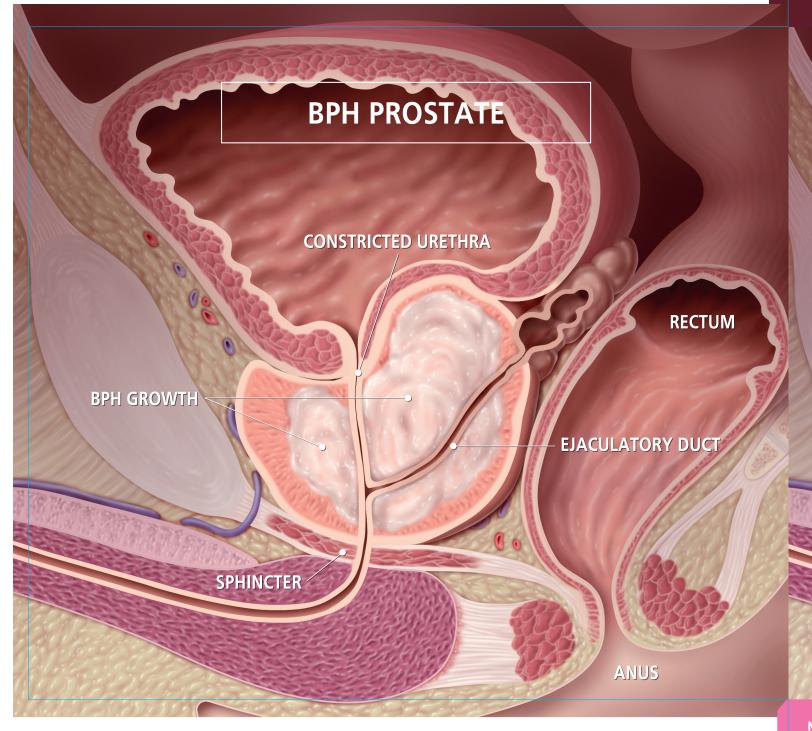
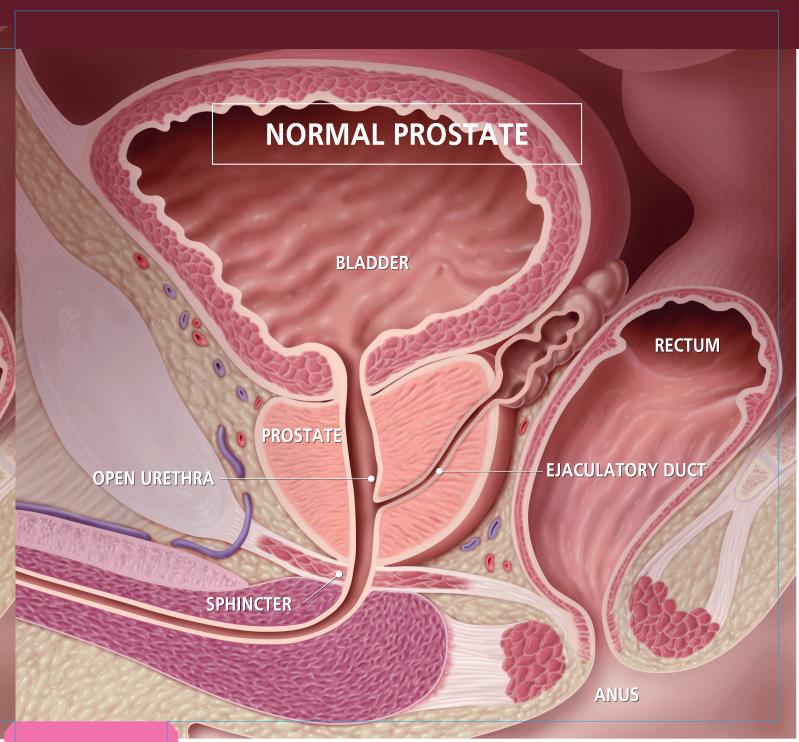


