℞ only **Prescription use only**

Catalogue #	Device Name
PV-002	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 benign prostatic hyperplasia (BPH), in men with prostatic urethral lengths greater than or equal to 3.75cm and prostatic volumes between 30cc and 80cc.

Contraindications:
Do not use the ProVee System for BPH in patients that have:

- Urinary incontinence due to an incompetent external sphincter
- Urethral pathologies that may prevent insertion of delivery system
- An active symptomatic urinary tract infection
- Current gross haematuria
- Microscopic haematuria of unknown cause
- Patients with known allergy to nickel or titanium
- Presence of an existing stent in the urethral tract

Additional Patient Selection Considerations

The ProVee System for BPH should not be used in patients with:

- A prostatic urethral length of less than 3.75cm
- A prostatic volume <30cc or >80cc
- An obstructing median lobe

Possible Complications:

Risk associated with the use of a minimally invasive device such as the ProVee System for BPH include but are not limited to:

- Dysuria
- Hematuria
- Micturition urgency
- Urge incontinence
- Pollakiuria
- Penile pain
- Bladder spasm
- Nocturia
- Painful ejaculation
- Urethral pain
- Urinary incontinence
- Retrograde ejaculation
- Constipation
- Cystitis
- Diarrhea
- Hematospermia
- Hypertonic bladder
- Pelvic discomfort

- Pelvic pain
- Penile discomfort
- Stress urinary incontinence
- Testicular pain
- Urinary tract infection (UTI)
- Perineal pain
- Muscle Spasms
- Genital discomfort
- Device dislocation (movement)

Product Description:
The ProVee System for BPH consists of two components: the ProVee Expander (implant) and a delivery system. The ProVee System for BPH is supplied with the Expander pre-loaded in the delivery system as a single use sterile device. The delivery system incorporates integrated imaging to allow the ProVee Expander to be deployed under direct vision. The delivery system is flexible and steerable to allow the patient to be positioned in either supine or lithotomy position. Deployment of the ProVee Expander occurs through manipulation of the delivery system handle which results in the withdrawal of the outer restraining sheath allowing the Expander to release from the delivery system. It has an irrigation feature to support visualisation by allowing the user to clear debris from the field of view through the delivery of saline or deionised water. The delivery system is minimally invasive at 16 Fr and designed to be compatible with the ProVee Video Processing Unit.

The ProVee System for BPH, which is a type BF applied part, is powered by the PV-003 ProVee Video Processing Unit, a reusable accessory item which supports the ProVee System for BPH in achieving its intended use. Treatment to occur in a clinical setting.

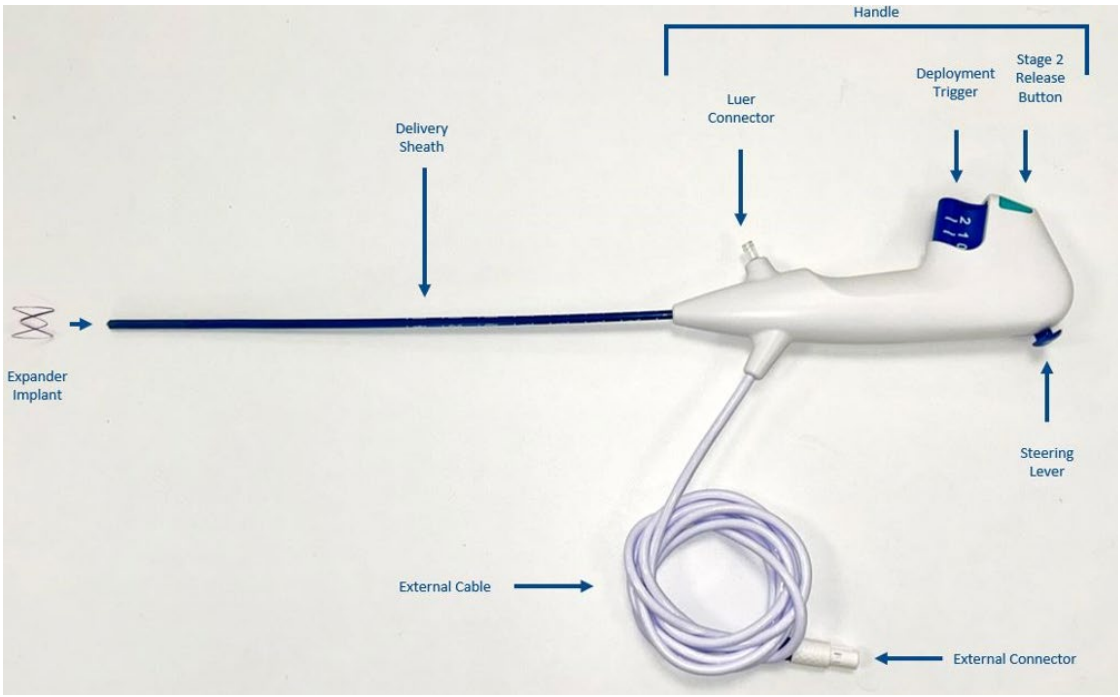

Figure 1: Delivery System and ProVee Expander

ProVee System for BPH Ancillary Equipment:

- ProVee Video Processing Unit, PV-003
- Standard Luer Connector Irrigation System

Environmental Limits During Use	
Ambient temperature (°C)	10-25
Relative humidity (%)	30-75, non-condensing
Atmospheric Pressure (kPa)	70-106
Environmental Limits During Transport and Storage	
Ambient temperature (°C)	-30 to 60
Relative humidity (% RH)	10 to 90

Warnings

- This device contains Nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this Expander. Prior to implantation, patients should be counselled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.
- ProVee System for BPH is not intended for use in patients with uncontrolled coagulopathy or patients on anticoagulant therapy who cannot safely temporarily suspend treatment in order to undergo the ProVee Implant procedure.
- The ProVee System for BPH can only be used in conjunction with ProVee Video Processing Unit. See IM-001 for warnings and instructions.
- No modification of the ProVee System for BPH is allowed. Modification of the ProVee System for BPH could affect clinical performance resulting in the implant being deployed in a clinically unacceptable position or to the device becoming electrically unsafe.
- Use prior to “Use By” date. The “Use By” date is located on the device label. If the device is used after its ”Use By” date it may no longer be sterile which could lead to patient infection.
- ProVee System for BPH is intended for Single Use Only – DO NOT RESTERILISE. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality. Re-use of single use only medical devices may result in exposure to viral, bacterial, fungal or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for this medical device. This product is not designed to be cleaned, disinfected or sterilised.
- Do not use if package is damaged or opened. ProVee System for BPH is provided sterile by ethylene oxide gas. Sterility will be maintained only if package is unopened and undamaged. The user should inspect packaging integrity prior to use. If damage is detected or sterile packaging compromised, user should not use the device.
- ProVee System for BPH camera images must not be used for diagnosis of any pathology. Doing so may result in incorrect or missing diagnosis.
- Always watch the live image on the display screen when inserting, positioning, or withdrawing the ProVee System for BPH. Do not insert or advance the device or deploy the implant if the live image is not displayed. If the device is used without live imaging this may lead to the implant being deployed in a clinically unacceptable location.
- Do not use ProVee System for BPH during defibrillation as this may result in electrical shock to the user.
- The distal tip of the ProVee System for BPH may get warm due to heating from the light emission part. Avoid long periods of contact between the distal tip of the ProVee System for BPH and the mucosal membrane as sustained contact with the mucosal membrane may cause mucosal injury.
- Do not look directly into the light emitted from the tip as this may lead to eye irritation/injury.

