Laborie

FOR DIGNITY. FOR LIFE.

OPTILUME® URETHRAL DRUG COATED BALLOON

UR UROLOGY & UROGYNECOLOGY

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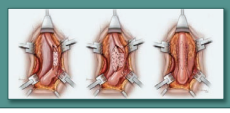
CURRENT STRICTURE TREATMENT OPTIONS – THE PROBLEM

Minimally Invasive

- Filiform Dilation
- Uncoated Balloon Dilation
- DVIU
  Direct Vision Internal Urethrotomy

Surgical

- Urethroplasty



Minimally Invasive standard of care has high rates of recurrence and are not durable. [1,2]

N=161	6m	24m
Stricture-free rate: 1st treatment	80%	60%
Stricture-free rate: 2nd treatment	80%	20%
Stricture-free rate: 3rd treatment	20%	0%

Urethroplasty, the gold-standard, is an invasive procedure that requires a long recovery period, including extended catheterization times, and access to GURS specialists is limited.

[1]Steenkamp JW, Heyns CF, de Kock ML. *J Urol* 1997;157:98-101
[2]Heyns CF, Steenkamp JW, de Kock ML. *J Urol* 1998;160:356-8

OPTILUME® Stricture

Urethral Drug Coated Balloon

Paclitaxel drug coating
Rapid & controlled drug release into diseased tissue

Dilation Balloon
Expands to create micro-fissures in the tissue, facilitating drug absorption

TAKEAWAY POINTS

- Minimally invasive treatment for Male Anterior Urethral Stricture
- 73% Freedom From Retreatment at 5 Years for Patients treated with Optilume[1]
- A recommended treatment in the American Urological Association Urethral Stricture Guidelines for recurrent bulbar urethral strictures <3cm in length.[2]

[1]Data on file. RP1277-001 rB
[2]Wessells H, Morey A, Vanni A, Rahimi L, Souter L. Urethral Stricture Disease Guideline Amendment (2023). J Urol. 2023 Apr 25:101097JU0000000000003482. doi: 10.1097/JU.0000000000003482. Epub ahead of print. PMID: 37096574.

OPTILUME® STRICTURE – SAFE, EFFECTIVE, DURABLE

SAFE	EFFECTIVE	DURABLE
Zero Device-related serious complications[1]	83% Freedom from reintervention at 1 year[2]	73% Freedom from reintervention at 5 years[3]
Zero Impact on erectile function[1]	104% Improvement in Qmax score at 1 year[2] (vs baseline 7.6, 1-year 15.5)	298% Improvement in Qmax score at 5 years[1] (vs. baseline 5, 5-year 19.9)
	59% Decrease in IPSS score at 1 year[2] (vs baseline 22.0, 1-year 9)	71% Decrease in IPSS score at 5 years[1] (vs. baseline 25.2, 5-year 7.2)

[1]Data on file. DSC016-004 r.J Robust I Clinical Study Final Report
[2]Elliott Sp et al., 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]Data on file; 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).
[4]Data on file. RP1277-001 rB

OPTILUME® STRICTURE – THE SOLUTION

An exciting, minimally invasive urethral stricture treatment, the Optilume® drug-coated balloon was developed in response to severe patient and physician dissatisfaction with current stricture solutions.

This proprietary technology combines balloon dilation and drug delivery and is well-tolerated by patients.[1]

Semi-compliant inflatable balloon
The semi-compliant inflatable balloon expands to create micro-fissures in the tissue, facilitating drug absorption

Radiopaque marker bands
The device has two radiopaque marker bands indicating the working length of the balloon where the drug coating is applied.

Paclitaxel and coating
A novel excipient molecularly binds paclitaxel to the balloon until the balloon inflates and dilates the tissue for rapid, controlled drug release.

