Teleflex Announces FDA Clearance for Expanded Indication of the UroLift® System for Treatment of Larger Prostates, Up to 100cc

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Minimally Invasive Procedure Now Available to Hundreds of Thousands More Men with Enlarged Prostate, Providing Safe and Effective Symptom Relief

WAYNE, Pa., Jan. 07, 2020 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX) today announced that the U.S. Food and Drug Administration (FDA) has granted the company an expanded indication for the use of its UroLift® System to treat larger prostates, between 80cc and100cc. This minimally invasive, in-office treatment provides rapid relief and recovery from the symptoms of benign prostatic hyperplasia (BPH).[1,2]

BPH, also known as enlarged prostate, is non-cancerous enlargement of the prostate that occurs as men age. The condition affects over 40 million men in the United States alone.[3] More than 40% of men in their 50s have BPH and over 80% of men in their 70s have BPH. The symptoms of BPH can include frequent urination and can cause loss of productivity, depression and decreased quality of life.[4] If left untreated, the condition can worsen over time and cause permanent bladder damage.[5]

“This new indication marks another exciting milestone for Teleflex and an opportunity for hundreds of thousands more men to benefit from the UroLift System and the durable and lasting relief it can provide from burdensome BPH symptoms,” said Dave Amerson, president of the Teleflex Interventional Urology business unit. “Over 100,000 men have been treated with the UroLift System worldwide and now many more will be candidates for this proven approach to treating enlarged prostate that may enable men to get off BPH medications and avoid major surgery.”

The collection of data presented to the FDA demonstrates that the UroLift System treatment is safe and effective in men with prostate sizes between 80cc and 100cc, with outcomes similar to the L.I.F.T. randomized controlled trial.[1] Further, there are no discernable differences in reported adverse events, indicating a comparable safety profile.

There is also a strong and growing body of clinical evidence supporting the safe, effective use of the UroLift System, including a large retrospective real-world study which highlights the results of 1,413 patients who received the UroLift System treatment across 14 sites in North America and Australia. Results were consistent with those seen in previous clinical studies of the UroLift System treatment, and included patient subgroups—such as those in retention, with large prostates and comorbidities such as diabetes and prostate cancer—not commonly seen in clinical trials.

“We have learned from the Real-World study and other clinical studies that the UroLift System is the only minimally invasive treatment option that delivers rapid relief and recovery in days not months[1],” said Thomas J. Mueller**, M.D., New Jersey Urology. “I am pleased that this indication will enable even more men to benefit from this groundbreaking technology.”

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,[2]] Patients also experienced significant improvement in quality of life. 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. 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 many markets worldwide. 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 sexual function.*[2,4] 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.

**Thomas J. Mueller, M.D., is a paid consultant of NeoTract | Teleflex Interventional Urology.

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1. Roehrborn, J Urology 2013 LIFT Study
2. Shore, Can J Urol 2014 Local Study
3. NeoTract US Market Model estimates for 2018 based on IQVIA Health Drug and Procedure data
4. Speakman et al. 2014 BJUI International
5. Tubaro et al. 2003 Drugs Aging
*No instances of new, sustained erectile or ejaculatory dysfunction

Source: Teleflex Incorporated