urological evaluation of the patient.

Caution - No anesthetic other than aqueous-based topical intraurethral anesthetic used for catheter placement is recommended.

Caution – The user must comply with strict adherence to aseptic techniques during the placement of applicators to avoid localized infections. If the Procedure Kit seal or internal sterile packaging seals are damaged or broken, the contents may not be sterile and could cause infection. Damaged or broken seal devices should be discarded or returned.

Caution - Treatment with Prolieve™ applies compression and deposits microwave energy, which converts to heat within the patient's prostate and in the immediately adjacent tissue. Some animal studies in the literature suggest there may be 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.

Device Related

Caution – Failure to use all the components of Prolieve™ with temperature sensors in accordance with the User Manual may result in insufficient therapy and/or increased risk of injury or infection to the patient.

Caution - Any nearby equipment operating on a similar frequency to that of Prolieve™ should be operated at a distance of at least 2 meters (6.5 ft.) (including locations behind adjacent walls) to avoid device-to-device interference. Such devices include but are not limited to cell phones and/or other sensitive treatment and monitoring equipment, e.g., drug infusion devices, physiological monitoring devices.

Caution – Prolieve™ is designed to operate in a room with adequate space for the patient, treatment bed, permanent instrument, with adequate lighting, and clinical personnel. The treatment room should also be clean and support the needs of the physician to treat in a sterile field. Failure to provide these may have a deleterious effect on the patient and or treatment result.

Caution - Any modifications made to equipment or software without explicit approval from the manufacturer poses a potential safety threat to the operators and patients. Only qualified, trained personnel should be allowed to operate the equipment. Please consult the User Manual for specific technical warnings and precautions on device operation.

Operator Related

Caution - Equipment covers must never be removed with primary power connected to the equipment due to a risk of electrical shock.

POTENTIAL ADVERSE EVENTS

Microwave heating devices and dilatation have the potential for producing adverse events as a result of the delivery of therapeutic heat, or of the exposure to electromagnetic radiation. Those adverse events

not seen in the clinical trials include: urethral stricture, pelvic abscess, allergic reaction including anaphylaxis, bladder neck contracture, urethral tear, rectal wall injury, infertility, and fistula.

ADVERSE EVENTS

The adverse events that were directly attributed to the procedure were urethral irritation, bladder spasms and complete urinary retention resolving by the 2-week visit.

A summary of the adverse events at treatment and during the follow-up evaluation of 1-year is presented in Table 1. The patients included in the Reported at Treatment column are the 125 randomized to Prolieve™ plus the 20 patients who crossed over from the Proscar® treatment arm. There were five patients in whom the treatment was cancelled and they are not included in the 140 patients followed in the post-treatment period for safety.

Adverse events experienced by the Proscar® patients were not recorded other than those events associated and similar to the Prolieve™ patients and are therefore not reported.

Table 1: Number and Rate of Adverse Events Reported During the Pivotal Investigation

Symptom	Reported at Treatment (N=145)	Reported During Post- Treatment (N=140)*				
		2- Week (N=131)	1-M (N=131)	3-M (N=129)	6- M (N=121)	12+M (N=103)
Anal irritation	1 (0.7%)					
Bladder spasm	17 (12%)	3 (2.3)		1 (0.8 %)	1 (0.8 %)	
Bleeding (mild to excessive)	5 (3.4%)					
Bowel irritation	1 (0.7%)					
Chronic pain at site		2 (1.5 %)	1 (0.8 %)	1 (0.8 %)	1 (0.8 %)	
Complete urinary retention	22 (15.2 %)	6 (4.6 %)				
Incomplete urinary retention		7 (5.3 %)	9 (6.9 %)	5 (3.9 %)	3 (2.5 %)	4 (3.9 %)
Erectile Dysfunction		1 (0.8 %)	2 (1.5 %)	1 (0.8 %)	1 (0.8 %)	1 (0.8 %)
Pressure sensation (minimal)	1 (0.7%)					
Prostatitis		1 (0.8 %)		1 (0.8 %)	1 (0.8 %)	1 (1.0 %)
Retrograde ejaculation					1 (0.8 %)	
Urethral injury (irritation)	2 (1.4%)	2 (1.5 %)				
Urinary clot retention			1 (0.8 %)			
Urinary incontinence		2 (1.5 %)	1 (0.8 %)	1 (0.8 %)	1 (0.8 %)	1 (1.0 %)
Urinary tract infection		1 (0.8 %)			1 (0.8 %)	1 (1.0 %)
Urinary urgency	3 (2.1%)					
Total	52 (35.9 %)	25 (19.1 %)	14 (10.7 %)	10 (7.8 %)	10 (8.3 %)	8 (7.8 %)

*Does not include the 5 patients in whom treatment was cancelled.