Atraumatic tapered tip
Travels easily over the guidewire and can cross tight strictures

[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

PACLITAXEL DRUG COATING

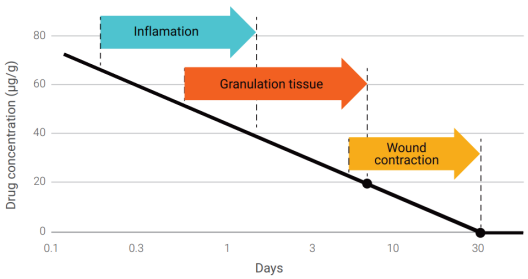
Paclitaxel is a proven anti proliferative drug that has been used in chemotherapy since the early 1990s[4]. As a mitotic inhibitor, paclitaxel's mechanism of action (MoA) works by stabilizing microtubules to prevent the metaphase/anaphase transition, preventing new cell division and migration, stopping new tissue growth and the fibrotic scarring that leads to strictures.

It is delivered locally, and absorption does not require prolonged exposure or sophisticated drug carriers. Cytostatic effect with low-dose administration maintains safety and integrity of surrounding tissue.

How it's delivered.

- Paclitaxel is suspended in a coating called an excipient that is uniformly applied to the balloon
- The balloon is inflated in the urethra, simultaneously dilating the stricture and creating microfissures that enhance the uptake of paclitaxel
- The excipient molecularly binds the paclitaxel to the balloon, until the inflated balloon comes in contact with the tissue for rapid drug release

Safe, therapeutic drug levels in tissue to 28 days



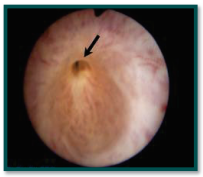
Urotronic internal data. Canine urethral model followed out to 70 days.

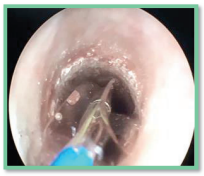
[4]Zasadil LM, Andersen KA, Yeum D, et al. Cytotoxity of paclitaxel in breast cancer is due to chromosome missegregation on multipolar spindles. Sci Transl Med 2014;6(229):229ra43

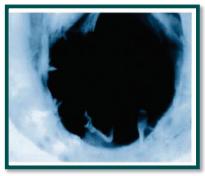
MODE OF ACTION

Mechanical Dilation

1. Guidewire placed across the stricture, Optilume® DCB introduced over the guidewire
2. Optilume® DCB inflated to appropriate ATM plastically deforming stricture and opening urethral lumen
3. Creates micro-fissures in the urothelium enabling focused delivery of paclitaxel directly to strictured urethra



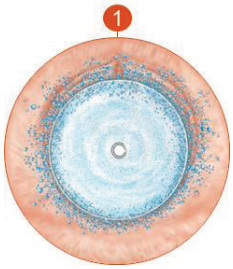


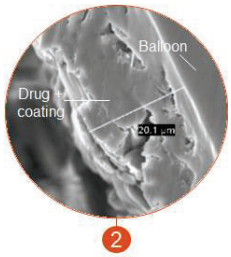


MODE OF ACTION

Simultaneous Drug Delivery

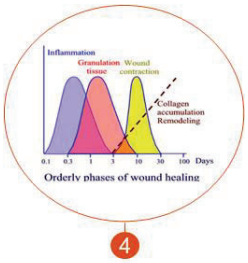
Paclitaxel is circumferentially delivered





Precision drug dose (3.5µg/mm²)

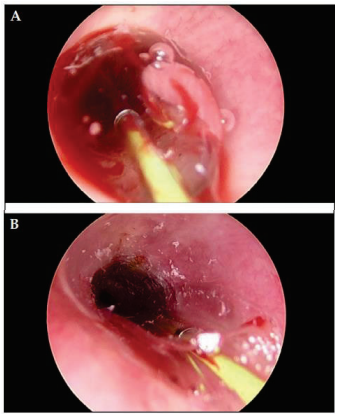
Hydrophobic drug is absorbed by target tissue



Paclitaxel remains present through inflammatory, proliferation and remodeling stages of wound healing