Precautions

- Training is required prior to first time use of the ProVee System for BPH.
- The ProVee System for BPH is not intended to be used in an aircraft environment.
- Care must be taken when catheterising a patient who has an implanted ProVee Urethral Expander, particularly in the first 3 months after implantation. 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 Urethral Expander, particularly in the first 3 months after implantation.
- In the event of any surgical resection of the prostate the surgeon should assess whether or not the ProVee Urethral Expander should be left in situ.

Operating Instructions:

1. Preparation

1.1. Remove the ProVee Video Processing Unit from the cardboard packaging. Closely examine the ProVee Video Processing Unit, cables and ancillary parts for any damage. Do not use if any parts are damaged.

1.2. Set up the ProVee Video Processing Unit by connecting the power supply to the power supply port on the ProVee Video Processing Unit. Refer to the ProVee Video Processing Unit Instruction Manual for further information as required.

1.3. Confirm that the ProVee System for BPH packaging components are unopened and undamaged. Do not use device if packaging is damaged or opened.

1.4. Patient to be prepared per standard clinical protocols for a urological procedure under local anaesthetic, moderate sedation, spinal anaesthetic or general anaesthetic as deemed clinically appropriate.

2. Preparation for Implantation Procedure

2.1. Lay the blister packaging on a flat surface and open by pulling the pull tab (see Figure 2).

Figure 2: Blister packaging and pull tab

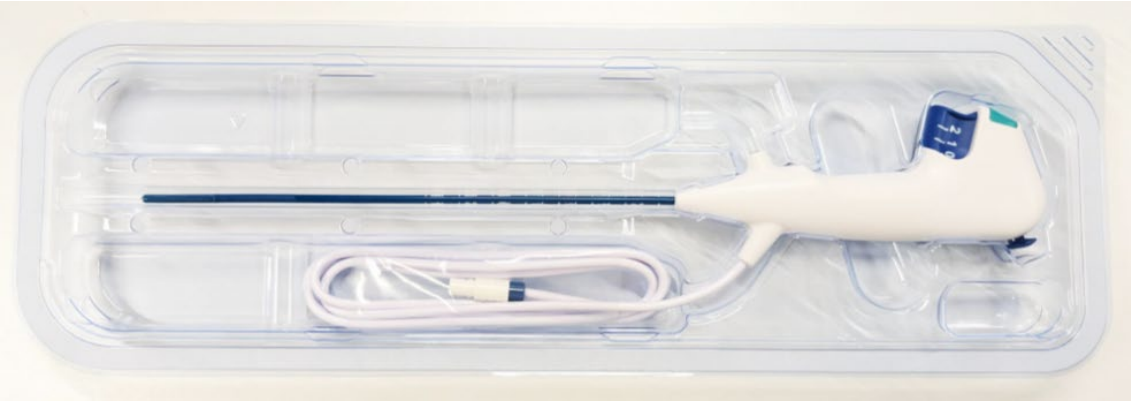

Figure 3: Remove device from the packaging tray

2.2. Aseptically remove the device from the blister packaging. Remove and dispose of the external cable packaging sleeve.

⚠ WARNING: Failure to maintain the sterility of the ProVee System for BPH and could lead to infection.

2.3. Inspect the device for any damage such as rough surfaces, sharp edges, or protrusions which may cause harm.

⚠ WARNING: Do not use if device is damaged.

2.4. Attach the external cable to the ProVee Video Processing Unit by plugging the External Connector into the Handle Connector Port on the ProVee Video Processing Unit.
2.5. Per VPU Instruction Manual, turn on the ProVee Video Processing Unit.
2.6. Check that live video is displayed, and that the orientation of the image is as expected on the display.

⚠ WARNING: Do not use if the live video is not displayed or the image is not in the expected orientation.

2.7. Attach the irrigant reservoir to the ProVee System for BPH irrigation port (luer connector).
2.8. Apply lubricant to the shaft of ProVee System for BPH.
2.9. Visually confirm that the deployment trigger is in the Stage 0 position as shown in Figure 4.

Figure 4: Deployment trigger and stage 2 release button at stage 0, 1 and 2 positions

2.10. Commence the irrigant flow and insert the ProVee System for BPH into the penile urethra.

⚠ WARNING: Do no start the procedure if there is no irrigation flow from the distal tip of the ProVee System for BPH.

3. Pre-deployment Positioning of the Expander

3.1. Advance the ProVee System for BPH into the prostatic urethra, using the steering lever to deflect the delivery sheath as needed. Moving the steering lever downward will deflect the distal tip anteriorly and moving the steering lever upward will deflect the distal tip posteriorly.
Note: the steering lever has a ratchet control and should be pushed towards the handle before moving the lever up or down. The ratchet allows the deflected position to lock in place once moved.

3.2. Advance the ProVee System for BPH until the bladder neck is visualised.

3.3. Confirm absence or presence of an intravesical median lobe. The ProVee System for BPH should not be used in patients with an obstructing prostatic median lobe.

3.4. With the system positioned at a point in the prostatic urethra within the obstructing lateral lobes, press the deployment trigger until it is not possible to press it any further (See Figure 4 & Figure 5). The Expander will come into the field of view as shown in Figure 5c.

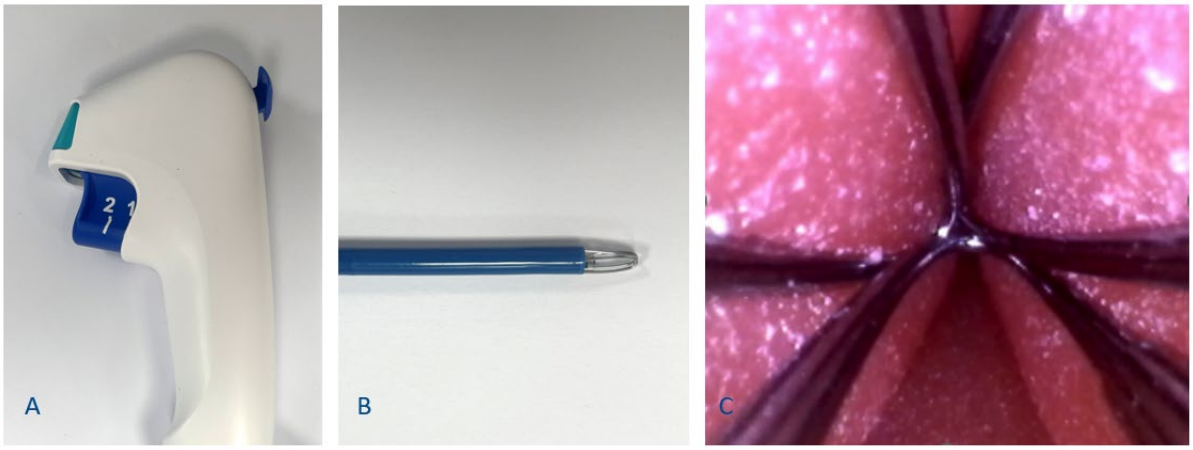

Figure 5: (A) Deployment trigger at the end of Stage 1 travel (B) partially deployed expander implant at the end of Stage 1 travel (C) view from the delivery sheath at the end of Stage 1 travel

3.5. Orientate the 3 visible apices such that they are in the 10 o'clock, 2 o'clock and 6 o'clock positions relative to the lateral lobes within the prostatic urethra.