Catheterizations associated with treatment: Sixteen percent (22/140) of the patients was catheterized post treatment. Sixty-four percent (14/22) of these catheterizations were for three days or less. All but one patient were catheterized for less than one week. There were 3 patients

who were catheterized for reasons other than urinary retention. One patient experienced bladder spasms requiring catheterization and a second patient had the catheter replaced during treatment due to a leak. The third patient had a false passage, Prolieve™ treatment was not initiated and the patient was catheterized for 3 days.

SUMMARY OF CLINICAL STUDY

Study Design

This multi-center, randomized, open-label trial compared a single outpatient treatment of symptomatic BPH with Prolieve™ lasting 45 minutes to that of a daily regimen of 5mg Proscar® (Finasteride). 166 patients were randomized at 14 centers in a 3:1 ratio of Prolieve™ to Proscar®. At the completion of the 6-month evaluation, patients randomized to Proscar® who had failed treatment and met the inclusion criteria, were permitted to crossover to receive treatment with Prolieve™.

The treatment consisted of applying microwave energy at $915 \text{ MHz} \pm 5 \text{ MHz}$ (50Watts maximum) to the prostate for 45 minutes at a rectal control temperature up to 41°C and a maximum rectal temperature of 42°C ; the automatic treatment abort temperature of the device. Effectiveness and safety were assessed during treatment and at post-treatment follow-up visits at 2 weeks, 1, 2, 3, 6, and 12 months.

Patient Assessment

Effectiveness: The primary objective of the study was to assess whether treatment with Prolieve™ would demonstrate clinical equivalency to treatment with Proscar®. Clinical equivalency was defined as having no less than 80% of the effectiveness of Proscar®. The primary endpoint of the study was the change in AUA Symptom Index score from baseline to 6 months. The response to treatment in the Prolieve™ treatment was evaluated out to 12 months post-treatment or longer for durability. The secondary effectiveness outcome measures included peak flow rate (PFR), post void residual (PVR) as well as evaluation of the following:

- The International Index of Erectile Function (IIEF-5): This section consists of questions asking the patient about their erectile function.
- Quality of Life (QOL): Six questions focused on the patient's feelings about his urinary condition, perception of urinary difficulties, sexual functions, activities of daily living, general well-being and social activities.
- Impact of Lower Urinary Tract Symptoms (LUTS) on Quality of Life: Six questions related to the patient's urinary problems and if these problems interfered with the patient's life.
- BPH Impact Index (BII): Four questions related to the patient's concern over his urinary problems and the amount of physical discomfort experienced.
- BPH Specific Interference with Activities (BSI): Seven questions related to the degree to which the patient's urinary problems interfered with some common activities.
- Sexual Function: Six questions pertaining to the patient's sexual function.
- Pain or discomfort: Four questions related to the presence, location, frequency and severity of pain or discomfort in the urethra.

Safety: The objective was to substantiate the safety profile of Prolieve™. Safety was assessed by the frequency of local and systemic side effects during treatment, and the occurrence of anticipated and unanticipated adverse effects during follow-up.

Accountability

A total of 190 patients were randomized in the study, 142 to Prolieve™ and 48 to Proscar®. Before the initiation of treatment, 24 patients chose to withdraw from the study prior to any attempt at treatment (17 Prolieve™ / 7 Proscar®). Therefore, while still maintaining the 3:1 ratio, a total of 125 patients in the Prolieve™ arm and 41 patients in the Proscar® arm were included in the statistical analysis and comprise the intent-to-treat population (Table 2). At the time the database was closed for analysis 92/125 (74%) of the patients in the treatment arm completed their 12-month follow-up. There were 20 patients treated with Prolieve™ following their participation in the pivotal trial in the Proscar® arm. The information for these 20 patients is included in the safety summary with the 125 patients originally randomized to Prolieve™. Five of the patients in the Prolieve™ intent-to-treat population went for treatment but treatment was canceled during the preparatory steps and these five patients are not included in the safety presentation for the post-treatment period.