OPTILUME® FEATURES AND BENEFITS

- Reduces the **high recurrence cycle** of failed endoscopic stricture management[6]
- **Minimally invasive, ambulatory treatment option**
- Procedure can be performed under both **rigid or flexible cystoscopy** for maximum patient comfort
- **Rapid & sustained** improvement in symptoms and flow[5]
- **Consistent safety** and side effect profile in-line with existing stricture management[3]
- **Local** or light anesthesia procedure
- Preserves sexual function[7]
- **Cost-effective** alternative to recurrent endoscopic management[7]



A. Direct visualization if inflated Optilume.®
B. Post-treatment deflation of balloon with visible coating adherent to Urothelium

[3]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; [5] Elliott SP, Virasoro R, Estrella R, et al. MP56-06 The Optilume Drug Coated Balloon for Recurrent Anterior Urethral Strictures: 3-year Results from the ROBUST I Study. *J Urol* 2021;206(3S):e971.; [6]Mann RA, et al. Can Urol Assoc J 2021;15(2):20-5. http://dx.doi.org/10.5489/cuaj.6661. [7]Data on file

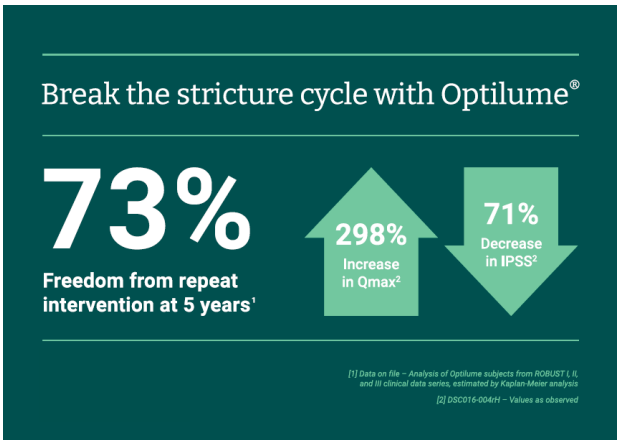
ROBUST Clinical Program Summary – Results Through 5 Years

TAKEAWAY POINTS

Freedom from Repeat Intervention
73% of the patients in the pooled data of ROBUST I, II, III remained free from repeat intervention through 5 Years

Flow Rate Increased To: 16.4 mL/sec

Symptom Scores Decreased To: 9.8



Optilume: Recommended in the AUA Urethral Stricture Disease Guideline

TAKEAWAY POINTS

The Optilume Urethral Drug Coated Balloon is a treatment option for recurrent short bulbar urethral strictures per recommendation from the American Urological Association.

American Urological Association

THE JOURNAL of UROLOGY®
Official Journal of the American Urological Association

Urethral Stricture Disease Guideline (2023)

"Surgeons may perform urethral dilation, or direct visual internal urethrotomy combined with **drug-coated balloons**, for recurrent bulbar urethral strictures <3cm in length."[1]

[1]Wessells H, Morey A, Vanni A, Rahimi L, Souter L. Urethral Stricture Disease Guideline Amendment (2023). J Urol. 2023 Apr 25:101097JU0000000000003482. doi: 10.1097/JU.0000000000003482. Epub ahead of print. PMID: 37096574.

ROBUST CLINICAL PROGRAM - OVERVIEW

Study	ROBUST I	ROBUST II	ROBUST III
Design	Single arm, prospective, multicenter	Single arm, prospective, multicenter	Randomized (2:1), prospective, single blind, multicenter
Geography	Latin America	United States	United States and Canada
Sites	4	5	22
Total Enrollment	53	16	127 ▪ Optilume® DCB: 79 ▪ Standard of Care: 48
Procedure	Optilume® DCB Pre-dilation ▪ Plain balloon: 31/53 (59%) ▪ DVIU: 8/53 (15%) ▪ Balloon + DVIU: 14/53 (26%)	Optilume® DCB Pre-dilation ▪ None: 9/16 (56.3%) ▪ Plain balloon: 3/16 (18.8%) ▪ DVIU: 2/16 (12.5%) ▪ Balloon + DVIU: 1/16 (6.3%)	Optilume® DCB Pre-dilation ▪ Plain balloon: 72/79 (91.1%) ▪ DVIU: 3/79 (3.8%) ▪ Balloon + DVIU: 4/79 (5.1%) Standard of Care ▪ Plain Balloon: 28/48 (58.3%) ▪ DVIU: 12/48 (25.0%) ▪ Rigid Rods: 8/48 (16.7%)