3.6. If the verumontanum is in view, align the Expander with the verumontanum such that it is positioned at the 6 o'clock apex.

3.7. If the verumontanum is not in view, position the system until the verumontanum is observed, align the Expander with the verumontanum such that it is positioned within the 6 o'clock apex.

3.8. Position the Expander in a suitable deployment location such that it is at a point within the prostatic urethra at the obstructing lateral lobes, with tissue prolapsing around it.

⚠ WARNING: The Expander must be positioned a **minimum** of 1.5cm from the anterior bladder neck, such that it does not disrupt the bladder neck. Depending on patient anatomy the Expander may be positioned more proximally. For example, in a longer prostate, deployment of the Expander 2cm from the bladder neck may be clinically more appropriate.

⚠ WARNING: Do not reset the trigger after it has been moved to Stage 1.

The 1cm graduations on the delivery system may be used as an aid for determining deployment position as required.

4. Expander deployment

4.1. Check Expander positioning relative to the anatomy and confirm the position for deployment.

4.2. Press the Stage 2 Release button until it is not possible to press it any further as shown in Figure 6.

4.3. Press the deployment trigger until it is not possible to press it any further as shown in Figure 6. The Expander will release from the delivery system.

Figure 6: Deployment Trigger and Stage 2 release button at the end of stage 2 travel

When pressing the deployment trigger do **not** move the ProVee System for BPH within the prostatic urethra i.e. maintain the position of the ProVee System for BPH. . Failure to maintain the position of the ProVee System for BPH during the depression of the Deployment Trigger can result in deployment of the Expander in an unintended position.

⚠ WARNING: Do not reset the trigger after it has been moved to Stage 2

4.4. Ensure the tip of the delivery sheath is in a neutral position (not deflected) within the Expander and withdraw the delivery system to confirm placement of the Expander in relation to anatomical features.

⚠ WARNING: If the tip of the delivery sheath is deflected when being removed from the urethra, it may catch on a peak of the Expander and affect its position within the anatomy.

4.5. Remove Delivery System from the prostatic urethra in one movement.

5. Removing a ProVee Expander

In the event removal of a ProVee Expander is deemed clinically necessary the Expander can be removed bythe grasper removal method as described below:

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

Summary of Clinical Study Results

ProVIDE Study

The ProVIDE study is a prospective, multicenter, 2:1 randomized (ProVee to Sham), double-blind, sham-controlled study to evaluate the safety and effectiveness of the ProVee Urethral Expander System (ProVee) for the treatment of symptomatic BPH. The ProVIDE study evaluated the ProVee Urethral Expander System which has the same intended use, intended patient population, implant delivery method and implant as the ProVee System for BPH but utilized an earlier version of the delivery system.

Eligible participants were men ≥ 45 years of age with International Prostate Symptom Score (IPSS) ≥ 13, prostate volume 30-80 cc, prostatic urethral length ≥ 3.75 cm, and maximum urinary flow rate (Qmax) < 12 mL/s with voided volume >125 mL. Subjects were excluded if they had obstructive median lobe, high bladder neck with absence of lateral lobes indicating primary bladder neck obstruction, acute urinary retention, postvoid residual (PVR) urine volume > 250 mL, active urinary tract infection, baseline prostate specific antigen (PSA) > 10 ng/mL, or confounding bladder or urinary tract pathology that could impact urinary function.

Subjects randomized to ProVee were treated with the investigational device. The implant was deployed under direct vision using a ureteroscope inserted into the central lumen of the ProVee delivery system. The sham procedure utilized the same ureteroscope inserted into a urethral access sheath to mimic the ProVee delivery system without implant deployment. After completion of 3-month assessments, subjects were unblinded and the patients who received the Sham were given the option for treatment with ProVee. Follow-up for subjects treated with ProVee included clinical assessments at 1 month, 3 months, 6 months and 12 months. Follow-up is planned through 5 years post-procedure.

Co-primary effectiveness endpoints were a comparison of the mean improvement in IPSS between ProVee and Sham at 3 months and the mean percent improvement from baseline in IPSS for the ProVee arm at 12 months. Primary safety endpoints were the rate of device or procedure related serious adverse events through 12 months and the rate of extended postoperative urinary catheterization (>7 days from treatment) for inability to void.

Outcomes were analyzed in the intent to treat (ITT) population and adverse events were adjudicated by an independent clinical events committee.

The following data summarize the ProVIDE results through 1 year.

Demographic and Baseline Characteristics

The study enrolled 221 men (randomized 150 ProVee and 71 sham) at 15 centers in the United States, 1 in Canada and 1 in Ireland. The average age of subjects was 64.1 years. The average IPSS at baseline was 24.2 and the average Qmax was 8.8 mL/s.

Table 1 Study Demographics

Characteristic	ProVee (N=150)	Sham (N=71)	Cross Over (N=64)
Age (years)	64.0 ± 8.7 (150)	64.5 ± 8.2 (71)	64.3 ± 7.8 (64)
Race			
American Indian or Alaska Native	0.0% (0/150)	0.0% (0/71)	0.0% (0/64)
Asian	1.3% (2/150)	0.0% (0/71)	0.0% (0/64)
Black or African American	5.3% (8/150)	1.4% (1/71)	1.6% (1/64)
Hawaiian or Pacific Islander	0.0% (0/150)	0.0% (0/71)	0.0% (0/64)
White	91.3% (137/150)	95.8% (68/71)	95.3% (61/64)
Multi-Racial	0.7% (1/150)	0.0% (0/71)	0.0% (0/64)
Other	1.3% (2/150)	1.4% (1/71)	1.6 (1/64)
Not Permitted	0.0% (0/150)	1.4% (1/71)	1.6% (1/64)
Ethnicity			
Hispanic or Latino	12.7% (19/150)	8.5% (6/71)	9.4% (6/64)
Not Hispanic or Latino	85.3% (128/150)	88.7% (63/71)	87.5% (56/64)
Not Permitted	2.0% (3/150)	2.8% (2/71)	3.1% (2/64)
Body Mass Index (kg/m^2)	28.1 ± 4.4 (150)	28.5 ± 5.8 (71)	28.1 ± 4.7 (64)
Mean ± SD (number of subjects) or percentage of subjects (proportion of subjects) shown.			

Table 2 Baseline Characteristics

Characteristic	ProVee (N=150)	Sham (N=71)	Cross-Over (N=64)
Prostate Volume (mL)	47.1 ± 14.0 (150)	49.5 ± 12.9 (71)	50.6 ± 12.9 (64)
Prostatic Urethral Length (cm)	4. 9± 0.6 (150)	4.9 ± 0.6 (71)	4.9 ± 0.6 (64)
IPSS Score	24.6 ± 5.0 (150)	23.4 ± 5.4 (71)	23.5 ± 5.3 (64)
IPSS V/S Score	1.5 ± 0.5 (150)	1.5 ± 0.5 (71)	1.4 ± 0.4 (64)
Qmax (mL/s)	8.8 ± 2.0 (150)	8.8 ± 2.2 (71)	8.9 ± 2.2 (64)
Post Void Residual (mL)	57.3 ± 59.4 (150)	59.3 ± 55.4 (71)	61.5 ± 57.1 (64)
PSA (ng/mL)	2.3 ± 1.8 (150)	2.6 ± 2.1 (71)	2.8 ± 2.2 (64)
Mean ± SD (number of subjects) shown. Abbreviations: IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; Qmax, maximum urinary flow rate; V/S, void/storage.			