Demographic Data

Eighty-three percent of the patients in both treatment arms were Caucasian (104/125, 34/41). The mean age of the patients in the Prolieve™ arm was 63.7 (43-87) years compared to 64.3 (50-83) years for patients in the Proscar® arm. The difference in the mean age between the treatment arms was not statistically significant.

Data Analysis and Results on Intent-to-Treat Population

Effectiveness: The primary effectiveness analysis was a repeated measure analysis using the least squares model for each follow-up evaluation comparing the two treatment arms. All patients with missing data at any follow-up evaluation or who did not attend a visit were included in the analysis as failures.

Repeated Measures Mean Improvement Comparison on Intent to Treat Population

Primary Effectiveness Variable: AUA Total Score

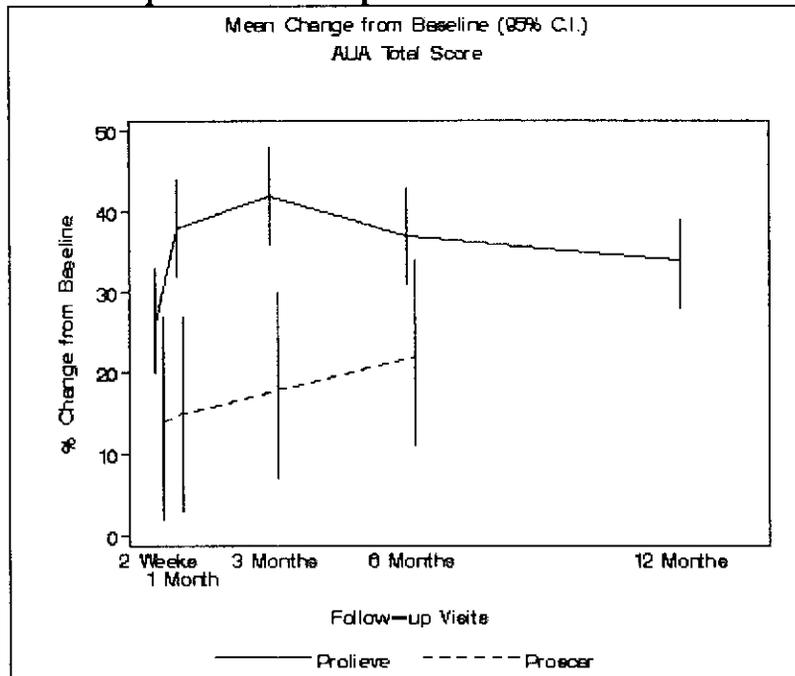
The mean improvement in AUA total score for the patients treated with Prolieve™ was greater than the mean improvement observed for patients treated with Proscar® at each follow-up evaluation (2 week, 1 month, 3 months, and 6 months) except the 12-month visit at which Proscar® patient data was not collected and are presented below in Table 2. Graph A below presents this information in graphic format. The vertical lines represent the confidence intervals.

**Table 2: Repeated Measures Analysis
Least Squares Mean Improvement in AUA Total Score**

Visit	Treatment Arm	Absolute Mean Improvement (95% CI)	Percent Improvement (95% CI)
2-week	Prolieve™	5.7 (4.3, 7.1)	26% (20, 33)
	Proscar®	2.8 (0.4, 5.3)	14% (2, 27)
1-month	Prolieve™	8.4 (7.1, 9.7)	38% (32, 44)
	Proscar®	3.0 (0.7, 5.2)	15% (3, 27)
3-month	Prolieve™	9.2 (8.0, 10.5)	42% (36, 48)
	Proscar®	3.6 (1.4, 5.8)	18% (7, 30)
6-month	Prolieve™	8.1 (6.9, 9.4)	37% (31, 43)
	Proscar®	4.4 (2.2, 6.7)	22% (11, 34)
12+ month	Prolieve™	7.4 (6.2, 8.6)	34% (28, 39)

*note: the data above is based on the Prolieve™ treated patients, N=125, and Proscar® treated patients, N=41.