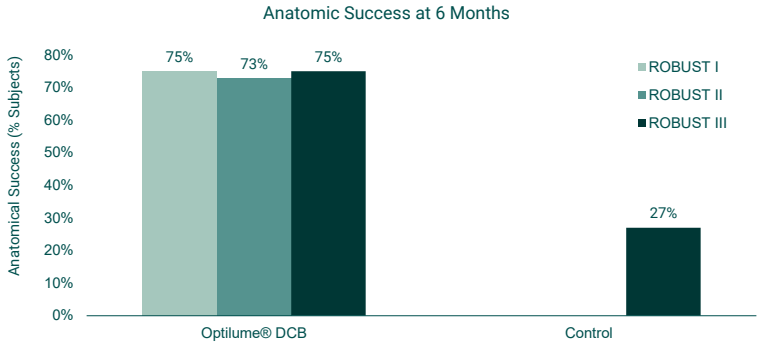
ROBUST CLINICAL PROGRAM - CHARACTERISTICS

Stricture Characteristics	ROBUST I	ROBUST II	ROBUST III
Stricture Length	0.9cm ± 0.5cm (53) ▪ Proportion ≥2cm: 1/53 (1.9%)	2.1cm ± 0.7cm (16) ▪ Proportion ≥2cm: 13/16 (81.3%)	1.6cm ± 0.8cm (79) ▪ Proportion ≥2cm: 36/79 (45.6%)
Prior Dilations	1.7 ± 0.8 (53) ▪ Proportion with ≥2: 43%	4.1 ± 4.9 (16) ▪ Proportion with ≥2: 100%	3.2 ± 1.73 (79) ▪ Proportion with ≥2: 100%
Anatomical location	Bulbar: 53/53 (100%) Penile: 0/53 (0%)	Bulbar: 16/16 (100%) Penile: 0/16 (0%)	Bulbar: 71/79 (89.9%) Penile: 8/79 (10.1%)
Etiology	Idiopathic: 2/53 (3.8%) Iatrogenic: 24/53 (45.3%) Traumatic: 27/53 (50.9%) Inflammatory: 0/53 (0.0%)	Idiopathic: 11/16 (68.8%) Iatrogenic: 2/16 (12.5%) Traumatic: 3/16 (18.8%) Inflammatory: 0/16 (0.0%)	Idiopathic: 42/78 (53.8%) Iatrogenic: 21/78 (26.9%) Traumatic: 14/78 (17.9%) Inflammatory: 1/78 (1.3%)
Baseline retention	27/53 (50.9%)	1/16 (6.3%)	26/79 (32.9%)
Prior Radiation	0/53 (0.0%)	0/16 (0.0%)	9/79 (11.4%)

Stricture characteristics represent a **difficult patient population for all studies**, particularly so for ROBUST II and ROBUST III (≥2 prior dilations and >2cm ≤3cm)

Similar stricture characteristics were seen in both Optilume® DCB and Control arms in ROBUST III

