

# *How I Do It: Optilume BPH catheter system*

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*Benign prostatic hyperplasia (BPH) is a common and progressive disease affecting aging men which has a significant impact on quality of life. The Optilume BPH Catheter System (Optilume BPH) is a prostatic dilation system that combines balloon dilation with a*

*localized transfer of paclitaxel to maintain long term patency. Optilume BPH can be deployed using standard rigid cystoscopy without general anesthesia in an office setting. Prospective data indicate that Optilume BPH has favorable functional and sexual patient outcomes. Readers will familiarize themselves with Optilume BPH, significant historical studies and the technique for deploying Optilume BPH.*

**Key Words:** BPH, prostate, MIST, Optilume

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## Introduction

### *Overview of procedure/technology*

Benign prostatic hyperplasia (BPH) is a common and progressive disease affecting aging men.<sup>1</sup> BPH management involves a stepwise approach of lifestyle alteration, medical therapy and surgery, Figure 1. When lifestyle alteration fails, medical and surgical

therapy are frequently complicated by unwanted functional and sexual side effects such as erectile dysfunction (ED), decreased libido, and ejaculatory problems.<sup>2,3</sup> Sexual health surveys indicate that maintenance of sexual function is significantly prioritized by BPH patients, with postoperative ejaculatory function and erections important to 92% and 95% of men respectively regardless of age.<sup>4</sup> To address these shortcomings, innovative minimally invasive surgical therapies (MIST) for the treatment of BPH have been developed. These technologies target rapid recovery and symptom relief, low complication rates, sexual preservation, and the ability to perform the procedure in an outpatient setting with sedation and local anesthesia.<sup>5</sup> MISTs represent an efficient and

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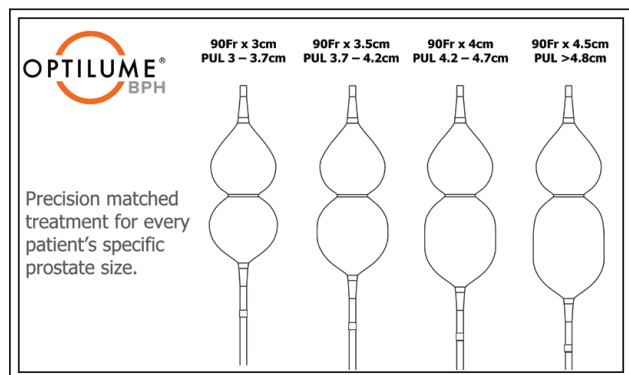
Less Invasive	Minimally Invasive	Invasive
BPH Drugs	Drug / Device <b>Optilume® BPH</b>	UroLift® Rezūm® TURP Lasers AquaBlation

**Figure 1.** Continuum of treatment options for men with BPH.

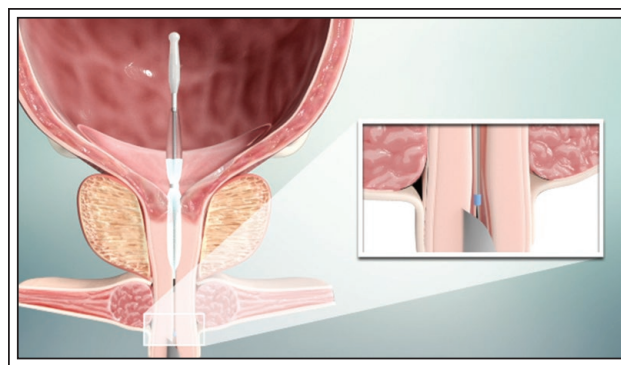
cost-effective bridge between medical therapy and surgical therapy and may decrease operating room burden and healthcare costs, while improving patient satisfaction.<sup>5</sup>

The Optilume BPH Catheter System (Urotronic, Inc., Minneapolis, MN, USA) is a novel MIST that combines mechanical dilation with the delivery of paclitaxel for the treatment of lower urinary tract symptoms (LUTS) secondary to BPH. Mechanical dilation with Optilume BPH achieves an anterior commissurotomy separating the lateral lobes of the prostate, while delivery of paclitaxel to the prostate adenoma is intended to maintain luminal patency during healing.<sup>6</sup> It is the first BPH MIST to offer combination (drug/device) therapy. While there is no theoretical upper limit in size, the device has been studied in prostate glands between 30 cc-80 cc. Efficacy in 100+cc prostates would be an area for future research. Regarding bladder neck contractures (BNC), the BPH product would not be the best choice for BNC unless one wanted to treat concurrently with BPH. The Optilume DCB for strictures device can be used for isolated BNC.

Prior to the procedure a transrectal ultrasound should be taken to determine prostate length. The Optilume BPH catheter system comes in four specific lengths that are precision matched to every prostate, Figure 2.