Figure 7 provides a subject accountability flow chart showing subject disposition through 12-months.

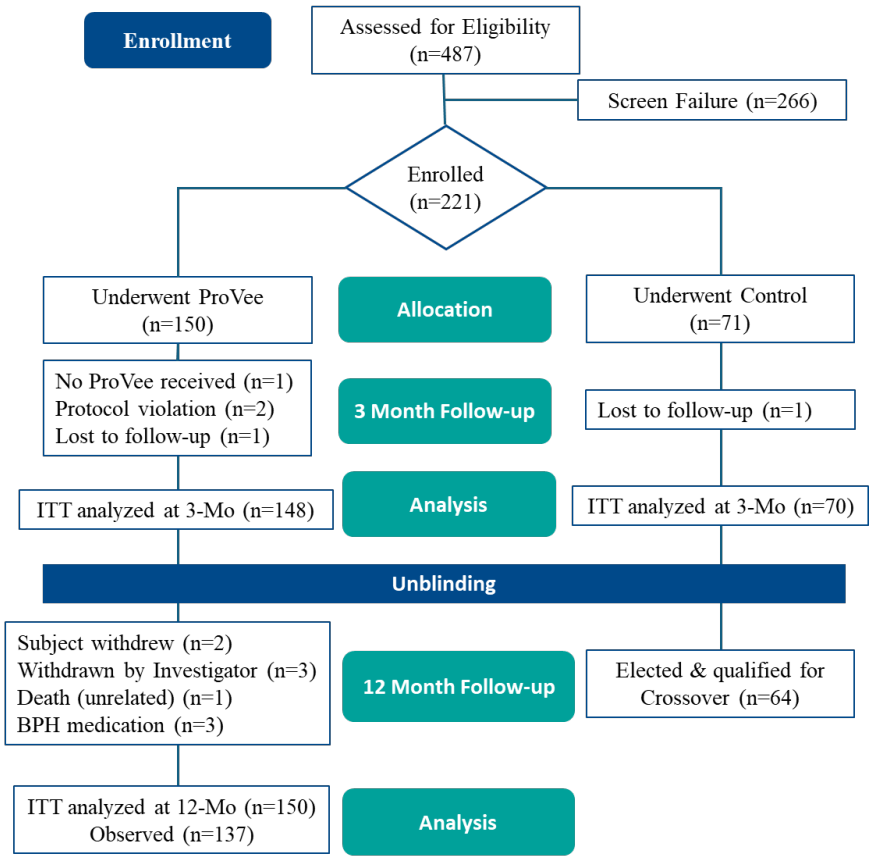

Figure 7: Subject disposition through 12-months.

Summary of Efficacy Results

Primary Efficacy Endpoints – Change in IPSS at 3 Months and 12 Months

The first co-primary efficacy endpoint was a comparison of the mean change in IPSS from baseline between the ProVee and Sham arms at 3 months. The study required a minimum statistical margin of 25% over Sham treatment alone to be considered a success. The ITT cohort included 218 subjects (148 ProVee, 70 sham) and no imputation was required for missing data as >95% (218/221) of randomized subjects were evaluable for this endpoint. At 3 months, the mean change in IPSS from baseline was -9.5 in the ProVee arm and -4.5 in the Sham arm. The mean change in IPSS in the Sham arm was -5.6 when incorporating the 25% super superiority margin. At 3 months, the mean improvement in the ProVee arm was more than 25% greater than the mean improvement in the Sham arm (-9.5 vs -5.6; p=0.001).

Table 3 Primary Efficacy Endpoint – Change in IPSS at 3 Months

Change in IPSS at 3 Months	ProVee (N=148)	Sham (N=70)	Difference [95% CI]	P-value
ITT	-9.5 ± 8.5	-4.5 ± 7.0	-5.0 [-7.3, -2.7]	0.001
P-value is obtained from a two-sample t-test (H_0: μProVee ≥ 1.25 x μSham versus H_1: μProVee < 1.25 x μSham). Abbreviations: CI, confidence interval; IPSS, International Prostate Symptom Score; ITT, intent to treat.				

The second co-primary efficacy endpoint was the mean percent change in IPSS from baseline to 12 months in the ProVee arm and required a minimum of 30% improvement to be considered a success. As the percentage of evaluable subjects at 12 months was <95% (137/150), missing data was imputed utilizing the Conditional Value Carried Forward approach. Subjects randomized to ProVee showed a mean IPSS improvement of >30% over baseline (p=0.002).

Table 4 Primary Efficacy Endpoint – Change in IPSS at 12 Months

Change in IPSS at 12 Months	ProVee (N=150)	P-value
Mean % Change in IPSS ± SD Median % Change in IPSS 95% CI	-38.3 (33.6) -41.8 [-43.7, -32.8]	0.002*
P-value is obtained from a one sample t-test (H_0: μProVee ≥ -30% versus H_1: μProVee < -30%). Abbreviations: CI, confidence interval; IPSS, International Prostate Symptom Score; ITT, intent to treat.		

Both study primary efficacy endpoints were met. Treatment with ProVee was super superior to Sham (>125%) and provided symptomatic improvement through 12 months (>30% over baseline).

Secondary Efficacy Endpoints – Symptomatic Improvement

Secondary efficacy endpoints included measures of symptomatic improvement including percent change in IPSS, IPSS responder rate, and change in quality of life (QoL). The IPSS responder rate is the percentage of subjects with ≥30% improvement in IPSS from baseline.

Table 5 Total IPSS

Total IPSS	Baseline	1 Month	3 Months	6 Months	12 Months
ProVee n Mean (SD) Mean Improvement from Baseline (SD) % Improvement from Baseline	 150 24.6 (5.0)	 150 15.2 (8.1) 9.3 (8.5) 36.9%	 148 15.1(8.3) 9.5 (8.5) 37.7%	 142 13.6 (7.8) 11.0 (8.4) 43.6%	 137 14.4 (8.0) 10.1 (8.4) 40.2%
Sham n Mean (SD) Mean Improvement from Baseline (SD) % Improvement from Baseline	 70 23.5 (5.4)	 70 17.5 (7.6) 6.0 (8.4) 22.5%	 70 19.0 (7.5) 4.5 (7.0) 18.0%	 — —	 — —

Table 6 IPSS Responder Rate

IPSS Responder Rate	1 Month	3 Months	6 Months	12 Months
ProVee n IPSS Responder Rate	 150 57%	 150 58%	 150 67%	 150 61%
Sham n IPSS Responder Rate	 71 41%	 71 30%	 —	 —
Crossover n IPSS Responder Rate	 64 56.3%	 64 64.1%	 63 54%	 50 34%

Table 7 IPSS QoL

IPSS QoL	Baseline	1 Month	3 Months	6 Months	12 Months
ProVee n Mean (SD) Mean Improvement from Baseline (SD)	 150 4.6 (1.1)	 150 3.2 (1.6) 1.4 (1.7)	 148 3.1 (1.7) 1.5 (1.9)	 142 2.6 (1.6) 2.0 (1.7)	 137 2.6 (1.7) 2.0 (1.7)
Sham n Mean (SD) Mean Improvement from Baseline (SD)	 71 4.5 (1.2)	 70 3.6 (1.4) 1.0 (1.4)	 70 3.8 (1.6) 0.8 (1.4)	 —	 —

Secondary Efficacy Endpoints – Functional Improvement

Secondary efficacy endpoints included measures of functional improvement assessed by uroflowmetry including Qmax and PVR.