ROBUST CLINICAL PROGRAM – 6-MONTH ANATOMIC SUCCESS

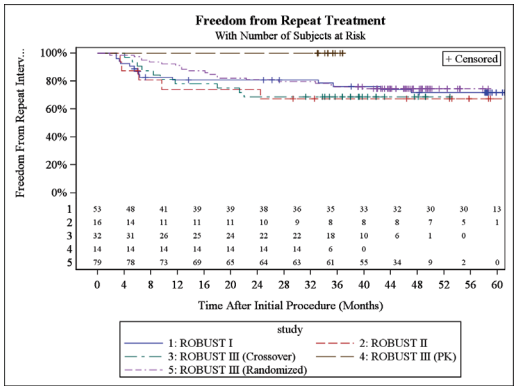


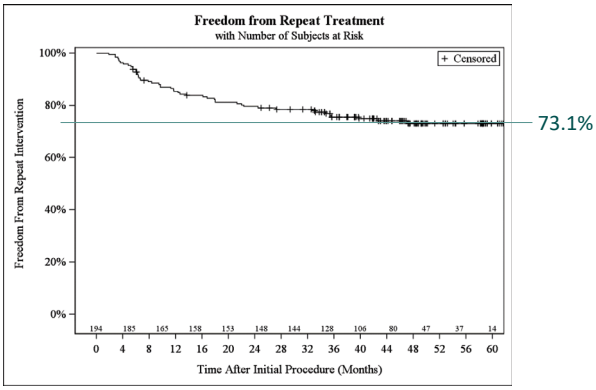
TAKEAWAY POINTS

Anatomic Success – ability to pass a 16F flexible cystoscope through treated area without prior repeat intervention

Consistent outcomes with the Optilume® DCB in increasingly difficult patient populations. Control outcomes similar among different types of dilation (DVIU, balloon, rigid rods) in ROBUST III.

ROBUST Clinical Program – Freedom from Repeat Intervention

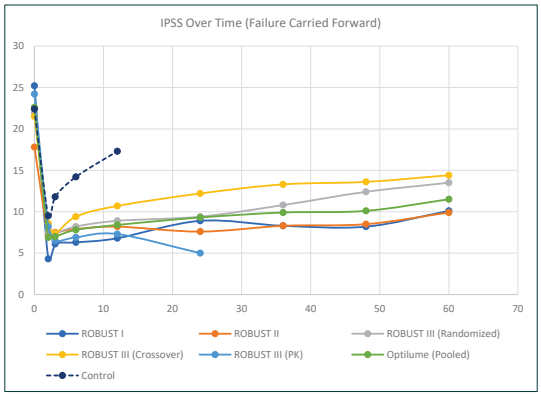


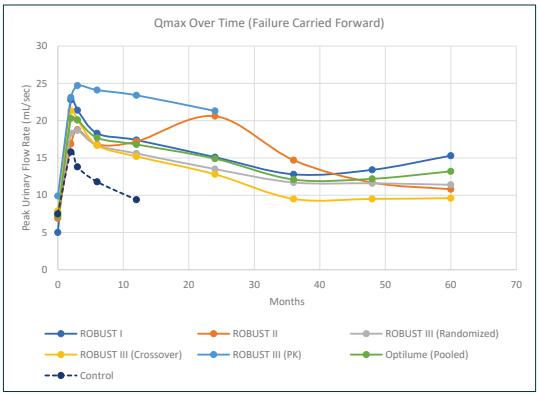


TAKEAWAY POINTS

- Freedom from repeat endoscopic treatment, urethroplasty, or clean intermittent catheterization through the stated follow up.

ROBUST Clinical Program – IPSS and Qmax





TAKEAWAY POINTS

- **Symptom Scores:** International Prostate Symptom Score (IPSS) remains steady through 4-year follow-up
- **Peak Flow Rate:** Qmax values are sustained at 4-year follow-up

OPTILUME® STRICTURE – CLINICAL DATA SUMMARY

ROBUST-I First-in Man Study & ROBUST-II Early Feasibility Study

ROBUST I Study

- Prospective, multicenter, single arm study evaluating the safety and efficacy of the Optilume® DCB in recurrent anterior urethral strictures.
- A total of 53 subjects were enrolled at 4 investigational centers in Panama and the Dominican Republic.
- Key eligibility criteria included anterior urethral strictures ≤2 cm in length with 1-3 prior dilations. Subjects with prior urethroplasty, Lichen Sclerosis, penile implants or artificial urinary sphincters, and prior pelvic radiation were excluded.
- Follow up is planned through 5 years post-treatment.

