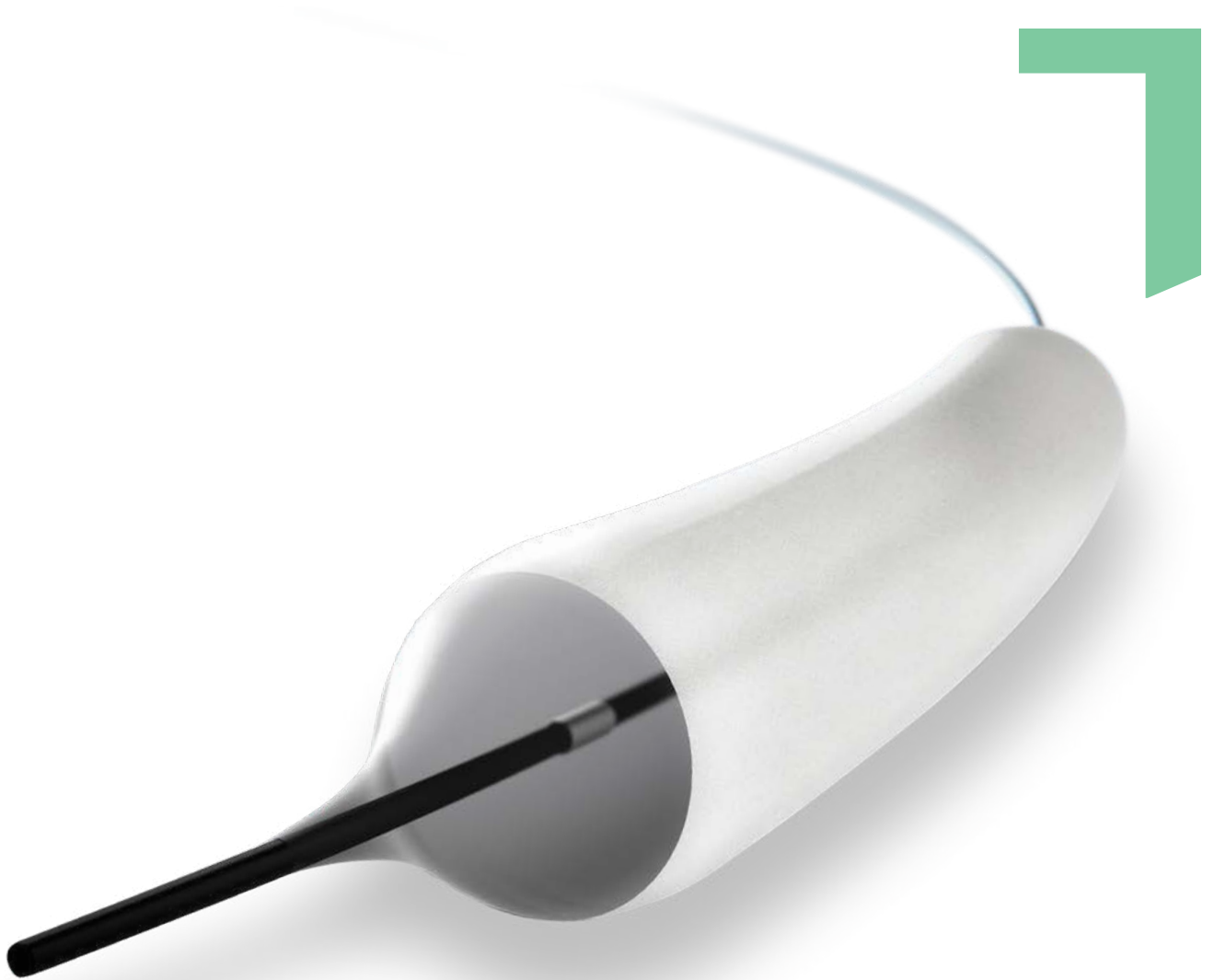


Break the anterior urethral stricture cycle

UROLOGY & UROGYNECOLOGY



OPTILUME

Optilume[®] urethral
drug coated balloon

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 alternative⁴ to endoscopic management that breaks the cycle of anterior urethral strictures.



