

# PROLIEVE®

THERMODILATATION

## The Relief You Deserve



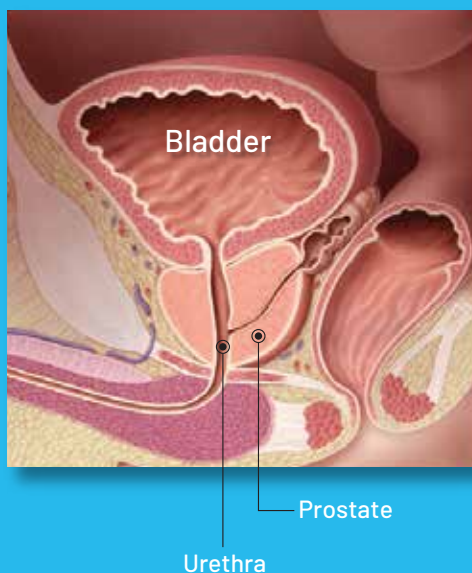
# WHAT IS BENIGN PROSTATIC HYPERPLASIA (BPH)?

Benign Prostatic Hyperplasia, or BPH is the condition in men where the prostate gland becomes enlarged. It is neither life-threatening nor cancerous. This condition affects about 42% of men aged 50-59 years and 65% of men aged 70 and more.<sup>1</sup>

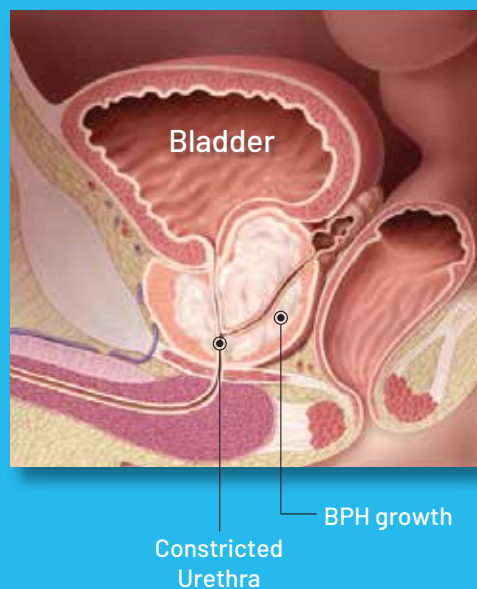
## WHAT ARE THE SYMPTOMS OF BPH?

- Frequent urination both days and nights
- Difficulty in starting urination
- Pain after ejaculation or during urination
- Dribbling at the end of urination
- Urgent feeling to urinate
- Interrupted sleep to urinate
- Urinary retention

