

Optilume® Order Numbers

		Balloon Length (3cm)	Balloon Length (5cm)
Inflated Balloon Diameter (Fr)	Content	Product SKU	Product SKU
18.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	1110-06030D	1110-06050D
24.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	1110-08030D	1110-08050D
30.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	1110-10030D	1110-10050D
N/A	Atrion QL4015 Disposable Inflation Device	96313	

1 Data on file. DSC016-004 rJ Robust I Clinical Study Final Report

2 Steenkamp JW, Heyns CF, de Kock MLS, Internal Urethrotomy Versus Dilatation as Treatment for Male Urethral Strictures: A Prospective, Randomized Comparison. Journal of Urology, Vol. 157:96-101. January 1997

3 Data on file. RP1277-001 rB

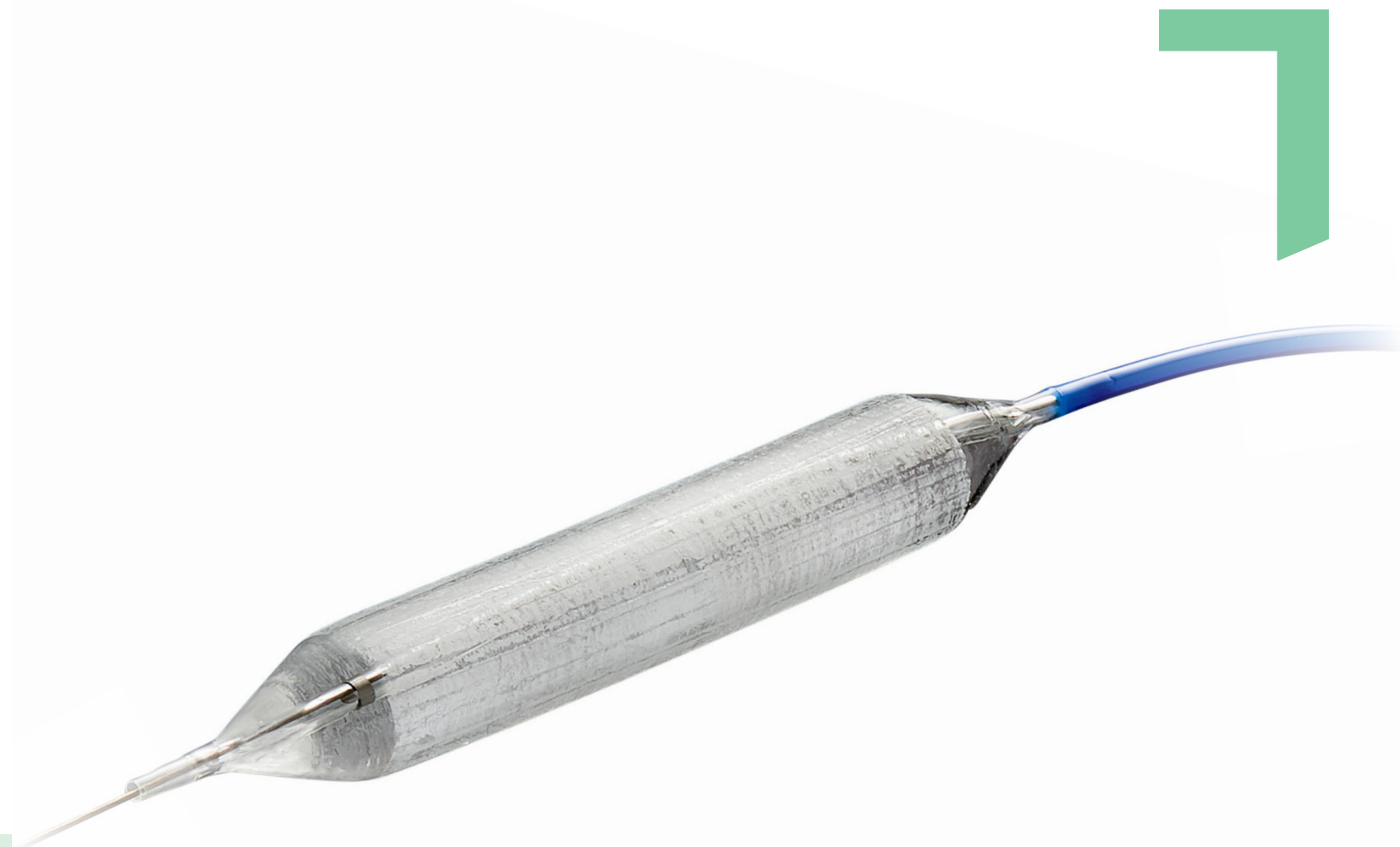
4 Data on file. TP1041

ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE.

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.

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Break the anterior urethral stricture cycle



To incorporate Optilume® into your practice, please visit us at www.optilume.com



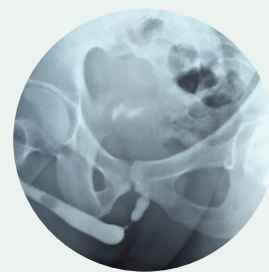
Simple. Safe. Durable.