**Figure 2.** The Optilume BPH DCB is precision matched to prostate size based on TRUS measurements.



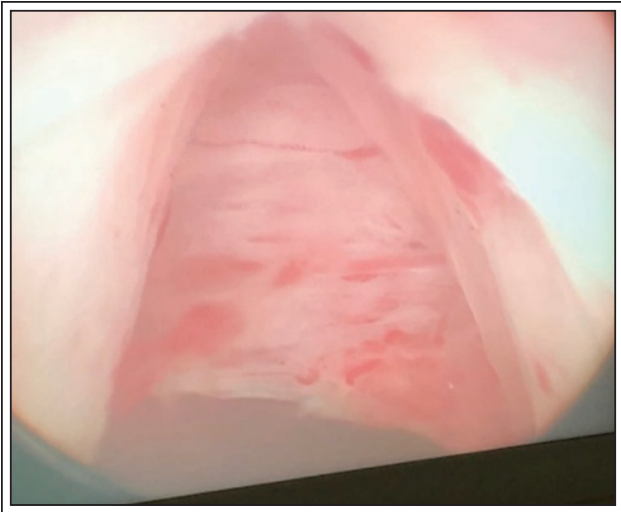
**Figure 3.** Positioning the Optilume BPH System utilizes a blue mark on the catheter shaft that is maintained in position distal to the external sphincter.

Under direct visualization with a rigid cystoscope and sedation, a pre-dilation balloon catheter is positioned within the prostate and placed so that the blue marker on the catheter shaft is just outside of the external sphincter, see Figure 3. A rigid cystoscope is required for insertion of the device. Some users have utilized a flexible cystoscope for the side-to-side positioning component, while most use a rigid cystoscope for that maneuver as well.

Maintain visualization of this blue marker during catheter inflation and leave the pre-dilation balloon inflated for a short period of time (1 minute) and then removed. This first dilation causes the prostate to separate at 12 o'clock, creating an anterior commissurotomy. Next, a drug-coated balloon repeats the same steps and delivers paclitaxel to the prostatic urethral surface, specifically the area anteriorly, while fully propagating the anterior commissurotomy. The unique shape of the balloon maintains positioning during inflation and provides for direct application of dilation force to the prostatic adenoma. The locally delivered paclitaxel interferes with the normal function of microtubules during cell migration and division, therefore blunting the injury response process and limiting the fibrosis and regrowth/fusion of the lateral lobes during healing. This results in maintaining long term urethral patency.<sup>6</sup> A Foley catheter is placed post-procedurally.

### Significant historical studies

Transurethral balloon dilation of the prostate has been historically used as a minimally invasive therapy for management of BPH. Clinical studies conducted in the early 1990s showed that balloon dilation was safe and effective initially, however long term durability was insufficient. Donatucci et



**Figure 4.** Anterior commissurotomy in prostate created by Optilume BPH system.

al conducted a randomized study comparing balloon dilation to transurethral resection of the prostate (TURP) showing similar initial improvement between therapies at 3 months post treatment, but reduced benefit through 1 year follow up in the balloon dilation group, particularly with regards to peak urinary flow rate.<sup>7</sup> Various mechanisms for symptom improvement after balloon dilation have been proposed, including compression of the prostatic adenoma, stretching of the prostatic capsule potentially disrupting  $\alpha$  1-adrenergic neuroreceptors, and separation of the lateral lobes by anterior commissurotomy.<sup>8-10</sup> Of these, creation of an anterior commissurotomy is anticipated to be the most beneficial in the long term by creating a wider cross-sectional area in the prostatic urethra to allow for increased urine flow. The creation of a durable anterior commissurotomy is the primary goal of Optilume BPH, Figure 4.

First-year results evaluating the safety and efficacy of Optilume were published in 2021 with the EVEREST-I study.<sup>6</sup> A total of 80 men were enrolled in this prospective, single-arm, non-randomized, open label, multicenter study. Key inclusion criteria included prostate volume of 20 cc to 80 cc and IPSS  $\geq$  13. The primary endpoint of a  $\geq$  40% reduction in IPSS from baseline was met at 3 months (22.3 to 8.1) with 81.3% (65/80) of patients reaching this target. At 1-year follow up, improvements appeared durable in IPSS (22.3 to 7.9, 64.9% reduction), IPSS QoL (4.6 to 1.3, 70.7% reduction), and Qmax (10.9 mL/s to 18.4 mL/s). There were no reported de novo ejaculatory or erectile dysfunction. Furthermore, adverse events

were minor and self-limiting. A 147-participant prospective, double-blinded, randomized controlled trial is currently being conducted to more thoroughly evaluate the safety and efficacy of Optilume under the PINNACLE trial, which has completed enrollment.

