℞ only **Prescription use only**

What is BPH or an enlarged prostate?

Benign Prostatic Hyperplasia (BPH) is a common condition in which the prostate enlarges. Prostate tissue tends to grow with age and while it is not a form of cancer, it can affect your quality of life. As the prostate enlarges, it presses on and blocks the urethra, causing bothersome urinary symptoms such as:[1,2]

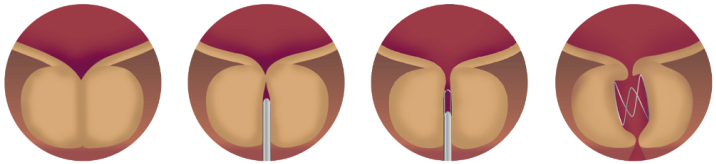
- Frequent need to urinate both day and night
- Weak or slow urinary stream
- A sense that you cannot completely empty your bladder
- Difficulty or delay in starting urination
- Urgent feeling of needing to urinate
- A urinary stream that stops and starts

How can BPH be treated with the ProVee System?

The ProVee device (expander implant) is designed to gently open the urethra to improve urine flow. It has been designed to improve urination without causing sexual problems. Unlike some other urinary symptom treatments, the ProVee device does not cut, pierce or apply heat to the prostate. The device is designed to stay in place but can be removed if needed. The device is delivered to the correct location by a special delivery system.

The delivery system, which carries the ProVee device, has a small camera at the end and is inserted through your urethra as shown in Figure 1 (Step 1). The camera allows your doctor to see inside your urethra to ensure the ProVee device is placed in the correct position Figure 1 (Step 2). A graphic of what the ProVee device will look like, and where it is placed in the prostate is shown in Figure 1 (Step 3).

Figure 1– The Procedure and ProVee device



Enlarged Prostate
An enlarged prostate can narrow or even block the urethra, causing bothersome urinary symptoms.

Step 1
The ProVee delivery system is placed through the obstructed urethra to access the enlarged prostate.

Step 2
The ProVee expander is partially deployed and is visualized relative to the landmarks of the prostatic urethra.

Step 3
The ProVee expander is designed to provide fast and effective relief by gently opening the obstructed urethra.

What are the indications for use and contraindications?

ProVee System for BPH Indications for Use:

The ProVee System for BPH is indicated for the treatment of obstructive lower urinary tract symptoms secondary to BPH, in men with prostatic urethral lengths greater than or equal to 3.75cm and prostatic volumes between 30cc and 80cc.

The ProVee System for BPH should not be used (contraindications) if you have:

- Urinary incontinence due to an incompetent external sphincter

[1] Lerner, L. B. *et al.* Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I-Initial Work-up and Medical Management. *J. Urol.* **206**, 806–817 (2021).

[2] Jacobsen, S. J. *et al.* Treatment for benign prostatic hyperplasia among community dwelling men: the Olmsted County study of urinary symptoms and health status. *J. Urol.* **162**, 1301–1306 (1999).

- Urethral pathologies that may prevent insertion of delivery system
- An active symptomatic urinary tract infection
- Current gross hematuria
- Microscopic hematuria of unknown cause
- You have a known allergy to nickel or titanium
- Presence of an existing stent in the urethral tract

Your urologist will be able to tell you if treatment with ProVee is right for you.

What materials are in the ProVee Implant?

The ProVee device (implant) contains Nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to the implant. Prior to implantation, patients should be counselled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

What are the risks with the ProVee System for BPH?

As with any urological procedure, side effects may occur. Most common adverse events are temporary, occurring within the first three months after the procedure, and can include blood in urine (hematuria), blood in semen (hematospermia), painful urination (dysuria), frequent urination, urgency, pelvic pain, and leakage of urine.[3] Rare side effects include nighttime urination, painful ejaculation, dry orgasm, urinary tract infection and device movement. These may lead to a serious outcome and may require intervention such as removal of the device. You should talk with your doctor about benefits and risks before moving forward with any treatment option.

You may need future treatment for BPH after receiving the ProVee device. You many need to have the ProVee device removed to receive future treatment.

How do I know if the ProVee System for BPH is right for me?

Your doctor will determine what examinations to perform to see if the ProVee System is right for you. The doctor will likely ask you to fill out a questionnaire to assess your symptoms, otherwise known as IPSS (International Prostate Symptom Score). Additionally, some of the common examinations may include Digital Rectal Exam (DRE), Transrectal Ultrasonography (TRUS), Bladder Ultrasound, Uroflow test, Cystoscopy, and Urinalysis.

What to expect during and after the ProVee procedure?

If you and your doctor decide that the ProVee System for BPH is right for you, your doctor will provide you with more detailed information relating to the treatment.