**Graph A: Repeated Measures Analysis
Least Squares Mean Improvement in AUA Total Score**



Effectiveness Results on Evaluable Patients-Prolieve™ Patients Only

AUA Responder Rates for Treated Patients: All patients having a 30% or greater improvement in AUA total score from baseline during the follow-up evaluation were considered responders. Only patients treated with Prolieve™ who were present at the

visit were included in the analysis, i.e., evaluable patients. The improvement percentages are shown in Table 3.

Table 3: Response for Total AUA Symptom Score in Percent Improvement

Visit	Group	Percent Response			
		Worsened	No Change 0 to 29%	Improved 30 to 100%	Missing
2 week	Prolieve™	27 (23%)	29 (24%)	59 (49%)	5 (4%)
	Proscar®	10 (24%)	20 (49%)	10 (24%)	1 (2%)
1 month	Prolieve™	14 (12%)	26 (22%)	74 (62%)	6 (5%)
	Proscar®	13 (32%)	11 (27%)	13 (32%)	4 (10%)
3 month	Prolieve™	8 (7%)	27 (23%)	79 (66%)	6 (5%)
	Proscar®	11 (27%)	8 (20%)	16 (39%)	6 (15%)
6 month	Prolieve™	6 (5%)	30 (25%)	69 (58%)	15 (13%)
	Proscar®	8 (20%)	14 (34%)	13 (32%)	6 (15%)
12 month	Prolieve™	8 (7%)	16 (13%)	68 (57%)	28 (23%)

*note: the data above is based on the Prolieve™ treated patients, N=120, and Proscar® treated patients, N=41.

Mean Improvement and Responder Analysis for Treated Patients: Only patients treated with Prolieve™ who were present at the visit were included in the analysis. The mean improvement of 10.1 (47%) (95% CI, 8.5, 11.6) for 92/120 patients observed at the 12+month visit indicates the improvement was sustained.

Secondary Effectiveness Parameters: The results for these secondary endpoints and analysis are described below. The secondary effectiveness analysis is performed on the intent-to-treat population, N=125 for the Prolieve™ patients and N=41 on the Proscar® patients.

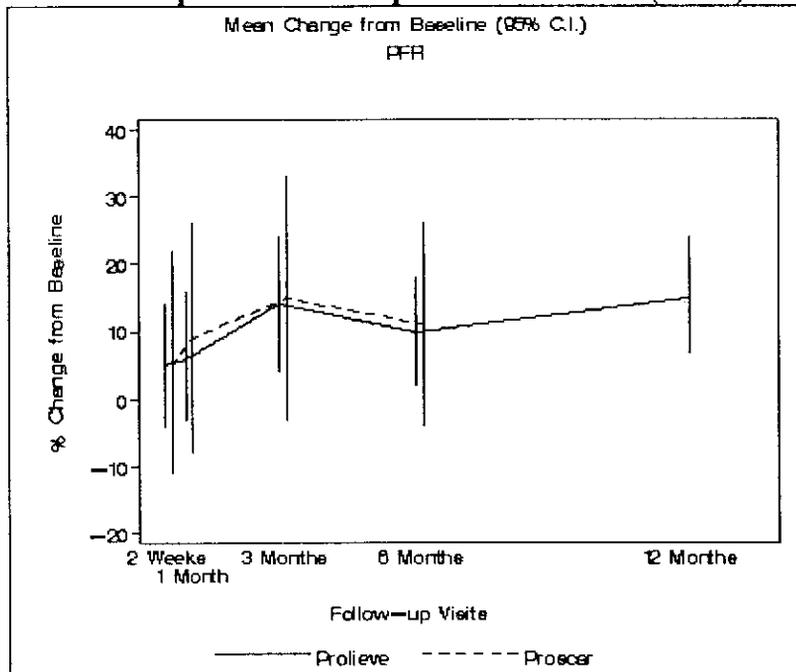
- *PFR:* The least squares mean improvement in peak flow rate data for the patients treated with Prolieve™ are shown in Table 4 below. A plot of these data is provided in Graph B.

