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Drug-Coated Balloon For Urethral Strictures Debuts In Europe, Version For BPH Planned

by Phil Greenfield

Urotronic set to complete a $20m series C, bringing its total funding to $61m for the development of drug-eluting balloon-based urology products.

Urotronic Inc will launch its first product in the EU, a paclitaxel-coated balloon for urethral strictures in men, after receiving CE mark approval on 14 September.

The Optilume treatment, which is already approved in Canada, New Zealand, Israel and Hong Kong, is a minimally invasive, outpatient procedure designed as an alternative to direct vision internal urethrotomy (DVIU, endoscopic cutting of the stricture) and the gold standard urethroplasty (major surgery to excise the stricture). These established procedures carry either a high risk of recurrence, lengthy treatment and recovery times or patient dissatisfaction. Non-coated balloons are also sometimes used, as are other endoscopic techniques, but their effect can be short-lived.

Optilume combines balloon dilation of the stricture with the delivery of paclitaxel to the urethral wall, via a proprietary balloon coating, to prevent recurrence of the blockage. The procedure takes as little as 15 minutes to perform and the effect has been shown to last for two years or more.

The effectiveness of Optilume for urinary strictures was demonstrated in the *ROBUST I* pilot study, in which 70% (32/46) of patients met the primary end point of a 50% improvement in International Prostate Symptom Score (IPSS) at two years. The mean IPSS score improved from 25.2 before treatment with Optilume to 6.9 after two years. ROBUST I enrolled and treated a total of 53 patients with recurrent strictures up to 2cm long who had received one to four previous endoscopic treatments.

ROBUST III, an ongoing prospective, multicenter trial is randomizing patients in a 2:1 ratio to Optilume or a control device, which may be a rod, uncoated balloon or DVIU, depending on

which approach is the best for the patient.

Over a million men in Europe suffer from strictures, which are caused by scarring from infections, trauma and other medical procedures that injure the lining of the urethra. They block the flow of urine and can result in a painful slowing of the urinary system and can significantly impact quality of life. However, only a small proportion, around 5-10%, seek treatment.

“Stricture is not a particularly big segment, however millions of patients globally suffer year over year," Urotronic CEO David Perry told *Medtech Insight*. He added that while urethroplasty provides satisfactory outcomes, it is associated with lengthy operating room time, extended hospital stay, prolonged patient recovery and patient dissatisfaction. Minimally invasive treatments are favored by patients, but carry a high risk of recurrence. "Optilume offers an innovative alternative for the treatment of urethral stricture via a minimally invasive procedure with the proven safety profile of existing techniques, while providing longer term durability breaking the 'stricture cycle' patients find themselves in,” said Perry.

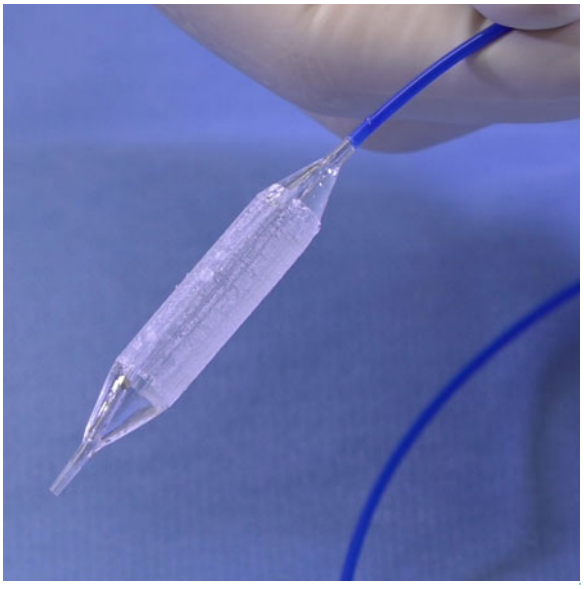
BPH Treatment A Bigger Potential Market

Urotronic is also advancing Optilume as a potential treatment for benign prostatic hyperplasia (BPH), using a specially developed balloon device. Following the successful EVEREST-1 Optilume pilot trial in men with BPH, the prospective, double-blind, randomized *PINNACLE* trial is aiming to confirm the safety and efficacy of the device in this setting. The trial, which is accruing patients with symptomatic BPH at 18 locations in the US, is randomizing men to either Optilume or a sham device.

Presenting EVEREST-1 data at the American Urological Association 2020 Virtual Experience in July, principal investigator Steven Kaplan said the Optilume system could provide TURP (transurethral resection of the prostate)-like results without cutting, burning, steaming, lasering, or leaving a permanent implant behind, and it is designed to minimize or eliminate the common adverse effects associated with other surgical BPH procedures.

Kaplan, who is professor of urology at the Icahn School of Medicine at Mount Sinai in New York, said that among the 79 patients evaluated at three months, 65 (82%) met the efficacy end point of an improvement of 40% or greater on the IPSS and there were no major device- or procedure-related adverse events at three months. The mean IPSS score was 22.3 at baseline and had improved to 8.3, 8.0, and 7.9 at three, six and 12 months, respectively. The mean peak flow rate was 10.9 mL/second at baseline and 19.6 mL/second at 12 months.

Three different balloon sizes allow for customized treatment based on ultrasound measurement of prostate length, height and total volume.



OPTILUME DRUG-COATED BALLOON *Source: Urotronic*

Nearly 12 million men in the US are actively treated for BPH, with at least 60% being managed by drugs, so the potential for this indication is significant. (Also see "*Market Intel: Minimally Invasive Procedures Gaining Traction In BPH Treatment Market*" - Medtech Insight, 18 Feb, 2020.)

Technology Developed By Peripheral Vascular Pioneer

Based in Plymouth, MN, Urotronic was founded in 2014 by *Lutonix Inc* co-founder Lixiao Wang, who created the first drug-coated balloon for peripheral vascular applications. Lutonix was sold to CR Bard (now part of *Becton, Dickinson and Company*) for $325m in 2011. (Also see "*Bard Buys Lutonix For Lead In Race To U.S. Market With Drug-Coated Balloon*" - Medtech Insight, 2 Jan, 2012.)

Wang kept the rights to the technology for urology applications, working with Perry to set up the new company.

Perry told *Medtech Insight* that Urotronic will soon close a $20m series C financing round that would fund it through to US Food and Drug Administration approval of both versions of Optilume, which he expects by the fourth quarter of 2021, as well as European launch of Optilume for BPH. This brings total funding for the company to $61m.

Urotronic is also planning to grow staff numbers, from the current 14 full-time staff, partly by making its eight contractors – including its CFO, VP of global sales and VP of regulatory – permanent employees, said Perry. The company has also recently moved into a larger building that will give it room for four manufacturing lines.

EU Launch Plans

James Wright, director of market access for the EMEA region, told *Medtech Insight* that "Optilume stricture will enter specific strategic markets across the EU immediately and upon relevant regulatory approvals in time, we will then launch Optilume BPH."

"Given the varying healthcare landscapes across the EU, in specific key strategic markets we will launch a go-direct strategy for Optilume while across Europe we are working with distribution partners to assist with launch plans, clinical education and procedural adoption in other specific geographies."

The company plans to work with key opinion leaders in urology in specific markets across the EU, including Oliver Kayes, consultant urologist at Leeds Teaching Hospital NHS Trust in Yorkshire, UK.

Editor's note*: This story was updated on 30 September 2020 to correct the year of the company's creation to 2014, not 2018 as previously stated.*