## Method and technique

### *Patient assessment*

Patients should be evaluated using standard methods as per urological society guidelines which may include review of medical history, physical exam, completion of validated questionnaires, uroflow studies and volumetric assessment. We also obtain a prostatic urethral length through transrectal ultrasound for surgical planning. Standardized questionnaires such as the IPSS and IIEF may also be conducted to track patient progress over time.

### *Patient preparation*

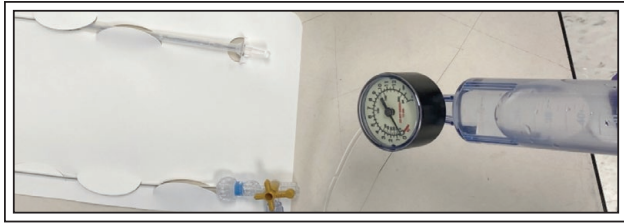
The patient is positioned in dorsal lithotomy and prepped and draped in usual fashion for rigid cystoscopy. Alternatively, local and oral anesthetic are administered as below:

- Intraurethral lidocaine jelly 2% 10 cc, clamp penis for 10 minutes
- Antibiotic prophylaxis (based on local antibiogram and AUA guidelines)
- Consider Valium – 1 (PO dose 2 mg)
- Consider Percocet – 1 (PO dose 2.5 mg/325 mg – 5 mg/325 mg)
- Consider Celebrex – 1 (PO dose 200 mg 1 hour before the procedure)
- Consider prostate block with 0.25% bupivacaine 30cc (apex, seminal vesicles, bladder neck)
- Consider intravesical lidocaine 2% 50 cc

We have found that using regular lubricating gel with cystoscopy is typically acceptable for patient comfort. Other MISTs have described using inhaled nitrous or methoxyflurane (Penthrox) for patient analgesia without requiring intravenous medication or monitoring of vitals. Anticoagulant medications should be safely discontinued prior to this procedure.

**TABLE 1. Optilume BPH balloon selection matrix based on prostatic urethral length**

Prostatic urethra length	
PUL $\geq$ 32 mm	PUL $\geq$ 37 mm
30 x 30 mm	30 x 35 mm



**Figure 5.** Preparing the pre-dilation balloon by removing residual air within it with the inflation device.

### Deploying Optilume BPH system

A selection matrix is used to select the correct size of pre-dilation balloon for the procedure, Table 1. The pre-dilation balloon is prepared by filling the inflation device half-way with sterile saline and connecting the inflation device to the balloon. The plunger on the inflation device is drawn back until no further air bubbles are seen to purge air from the balloon device, Figure 5.

Rigid cystoscopy (minimum sheath size 19.5 Fr) is performed in standard sterile fashion to examine the bladder and prostate. The telescope and bridge is removed with a thumb on the sheath to keep the bladder distended. The appropriately sized pre-dilation balloon is placed through the sheath. The rigid cystoscope sheath is back loaded over the balloon shaft so that only the balloon remains in the patient. The optics are then reassembled and the rigid cystoscope is re-positioned distal to the external sphincter for visualization. A smaller sheath size (e.g. 17 F) maybe be used for visualization for this step. A smaller sheath also minimizes trauma during exchanges between balloons.

The inflation device is attached to the pre-dilation balloon. Under direct visualization with the cystoscope, adjust the position of the balloon by pushing/pulling the catheter shaft until the proximal balloon is located in the prostatic urethra. Proper positioning is achieved when the proximal balloon bond (where the balloon attaches to the catheter shaft) is visualized with the cystoscope and positioned



**Figure 6.** Positioning of the balloon within the prostatic urethra.

within the external sphincter, while the blue marker is positioned just distally to the sphincter, Figure 6.

Inflate the pre-dilation balloon to 3 atmospheres of pressure for one minute then deflate the balloon. The rate of inflation and deflation should be approximately 1 atmosphere of pressure every 30 seconds. A commissurotomy is achieved with either an elevated heart rate (approximately 10 bpm), or a gradual pressure drop in the balloon indicating the commissure has yielded which decreases the pressure in the balloon. The balloon may need to be aspirated multiple times to ensure it is fully deflated before removing.

After removing the pre-dilation balloon, advance the rigid cystoscope into the prostate to confirm that there is a satisfactory anterior commissurotomy. If there are no signs of an anterior commissurotomy, repeat the balloon dilatation for a total maximum pressure of 3.5 to 4 atmospheres. Remove the pre-dilation balloon.