Table 8 Qmax

Qmax (mL/s)	Baseline	1 Month	3 Months	6 Months	12 Months
ProVee n Mean (SD) Mean Improvement from Baseline (SD) % Improvement from Baseline	 150 8.8 (2.0)	 149 14.7 (6.9) 5.9 (6.9) 77.9 (107.2)	 148 14.6 (6.6) 5.8 (6.6) 77.7 (116.9)	 137 14.9 (7.0) 6.0 (6.9) 78.9 (103.8)	 136 14.2 (6.8) 5.4 (6.7) 71.3 (98.9)
Sham n Mean (SD) Mean Improvement from Baseline (SD) % Improvement from Baseline	 71 8.8 (2.2)	 70 11.6 (5.1) 2.9 (5.1) 42.3 (89.3)	 70 12.4 (5.5) 3.6 (5.1) 46.6 (68.4)	 —	 —

Table 9: PVR

PVR (mL)	Baseline	1 Month	3 Months	6 Months	12 Months
ProVee n Mean (SD) Mean Improvement from Baseline (SD)	150 57.3 (59.4)	148 40.9 (52.6) 17.0 (53.4)	147 44.2 (68.9) 13.9 (68.3)	137 50.4 (65.1) 8.3 (64.1)	135 46.1 (57.3) 10.0 (54.1)
Sham n Mean (SD) Mean Improvement from Baseline (SD)	71 59.3 (55.4)	70 55.6 (72.9) 4.0 (56.6)	70 57.0 (67.1) 2.5 (62.4)	—	—

Secondary Efficacy Endpoint – Rate of Re-intervention

Five subjects in the ProVee arm were prescribed pharmacological agents for BPH prior to the 12-month visit. There were no incidences of secondary reintervention using alternative surgical LUTS therapy prior to the 12-month visit.

Summary of Safety Results

Primary Safety Endpoint – Rate of Device/Procedure Related Serious Adverse Events at 12 Months

No subject in either treatment arm experienced a device or procedure related serious adverse event (SAE) through 12 months.

Primary Safety Endpoint – Rate of Postoperative Urinary Catheterization

No subject in either treatment arm required extended postoperative urinary catheterization (>7 days from treatment).

A summary of the secondary safety and efficacy endpoint data is provided below – these secondary endpoints were not supported by hypothesis testing.

Secondary Safety Endpoint – Pain Assessment Questionnaire

Pain was assessed following the index procedure using the Faces Pain Scale-Revised Questionnaire (FPS-R). The ongoing pain assessment at follow-up visits was typically somewhere between 'no pain at all' and 'barely noticeable' for both treatment arms.

Table 10 FPS-R Pain Score

FPS-R Pain Score	Baseline	Discharge	1 Month	3 Months	6 Months	12 Months
ProVee n Mean ± SD	150 1.0 ± 1.8	150 1.0 ± 1.78	150 0.9 ± 1.77	147 1.1 ± 2.0	144 0.9 ± 1.8	141 0.8 ± 1.7
Sham n Mean ± SD	70 1.0 ± 1.8	71 1.1 ± 2.0	70 0.5 ± 1.4	70 0.4 ± 1.3	—	—

Secondary Safety Endpoint – Sexual Health Questionnaires

Change in sexual health in the ProVee arm was characterized using the International Index of Erectile Function, specifically the Erectile Function domain (IIEF-5), and Male Sexual Health Questionnaire – Ejaculatory Dysfunction (MSHQ-EjD) questionnaires. Sexual function was not impacted by treatment with ProVee. There was no incidence of de novo sustained retrograde ejaculation or erectile dysfunction after treatment with ProVee.

Table 11 IIEF-5

	Baseline	3 Months	6 Months	12 Months
IIEF-5 n Mean (SD) Mean Change (SD)	 149 17.0 (6.5)	 146 17.5 (6.9) 0.5 (5.1)	 139 17.6 (6.9) 0.7 (4.7)	 132 17.3 (6.6) 0.1 (5.4)

Table 12 MSHQ-EjD

MSHQ-EjD	Baseline	3 Months	6 Months	12 Months
Ejaculatory Function n Mean (SD)	 150 8.9 (3.8)	 146 10.1 (4.2)	 139 9.9 (4.3)	 132 9.8 (3.9)
Ejaculatory Bother n Mean (SD)	 150 2.1 (1.6)	 147 1.4 (1.6)	 139 1.6 (1.7)	 132 1.6 (1.5)

Secondary Safety Endpoint – Rate of Adverse Events Classified as Clavien-Dindo Grade IIIb

The rate of adverse events classified as Clavien-Dindo Grade IIIb through 3 months was 0.5% (1/221). One subject developed squamous cell carcinoma of the tongue which was reported at day 84 post index procedure and adjudicated as unrelated to the study device or procedure.

Secondary Safety Endpoint – Rate of Device Removal Related Adverse Events

Six patients (4%) had the device removed during the 12-month follow up period. There were no reported retrieval procedure-related adverse events.

Summary of Device/Procedure Related Adverse Events

There were no device or procedure related serious adverse event (SAE) through 12 months. Device and procedure related adverse events in the ProVee arm and in the Sham arm are summarized in the table below. These events were typically mild, transient and commonly associated with urological procedures. Most related adverse events occurred within 3 months of the index procedure.

Table 13 Device Related Adverse Events by Treatment Arm and Time Period

Adverse Event	ProVee (N=150) 0-3 Months		Sham (N=71) 0-3 Months		ProVee (N=150) 3-12 Months	
	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)
Dysuria	7	7 (4.7%)	0	0 (0.0%)	0	0 (0.0%)
Haematuria	6	6 (4.0%)	0	0 (0.0%)	1	1 (0.7%)
Micturition urgency	4	4 (2.7%)	0	0 (0.0%)	0	0 (0.0%)
Urge incontinence	2	2 (1.3%)	0	0 (0.0%)	0	0 (0.0%)
Bladder spasm	2	2 (1.3%)	0	0 (0.0%)	0	0 (0.0%)
Penile pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Pollakiuria	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Nocturia	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Painful ejaculation	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Urethral pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Hematospermia	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Pelvic discomfort	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Pelvic pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Penile discomfort	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Stress urinary incontinence	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Perineal pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Total Related AEs	**32**	**17 (11.3%)**	**0**	**0 (0.0%)**	**1**	**1 (0.7%)**

Table 14 Procedure Related Adverse Events by Treatment Arm and Time Period

Adverse Event	ProVee (N=150) 0-3 Months		Sham (N=71) 0-3 Months		ProVee (N=150) 3-12 Months	
	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)
Dysuria	9	9 (6.0%)	1	1 (1.4%)	0	0 (0.0%)

