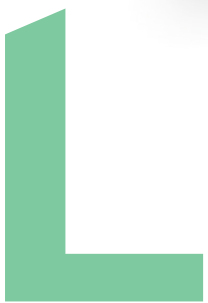


# Break the cycle of recurrent anterior urethral strictures

UROLOGY & UROGYNECOLOGY



# Simple. Safe. Durable.

## A breakthrough treatment for recurring anterior urethral strictures

For patients who have failed prior endoscopic management, 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 recurrence.<sup>1</sup>

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

Optilume® is the cost-effective alternative<sup>4</sup> to recurrent endoscopic management that breaks the cycle of recurring 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



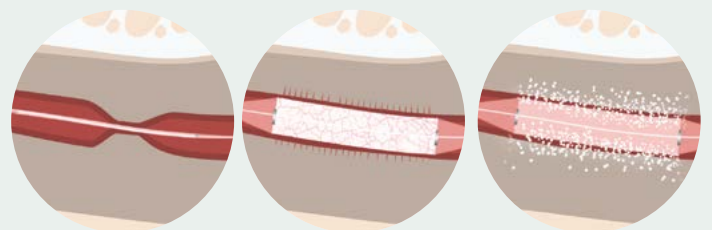
6 months

#### 24-month follow-up

IPSS: 1  
Qmax: 18 mL/sec

## Simple

Easily achieve relief



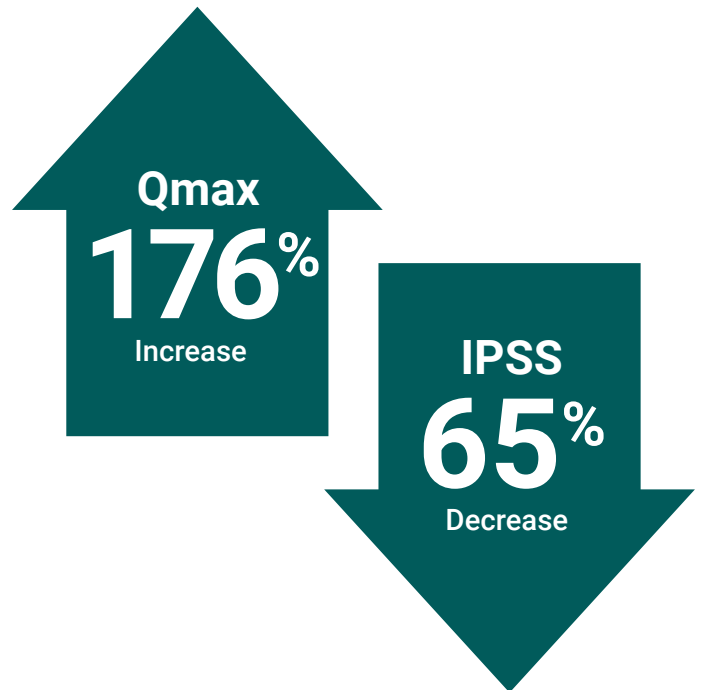
1. Insert proprietary semi-compliant balloon
2. The balloon expands the lumen creating microfissures in the tissue
3. The coating releases paclitaxel directly into the fissured tissue. Paclitaxel is absorbed by the urothelium where it resides through 28 days, reducing cell proliferation and fibrotic scar tissue generation<sup>4</sup>

## 3-year freedom from reintervention rate

# 77%

▲ At 3 years,<sup>3</sup> 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<sup>1,3</sup>**

**No impact on erectile function<sup>1</sup>**

## Durable

The breakthrough treatment to break the cycle

Optilume<sup>®</sup> delivers **sustained relief<sup>3</sup>** due to paclitaxel's ability to limit fibrosis that leads to recurrence<sup>4</sup>



## 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	OPTBDL7000C	OPTBDL7001C
24.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	OPTBDL7002C	OPTBDL7003C
30.0	Optilume® Urethral Drug Coated Balloon & Inflation Device	OPTBDL7004C	OPTBDL7005C

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.

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