ROBUST II Study

- Prospective, multicenter, single arm study evaluating the safety and early feasibility of the Optilume® DCB.
- A total of 16 subjects were enrolled at 5 investigational centers. Key eligibility criteria were similar to ROBUST I with the exception of allowing stricture length up to 3cm and requiring a minimum of 2 prior endoscopic treatments of the stricture.
- Study strictures were an average of 2.1cm in length and had an average of 4.1 prior dilations. Freedom from stricture recurrence at 6 months was 73% (11/15).
- Subject follow-up is complete through 1 year and 2-year follow-up is ongoing.

Table 13-9: ROBUST I Efficacy Results

Measure	Baseline	3 Months	6 Months	1 Year	2 Years	3 Years
IPSS	25.2 ± 4.5 (53)	6.1 ± 7.6 (51)	4.6 ± 5.2 (45)	4.5 ± 3.9 (40)	6.9 ± 7.7 (38)	5.5 ± 6.9 (33)
IPSS QoL	4.9 ± 0.9 (53)	0.8 ± 1.3 (51)	0.7 ± 0.9 (45)	0.7 ± 0.9 (40)	0.9 ± 1.5 (38)	0.7 ± 1.2 (33)
Qmax (mL/sec)	5.0 ± 2.6 (46)	22.2 ± 12.5 (51)	19.8 ± 10.8 (45)	20.1 ± 10.0 (39)	17.5 ± 10.4 (38)	15.1 ± 8.3 (33)
PVR (mL)	141.4 ± 105.1 (43)	36.5 ± 37.7 (51)	30.0 ± 42.8 (45)	24.6 ± 32.1 (39)	45.5 ± 49.5 (38)	50.2 ± 62.5 (33)

Table 13-10: ROBUST-II Efficacy Results

Measure	Baseline	3 Months	6 Months	1 Year
IPSS	18.4 ± 4.9 (16)	7.5 ± 6.4 (16)	7.0 ± 6.7 (14)	6.0 ± 6.1 (9)
IPSS QoL	4.4 ± 1.3 (16)	1.8 ± 1.8 (16)	1.6 ± 1.5 (14)	1.4 ± 1.5 (9)
Qmax (mL/sec)	6.9 ± 3.7 (16)	18.9 ± 16.4 (15)	17.5 ± 9.4 (13)	20.8 ± 9.1 (9)
PVR (mL)	187.1 ± 227.1 (16)	79.3 ± 80.3 (15)	64.1 ± 40.2 (13)	66.4 ± 57.5 (9)

OPTILUME® STRICTURE – CLINICAL DATA SUMMARY

ROBUST-III Pivotal Randomized study

ROBUST III Study

- ROBUST III study is a prospective, 2:1 randomized, multicenter, single blind trial comparing the Optilume® DCB against SOC endoscopic management of recurrent anterior urethral strictures. Eligibility criteria included visually confirmed anterior urethral strictures ≤3cm in length and <12F in diameter with at least 2 prior endoscopic treatments. Subjects with active UTI, prior urethroplasty, Lichen Sclerosis, uncontrolled diabetes (HbA1C >8%), and unresolved or untreated confounding urologic conditions (e.g. BPH, BNC, OAB) were excluded.
- Follow-up visits were completed at the time of Foley removal (2-5 days), 30 days, 3 months, 6 months, and 12 months post-treatment. Subjects were blinded to treatment received through primary follow-up of 6 months. Long term follow-up is planned through 5 years for subjects receiving the Optilume® DCB.
- Subjects randomized to SOC endoscopic management were allowed to cross over to receive the Optilume® DCB prior to the close of the 12-month follow-up window if stricture recurrence was confirmed by recurrent lower urinary tract symptoms (LUTS) and urethral diameter <12F measured by urethrogram. Subjects crossing over to receive the Optilume® DCB will be followed according to the standard follow-up schedule through 5 years, beginning on the date Optilume® DCB treatment was received.

