Break the anterior urethral stricture cycle

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 alternative³ to endoscopic management that breaks the cycle of anterior urethral strictures.

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

Baseline | 6 months
--- | ---
Length of stricture: 1.0 cm | Length of stricture: 1.0 cm
IPSS: 29 | IPSS: 1
Qmax: 4 mL/sec | Qmax: 18 mL/sec
3-year freedom from reintervention rate

77%

At 3 years, 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 function\(^1\)

Durable

The breakthrough treatment to break the cycle

Optilume\(^\circ\) delivers sustained relief\(^3\) due to paclitaxel’s ability to limit fibrosis that leads to anterior urethral stricture\(^4\)

\(^1\) \(^3\)
## Optilume® Order Numbers

<table>
<thead>
<tr>
<th>Inflated Balloon Diameter (Fr)</th>
<th>Content</th>
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<th>Product SKU</th>
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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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4 Data on file.

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

Manufactured by Urotronic, Inc.