**Table 4: Repeated Measures Analysis
Least Squares Mean Improvement in PFR (cc/sec)**

Visit	Treatment Arm	Absolute Mean Improvement (95% CI)	Percent Improvement (95% CI)
2 week	Prolieve™	0.5 (-0.4, 1.3)	5% (-4, 14)
	Proscar®	0.5 (-1.0, 2.0)	5% (-11, 22)
1 month	Prolieve™	0.6 (-0.3, 1.5)	6% (-3, 16)
	Proscar®	0.8 (-0.7, 2.4)	9% (-8, 26)
3 month	Prolieve™	1.4 (0.4, 2.3)	14% (4, 24)
	Proscar®	1.4 (-0.3, 3.0)	15% (-3, 33)
6 month	Prolieve™	1.0 (0.2, 1.7)	10% (2, 18)
	Proscar®	1.0 (-0.3, 2.4)	11% (-4, 26)
12+ month	Prolieve™	1.5 (0.7, 2.3)	15% (7, 24)

*note: the data above is based on the Prolieve™ treated patients, N=125, and Proscar® treated patients, N=41.

**Graph B: Repeated Measures Analysis
Least Squares Mean Improvement in PFR (cc/sec)**



- *QOL*: The mean improvement for the patients treated with Prolieve™ was 4.5 (19%) compared to 1.1 (5%) for the patients treated with Proscar® at the 6-month

visit (95% CI, 5, 25). This improvement was sustained to the 12+-month visit where the mean improvement was 4.2 or 18% (95% CI, 14, 22).

- *LUTS*: The mean improvement for the patients treated with Prolieve™ was 2.3 (17%) compared to 0.8 (6%) for the patients treated with Proscar® at the 6-month visit (95% CI, 3, 18). The improvement observed in the patients treated with Prolieve™ was sustained to the 12+-month visit where the mean improvement was 2.0 or 14% (95% CI, 11, 18).
- *BSI*: The mean improvement for the patients treated with Prolieve™ was 3.4 (19%) compared to 0.8 (5%) for the patients treated with Proscar® at the 6-month visit (95% CI, 2, 27). The improvement observed in the patients treated with Prolieve™ was sustained to the 12+-month visit where the mean improvement was 3.8 or 20% (95% CI, 15, 26).
- *BII*: The mean improvement for the patients treated with Prolieve™ was 2.2 (23%) compared to 1.0 (12%) for the patients treated with Proscar® at the 6-month visit (95% CI, 0, 24). The improvement observed in the patients treated with Prolieve™ was sustained to the 12+-month visit where the mean improvement was 2.1 or 23% (95% CI, 17, 28).
- *IIEF-5*: The comparison between the two treatment arms with respect to erectile function appear to be similar at each of the follow-up visits.
- *PVR*: The PVR mean change from baseline for the two treatment arms appear to be similar at each of the follow-up visits.
- *Sexual Function*: A comparison of responses by patients in the two treatment arms was made for the questions asking if the patient experienced pain with erections, intercourse and/or ejaculations. Less than 1% of patients treated with Prolieve™ experienced some form of erectile dysfunction following treatment.
- *Pain and Discomfort*: No differences were observed between the two treatment arms at any of the follow-up evaluations with respect to pain and discomfort.
- *Prostate weight and response rates*: A covariate analysis based on prostate weight was performed to assess the impact of treatment success with respect to prostate size. A comparison in response rates based on AUA total score and prostate weight was made for the patients treated with Prolieve™. Those patients with prostate weights of ≤40grams were included in one group while patients with prostate weights >40 grams were placed in the other group. At the 6-month visit the patients in the ≤40gram group had a 71% (51/72) AUA responder rate (percent improvement of 30% or greater compared to baseline) compared to 34% (18/53) for the patients in the >40gram group (95% CI, 20.4, 53.4). These results demonstrated that patients with prostates >40grams did not demonstrate as significant a response as patients with prostate weights of ≤40grams.

MAINTAINING DEVICE EFFECTIVENESS

Please refer to the User Manual for complete instruction on device maintenance required by Celsion. Celsion recommends the following actions be performed by the user:

Weekly

- Cleaning of all cooling air inlets

Each 12-month period

- Microwave power output calibration
 - Temperature system validation
 - System electrical safety verification
-
- To help maintain the device's proper operation it is important to follow the specified shutdown procedure. The specified instructions are in the User Manual. In general, be certain to close all windows on the Prolieve™ computer screen by single, left mouse clicks on the upper right hand corner of each window. Select the Shut Down option and wait until the message "it is now safe to turn off your computer" appears.
 - Always place the power button in the off position when treatment is completed.
 - Backup power should be available to permit proper shutdown in the event of a power outage.
 - Prolieve™ requires no lubrication
 - For any needed service, call 888-272-1001.