### NORMAL PROSTATE



### BPH PROSTATE

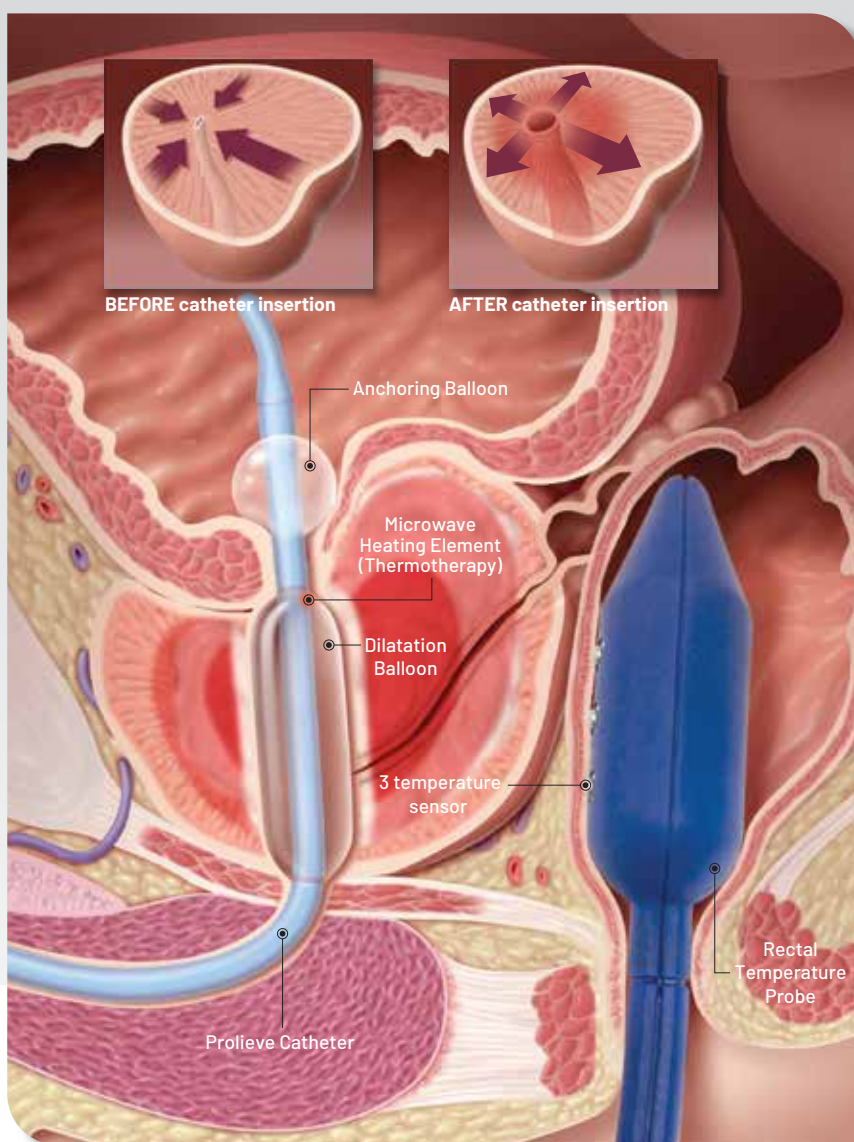


# HOW DOES PROLIEVE® WORK TO MANAGE BPH?

Prolieve® is a safe and effective non-surgical, medication-free treatment for patients suffering from BPH.

Prolieve® uses a unique technique known as thermodilatation to treat BPH by reducing the size of the enlarged prostate, helping to open up the urine channel and provide immediate symptomatic relief.

Prolieve® is also clinically proven to preserve sexual and urinary functions.<sup>2</sup>



# HOW DOES A PROLIEVE® PROCEDURE WORK?

- STEP 1** Your doctor will call you in the treatment room to change to procedure gown and lie down on a bed as the Prolieve® device and kit are being prepared.
- STEP 2** Your doctor will first insert the thermotherapy catheter via your penis. There should be minimal discomfort to this insertion as the catheter is applied with local anesthesia.
- STEP 3** Once the thermotherapy catheter reaches your prostate and ends at your bladder, the anchoring balloon located inside the bladder will be inflated with water. This anchoring balloon is to ensure the catheter is tightly positioned.
- STEP 4** Your doctor will then insert the rectal probe via your anus. This rectal probe comes with 3 temperature sensors that will be positioned near your prostate, to provide feedback to the thermotherapy catheter of the amount of energy to emit. (Please refer to the previous page for the 2D diagram)
- STEP 5** The Prolieve® device will then begin to allow flow of water through the balloon located at the thermotherapy catheter. This will dilate the balloon and expand the size of your urethra channel, and press the catheter against your prostate. (Please refer to the previous page for the 2D diagram). You may feel a bit of a need to pee, but this is normal.
- STEP 6** Finally Prolieve® device will turn on, emitting energy from the catheter to your prostate. Temperature will slowly rise to about 48°C. This process will last for 45 minutes.
- STEP 7** After 45 minutes, the device will be turned off as the temperature slowly drops to your body temperature. Your doctor will remove both the thermotherapy catheter and the rectal probe and ask you to slowly stand up and attempt to urinate. You may feel immediate relief during this period. Please let your doctor know if you may need additional temporary catheter to help instead.
- STEP 8** You may be asked to spend another hour or so to relax before discharge.

# WHY CHOOSE PROLIEVE®



## IMMEDIATE EFFECT

Patient will feel immediate relief after the procedure.<sup>3</sup>



## LOW CATHETERIZATION RATE

Our 5-year study shows that 85% of patients do not need to be catheterized after treatment<sup>4</sup>.



## EFFECTIVE ALTERNATIVE TO MEDICATION

Promptly alleviates BPH symptoms with significantly greater outcome compared to oral medications<sup>5</sup>.



## NO IMPLANTS

Prolieve® is a procedure that does not leave any implants or foreign objects in your body.



## MINIMAL SEXUAL SIDE EFFECTS

Risk of erectile dysfunction is low<sup>4</sup>.



## WELL TOLERATED

Performed under local anaesthesia, 86% of patients reported no or mild discomfort during and after the Prolieve® treatment<sup>4</sup>.