Haematuria	7	7 (4.7%)	2	2 (2.8%)	0	0 (0.0%)
Urge incontinence	4	4 (2.7%)	0	0 (0.0%)	0	0 (0.0%)
Pollakiuria	4	4 (2.7%)	2	1 (1.4%)	0	0 (0.0%)
Penile pain	3	3 (3.3%)	0	0 (0.0%)	0	0 (0.0%)
Bladder spasm	3	3 (3.3%)	0	0 (0.0%)	0	0 (0.0%)
Micturition urgency	2	2 (1.3%)	0	0 (0.0%)	0	0 (0.0%)
Urinary incontinence	2	2 (1.3%)	0	0 (0.0%)	0	0 (0.0%)
Retrograde ejaculation	2	2 (1.3%)	0	0 (0.0%)	0	0 (0.0%)
Nocturia	1	1 (0.7%)	1	1 (1.4%)	0	0 (0.0%)
Painful ejaculation	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Urethral pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Penile discomfort	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Hematospermia	1	1 (0.7%)	1	1 (1.4%)	0	0 (0.0%)
Constipation	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Cystitis	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Diarrhoea	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Hypertonic bladder	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Pelvic pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Stress urinary incontinence	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Testicular pain	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Urinary tract infection	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Muscle Spasms	1	1 (0.7%)	0	0 (0.0%)	0	0 (0.0%)
Genital discomfort	0	0 (0.0%)	1	1 (1.4%)	0	0 (0.0%)
Device dislocation	0	0 (0.0%)	0	0 (0.0%)	1	1 (0.7%)
Total Related AEs	**50**	**31 (20.7%)**	**8**	**5 (7.0%)**	**1**	**1 (0.7%)**

ProVIDE Cross-Over Arm

Following unblinding 64 subjects that underwent the sham procedure elected to be treated with the ProVee device (cross-over arm). The demographic and baseline characteristics for the Cross-over subjects are provided in Tables 1 and 2.

For these cross-over subjects follow-up is planned through 5 years post-procedure. All 64 subjects were successfully treated with a ProVee device. No subject required post procedural catheterization. No subjects were lost to follow-up.

At 12-months there was a mean 33.1% improvement from baseline in IPSS see Table 15.

Table 15 Cross-Over Arm Primary Efficacy Endpoint

Change in IPSS at 12 MonthsChange in IPSS at 12 Months	ProVee crossover (N=62)
Mean % Change in IPSS ± SD Median % Change in IPSS 95% CI	-33.1 ± 36.0 -33.3 [-42.3, -24.0]
Abbreviations: CI, confidence interval; IPSS, International Prostate Symptom Score	

There were no device or procedure related serious adverse event (SAE) through 12 months. These events were typically mild, transient and commonly associated with urological procedures. Most related adverse events occurred within 3 months of the index procedure.

Table 16 Cross-Over Arm Adverse Events to 12 months

Adverse Event	Cross Over (N=64) 0-3 Months		Cross Over (N=64) 3-12 Months	
	No. Events	No. Subjects (%)	No. Events	No. Subjects (%)
Dysuria	14	7 (10.9%)	0	0 (0.0%)
Micturition urgency	14	7 (10.9%)	0	0 (0.0%)
Haematuria	12	6 (9.4%)	0	0 (0.0%)
Bladder spasm	6	3 (4.7%)	0	0 (0.0%)
Painful ejaculation	6	3 (4.7%)	0	0 (0.0%)
Urinary incontinence	4	2 (3.1%)	0	0 (0.0%)
Hematospermia	4	2 (3.1%)	0	0 (0.0%)
Stress urinary incontinence	4	2 (3.1%)	0	0 (0.0%)
Urge incontinence	2	1 (1.6%)	0	0 (0.0%)
Pollakiuria	2	1 (1.6%)	0	0 (0.0%)
Penile pain	2	1 (1.6%)	0	0 (0.0%)
Perineal pain	2	1 (1.6%)	0	0 (0.0%)
Total Related AEs	**72**	**24 (37.5%)**	**0**	**0 (0%)**

ProVIDE II Bridging Study

The ProVIDE II Bridging study is a prospective, multicenter, non-randomized bridging study to evaluate the performance of the ProVee System for BPH when deploying the ProVee implant in subjects with symptomatic urinary obstruction secondary to BPH. Eligibility criteria were the same as the ProVIDE study. Follow-up for subjects included clinical assessments at 1 month and 3 months. Follow-up is planned through 5 years post-procedure.

The primary effectiveness endpoint evaluated technical success, defined as the percentage of subjects where the implant is deployed in the location intended by the user. Primary safety endpoints were the rate of device or procedure related serious adverse events through 3 months and the rate of extended postoperative urinary catheterization (>7 days from treatment) for inability to void.

Safety and efficacy outcomes were analyzed in the ITT cohort. Adverse events were adjudicated by an independent clinical events committee.

The following data summarize the ProVIDE II Bridging study results through 3 months.

Demographic and Baseline Characteristics

The study enrolled and treated 40 men at 7 centers in the United States and one in Ireland. The average age of subjects was 64.0 years. The average IPSS at baseline was 23.5 and the average Qmax was 8.1 mL/s.

Table 17 Study Demographics

Characteristic	ProVee (N=40)
Age (years)	64.0 (8.7)
Race	
American Indian or Alaska Native	0.0% (0/40)
Asian	0.0% (0/40)
Black or African American	2.5% (1/40)
Hawaiian or Pacific Islander	0.0% (0/40)
White	95.0% (38/40)
Multi-Racial	0.0% (0/40)
Other	2.5% (1/40)
Not Permitted	0.0% (0/40)
Ethnicity	
Hispanic or Latino	12.5% (5/40)
Not Hispanic or Latino	85.0% (34/40)
Not Permitted	2.5% (1/40)
Body Mass Index (kg/m^2)	28.3 (3.9)
Mean (SD) or percentage of subjects (proportion of subjects) shown.	

Table 18 Baseline Characteristics

Characteristic	ProVee (N=40)
Prostate Volume (mL)	47.8 (13.6)
Prostatic Urethral Length (cm)	4.8 (0.6)
IPSS Score	23.5 (5.4)
IPSS V/S Score	1.5 (0.3)
Qmax (mL/s)	8.1 (2.4)
Post Void Residual (mL)	72.7 (56.8)
PSA (ng/mL)	2.9 (2.0)
Mean (SD) shown. Abbreviations: IPSS, International Prostate Symptom Score; PSA, prostate specific antigen; Qmax, maximum urinary flow rate; V/S, void/storage.	

Figure 8 is a subject accountability flow chart showing subject disposition through 3-months.

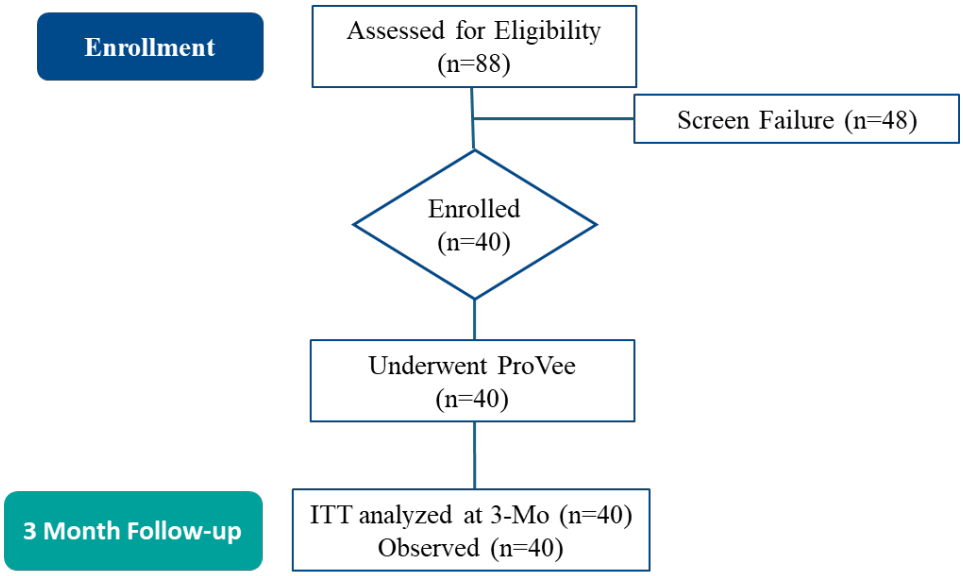

Figure 8: Subject disposition through 3-months

Summary of Efficacy Results

Primary Efficacy Endpoint – Technical Success

The primary efficacy endpoint was the rate of technical success defined as the percentage of subjects where the expander was deployed in the location intended by the user. A rate >95% was required for study success. This endpoint was evaluated in the ITT cohort of 40 subjects treated with ProVee. The primary efficacy endpoint was met with a technical success rate of 100%.