A breakthrough treatment for anterior urethral strictures

For patients who suffer from anterior urethral strictures, today there is Optilume® – a breakthrough urethral drug coated balloon (DCB) treatment that dilates the urethral lumen and delivers paclitaxel directly to the stricture, significantly reducing the incidence of stricture.¹

Until now, there has been no treatment for anterior urethral stricture that provides ambulatory recovery, minimal complications and durable outcomes, all in a simple outpatient procedure.²

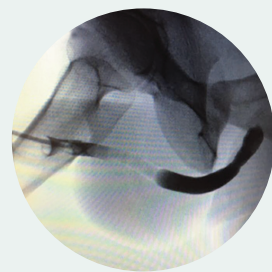
Optilume® is the cost-effective alternative¹ to endoscopic management that breaks the cycle of anterior urethral strictures.



Baseline

Baseline

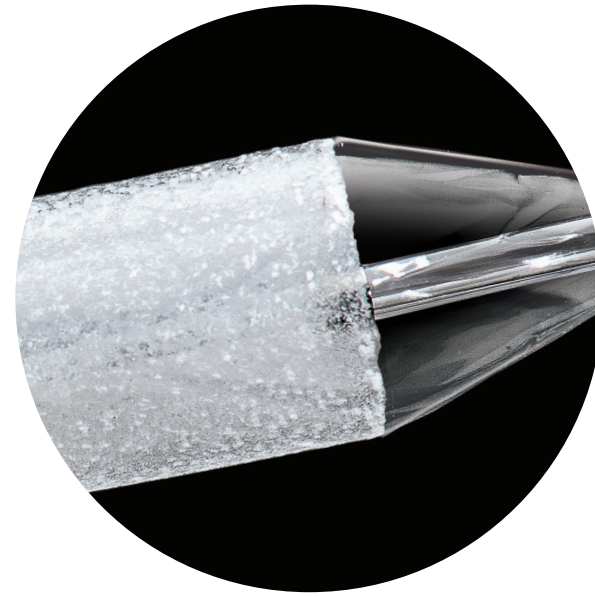
Length of stricture: 1.0 cm
IPSS: 29
Qmax: 4 mL/sec



6 months

24-month follow-up

IPSS: 1
Qmax: 18 mL/sec



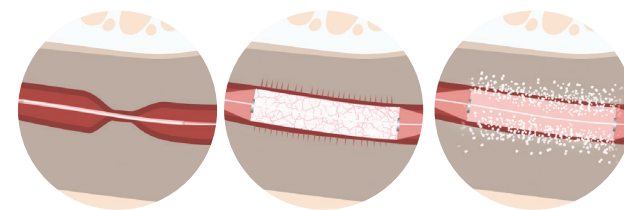
▲ Paclitaxel coating

The Optilume® Balloon Catheter has a significant opportunity to be a game changer for this disease.

– Gerald H. Jordan MD, FACS, FAAP (hon), FRCS (hon)

Simple

Easily achieve relief



1. Insert proprietary semi-compliant balloon
2. The balloon expands the lumen creating microfissures in the tissue
3. The coating releases paclitaxel directly into the fissured tissue. Paclitaxel is absorbed by the urothelium where it resides through 28 days, reducing cell proliferation and fibrotic scar tissue generation⁴

Safe

Proven on a very difficult patient population

In the ROBUST trials with patients who had received multiple prior dilations, there were:

No device-related serious complications¹

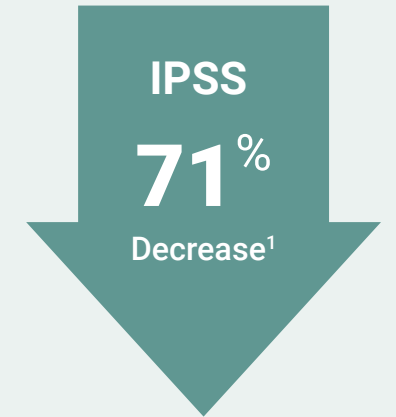
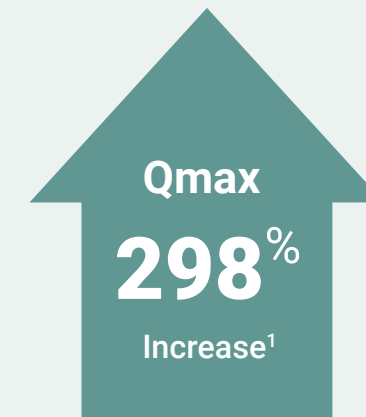
No impact on erectile function¹

Effective

73%

Freedom from repeat intervention at 5 years³

▲ At 5 years, durability continued with 73% FFRI, with a 298% increase in Qmax and a 71% decrease in IPSS.



Durable

The breakthrough treatment to break the cycle

Optilume® delivers **sustained relief** due to paclitaxel's ability to limit fibrosis that leads to anterior urethral stricture¹

