

What is anterior urethral stricture disease?

An anterior urethral stricture is a narrowing of the urethra caused by scarring, that obstructs the flow of urine. If left untreated, the obstruction caused by an anterior urethral stricture can lead to a reduced quality of life, bladder and kidney damage, and urinary tract infections in men.³

Common symptoms include:

- Hesitancy when waiting for the stream of urine to begin
- Weak or irregular flow
- Straining to urinate
- Painful urination
- A sense of incomplete emptying
- Dribbling after urination

Ask your urologist if Optilume® may be the right solution for your anterior urethral stricture disease

Learn more at www.optilume.com

- 1 Steenkamp JW, Heyns CF, de Kock MLS, Internal Urethrotomy Versus Dilation as Treatment for Male Urethral Strictures: A Prospective, Randomized Comparison. *Journal of Urology*, Vol. 157:96-101. January 1997
- 2 Elliott SP, Coutinho K, Robertson KJ, D'Anna R, Chebli K, Carrier S, Aube-Peterkin M, Cantrill CH, Ehler 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
- 3 Tritschler S, Roosen A, Füllhase C, Stief CG, Rübber H. Urethral stricture: etiology, investigation and treatments. *Dtsch Arztebl Int.* 2013;110(13):220-226. doi:10.3238/arztebl.2013.0220
- 4 Rosenfield K, Jaff MR, White CJ, et al. Trial of Paclitaxel-Coated Balloon for Femoropopliteal Artery Disease. *NEJM* 2015;372(2):145-53
- 5 Data on file: TP1041
- 6 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.

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.

Manufactured by Urotronic, Inc.

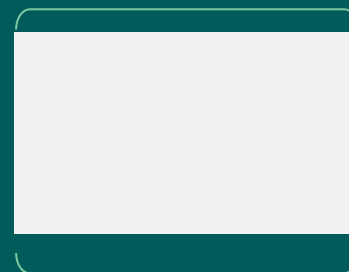
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UROLOGY & UROGYNECOLOGY

Are you ready to break the anterior urethral stricture cycle?



OPTILUME
Optilume® urethral drug coated balloon

MKT-00550 [A] 01/22



At last, a breakthrough treatment for strictures

Current endoscopic anterior urethral stricture treatments are common practice and often ineffective, leading to multiple repeat procedures with diminishing results.¹

Optilume® is an effective alternative to traditional endoscopic stricture treatments, offering minimally invasive, immediate relief.² Optilume® works by inhibiting new scar tissue growth that often recurs after dilations or direct visual internal urethrotomy (DVIU).

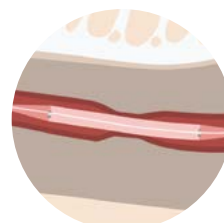
All this in a simple out-patient procedure.

What is Optilume® and how is it used?

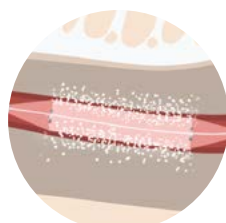
- Optilume® is a small, cylindrical balloon coated with medication engineered to simultaneously open the urethra and slow or stop stricture regrowth
- Similar balloons have successfully prevented re-treatment in cardiovascular procedures for several years⁴
- Recovery is mild⁵
- No impact on erectile function²



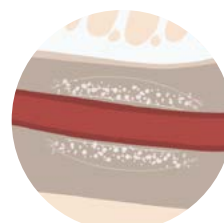
Insertion



Dilation



Drug release



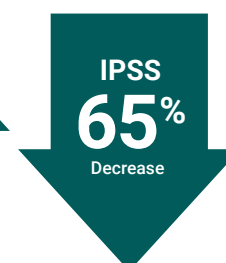
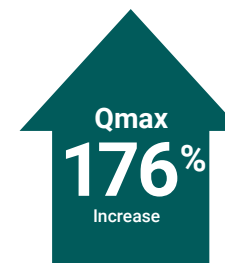
Durability⁴

Proven results

- Paclitaxel, the drug that coats the balloon, is a proven antiproliferative drug that has been effectively used in millions of patients worldwide since the early 1990's, in various applications

3-year freedom from reintervention rate

77%



▲ At 3 years,⁴ 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). Robust I clinical study, n=43

Simple. Safe. Durable.

This changes everything