Table 19 Primary Efficacy Endpoint – Technical Success

	ProVee (N=40)
Rate of technical success	100.0% (40/40)

Secondary Efficacy Endpoints – Symptomatic Improvement

Secondary efficacy endpoints included measures of symptomatic improvement including percent change from baseline in IPSS, IPSS responder rate, and change in QoL. The IPSS responder rate is the percentage of subjects with ≥30% improvement in IPSS from baseline.

Table 20 IPSS Responder Rate, Total IPSS and IPSS QoL

	Baseline	1 Month	3 Months
Total IPSS n Mean (SD) Mean Improvement from Baseline (SD) % Improvement from Baseline (SD)	 40 23.5 (5.4)	 40 12.6 (6.6) 10.9 (8.3) 43.8 (36.2)	 40 12.3 (6.0) 11.2 (7.5) 45.7 (27.9)
IPSS Responder Rate n IPSS Responder Rate	 —	 —	 40 65%
IPSS QoL n Mean (SD) Mean Improvement from Baseline (SD)	 40 4.6 (1.0)	 40 2.4 (1.5) 2.2 (1.6)	 40 2.5 (1.7) 2.1 (1.6)

A summary of the secondary safety and efficacy endpoint data is provided below – these secondary endpoints were not supported by hypothesis testing.

Secondary Efficacy Endpoints – Functional Improvement

Secondary efficacy endpoints included measures of functional improvement assessed by uroflowmetry including Qmax and PVR.

Table 21 Qmax and PVR

	Baseline	1 Month	3 Months
Qmax (mL/s) n Mean (SD) Mean Improvement from Baseline (SD) % Improvement from Baseline	 40 8.1 (2.4)	 39 14.5 (5.3) 6.3 (4.7) 83.3 (64.5)	 38 15.3 (6.0) 7.1 (5.9) 102.5 (100.6)
PVR (mL) n Mean (SD) Mean Improvement from Baseline (SD)	 40 72.7 (56.8)	 39 43.3 (59.0) 27.6 (62.3)	 37 45.7 (45.5) 26.6 (61.5)

Secondary Efficacy Endpoint – Rate of Re-intervention

There was no incidence of secondary intervention through 3-months using alternate surgical therapy or pharmacological agents for BPH.

Summary of Safety Results

Primary Safety Endpoint – Rate of Device/Procedure Related Serious Adverse Events at 3 Months

No subject experienced a device or procedure related serious adverse events through 3 months.

Primary Safety Endpoint – Rate of Postoperative Urinary Catheterization

No subject required extended postoperative urinary catheterization (>7 days from treatment).

Secondary Safety Endpoint – Rate of Device/Procedure Related Adverse Events

The rate of device/procedure related adverse events was 12.5% (5/40). These events were typically mild, transient and commonly associated with urological procedures.

Table 22 Device/Procedure Related Adverse Events

Adverse Event	ProVee (N=40)	
	No. Events	No. Subjects (%)
Micturition urgency	1	1 (2.5%)
Pollakiuria	1	1 (2.5%)
Haematuria	2	2 (5%)
Nocturia	1	1 (2.5%)
Urinary tract infection	2	2 (5%)
Total Related AEs	**7**	**5 (12.5%)**

Secondary Safety Endpoint – Pain Assessment Questionnaire

Pain was assessed following the index procedure using the FPS-R questionnaire. The ongoing pain assessment at follow-up visits was typically somewhere between 'no pain at all' and 'barely noticeable'.

Table 23 FPS-R Pain Score

	Discharge	1 Month	3 Months
FPS-R Pain Score n Mean (SD)	 40 2.5 (2.1)	 40 0.4 (0.8)	 40 0.6 (1.2)

Secondary Safety Endpoint – Sexual Health Questionnaires

Sexual health was characterized using the IIEF-5 and MSHQ-EjD questionnaires. Sexual function was not impacted by treatment with ProVee, with measures showing mild improvements in erectile and ejaculatory function. There was no incidence of de novo sustained retrograde ejaculation or erectile dysfunction after treatment with ProVee.

Table 24 Sexual Health Questionnaires

	Baseline	3 Months
IIEF-5 n Mean (SD)	 40 16.2 (6.3)	 40 17.5 (6.3)
MSHQ-EjD Ejaculatory Function n Mean (SD)	 40 8.7 (4.1)	 40 9.8 (4.1)
MSHQ-EjD Ejaculatory Bother n Mean (SD)	 40 2.2 (1.6)	 40 1.5 (1.6)

Secondary Safety Endpoint – Rate of Adverse Events Classified as Clavien-Dindo Grade IIIb

No subject experienced an adverse event classified as Clavien-Dindo Grade IIIb or higher through 3 months.

Secondary Safety Endpoint – Rate of Device Removal Related Adverse Events

There were no device removals in the bridging study, and accordingly, there were no reported retrieval procedure-related adverse events.

Summary of Device/Procedure Related Adverse Events

There were no device or procedure related serious adverse events through 3 months. The rate of device/procedure related adverse events was 12.5% (5/40). These events were typically mild, transient and commonly associated with urological procedures.

Table 25 Device Related Adverse Events

Adverse Event	ProVee (N=40)	
	No. Events	No. Subjects (%)
Haematuria	1	1 (2.5%)
Total Related AEs	**1**	**1 (2.5%)**

Table 26 Procedure Related Adverse Events

Adverse Event	ProVee (N=40)	
	No. Events	No. Subjects (%)
Urinary tract infection	2	2 (5.0%)
Micturition urgency	1	1 (2.5%)
Pollakiuria	1	1 (2.5%)
Haematuria	1	1 (2.5%)

Nocturia	1	1 (2.5%)
Total Related AEs	**6**	**4 (10.0%)**

Supplemental Clinical Study

PROVE was a prospective, non-randomized, open label, single center study to evaluate the safety and feasibility of the ProVee Urethral Expander System for the treatment of LUTS secondary to BPH. Eligible subjects were males ≥ 50 years of age with LUTS secondary to BPH, IPSS > 15, Qmax <12 mL/s and prostate volume 30-80 cc. No washout for medications was mandated. Follow up visits were performed at 2 weeks, 1, 3, 6, 12 and 24 months using the IPSS, Qmax, PVR, IIEF, pain score and flexible cystoscopy at 3, 6 and 12 months.

