# Teleflex Announces Publication of a Large Real-World Study Confirming Results from Controlled Clinical Studies of the UroLift® System

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**Results from Multi-Center Study Support the Application of Minimally Invasive Treatment for Broader BPH Population**

WAYNE, Pa., July 09, 2019 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX) today announced the publication of positive results from a multi-center study reaffirming the safety and effectiveness of the minimally invasive UroLift® System for the treatment of benign prostatic hyperplasia (BPH) in real-world patient populations. This is the largest, most comprehensive study to examine a minimally invasive BPH procedure in a real-world setting. Results were published in the *Journal of Endourology*.

The Real-World Retrospective study was designed to evaluate the safety and effectiveness of the UroLift System in a real-world setting and to determine whether clinical outcomes are consistent with those found in controlled studies. The multi-center, retrospective study examined the results of 1,413 consecutive patients who received the UroLift System treatment over two years across 14 sites in North America and Australia.

“Not only are the real-world results from this large, multi-center study consistent with the L.I.F.T study, this study also provides data in populations of patients who were not studied in the L.I.F.T study but are seen in a real-world clinic setting,” said Gregg Eure, M.D., urologist at Urology of Virginia in Virginia Beach, Virginia, a lead investigator and co-author of the study. “These findings should give urologists and patients the confidence to adopt the UroLift System within the broader BPH population.”

The randomized L.I.F.T. clinical trial demonstrated that treatment with the UroLift System provides patients rapid and durable symptom relief.[1,2] The minimally invasive procedure, which works without cutting, heating, or removing prostate tissue, demonstrates an excellent safety profile and preserves sexual function.[1,2,10] Unlike BPH thermal therapies such as the most recent steam treatment, the real-world results for the UroLift System treatment showed complication rates and a patient experience that were consistent with controlled clinical trials.[3-8]

Data published from the study show that patients from multiple subgroups treated with the UroLift System experienced improvements in IPSS (International Prostate Symptom Score) and QoL (Quality of Life) score:

- Consistent with the L.I.F.T. study, symptoms improved significantly from baseline at all follow up time points through two years, and most perioperative adverse events were mild to moderate, resolving by four weeks
- In a cohort-matched comparison to L.I.F.T. study patients with moderate-severe symptoms (IPSS ≥13), symptom improvement was similar at all time points
- Of the 165 patients in retention at baseline, 83% became catheter-free by one-month post-procedure and 87% were catheter-free by the end of the study; IPSS scores were similar to non-retention patients
- In the 73 patients with prior prostate cancer treatment, mean IPSS improved at all time points with no significant difference in adverse events of interest compared to other patients
- IPSS improvement was similar regardless of prostate volume (< 30cc; 30cc to <80cc; ≥80cc)[9]

“With over 100,000 men treated worldwide, the UroLift System has become an accepted standard of care treatment for BPH that provides patients rapid symptom relief and recovery,” said Dave Amerson, president of the Teleflex Interventional Urology business unit. “We are pleased that these highly positive results continue to demonstrate that outcomes found in a real-world setting are consistent with those in the pivotal L.I.F.T study, and also highlight the effectiveness and versatility of the UroLift System treatment for BPH in diverse patient populations.”

Findings from this large, multi-center study support the application of the UroLift System in the broader BPH population, including challenging patients such as those in retention and those who have been treated for prostate cancer. Individuals with lower prostate volumes (<30cc) experienced significant symptomatic relief with a favorable safety profile, highlighting the unique benefits of the UroLift System for these patients. Unlike some BPH thermal therapies, the indication for the UroLift System has no lower limit on prostate volume.

**About the UroLift® System**

The FDA-cleared UroLift System is a proven, minimally invasive technology for treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The UroLift permanent implants, delivered during a minimally invasive transurethral outpatient procedure, relieve prostate obstruction and open the urethra directly without cutting, heating, or removing prostate tissue. Clinical data from a pivotal 206-patient randomized controlled study showed that patients with enlarged prostate receiving UroLift implants reported rapid and durable symptomatic and urinary flow rate improvement without compromising sexual function.[1,10] Patients also experienced significant improvement in quality of life.[1] Over 100,000 men have been treated with the UroLift System worldwide. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.[1] The Prostatic Urethral Lift procedure using the UroLift System is recommended for the treatment of BPH in both the American Urological Association and European Association of Urology clinical guidelines. The UroLift System is available in the U.S., Europe, Australia, Canada, Mexico and South Korea. Learn more at www.UroLift.com.

**About Teleflex Interventional Urology**

The Teleflex Interventional Urology Business Unit is dedicated to developing innovative, minimally invasive and clinically effective devices that address unmet needs in the field of urology. Our initial focus is on improving the standard of care for patients with BPH using the UroLift System, a minimally invasive permanent implant system that treats symptoms while preserving normal sexual function.[1,10] Learn more at www.NeoTract.com.

**About Teleflex Incorporated**

Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit www.Teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rusch®, UroLift® and Weck® – trusted brands united by a common sense of purpose.

Dr. Gregg Eure is a paid consultant of Teleflex Incorporated.

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2. Roehrborn, et al., Can J Urol 2017; 24(3): 8802-8813
3. Darson, et al., Res Rep Urol 2017; 9: 159-168
4. Mollengarden, et al., Prostate Cancer Prostatic Dis 2018; 21(3): 379-385
5. Mooney, et al., J Urol 2019; 201(4S): PD10-11 AUA abstract
6. Yang, et al., 2018; WCE 2018 Poster 2018, UP3-33
7. McVary et al., J Urol 2016; 195(5): 1529-1538
8. McVary, et al., J Sex Med 2016; 13(6): 924-33
9. UroLift System is contraindicated for prostates >80cc in the US and >100cc outside the US
10. No instances of new, sustained erectile or ejaculatory function

Source: Teleflex Incorporated