

Section 1: Application Summary

Name of Product	UroLift® Delivery System
Australian launch date	Relaunched the UroLift® Delivery System July 2018
Products used in (please select)	✓ diagnosis ✓ prevention ✓ treatment ✓ management
Contact details	Thuy.Le@teleflex.com or 0439 488 324

Your details

Name	Thuy Le	Position	Marketing Manager
Email	Thuy.le@teleflex.com	Phone	0439 488 324
Name of Company	Teleflex	ABN	74096142675

Executive Summary: [200 words max.] NB Executive Summary must be suitable for use in Award promotion

Teleflex is a leading global provider of medical technologies designed to improve the health and quality of people's lives. Teleflex's diverse portfolio offers solutions in the fields of urology, surgical, vascular and interventional access, anaesthesia, cardiac care, respiratory care and emergency medicine and is home to trusted brands such as UroLift®, Rusch®, Weck® Pilling®, Arrow®, LMA®, Deknatel® and Hudson RCI®.

In Urology, Teleflex is a leader in the minimally invasive management of benign prostatic hyperplasia (BPH) with an innovative and proven technology called the UroLift® System.

There are 2.4 million Australian men over the aged of 50 suffer from enlarged prostate or Benign Prostatic Hyperplasia (BPH). Symptoms of BPH may include frequent urination, difficulty starting to urinate or trouble emptying the bladder and men need to get up multiple times per night, which can lead to lost and disturbed sleep. There is significant impact on their quality of life, with behavioural changes including reduced participation in sport, social and travel activities.

With UroLift® patients experience rapid relief and recovery in days, increased urinary flow rates, no tissue destruction and preservation of sexual function compared to medication and surgery.

Section 2: Product Details

Describe the technology [300 words max.]

The UroLift® System is a truly minimally invasive approach to treating BPH that shows symptom relief significantly better than medication with a risk profile better than surgery.

The UroLift® is the only BPH procedure that does not require thermal energy or removal of prostate tissue. Small transprostatic implants are deployed within the prostate to mechanically open the prostatic fossa, rather than relying on an extended healing response to achieve de-obstruction. It has truly redefined the paradigm on BPH treatment by giving patients the only minimally invasive therapy that significantly improves the quality of life of patients. It is the ONLY treatment with no new, sustained erectile or ejaculatory dysfunction and is a simple and straight forward procedure that offers a better patient experience.

In summary the UroLift® offers:

- Rapid relief and recovery in days.
- The only BPH procedure which shows no new, sustained erectile or ejaculatory dysfunction.
- No tissue destruction.
- Proven durability through 5 years with 25 peer-reviewed clinical publications.

At present, over 100,000 men have been treated with the UroLift® System worldwide. We continue to focus on improving the quality of life of more men suffering from BPH.

What health problem is the technology addressing and how does it address the problem? [300 words max.]

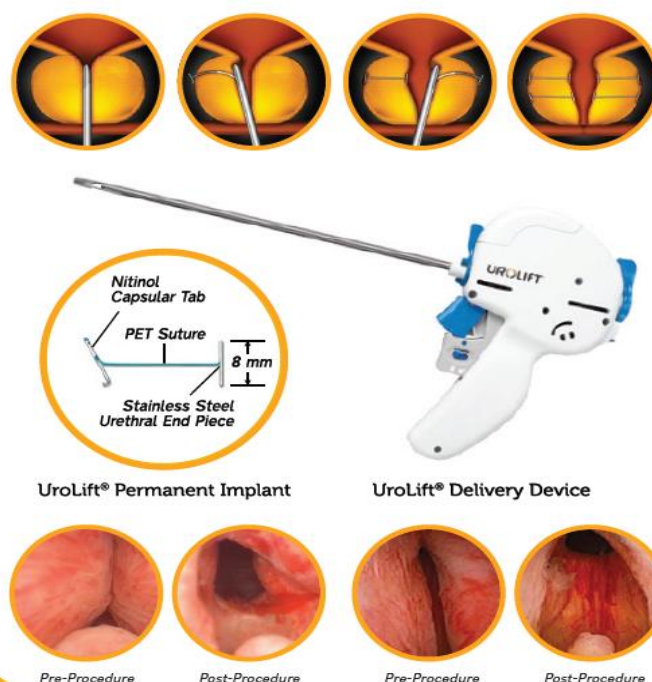
2.4 million Australian men over the aged of 50 suffer from enlarged prostate or Benign Prostatic Hyperplasia (BPH). More than 50% of men over the age of 60 are diagnosed with BPH and by 85 the number climbs to 90%.

Symptoms include frequent urination, getting up multiple times per night, difficulty starting to urinate and emptying the bladder. Research reveals that 68% of men with BPH say these symptoms impact their quality of life including disruption of sleep patterns, negative impact on relationships, resulting in social isolation and depression.

Before UroLift® System, men had three pathways for BPH treatment:
Watch and Wait, medication or tissue destructive surgery.