A total of 10 subjects were enrolled and treated at The Royal Melbourne Hospital, Melbourne, Australia. The age range was 58 – 75 with a mean IPSS of 23 and mean Qmax of 8 ml/s. The primary endpoint of the study was the successful deployment of the ProVee implant. Secondary endpoints included: the rate of device or procedure related complications throughout the follow-up period; the change from baseline in IPSS and Qmax throughout the follow up period.

The primary endpoint was successfully met, with all subjects having a ProVee device deployed in the intended location. Following the deployment procedure, all subjects voided and no subject required post procedural catheterization. No subjects were lost to follow-up and there were no device or procedure related SAEs in any subject throughout the 24-month study period. At 24-months, there was a 40% improvement from baseline in Qmax and men not on LUTS medication prior to the procedure showed an average improvement from baseline in IPSS of 37%. There were no surgical re-treatments through 24-months.

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.

Note: The safety of the delivery system has not been evaluated in the MR environment, and therefore, the delivery system should not be used within the MR environment.

Patient implant cards are provided to inform the patient that the Expander is MR Conditional and can safely be scanned only under specific MR conditions.

Storage:
Keep dry, keep away from sunlight and do not use if the package is damaged.

Maintenance and Service
The ProVee System for BPH is a single-use device and does not contain any serviceable parts.

Disposal of the Product, Accessories and Packaging materials:
Dispose of all products and packaging materials in accordance with hospital, administrative and/or local government policy.

Trademarks:
ProVee is a registered trademark of ProVerum Ltd.

Disclaimer:
The exclusions and limitations set out below are not intended to and should not be construed so as to contravene any mandatory provisions of applicable law. If any part or term of this disclaimer is held by a court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portions of this disclaimer shall not be affected, and all rights and obligations shall be construed and enforced as if this disclaimer did not contain the particular part or term held to be invalid.

Warranty / Liability:
The product and each component of its system have been designed, manufactured, tested and packaged with all reasonable care. The warnings contained in the ProVee System for BPH Instructions for Use are expressly considered as an integral part of this provision. ProVerum warranties the product until the expiration date indicated on the same. The warranty is valid provided that the use of the product was consistent with the Instructions for Use. ProVerum disclaims any warranty of merchantability or fitness for a particular purpose of the product. ProVerum is not liable for a particular purpose of the product. Except in the case of fraud or grave fault on ProVerum part, compensation of any damage to the buyer will not, in any event, be greater than the invoice price of the disputed products. The guarantee contained in this provision incorporates and substitutes the legal guarantees for defects and compliance, and excludes any other possible liability of ProVerum, however originating, from its product supplied. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable. If any clause of the disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects ProVerum legitimate interest in limiting its liability or warranty. No person has any authority to bind ProVerum to any warranty or liability regarding the product.

Graphic Symbols Contained in Device Labelling

REF	Catalogue Number	LOT	Batch Code
QTY	Quantity		Use-by date
	Legal Manufacturer	Rx only	Prescription Use Only
MD	Medical device		Type BF Applied Part
	Refer to instruction manual		Caution
	Consult instructions for use		Do Not Re-use
	Keep Away from Sunlight	MR	MR Conditional
	Do Not Use If Package Is Damaged		Keep Dry
STERILE EO	Sterilized using Ethylene Oxide		Do Not Re sterilize
	Single Sterile Barrer System	UDI	Unique Device Identification
	Non-pyrogenic		Humidity limitation
	Temperature limit		

Legal Manufacturer
ProVerum Ltd.
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Astor Hall
4-8 Eden Quay
Dublin 1
Ireland
D01 N5W8
Made in Ireland

Appendix 1. Electromagnetic Compatibility

Like other electrical medical equipment, the system (ProVee System for BPH when used in conjunction with the ProVee Video Processing Unit) requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC) the system must be installed and operated according to the EMC information provided in this instructions for use and the ProVee Video Processing Unit instruction manual.

The ProVee System for BPH provides live imaging of the urinary tract when used in conjunction with the ProVee Video Processing Unit. If the live imaging is lost or degraded due to EM disturbances this may result in a loss of the live image (black screen/flickering) or poor image quality. If this occurs, stop and wait for the live image to recover. If the issue persists refer to the troubleshooting section in the ProVee Video Processing Unit instruction manual.

The system has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Guidance and manufacturer's declaration – electromagnetic Immunity			
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 test level**	**Compliance level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 2, 4, 6, 8 kV contact +/- 2, 4, 8, 15 kV air	+/- 2, 4, 6, 8 kV contact +/- 2, 4, 8, 15 kV air	If floors are covered with synthetic material the relative humidity shall be least 30 %.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV for power supply lines Not applicable	Mains power quality shall be that of a typical hospital environment.
Surge IEC 61000-4-5	+/- 2 kV lines(s) to earth +/- 1 kV lines(s) to line(s)	+/- 2 kV lines(s) to earth +/- 1 kV lines(s) to line(s)	Mains power quality shall be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variation on power supply lines IEC 61000-4-11	0% UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0° 0% UT for 250/300 cycles	0% UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0° 0% UT for 250/300 cycles	Mains power quality shall be that of a typical hospital environment. If the system requires continued operation during power mains interruptions, it is recommended that an uninterruptible power supply is used.
	Note - UT is the AC Mains voltage prior to application of the test level		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Proximity magnetic fields IEC 61000-4-39	134.2 kHz at 65 A/m 13.56 MHz at 7.5 A/m	65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz	Proximity magnetic fields s should be at levels characteristic of a typical location in a typical hospital environment.

Guidance and manufacturer's declaration – electromagnetic Immunity			
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 test level**	**Compliance level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz 6 Vrms in ISM bands from 150 kHz to 80 MHz	3 Vrms from 150 kHz to 80 MHz 6 Vrms in ISM bands from 150 kHz to 80 MHz	The ISM bands between 0.15 MHz and 80 MHz are: 6.765 MHz to 6.795 MHz 13.553 MHz to 13.567 MHz 26.957 MHz to 27.283 MHz 40.66 MHz to 40.70 MHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. These guidelines may not apply in all situations. electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	3 V/m from 80MHz to 2.7 GHz	3 V/m from 80MHz to 2.7 GHz	
Proximity Fields from RF wireless communications equipment. IEC 61000-4-3	380 - 390 MHz: 27 V/m 430 - 470 MHz: 28 V/m 704 - 787 MHz: 9 V/m 800 - 960 MHz: 28 V/m 1700 - 1990 MHz: 28 V/m 2400 - 2570 MHz: 28 V/m 5100 - 5800 MHz: 9 V/m	380 - 390 MHz: 27 V/m 430 - 470 MHz: 28 V/m 704 - 787 MHz: 9 V/m 800 - 960 MHz: 28 V/m 1700 - 1990 MHz: 28 V/m 2400 - 2570 MHz: 28 V/m 5100 - 5800 MHz: 9 V/m	

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 2: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

Guidance and manufacturer's declaration – electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The ProVee System for BPH when used in conjunction with the ProVee Video Processing Unit uses radio frequency (RF) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ProVee System for BPH when used in conjunction with the ProVee Video Processing Unit is suitable for in a hospital environment. The system should not be used in a domestic environment or connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes. If the system is used in a domestic establishment or connected directly to a public low-voltage power supply network that supplies buildings for domestic purposes, it may not offer adequate protection to the radio-frequency communication service.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	