

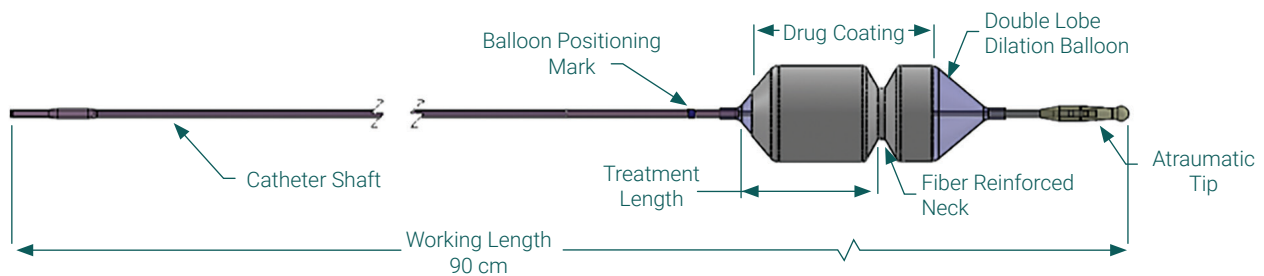
PRODUCT SPECIFICATIONS

UROLOGY & UROGYNECOLOGY

Optilume[®] BPH Catheter System

Description

The Optilume[®] BPH Catheter System is a combination drug/device minimally invasive surgical therapy (MIST) comprised of an uncoated pre-dilation balloon catheter and a separate drug coated balloon (DCB) catheter. The distal end of each catheter has a semi-compliant, inflatable, double lobe balloon that is used to dilate the prostate. The double-lobe DCB catheter is coated with a proprietary coating containing the active pharmaceutical agent paclitaxel. The drug coating covers the working length of the balloon body.



Indications for Use

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.

Contraindications

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
- Patients with a penile prosthesis

Storage

The Optilume[®] BPH Catheter System should be stored at room temperature between 15°C and 30°C (59°F and 86°F) in a dry location in its original packaging. The device should be used prior to the "Use By" date on the package label.



PRODUCT SPECIFICATIONS

PRODUCT USAGE	
System Compatibility	Minimum 19.5 Fr rigid cystoscope sheath
Procedure Type	Balloon Dilation
CERTIFICATION	
PMA Number	P220029
PMA Approval Date	June 30, 2023
FDA Classification Rule	Class III
TECHNICAL DATA	
Balloon Lengths	30, 35, 40, 45 mm
Balloon Diameters	90 Fr (30 mm)
Rated Burst Pressure	All sizes: 4 atm
Crossing Profile	14.5 Fr
Catheter Design	Fixed Wire
Catheter Length	90 cm
Balloon Markers	Blue positioning marker used to position the balloon within the Prostatic Urethra (see IFU for procedural steps)

TECHNICAL DATA <i>cont.</i>	
Drug	Paclitaxel
Drug Dose	2.4 ug/mm ²
Drug Coated Area	Balloon Body (Shown by shaded area in image)
MATERIAL	
Catheter Principal Elements	Pebax, Nylon 12, Stainless Steel, Silicone
STERILIZATION	
Single Use/Disposable	Yes
Sterile	Yes, Ethylene Oxide
Place of Sterilization	Steris Applied Sterilization Technologies, Coon Rapids, Minnesota
Shelf Life	<ul style="list-style-type: none"> Pre-dilation Catheter: 24 months DCB Catheter: 24 months
PACKAGING	
Package Material	Tyvek® and PET/LDPE/Nylon composite
Quantity Per Box	One (1) catheter

The Optilume BPH Catheter System is provided as a convenience kit, containing one pre-dilation balloon catheter, one DCB catheter, a single-use inflation device and the accessories needed to complete a procedure.

Catalogue Number	Description	Pre-dilation Catheter Size	DCB Catheter Size	Rated Burst Pressure (RBP)	Paclitaxel Dose (µg)
1189-30030	Optilume® BPH Prostatic Dilatation Kit 30 x 30 mm	90 Fr (30mm) x 30 mm	90 Fr (30mm) x 30 mm	4 atm	10,262
1189-30035	Optilume® BPH Prostatic Dilatation Kit 30 x 35 mm	90 Fr (30mm) x 30 mm	90 Fr (30mm) x 35 mm	4 atm	11,433
1189-30040	Optilume® BPH Prostatic Dilatation Kit 30 x 40 mm	90 Fr (30mm) x 30 mm	90 Fr (30mm) x 40 mm	4 atm	12,567
1189-30045	Optilume® BPH Prostatic Dilatation Kit 30 x 45 mm	90 Fr (30mm) x 30 mm	90 Fr (30mm) x 45 mm	4 atm	13,661

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*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.

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