# FREQUENTLY ASKED QUESTIONS

## **Am I suitable for Prolieve® treatment?**

Prolieve® is indicated to use for a specific group of BPH; such as your prostate size is between 20 gram to 80 gram, among others. It's important that your doctor has assessed your prostate before deciding if Prolieve® is suitable for you.

## **Should I continue my medication after prolieve treatment?**

Prolieve® treatment aims to provide relief of BPH symptoms without the need to continue your BPH medication. However, your doctor will advise if continued use of BPH medication is necessary.

## **How soon will my symptoms improve?**

You may be able to urinate with ease immediately after the procedure. Others may see gradual improvements over time. Most patients do not need catheter to keep open your urinating channel (urethra).

## **How long will my results last?**

Prolieve® has long-term results that prove patients to remain BPH-free for as long as 5 years. It is important to take note that BPH is a continuous progression of life, similar to normal aging. Hence, regular visits to your healthcare practitioners after the procedure is recommended.

## **Will Prolieve® treatment affect my sexual function?**

Approximately 97% of patients treated with the Prolieve® System did not experience any form of erectile dysfunction after procedure.

## **Is the procedure painful?**

Prolieve® procedure begins with administering local anesthetic to the site of catheter insertion. This ensures that you will feel only slight discomfort throughout the session. Discomfort also would be felt with the temperature probe given rectally. Overall procedure is well-tolerated.

# WHAT DO I DO TO PREPARE FOR PROLIEVE® PROCEDURE?

## BEFORE



- Your doctor may advise you to empty your bowel the day before the treatment. Please consult your doctor on this.
- Arrange for your transportation back home after the procedure, as it is not advisable to drive home by yourself.

## DURING



- Your doctor may check that the catheter is in place using an ultrasound.
- Treatment will last for 45 minutes with an additional 5 minutes for cooling down.
- You may feel a slight burning sensation as the temperature increases and this is normal as the heat is exerted on your prostate.

## AFTER



- You may be able to pass urine right after the procedure. Most patients will be able to go home after that without the need of a catheter.
- Speak to your doctor should you have any discomfort.
- Your doctor may advise you to return for a follow up consultation.

# PROLIEVE®

## THERMODILATATION

### Abbreviated Product Information

**Indication:** The Prolieve® Thermodilatation System is a transurethral thermodilatation 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 1.2cm to 5.5cm and in whom drug therapy 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 <20g or >80g, peripheral arterial disease with intermittent claudication or Leriche Syndrome, protruding median lobe with obstruction, metallic implants, implanted cardiac pacemakers or defibrillators, previous transurethral prostatectomy, previous history of pelvic radiation, renal impairment, coagulation disorder, 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.

**Warning And Precautions:** The safety and effectiveness of the Prolieve® System for men <50 and >80 years old has not been established in clinical studies.

**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, erectile dysfunction.

For Healthcare Professionals Only. Full prescribing information is available on request.

#### References:

1. Teh, CG, et. al., Prevalence of Symptomatic BPE Among Malaysian Men Aged 50 and Above Attending Screening During Prostate Health Awareness Campaign; *Med J Malaysia* 2001; 56(2); page 186.
2. Olweny, E. O., Jow, S., & Jow, W. W. (2022). Prolieve Transurethral Thermodilatation for Treatment of Symptomatic Benign Prostatic Hyperplasia: 5-Year Results from a Prospective Multicenter Trial. *Journal of Endourology*, 36(1), 117–123. <https://doi.org/10.1089/end.2021.0240>.
3. Chow, WM, Microwave Thermodilatation Therapy For Symptomatic BPH: First 50 Asian Patients With Failed Medical Therapy, UAA 2023 Poster Presentation, Sep 2023.
4. Bidargaddi, V & Mon, J, 'Post-Marketing Study Using Prolieve for the Treatment of Benign Prostatic Hyperplasia (BPH), 120-Month Post-Approval Study Annual Status Report, Unpublished Report, February 19, 2004, Columbia, United States.
5. Bock, B, et. al., Microfocus BPH800 Urethroplasty System Versus Finasteride: Result Of A Multi-Center, Randomized Trial In Symptomatic Patients With Benign Prostatic Hyperplasia; *Journal of Urology* 2004; 171(4); page 410.

**Medifocus Inc.** 193101000021(719-V)  
9150 Rumsey Road Suite A4 Columbia, MD US 21045  
Tel: 001-443-8644372