ALTERNATIVE TREATMENTS

For symptomatic bladder obstruction secondary to BPH, the alternative procedures include those shown below.

- "Watchful waiting," some patients may improve or stabilize the symptoms.
- Drug therapy with a single drug or combined therapy with an alpha blocker and Finasteride (Proscar®). The combination relaxes the bladder neck and prostatic urethra and Finasteride can shrink the volume of BPH growth.
- Microwave thermotherapy (TUMT) using intraprostatic temperatures >46°C is effective in partially relieving symptoms of BPH. There are several devices approved for this purpose.
- TUNA that uses radiofrequency energy to destroy intraprostatic tissue resulting in opening of the obstruction.
- Urethral stents placed in the prostatic urethra to expand the opening of the channel.
- Laser treatment for resection, electrovaporization or coagulation of the BPH tissue.

- TURP, transurethral removal, piece by piece of BPH growth with an electrical loop.
- Transurethral incision of the prostate (TUIP), this is limited to prostates <30gm, and
- Open surgery via different approaches (suprapubic, retropubic or perineal) removes only the inner part of the gland.

The treating physician should discuss the alternatives prior to treatment.

PATIENT COUNSELING INFORMATION

Patient counseling is the responsibility of the treating physician. However, Celsion Corporation provides the following suggestions:

- **Purpose, alternatives and the desired outcomes. Discuss the following with the patient:**
 1. Reconfirm the diagnosis.
 2. The purpose of the Prolieve™ treatment.
 3. The alternative treatments and their side effects.
 4. The desired outcome of the Prolieve™ treatment including the fact that it is not a curative procedure.
- **Pretreatment instructions. Advise the patient of the following:**
 1. He may have a prophylactic antibiotic therapy recommended prior to treatment.
 2. He will be asked to empty his bladder.
 3. His vital signs will be monitored.
 4. He will feel bladder urgency during the treatment.
 5. He will have an aqueous based topical anesthetic applied.
 6. He will feel suprapubic heat during treatment; actual pain should be reported immediately to the medical team.
- **Procedure description. Advise the patient of the following to facilitate his understanding of the procedure:**
 1. The physician and technician will prepare the machine for use.
 2. A topical anesthetic will be applied to the opening of the urethra.
 3. A catheter will be inserted into the bladder, and different methods, such as x-ray or ultrasound, may be used to verify the exact location of the equipment.
 4. A temperature monitor with a prophylactic cover will be inserted to monitor the treatment.
 5. Heat generated by microwave power will be applied to the prostate gland and compression will be applied to the wall of the urethra.
 6. The catheter and temperature monitor will be removed at the conclusion of the treatment.
 7. The preparation and procedure should take about 60 to 90 minutes.

- **Adverse events. Advise the patient of all potential adverse events associated with the procedure: (See Table 1).**
- **Follow up expectations. Advise the patient of the following:**
 1. Follow up visits or tests are required.
 2. Adverse events such as blood in the urine are common for 3 to 5 days after the procedure.
 3. Pain and discomfort may last for up to 7 days after the procedure.
 4. Patient should take pain medication as recommended by the physician.
 5. When he is to contact the physician.

HOW SUPPLIED

The main components of Prolieve™ are the permanent instrument and the single-use Procedure Kit.

The permanent instrument consists of:

- Instrument cabinet
- Cables
- Rectal Temperature Monitor

The single-use Procedure Kit consists of:

- Sterile, Microwave Transurethral Catheter
- Heat Exchanger Cartridge
- Sterile Water, 500 mL bag

Disposable user supplies consist of:

- 5cc Syringe (for inflation of location balloon)
- KY Jelly
- Aqueous-based, 2% Lidocaine Jelly (packaged in a sterile syringe)
- General Prophylactic for use with the RTP
- Absorption pad 2 foot by 2 foot (or equivalent coverage)
- 4" x 4" sponges (sterile gauze)
- Gauze Tape
- Ultrasonic Gel (if ultrasound imaging is anticipated)

USER MANUAL

The User Manual is a separate document.

PATIENT INFORMATION

Patient labeling is available to assist the physician in counseling the patient about this device and the procedure. The patient labeling should be provided to the patient in a timely manner.

REFERENCES

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