Single-use microwave procedure kits include:

- 18Fr x 36cm long microwave transurethral catheter, which has a 5cc retention balloon and a 46Fr x 3.7cm long compression balloon for prostatic dilation
- A disposable rectal temperature monitor
- A heat exchanger cartridge system (HXC)
- 500ml bag of sterile water

Prolieve Thermodilatation® System

Prolieve Thermodilatation® System

Ordering Information

Order Number	*Description*
M00**68808000**	Prolieve Thermodilatation System
M00**68808260**	Prolieve Thermodilatation System Kit
M00**68808121**	Prolieve Thermodilatation System Console Printer Paper – Box 2
M00**68808130**	Prolieve Thermodilatation System Microwave Cable
M00**68808400**	Prolieve Thermodilatation System User Manual

Please refer to user manual for complete directions for use.

INDICATIONS The Prolieve Thermodilatation® System is a transurethral microwave therapy device for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH) in men with a prostate size of 20 to 80 grams and prostatic urethra length between 1.2 cm and 5.5 cm and in whom drug therapy (finasteride or Proscar®) is typically indicated.

CONTRAINDICATIONS Patients who have significantly decreased pain responses, severe urethral stricture prohibiting catheterization, current urinary or prostatic infection, penile or urinary sphincter implants, prostate sizes <20 g or >80 g, peripheral arterial disease with intermittent claudication or Leriche's Syndrome, protruding median lobe with obstruction, metallic implants, implanted cardiac pacemakers or defibrillators, previous transurethral prostatectomy, renal impairment, coagulation disorders, neurological disorders that may affect bladder function, bladder stones, evidence of prostate or bladder cancer or have an interest in the preservation of future fertility.

WARNINGS AND PRECAUTIONS All components of the Prolieve System must be used in accordance with the User Manual. The emission of microwave energy must be off during placement and removal of the catheter. Patient comments of pain or excess heat should be investigated. Failure to monitor adequately and deliver the procedure per User Manual may lead to decreased patient safety and/or reduced clinical effectiveness. A single high dose of microwave radiation to the testes, or testicular heating for a prolonged period, may result in temporary or permanent sterility. No anesthetic other than aqueous-based topical intraurethral anesthetic used for catheter placement is recommended. The safety and effectiveness of the Prolieve System for men <50 and >80 years old has not been established in clinical studies. If procedure kit seal or internal sterile packaging seals are damaged or broken, the contents may not be sterile and could cause infection.

POTENTIAL ADVERSE EFFECTS that may occur include but are not limited to bleeding, bowel irritation, urethral injury (irritation), chronic pain at site, bladder spasms, urinary retention (complete or incomplete), urinary incontinence, prostatitis, pressure sensation, urinary urgency, urinary tract infection, urethral tear, anal irritation, urethral stricture, infertility, retrograde ejaculation and erectile dysfunction.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Individuals depicted in this material are models and included for illustrative purposes only; models depicted are not users and do not endorse the Prolieve® System.

Medifocus Inc

Medifocus, Inc.
10240 Old Columbia Road, Suite G
Columbia, MD 21046
www.medifocusinc.com

Sales: 888-326-5335
Scheduling: 866-868-7672

BVU2370 Rev A 2000 11/13

Prolieve Thermodilatation® System

Medifocus Inc

Prolieve Thermodilatation® System

Well-tolerated[1]

- Topical anesthesia only
- 94% of patients report no or mild pain during treatment
- 82% of patients go home without a catheter
- 99% of patients treated did not experience any form of erectile dysfunction following the treatment

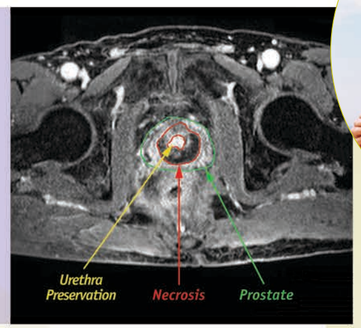
Effective[1]

- At two-weeks postprocedure, 51% of treated patients (59/115*) had a >30% improvement in AUA symptom score
- At one-year postprocedure, 74% of treated patients (68/92*) had a >30% improvement in AUA symptom score
- At two-years postprocedure, 64% of treated patients (28/44*) had a >30% improvement in AUA symptom score

64%
>30% AUA Improvement at 2 years

Practice-friendly

- Requires little setup time or office space
- Requires limited office recovery time



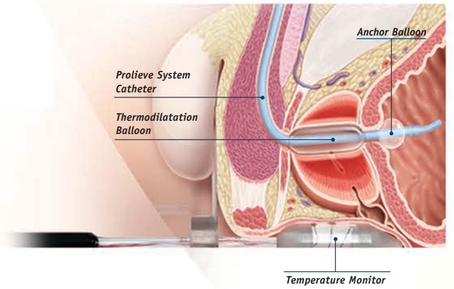
Gadolinium enhanced MRI showing areas of necrosis and viable prostatic tissue following treatment with the Prolieve® System.[2]

A welcome change in the treatment of BPH symptoms.

The Prolieve System enhances operator use and provides effective relief of the symptoms of BPH.

- The Thermodilatation balloon dilates the prostatic urethra and compresses the surrounding prostatic tissue
- A microwave antenna within the catheter heats the prostate tissue
- The Prolieve System's computer monitors the temperature adjacent to the treatment area by means of a rectal temperature monitor equipped with 3 separate sensors
- The Prolieve System's computer assists physicians with prompts, safety alerts, and postprocedure treatment reports

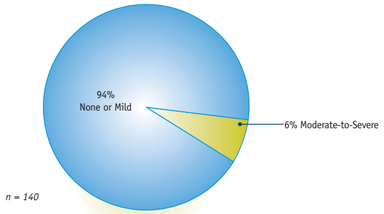
The Prolieve Thermodilatation System technology is designed to both heat the prostate and dilate the prostatic urethra while multiple temperature sensors monitor safe temperature.



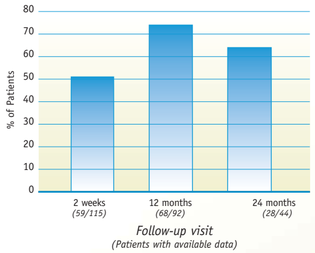
This depiction of heating of the prostate is for illustrative purposes only and is not intended to represent actual temperatures or temperature distributions within the prostate during treatment with the Prolieve System.

Tolerability of Transurethral Microwave Therapy[1]

Intraprocedural Discomfort



>30% Improvement AUA Symptom Score[1]



Follow-up visit
(Patients with available data)

[1] Neal Shore, MD *"Prolieve Thermodilatation System, A New Advance in the Treatment of BPH."* West Section AUA, Vancouver, Canada, August 2005.

[2] Thayne Larson, MD *"Microwave Thermotherapy Temperatures Achieved by the Prolieve Thermodilatation System Result in Coagulative Necrosis and a Patent Post Treatment Prostatic Urethra."* 22nd World Congress on Endourology and SWL, Mumbai, India, November 2 - 5, 2004.

*Denominator represents the total number of patients not including those who discontinued.