Table 13-3. Primary Safety Endpoint Results

Endpoint	Control n/N (%)	Optilume DCB n/N (%)
Serious device or procedure related complication through 3 months post-treatment	0/48 (0.0%)	0/79 (0.0%)
Formation of Fistula	*0/48 (0.0%)*	*0/79 (0.0%)*
Unresolved De Novo Stress Urinary Incontinence	*0/48 (0.0%)*	*0/79 (0.0%)*
Urethra Rupture or Burst	*0/48 (0.0%)*	*0/79 (0.0%)*

Table 12-6. Primary Efficacy Endpoint Results (Complete Case)

Endpoint	Control (n=48)	Optilume DCB (n=79)	Difference [95% CI]	p-value
Proportion of Subjects Stricture Free	26.8% (11/41)	74.6% (50/67)	47.8% [28.7% – 66.9%]	<0.0001

P-value is based on two-sample continuity corrected Chi-square test.

A total of 19 subjects are missing the primary endpoint assessment in the randomized cohort. The rate of missing primary endpoint data was balanced between arms, with 12 (15.2%) in the Treatment arm and 7 (14.6%) in the Control arm. Five (5) subjects missed their 6-month visit due to COVID concerns, 6 subjects had their 6-month visit done remotely due to site or government COVID policy, 4 subjects withdrew from the study prior to the 6-month visit, and 4 subjects missed their 6 month visit for reasons not known to be directly related to COVID.

Endpoint	Control (n=48)	Optilume DCB (n=79)	Difference[a] [90% CI]	p-value[a]
Change in Qmax at 6 Months n Mean ± Std Dev	 31 5.6 ± 7.8	 65 9.1 ± 9.1	 +4.78 [1.94 - 7.61]	 0.0031

[a] Estimate of the difference (Optilume-Control), 95% CI, and 1-sided p-value are based on the model based estimates resulting from multiple-imputation of missing data.

OPTILUME® STRICTURE – PATIENT SELECTION

Optilume® DCB Indications

- The Optilume® Urethral Drug Coated Balloon is used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture
- It is designed to be used in adult males for urethral stricture of ≤3 cm in length

Contraindications

- The Optilume® Urethral Drug Coated Balloon is contraindicated for use in patients with known hypersensitivity to paclitaxel or structurally related compounds, and
- In patients with implants such as penile prosthesis or artificial urinary sphincter

Optilume® DCB Product Selection[7]

- Select a balloon length that is a minimum of 1cm longer that the stricture
- If the stricture is greater than 2cm, a 5cm balloon should be chosen
- Select a balloon diameter that is slightly larger than the diameter of the healthy urethra adjacent to the distal edge of the stricture. (Most common is 30F. 18, 24, and 36F are also available)
- Either a rigid or flexible cystoscope can be used in conjunction with a flexible tip 0.038" or 0.035" guidewire
- Use a standard inflation device with a pressure gauge rated for at least 15atm, filled with saline or a mixture of 50:50 contrast:saline mix
- Minimize handling and do not wipe the balloon with dry, wet or lubricated gauze, or any solvent that could damage the integrity of the drug coating
- Refer to the IFU for information on device handling and balloon size selection (Optilume DCB IFU 1111-003)

[7]Elterman DS, Coutinho K, Hagedorn JC. How I do it: the Optilume drug-coated balloon for urethral strictures. *Can J Urol* 2020; 27)+(4); 10322-10328

OPTILUME® MOST COMMON USE

OPTBDL7002B	Optilume® DCB and Inflation Device	24Fr	3cm	75cm	12 atm	2,639
OPTBDL7003B	Optilume® DCB and Inflation Device	24Fr	5cm	75cm	12 atm	4,398
OPTBDL7004B	Optilume® DCB and Inflation Device	30Fr	3cm	75cm	10 atm	3,299
OPTBDL7005B	Optilume® DCB and Inflation Device	30Fr	5cm	75cm	10 atm	5,498

