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UROLOGY & UROGYNECOLOGY

PRODUCT SPECIFICATIONS

Optilume® Urethral Drug Coated Balloon

Intended Use

Optilume® Urethral Drug Coated Balloon is intended for the treatment of strictures in the anterior urethra in adult males.

Description

The Optilume® Urethral Drug Coated Balloon is a 0.038" (0.97 mm) over-the-wire (OTW) guidewire compatible catheter with a dual lumen design and a tapered atraumatic tip. Balloon diameters of 6 mm-10 mm (18 Fr-30 Fr) are flexible cystoscope compatible. The Optilume® DCB is used to exert radial force to dilate narrow urethral segments (strictures). The distal end of the catheter has a semi-compliant inflatable balloon that is coated with a proprietary coating containing the active pharmaceutical paclitaxel. The drug coating covers the working length of the balloon body. The device has two radiopaque marker bands that indicate the working length of the balloon.

Indications for Use

The Optilume® Urethral Drug Coated Balloon is used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for anterior urethral strictures of ≤ 3 cm in length.

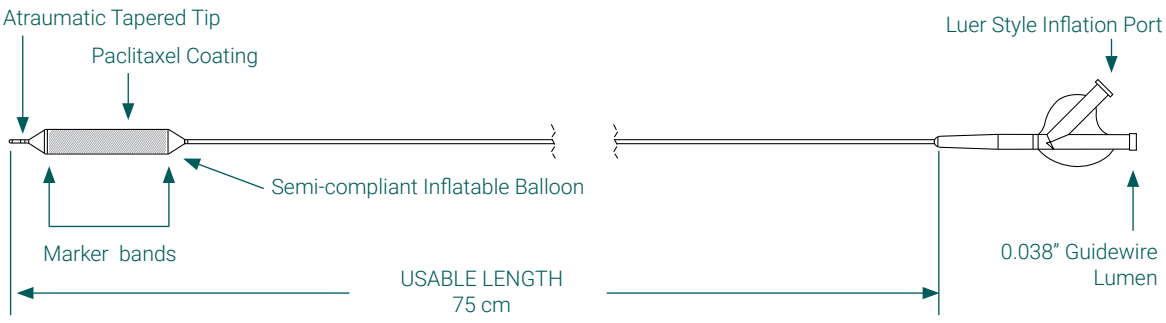
Storage

The Optilume® Urethral Drug Coated Balloon should be stored at room temperature in a dry location in its original packaging. The device should be used prior to the "Use by" date on the packaging.

Contraindications

The Optilume® Urethral Drug Coated Balloon is contraindicated for use in:

- Patients with known hypersensitivity to paclitaxel or structurally related compounds
- Patients with urologic implants such as penile implants and artificial urinary sphincters



PRODUCT SPECIFICATIONS

PRODUCT USAGE	
System Compatibility	18 Fr-30 Fr: Rigid and Flexible Cystoscope Compatible Minimum Working Channel Size: 2.1mm (6 Fr) 36 Fr Not Flexible Cystoscope Compatible
Procedure Type	Male Anterior Urethral Stricture Dilation
CERTIFICATION	
PMA Number	P210020
PMA Approval Date	03Dec21
FDA Classification Rule	Class III
TECHNICAL DATA	
Balloon Lengths	3 and 5 cm
Balloon Diameters	18 Fr, 24 Fr, 30 Fr, 36 Fr
Rated Burst Pressure	18 Fr and 24 Fr: 12 atm; 30 Fr: 10 atm; 36 Fr: 8 atm
Crossing Profile	18 Fr, 24 Fr, and 30 Fr: 0.083" (6.3 Fr); 36 Fr: 0.118" (9.0 Fr)
Catheter Design	Over-the-Wire (OTW)
Guidewire Compatibility	0.038" Maximum
Catheter Length	75 cm

TECHNICAL DATA *cont.*	
Balloon Fold Configuration	5-fold
Balloon Markers	Platinum-Iridium
Drug	Paclitaxel
Drug Dose	3.5 µg/mm^2
Drug Coated Area	Balloon Body *(Shown by cross-hatch in image on front)*
MATERIAL	
Catheter Principal Elements	Nylon 12, Pebax, Polycarbonate, and Platinum-Iridium
STERILIZATION	
Single Use/Disposable	Yes
Sterile	Ethylene Oxide
Place of Sterilization	Steris Applied Sterilization Technologies, Coon Rapids, Minnesota
Shelf Life	2 Years
PACKAGING	
Package Material	Tyvek® and PET/LDPE/Nylon composite
Quantity Per Box	One (1)

Product Number	Description	Diameter	Length	Rated Burst Pressure (RBP)
OPTBDL7000B	Optilume® Urethral Drug Coated Balloon & Inflation Device	18 Fr	3 cm	12 atm
OPTBDL7001B	Optilume® Urethral Drug Coated Balloon & Inflation Device	18 Fr	5 cm	12 atm
OPTBDL7002B	Optilume® Urethral Drug Coated Balloon & Inflation Device	24 Fr	3 cm	12 atm
OPTBDL7003B	Optilume® Urethral Drug Coated Balloon & Inflation Device	24 Fr	5 cm	12 atm
OPTBDL7004B	Optilume® Urethral Drug Coated Balloon & Inflation Device	30 Fr	3 cm	10 atm
OPTBDL7005B	Optilume® Urethral Drug Coated Balloon & Inflation Device	30 Fr	5 cm	10 atm
OPTBDL7006B	Optilume® Urethral Drug Coated Balloon & Inflation Device	36 Fr	3 cm	8 atm
OPTBDL7007B	Optilume® Urethral Drug Coated Balloon & Inflation Device	36 Fr	5 cm	8 atm

Please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. The Optilume® DCB is indicated for use in patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for anterior urethral strictures of ≤3cm in length. The Optilume® DCB is contraindicated for patients with known hypersensitivity to paclitaxel or structurally related compounds and patients with urologic implants such as penile implants or artificial urinary sphincters. Paclitaxel may be present in semen after treatment with the Optilume® DCB. The risks associated with paclitaxel in semen and the impact on sperm and spermatogenesis are unknown. Men should abstain or use a condom for 30 days and men with partners of child-bearing potential should use highly effective contraceptive and avoid fathering children for 6 months after treatment. Monitor for signs of anaphylaxis or hypersensitivity to paclitaxel. Potential risks can include, but are not limited to, the following: blood in the urine (hematuria), painful urination (dysuria), urinary tract infection (UTI), and urinary retention.

OPTILUME

Optilume® urethral drug coated balloon

For further information, please visit us at **www.optilume.com**

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Learn more

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