**TABLE 2. BPH drug coated balloon selection matrix**

Prostate volume and height	Prostatic urethra length			
	PUL 32-37 mm	PUL 37-42 mm	PUL 42-47 mm	PUL > 47 mm
Vol 20 to 80 g	30 x 30 mm	30 x 35 mm	30 x 40 mm	30 x 45 mm
Prostate height ≥ 20mm				

Select an appropriately sized Optilume BPH drug coated balloon (DCB) with the selection matrix, Table 2. Repeat the same steps with the drug-coated balloon as with the pre-dilation balloon. After inflation, confirm placement by trying to advance the catheter into the bladder. If the catheter can't be advanced it has locked onto the bladder neck and is in the correct position. Leave the drug-coated balloon inflated for 10 minutes instead of 1 minute. The scope does not need to remain in the patient while the drug-coated balloon is inflated within the patient. A set of familiar assistant hands can be helpful during the procedure. Deflate the drug-coated balloon and remove it from the patient. Again, the balloon may need to be aspirated multiple times to ensure it is fully deflated before removing.

Placement of a Foley catheter for at least 2 days is recommended by the manufacturer to prevent disturbance of the drug coating after dilation. We have found that a 22 Fr or 24 Fr 3-way foley catheter with 30 cc in the balloon works well. After placement of the Foley in the procedure room, place under moderate traction and hand flush the bladder with 5-10 60 cc Toomey syringes. Secure the Foley to the leg via tape or Statlock device under moderate traction and run continuous bladder irrigation for 30 minutes. After 30 minutes, the traction can be relieved, and the patient can be discharged home with the foley catheter. Others have reported success with a 20 F 2-way catheter placed with moderate traction and hand flushing in the procedure room and just prior to discharge for cases with minimal bleeding.

### *Managing patient postoperatively*

Patient experience may vary and a small percentage of patients report mild to moderate discomfort. We recommend counseling and preparing your patients for the possibility that they may experience some of the following symptoms and ensuring that they have the necessary tools available to them during the 5 to 7 days to manage comfortably. Below are our recommendations for maximizing patient comfort and recovery.

Patients may describe a feeling of discomfort or pressure in the bladder or penis with the catheter. We recommend discharging patients with ample analgesics to be taken in a graduated fashion depending on severity of discomfort for the duration of the catheter. All patients should consider taking acetaminophen (as per label, do not exceed maximal dosing) for reduction of inflammation and pain during recovery. An opioid such as codeine (1 tablet as needed, max 3 times per day) and short-acting anticholinergic such as levsin (0.125 mg-0.250 mg every 4 hours as

needed) may also be prescribed. These aforementioned medications should be used judiciously, as their side-effects may be more severe than the discomfort from the catheter. Anticholinergics should be discontinued the night before planned Foley removal to limit risk of medication induced retention.

It is important to inform patients that they can expect some mild hematuria, particularly during the first 48 hours following Optilume dilation. Patients should be counseled that this is normal and will self-resolve. Patients should stay well hydrated and be reassured that hematuria is not an issue. Blood thinners may be held if clinically appropriate in severe cases, however this is extremely rare.

### *Trial of void and symptoms after removal*

After 2 to 3 days of the foley catheter left in-situ, the patient returns for a trial of void. The patient is counseled about indications to seek medical care such as fever, intractable nausea/pain or clot retention. Patients can expect to see an immediate improvement in their urinary flow following catheter removal. Optilume BPH contains the drug paclitaxel, which may be present in their urine and semen for up to 6 months after treatment. Subjects should be counselled to abstain from sexual activity or wear a condom for the first 30 days after treatment to avoid exposing their partner to the drug. If their partner is of child-bearing potential, the should continue to utilize effective contraception for 6 months as a precaution against potential harm to a fetus. We typically see patients 4-6 weeks after the procedure for reassessment.

## Discussion and conclusions

The Optilume BPH catheter system is a MIST effective for treating a wide range of prostate glands without the need for general anesthesia. The technology promises to bridge the gap between conservative medical therapy and more invasive surgical therapy by being deployable using a standard rigid or flexible cystoscope in the urology office. Results of prospective studies and recent randomized controlled trials are promising. We believe that a standardized technique, such as this, can be easily reproducible for a successful outcome. Like everything that is new, take your time, build your experience and confidence, learn and refine your technique.

## Disclosures

Dr. Elterman is a consultant/investigator for Boston Scientific, Procept BioRobotics, Olympus, Urotronic,

Prodeon, and Zenflow. Dr. Chughtai is a consultant for Boston Scientific, Olympus, Procept and Prodeon. Dr. Zorn is a consultant/investigator for Boston Scientific and Procept BioRobotics. Dr. Bhojani is a consultant/investigator for Boston Scientific, Procept BioRobotics, and Olympus. Dr Te is a consultant/investigator for Urotronic and ProVerum. Dr. Kaplan is a consultant/investigator for Urotronic and ProVerum. Dr. Gao has no disclosure. □

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