A Minimally Invasive Treatment for Benign Prostatic Hyperplasia



SCAN TO TAKE YOUR FIRST STEP TOWARDS RELIEF





NORMAL / BPH PROSTATE

# 45 MINUTE THERMODILATATION TREATMENT **FOCAL HEAT** Provides non excessive thermotherapy to the prostate Raises intraprostatic temperature 45°C+ to trigger apoptosis **ANCHOR BALLOON** Secures the catheter in the optimal treatment position TEMPERATURE MONITOR **DILATATION BALLOON** Measures intraprostatic temperature non-invasively • Widens the constricted urethra Helps to prevent "heat sink" Safety feedback mechanism

### PROLIEVE® CATHETER

• Provides continuous cooling to reduce inflammation

PROLIEVE® TREATMENT

# **END RESULT - IMMEDIATE RELIEF** 5 MINUTE COOL DOWN reserves the integrity of the rethra mucosal lining WIDENED URETHRA A NATURAL "BIOLOGICAL" STENT!

COOL DOWN & BIOLOGICAL STENT

## **TREATMENT OPTIONS**

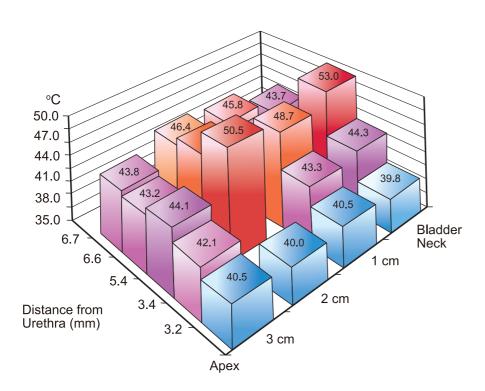
FEATURES	PROLIEVE <sup>1</sup>	IMPLANT SYSTEM	STEAM THERAPY	SURGERY
Minimally Invasive Treatment	✓	<b>✓</b>	<b>✓</b>	
Preservation of Sexual Function	<b>✓</b>	<b>✓</b>	<b>√</b>	
No Foreign Object in the Body	✓		<b>√</b>	<b>✓</b>
Typically, No Catheter Required Post-Procedure	✓	✓		
Safe and Suitable for High-Risk Patients	✓			
Immediate Relief, Prompt Return to Normal Activities	✓	✓		
No True Breach of Urethra *	✓			
Can be Performed as an Outpatient Procedure	<b>✓</b>			

<sup>(1)</sup> Please refer to Prolieve Prescribing Information and FDA Post Approval Study (PAS) for references. \* For use only as intended and in accordance to approved indications.

### **ADVANTAGES OF PROLIEVE®**

- 1. FDA approved. Proven fast, safe and effective with 120,000+ cases done<sup>1</sup>
- 2. 94% patients go home without a post-treatment catheter <sup>2</sup>
- 3. Minimal side effects, immediate relief and fast recovery <sup>1</sup>
  - Low incidence of erectile dysfunction, 2.0 per 100 person-years
  - Low incidence of retrograde ejaculation, 1.8 per 100 person-years
- 4. Well tolerated and can be done as an outpatient procedure <sup>1</sup>
- 5. Improvements in Qmax, PMRV and IPSS Scores <sup>1</sup>
  - Qmax: Baseline 8.55ml/s vs Year 5: 13.04ml/s
  - PMRV: Baseline 190ml (mean) vs Year 5: 50ml (mean)
  - IPSS: Baseline 20.12 vs Year 5: 12.86
- (1) Bidargaddi, V & Mon, J, Post-Marketing Study Using Prolieve for the Treatment of BPH and 120-Month Post-Approval Study 5-Year Follow Up Report, 2018.
- (2) Shore et al 2010.

### PROLIEVE® INTRAPROSTATIC THERMAL MAPPING



- Maximum temperatures measured at lateral & parallel to the urethra.
- The balloon act to protect the urethra by maintaining the urethra wall near body temperature 39.8°- 40.5°C, in addition to the cooling stream of irrigation at 34°-35°C.
- Tissue ablation achieved where sustained temperatures > 45°C.
- Higher temperatures near bladder neck
   & mid-gland than apex.

Adapted from Urology Times, Office-Based Microwave Therapy: A First Line Treatment for BPH Advanstar Communications Inc. July 2007

# PROLIEVE® THERMODILATATION SYSTEM

The Least Invasive Treatment for BPH. Proven Fast, Safe and Effective

Schematic illustrations of the prostate anatomy



### **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 grams or >80 grams, 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 about 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.

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Schematic illustrations of the prostate anatomy