- Watchful Waiting typically results in symptoms worsening over time, impacting on bladder health.
- Medication can take weeks or months to work with limited and variable success while causing unbearable side-effects including tiredness, dizziness and sexual dysfunction. These side-effects are debilitating that 1 out of 5 patients take themselves off drug therapy due to lack of results and side-effects.
- Tissue destructive surgery has significant downsides including urinary incontinence, catheterisation, sexual dysfunction and a longer recovery time.

The UroLift® is a truly minimally invasive approach to treating BPH that shows symptom relief significantly better than medication with a risk profile better than surgery.



(Images courtesy of Dr. Peter Chin, Wollongong NSW Australia)

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What other products are currently available to address this issue and how does this technology differ from and/or improve on existing technology? [300 words max.]

Historically, the available surgical interventions include removal of prostate tissue, injure, heat or ablate the prostate tissue or opening the prostate which cause significant downsides including urinary incontinence, catheterisation, sexual dysfunction and a longer recovery time. Watchful Waiting typically results in symptoms worsening over time, impacting on bladder health. Medication can take weeks or months to work with limited and variable success while causing unbearable side-effects including tiredness, dizziness and sexual dysfunction.

The UroLift® System is the only BPH procedure that does not require thermal energy or removal of prostate tissue. Small transprostatic implants are deployed within the prostate to mechanically open the prostatic fossa, rather than relying on an extended healing response to achieve de-obstruction. It has truly redefined the paradigm on BPH treatment by giving patients the only minimally invasive therapy that significantly improves the quality of life of patients. It is the ONLY treatment with no new, sustained erectile or ejaculatory dysfunction^{4,5} and is a simple and straight forward procedure that offers a better patient experience.

The UroLift® has been significantly studied for over 12 years, which is chronicled in over 25 peer-reviewed publications, including two randomized multi-center studies, five-year durability data and seven open label studies. Results across these numerous studies in different clinical settings, healthcare systems, patient demographics and surgeons' experiences have consistently shown rapid and durable relief from lower urinary tract symptoms (LUTS) and a unique preservation of both erectile and ejaculatory function.

In May 2018, the American Urology Association updated its BPH Guidelines, which included a recommendation that Urologists should consider the Prostatic Urethral Lift (PUL) for the treatment of certain men with LUTS presumed secondary to BPH. It recognises UroLift® is now a part of the standard of care in BPH treatment.

Having regard to the consumer's quality of life, does the product provide a balance between invasiveness and efficacy? [300 words max.]

The International Prostate Symptom Score (IPSS) is a globally used standardised screening tool for tracking, diagnosing and measuring symptoms of BPH. The IPSS also rates the patient's perceived quality of life and is recognised by urologists and international bodies around the world.

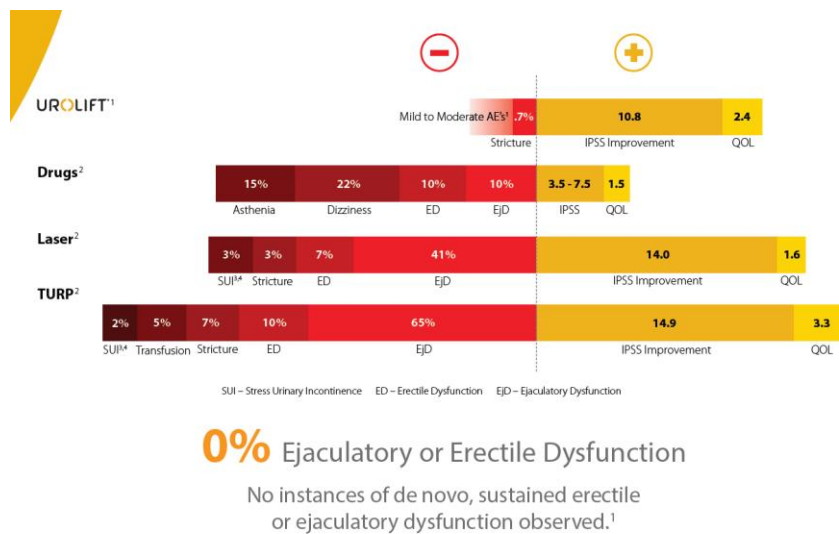
The level 1 data (FDA IDE study) for UroLift® showed a 10.8-point decrease in IPSS and a 59% increase in QMAX at one year. Also demonstrated and published in the FDA IDE study was a five-year relief of symptoms and improvement of flow, similar to the gold standard of TURP with a side-effect profile favourable to drug therapy.

Internationally, the patient experience has been so positive that many urologists are offering it as an earlier treatment option. Below, Peter Tonaros, a patient who suffered from BPH in Australia said "since having the UroLift procedure it has changed my life. I have peace with sleeping, my wife is not kicking me out of bed as I don't get up and move around during the night anymore and I feel better about myself." Peter's testimonial can be provided if requested as the file was too big to send in the submission. This reflects the experience of over 100,000 men who have turned to the UroLift® procedure for successful symptom relief of BPH.