Your doctor will use the ProVee device to relieve the obstruction caused by the enlarged prostate that is pressing on your urethra. The procedure can be performed as a same-day outpatient procedure. You may be given medication to feel comfortable during the treatment. This typically helps minimize discomfort during the procedure, though everyone's definition for pain and discomfort varies greatly. Typically, no catheter and no overnight stay is required post-treatment[1].

How quickly can I expect to have symptom relief?

Most patients experience minimal downtime and symptom relief within a month following the procedure. Results may vary.

[3] ProVIDE and ProVIDE II clinical data on file with ProVerum Ltd.

When can I resume my usual activities?

Most men experience recovery in days, not months.[1] Your doctor will discuss any restrictions and your specific situation after your procedure.

Will I need to continue taking my BPH medications after the procedure?

You and your doctor will decide if continued use of BPH medication is necessary.

Will my sexual function be affected by the ProVee System for BPH procedure?

ProVerum's clinical studies[3] have shown the ProVee System for BPH does not adversely affect sexual function.

What happens if the implants need to be removed?

If needed, your urologist can remove the ProVee device. ProVerum's clinical studies demonstrate the ProVee device can be safely removed[2].

Do I need a catheter after the ProVee System for BPH procedure?

Typically, no catheter is required after treatment with ProVee System for BPH [2]. Your doctor will determine if you need a catheter at the time of the procedure based on your specific clinical requirements.

Can I have an MRI after the ProVee System procedure?

The ProVee device is Magnetic Resonance Imaging (MRI) "Conditional" which means you can be scanned at any time after the procedure in an MRI system which meets the following conditions. Please share the following information with your radiology technician:

Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (3000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Any transmit coil may be used
RF receive coil type	Any receive coil may be used
Maximum whole body SAR (W/kg)	2.0 W/kg
Limits on scan duration	60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 8 mm when imaged with a gradient echo pulse sequence and a 3 T MRI system

If information about a specific parameter is not included, there are no conditions associated with that parameter.

What to look for post-procedure and when to contact your doctor?

As with any urological procedure, side effects may occur. If you are having any symptoms of discomfort when you urinate, see blood in your urine or if your urine becomes cloudy or discolored, please call your doctor.

If in the future you need to see a doctor for your urinary symptoms or if you are in hospital for a different operation please let your doctor know that you have a ProVee implant present in your prostate.

You should report all complaints and adverse events to your doctor. Any serious incident that occurs in relation to the device should be reported to the manufacturer (ProVerum Ltd.).

Summary of Clinical Study Results

The ProVee device has been evaluated in the ProVIDE and ProVIDE II clinical studies[3] The ProVIDE study enrolled 221 men at 17 centers. The ProVIDE Study demonstrated an improvement in BPH symptoms at 3-months when compared to placebo (sham) treatment and an improvement in BPH symptoms at 12 months compared to baseline. 64 men that had the sham treatment went on to have the ProVee device. There were no device or procedure related serious adverse events through 12-months and no one required post-procedure catheterization.

The ProVIDE II study enrolled 40 men at 8 centers. There were no device or procedure related serious adverse events through 3-months and no one required post-procedure catheterization.

Visit www.proverummedical.com for additional information.

MRI safety information

Non-clinical testing has demonstrated that the ProVee Expander is MR Conditional with the following considerations.

Name/identification of device	ProVee Expander
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (3000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Any transmit coil may be used
RF receive coil type	Any receive coil may be used
Maximum whole body SAR (W/kg)	2.0 W/kg
Limits on scan duration	60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 8 mm when imaged with a gradient echo pulse sequence and a 3 T MRI system

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Device Specification Precautions

- Care must be taken when catheterising a patient who has an implanted ProVee Expander, particularly in the first 3 months. It is recommended that the smallest catheter size that will treat the condition is utilised.
- Care must be taken when performing cystoscopic procedures in a patient who has an implanted ProVee Expander, particularly in the first 3 months.
- In the event of any surgical resection of the prostate the surgeon should assess whether or not the ProVee Expander should be left in situ.

Removing a ProVee Expander

Grasper removal method:

1. Under direct vision insert a ≥19.4Fr non-beaked sheath with a minimum working channel of 12Fr into the prostatic urethra until the implant is visualised.
2. Insert a 10Fr rigid inverted rat tooth grasper down the working channel of the sheath.
3. Grasp a distal apex of the implant and track the working channel of the sheath over the grasped apex by moving the sheath forwards.
4. Keeping the grasper closed, firmly pull the implant through the working channel of the sheath by retracting the grasper into the sheath.
5. Inspect the implant to confirm that the entire implant has been removed.