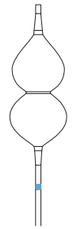
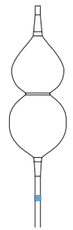
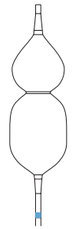
Optilume® BPH Catheter System Product Codes

The Optilume BPH Catheter System is provided as a convenient kit, containing one pre-dilation balloon (90 Fr (30 mm) x 30 mm) catheter, one Drug Coated Balloon (DCB) catheter (size determined by TRUS measurement - see below), a single-use inflation device, and the accessories needed to complete a procedure.

Each DCB, regardless of size, should be inflated to a maximum of 4 atm (RBP).

Measurement of Prostatic Urethral Length (PUL) determines the appropriate Optilume BPH catheter system. PUL measurement should be taken via Transrectal Ultrasound (TRUS) from mid-sagittal plane as a direct line, regardless if an Intravesical Prostatic Protrusion (IPP) is present, from base of the bladder neck to the proximal edge of the external urinary sphincter.

	PUL 3.2 - 3.7cm	PUL 3.7 - 4.2cm	PUL 4.2 - 4.7cm	PUL >4.7cm
				
Description	30mm BPH Dilation Kit	35mm BPH Dilation Kit	40mm BPH Dilation Kit	45mm BPH Dilation Kit
Catalogue Number	1189-30030	1189-30035	1189-30040	1189-30045
DCB Size	90Fr (30 mm) x 30 mm	90Fr (30 mm) x 35 mm	90Fr (30 mm) x 40 mm	90Fr (30 mm) x 45 mm
Paclitaxel Dose (µg)	10,262 (µg)	11,433 (µg)	12,567 (µg)	13,661 (µg)

1 Urotronic, Inc. Urotronic announces presentation of data from two clinical trials evaluating Optilume® BPH system's effectiveness and durability. PR Newswire: press release distribution, targeting, monitoring and marketing. May 1, 2023. Accessed June 11, 2023. https://www.prnewswire.com/news-releases/ urotronic-announces-presentation-of-data-from-two-clinical-trials-evaluating-optilume-bph-systems-effectiveness-and-durability-301812072.html

2 Kaplan, S.A. J Urol 2024;211(5S):e426

3 Kaplan, S.A. Prostate Cancer Prostatic Dis (2024)

The Optilume BPH Catheter System is indicated for the treatment of obstructive urinary symptoms associated with Benign Prostatic Hyperplasia (BPH) in men ≥ 50 years of age. The Optilume BPH Catheter System is contraindicated for use in: Patients with known hypersensitivity to paclitaxel or structurally related compounds, patients with an active urinary tract infection, patients with an artificial urinary sphincter, or patients with a penile prosthesis. The Optilume BPH DCB contains paclitaxel, a known genotoxic aneugen capable of causing chromosomal abnormalities in sperm. Paclitaxel is present in semen for an extended duration after treatment with Optilume BPH. The risks associated with these paclitaxel concentrations in semen are unknown. The effect of treatment with the Optilume BPH DCB on sperm and spermatogenesis is also unknown. Men should abstain from sex or use barrier contraception (wear a condom) for 30 days post treatment to avoid exposure of sexual partner to paclitaxel. Paclitaxel may still be present at low levels after 30 days. Potential adverse effects after treatment with the Optilume BPH Catheter System are similar to standard cystoscopic procedures and mechanical dilation and include, but are not limited to fever, bleeding, pain, urinary tract infection, false route of the urethra, dysuria, difficult urination, frequency/urgency/irritative urinary symptoms, urinary retention and related symptoms, blood in urine (hematuria), urinary incontinence, urethrorrhagia, blood in semen (hematospermia), ejaculatory dysfunction, bladder perforation, urethral and/or bladder neck strictures, injury or perforation to the urethra, sphincter or prostatic capsule, and inflammation of genitourinary system (prostatitis, orchitis, balanitis).

*Trans-women, with or without gender reassignment, may have a prostate. If BPH is diagnosed in a trans-woman, this is managed in the same way as for cisgender men.