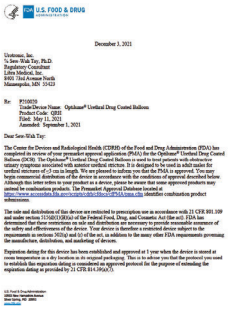
OPTILUME® STRICTURE – IFU

WARNINGS

- The Optilume® DCB is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- The foil pouch and the outer surface of the inner Tyvek pouch are NON-STERILE. The CONTENTS of the inner Tyvek pouch are STERILE.
- Do not use this device if there is an active infection in the urinary tract (UTI). Infection must be resolved before treating the stricture with the Optilume® DCB.
- Do not use after the "Use By" date.
- Men should abstain from sex or use barrier contraception (wear a condom) for 30 days post treatment to avoid exposure of sexual partner to paclitaxel. Paclitaxel may still be present at very low levels after 30 days, see Section 12.1.9.
- The Optilume® DCB contains paclitaxel, a known genotoxic aneugen. Because paclitaxel may be present in semen after treatment with the Optilume® DCB (Section 12.1.9), men with partners of child-bearing potential should use highly effective contraceptive and avoid fathering children until at least 6 months after treatment with the Optilume® DCB. Paclitaxel was detectable in semen in 60% (9/15), 39% (5/13) and 8.3% (1/12) of subjects at 1 month, 3 months, and 6 months post-treatment, respectively.
- Maximum paclitaxel concentrations in semen were 17.6, 3.5, and 0.9 ng/mL at 1 month, 3 month and 6 months, respectively, while group mean (SD) paclitaxel concentrations in semen at those same timepoints were 3.0 (4.9), 0.5 (1.0), and 0.1 (0.2) ng/mL. Mean paclitaxel semen concentrations approached the lower limit of quantitation (0.1 ng/mL) at 6 months post-treatment. The risks associated with these paclitaxel concentrations in semen are unknown. The effect of treatment with the Optilume® DCB on sperm and spermatogenesis is also unknown.
- Do not manipulate the Optilume® DCB in an inflated state. Aspirate (deflate) the balloon completely before gently removing the device from the urethra.
- If resistance is encountered at any time during the insertion or withdrawal of the device do not force passage. Resistance may cause damage to device or urethra.
- The impact of multiple treatments with the Optilume® DCB for the same stricture has not been extensively studied. Multiple treatments of the same stricture will increase exposure to paclitaxel, the risks associated with this are currently unknown.

OPTILUME® REGULATORY INFORMATION

Product Classification Details	Description
Generic Name	Catheter, Balloon, Urethral, Drug-Coated
Trade Name	Optilume® Urethral Drug Coated Balloon
Indications for Use	The Optilume® Urethral Drug Coated Balloon is used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for urethral strictures of ≤3 cm in length.
PMA Number	P210020
FDA Classification	Class III
Approval Date	12/03/2021
Product Code	QRH
Target Area	Urethra
Technical Method	Exert radial force to dilate narrow urethral segment (strictures)
Submission Type	PMA



December 3, 2021

Urotronic, Inc.
℅ Jane Wah Tay, Ph.D.
Regulatory Consultant
Lifes Medical, Inc.
8401 73rd Avenue North
Minneapolis, MN 55428

Re: P210020
Trade/Device Name: Optilume® Urethral Drug Coated Balloon
Product Code: QRH
Filed: May 11, 2021
Amended: September 1, 2021

Dear Jane Wah Tay:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed the review of your premarket approval application (PMA) for the Optilume® Urethral Drug Coated Balloon (DCB). The Optilume® Urethral Drug Coated Balloon is used to treat patients with obstructive urinary symptoms associated with anterior urethral stricture. It is designed to be used in adult males for urethral strictures of ≤3 cm in length. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that such restrictions are necessary for the safe and effective use of the device because of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 1 year when the device is stored at room temperature in a dry location as its original packaging. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(3).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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[7] Data on file

[8] CPT is a registered trademark of the American Medical Association. Copyright 2020. All rights reserved.

[9] CMS 2024 Physician Fee Schedule. Addendum B.

[10] CMS 2024 Hospital Outpatient Fee Schedule. Addendum B.

[11] CMS 2024 Ambulatory Surgery Center Fee Schedule. Addendum B.

[12] 2024 Healthcare Common Procedure Coding System (HCPCS) Level II Expert. ©2024 AAPC.

[13] 2024 Revenue Code. National Uniform Billing Committee (NUBC) -https://www.nubc.org/.

QUESTIONS?