Patients experience rapid symptomatic improvement, increased urinary flow rates and preservation of sexual function compared to medication and surgery as evidenced in the graphs below. UroLift® outcomes are similar to gold standard TURP (10.8-11.4 IPSS improvement vs 14/14.8 respectively) with minimal side-effects fewer than drug therapy.

The post-procedure care for UroLift® patients is also significantly reduced with minimal or no catheterisation and patient return back to normal activities. These results have been reproduced and seen across all UroLift® 25 PUL studies including two randomised studies. Results published in journals such as at the BJUI, European Urology, the Journal of Urology. These are represented graphically below.



Include scientific evidence to support the claims. This may include published data, unpublished scientific data, results of clinical trials and/or patient feedback. Photographs may be submitted. Product samples will not be accepted.

The UroLift® System was designed for Urologists to treat a mechanical problem with a mechanical solution by opening the constricting lateral lobes of the prostate thereby reducing LUTS without the majority of side-effects and disadvantages of both drugs and surgical therapies.

There UroLift® System also has been significantly studied for over 12 years, which is chronicled in over 25 peer-reviewed publications, including two randomized multicenter studies, five-year durability data and seven open label studies. Results across these numerous studies in different clinical settings, healthcare systems, patient demographics and surgeons' experiences have consistently shown rapid and durable relief from lower urinary tract symptoms (LUTS) and a unique preservation of both erectile and ejaculatory function.⁴

The L.I.F.T study, (Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS), the largest, prospective, multicenter, randomized, controlled trial on the minimally invasive PUL to date stated:

PUL offers rapid improvement in symptoms, QOL and flow rate that is durable to 5 years. These improvements were achieved with minimal use of a postoperative urinary catheter, rapid return to normal, and preservation of both erectile and ejaculatory function. Symptom improvement was commensurate with patient satisfaction. PUL offers a minimally invasive option in the treatment of LUTS due to BPH.

UroLift® has been proven to provide long-term (durable) symptom relief,⁴ while being a truly minimally invasive procedure from the perspective of the surgeon and patient. Overseas, UroLift® is done under local anaesthetic requiring no overnight stay and provides symptom relief with minimal disruption to a patient's life. It also reduces the overall cost to the health system by shortening overnight hospital stays associated with traditional surgical interventions.

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UroLift® has been included in the AUA and NICE guidelines and fits well within the urologists current and regular skillset, thereby having a relatively short learning curve. In May 2018, the American Urology Association updated its BPH Guidelines, which include a recommendation that Urologists should consider the Prostatic Urethral Lift (PUL) for the treatment of certain men with LUTS presumed secondary to BPH. It recognises the UroLift is now a part of the standard of care in BPH treatment.

AUA GUIDELINE HIGHLIGHTS:

- Urologists “should consider” PUL....
- Patients “should be made aware that surgical treatment can cause ejaculatory dysfunction (EjD) and may worsen ED.”
- “In men so concerned about new onset of ED and/or EjD, PUL likely does not pose additional risk.”



PROSTATIC URETHRAL LIFT (PUL)

14. Clinicians should consider PUL as an option for patients with LUTS attributed to BPH provided prostate volume <80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP. (Moderate Recommendation;



American
Urological
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In addition to this, the UroLift® procedure was identified by Urologist Mr Jim Duthie in New Zealand to be the chosen technique to be held as an in-surgery Skype mentoring procedure. This world first included Sydney based Professor Henry Woo providing guidance via a Skype link. Professor Henry Woo, along with Associate Professor Peter Chin, were also involved in performing the first UroLift® procedure in Australia as part of the safety and feasibility study.

Associate Professor Peter Chin from Australia has said “The UroLift® System is a minimally invasive procedure for treating lower urinary tract symptoms due to BPH. Permanent implants lift and hold the enlarged prostate tissue out of the way, so it no longer blocks the urethra, without the need to cut, heat or remove prostate tissue. What makes UroLift® different to others out there is that it is the only BPH treatment that does not cause sexual dysfunction because you are not burning or removing tissue.”

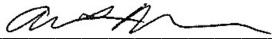
Due to the UroLift® System providing significant positive patient outcomes it has received numerous international awards including:

- Emerging Growth Company, Phoenix Awards, 2018
- Med Tech Innovator Award, 2018
- Most Promising New Product, Phoenix Awards, 2016
- Game Changer Award, Tri-Valley Innovation, 2017
- Edison Award, Bronze, 2015

Section 3: Declaration

I certify that the information provided in this application is accurate and that the company accepts the Rules of the Award. Representative/s of the company will participate in promotional activities relating to the Award.

Name: Thuy Le Position: Marketing Manager

Signature of the CEO/Authorised Representative: 

Date: 23 / 07 / 2019

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Please send your application to MTAA Secretariat – Kerrin Rennie Award

CLOSING DATE: 26 JULY 2019