To add Optilume® BPH to your practice, please visit **optilume.com/BPH**

Laborie

USA

T +1 800 522 6743

E optilume@laborie.com

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UROLOGY & UROGYNECOLOGY

Restore the flow

Safe, effective and durable BPH relief

OPTILUME® BPH DRUG-COATED UROLOGY BALLOON

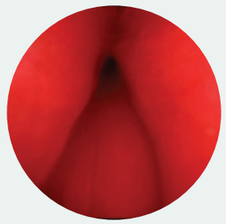
Optilume® BPH Catheter System

Introducing the next-generation of minimally invasive BPH treatment

Optilume® BPH revolutionizes the treatment paradigm by providing immediate and durable symptom relief for men* experiencing BPH induced lower urinary tract symptoms.[2,3]

This minimally invasive surgical therapy combines mechanical dilation with concurrent localized delivery of paclitaxel for treating BPH. Mechanical dilation with the proprietary double-lobe balloon technology achieves an anterior commissurotomy (split) releasing the constricting lateral lobes, while the delivery of paclitaxel prevents re-fusion of the lobes and maintains patency during healing.

OPTILUME® BPH DRUG-COATED UROLOGY BALLOON



Baseline

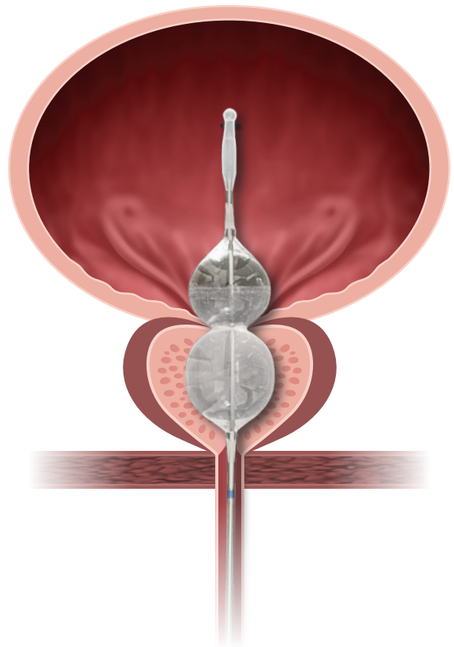
Baseline

IPSS: 23.4
Qmax: 8.9 mL/sec[3]

6 months

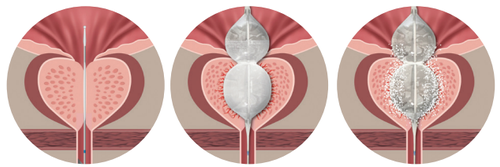
2-year follow-up

IPSS: 11.0
Qmax: 19 mL/sec[3]



Optilume® BPH is not your grandfather's BPH balloon – it's the next generation of minimally invasive technology, creating a new drug device space among BPH therapies[1]

– **Steven A. Kaplan, MD**



▲ **In-office/outpatient catheter procedure**

1. Custom sizing to individual patient prostatic anatomy for optimal outcomes.
2. Transurethral delivery of the Optilume® BPH semi-compliant drug coated balloon to the enlarged prostate.
3. Inflation of the drug coated balloon, creates an anterior commissurotomy (split) and concurrently delivers an anti-mitotic pharmaceutical agent, paclitaxel.
4. A foley catheter is placed for a minimum of 2 days allowing adequate healing of the prostate, and absorption of paclitaxel.

Safe

Safety profile in-line with existing BPH MISTs[2,3]

In the 5-year EVEREST trial and 2-year PINNACLE trial follow-up, there was:

No impact on erectile and ejaculatory function[2,3]

Effective

The highest Qmax reported in BPH MIST trials to date, PINNACLE 2-year endpoint follow-up:[3]

Qmax

19 ml/sec[3]

(113% improvement)

IPSS 53% Decrease[3]

PVR 20% Decrease[3]

Durable

Clinical results show long-lasting relief[2,3]

The PINNACLE randomized control trial[3] shows excellent results through 2-year primary endpoint follow up (3% retreatment rate)[3] and is supported by the EVEREST feasibility study[2] showing **sustained improvements up to 5 years** (Qmax: 20.6 mL/sec, IPSS: 46% improvement).[2]

Optilume® BPH does not require cutting, heating, burning, lasering, steaming, or implantation.