

PRODUCT SPECIFICATIONS

UROLOGY & UROGYNECOLOGY

Optilume[®] Urethral Drug Coated Balloon

Intended Use

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

Description

The Optilume[®] Urethral Drug Coated Balloon Dilation Catheter 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 Catheter is used to treat men ≥ 18 years of age with bothersome urinary symptoms associated with recurrent anterior urethral stricture. It is designed to be used as a dilation balloon for a single, tandem or diffuse recurrent anterior urethral stricture of ≤ 3 cm in length or used as an adjunctive therapy with other dilation devices and/or procedures.

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.

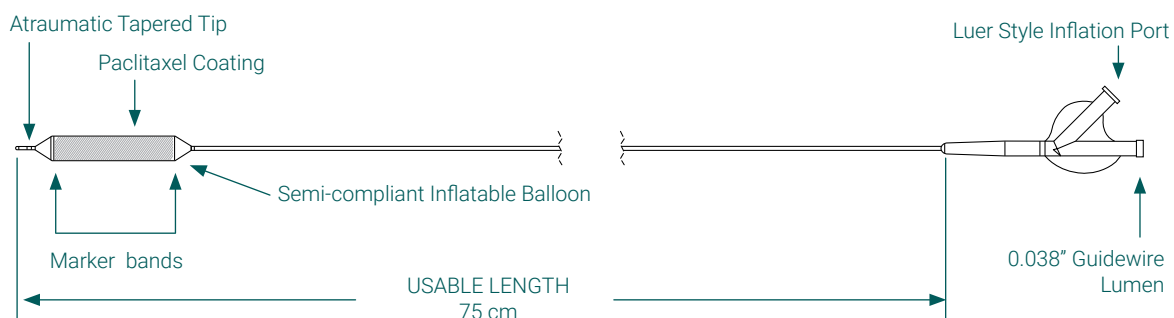
Use in Special Populations

The safety and effectiveness of the Optilume[®] Urethral Drug Coated Balloon has not been established in pediatric patients (< 18 years of age) or in women. Use of the Urethral DCB in patients ≥ 18 years of age and older is at the discretion of the physician.

Contraindications

The Optilume[®] Urethral Drug Coated Balloon Dilation Catheter is contraindicated for use in:

- Patients with known hypersensitivity to paclitaxel or structurally related compounds
- Patients with lesions that cannot be crossed with a 0.038" guidewire



PRODUCT SPECIFICATIONS

PRODUCT USAGE	
System Compatibility	18 Fr-30 Fr: Rigid and Flexible Cystoscope Compatible Minimum Working Channel Size: 2.1mm (6Fr)
Procedure Type	Male Anterior Urethral Stricture Dilatation
CERTIFICATION	
Relevant Product Standards	ISO13485, ISO14971, ISO10993, ISO10555, EN556, ISO15223
CE Notified Body	PCBC (Polskie Centrum Badań i Certyfikacji S.A.) - Poland
CE Mark Number	1434
CE Class	Class III (Rule 13)
Declaration of Conformity	Annex II of Directive 93/42/EEC
TECHNICAL DATA	
Balloon Lengths	3 and 5 cm
Balloon Diameters	18 Fr, 24 Fr, 30 Fr
Rated Burst Pressure	18 Fr and 24 Fr: 12 atm; 30 Fr: 10 atm
Crossing Profile	18 Fr, 24 Fr, and 30 Fr: 0.083" (6.3 Fr)
Catheter Design	Over-the-Wire (OTW)

TECHNICAL DATA cont.	
Guidewire Compatibility	0.038" Maximum
Catheter Length	75 cm
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	18 Months
PACKAGING	
Package Material	Tyvek® and PET/LDPE/Nylon composite
Quantity Per Box	One (1)

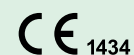
Product Number	Description	Diameter	Length	Rated Burst Pressure (RBP)	Paclitaxel Dose (µg)
OPTBDL7000C	Optilume® Drug Coated Balloon & Inflation Device	18 Fr	3 cm	12 atm	1,979
OPTBDL7001C	Optilume® Drug Coated Balloon & Inflation Device	18 Fr	5 cm	12 atm	3,299
OPTBDL7002C	Optilume® Drug Coated Balloon & Inflation Device	24 Fr	3 cm	12 atm	2,639
OPTBDL7003C	Optilume® Drug Coated Balloon & Inflation Device	24 Fr	5 cm	12 atm	4,398
OPTBDL7004C	Optilume® Drug Coated Balloon & Inflation Device	30 Fr	3 cm	10 atm	3,299
OPTBDL7005C	Optilume® Drug Coated Balloon & Inflation Device	30 Fr	5 cm	10 atm	5,498

©2021 Laborie. All rights reserved.



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

This document is for use in the European Union only. Manufactured by Urotronic, Inc.



Laborie

USA

T +1 802 857 1300
+1 800 522 6743

E optilume@laborie.com
W laborie.com



Learn more

MKT-00555 [A] 01/22