▲ 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)

OPTILUME

Optilume® urethral drug coated balloon



Baseline

Baseline

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



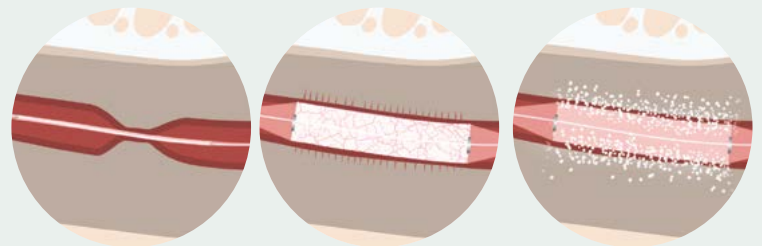
6 months

24-month follow-up

IPSS: 1
Qmax: 18 mL/sec

Simple

Easily achieve relief



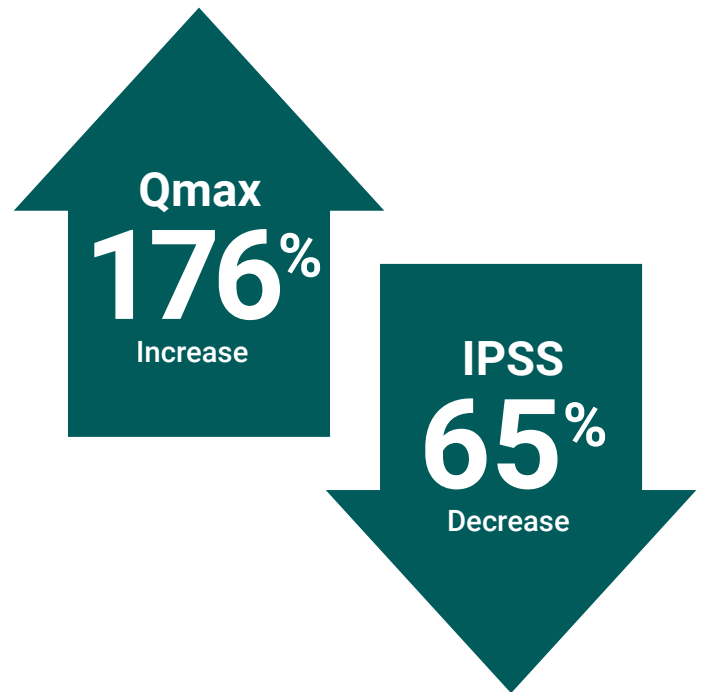
1. Insert proprietary semi-compliant balloon
2. The balloon expands the lumen creating microfissures in the tissue
3. The coating releases paclitaxel directly into the fissured tissue. Paclitaxel is absorbed by the urothelium where it resides through 28 days, reducing cell proliferation and fibrotic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

3-year freedom from reintervention rate

77%

▲ At 3 years,³ durability continued with 77% **FFRI**, with a **176% increase in Qmax** (Baseline 5.1, 3-year 14.1) and a **65% decrease in IPSS** (Baseline 25.2, 3-year 8.8)

Qmax & IPSS are using FCF rates –Includes worst observed value carried forward for subjects undergoing repeat intervention of the study stricture (i.e. clinical failures). Robust I clinical study, n=43



Safe

Proven on a very difficult patient population

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

No device-related serious complications^{1,3}

No impact on erectile function¹

Durable

The breakthrough treatment to break the cycle

Optilume[®] delivers **sustained relief³** due to paclitaxel's ability to limit fibrosis that leads to anterior urethral stricture⁴



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	OPTBDL7000B	OPTBDL7001B
24.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	OPTBDL7002B	OPTBDL7003B
30.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	OPTBDL7004B	OPTBDL7005B
36.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	OPTBDL7006B	OPTBDL7007B
Optilume® Urethral Drug Coated Balloon/Basic Balloon Inflated Diameter (Fr)	Content	Product SKU	Product SKU
24.0 / 18.0	Optilume® Urethral Drug Coated Balloon, Basic Balloon (3cm) & Inflation Device	OPTBDL7008B	OPTBDL7009B
30.0 / 24.0	Optilume® Urethral Drug Coated Balloon, Basic Balloon (3cm) & Inflation Device	OPTBDL7010B	OPTBDL7011B

1 Elliott SP, Coutinho K, Robertson KJ, D'Anna R, Chevli K, Carrier S, Aube-Peterkin M, Cantrill CH, Ehlert MJ, Te AE, Dann J, DeLong JM, Brandes SB, Hagedorn JC, Levin R, Schlaifer A, DeSouza E, DiMarco D, Erickson BA, Natale R, Husmann DA, Morey A, Olsson C and Virasoro R, One-Year Results for the ROBUST III Randomized Controlled Trial Evaluating the Optilume Drug-Coated Balloon for Anterior Urethral Strictures, *The Journal of Urology*® (2021), doi: 10.1097/JU.0000000000002346

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 Elliott SP, Virasoro R, Estrella R, et al. MP56-06 The Optilume Drug Coated Balloon for Recurrent Anterior Urethral Strictures: ROBUST I Clinical Study 3-year follow up, N = 43. *J Urol* 2021;206(3S):e971.

4 Data on file.

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

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Learn more

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