NeoTract Announces FDA Clearance of Expanded Indications for UroLift® System

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Men with BPH with an Obstructive Median Lobe and those age 45 Years Old or Older Now Also Eligible for Treatment

WAYNE, Pa.--(BUSINESS WIRE)--Feb. 20, 2018-- NeoTract, a wholly owned subsidiary of Teleflex Incorporated (NYSE: TFX) focused on addressing unmet needs in the field of urology, today announced that the U.S. Food and Drug Administration (FDA) has cleared new indications for the UroLift® System for the treatment of enlarged prostate, or benign prostatic hyperplasia (BPH). These expanded indications mean that patients who have an obstructive median lobe and those as young as 45 are now eligible to receive treatment with the UroLift System for their BPH symptoms.

Previously, the UroLift System was contraindicated in patients with an obstructive median lobe and only cleared for use in men 50 years of age or older. The MedLift study provided clinical evidence to support the safe and effective treatment of obstructive median lobes and to remove the contraindication.

“We are excited that more men with enlarged prostate are now eligible for treatment with the UroLift System,” said Dave Amerson, president, NeoTract | Teleflex Interventional Urology. “The clinical data we have amassed on the UroLift System, including the five-year data from the L.I.F.T. IDE study, has solidified the product’s position as an important standard-of-care treatment for men with BPH and is further bolstered by these expanded indications. We are diligently training current UroLift users on how to treat obstructive median lobes with the UroLift System so they continue to see optimal patient outcomes.”

The treatment using the UroLift System has demonstrated that it can get men off BPH medications and allow them to avoid major surgery, while preserving sexual function. Results of the five-year L.I.F.T. study demonstrate that the UroLift System treatment provides a highly tolerable, minimally invasive procedural experience, rapid reduction of symptoms after the procedure while preserving sexual function, and sustained improvements in QoL (Quality of Life) score, IPSS (International Prostate Symptom Score), and Qmax (peak urinary flow rate). In addition, the retreatment rate was just 2-3% per year, which compares well to the 1-2% expected rate for the gold standard TURP.[1]

Nearly 40 million men in the United States are affected by BPH, which occurs with advancing age when the prostate gland that surrounds the male urethra becomes enlarged and begins to obstruct the urinary system. Symptoms of BPH often include interrupted sleep and urinary problems, and can cause loss of productivity and decreased quality of life.

Medication is often the first-line therapy for enlarged prostate, but relief can be inadequate and temporary. Side effects of medical therapy can include sexual dysfunction, dizziness and headaches, prompting many patients to discontinue using drugs. For these patients, the classic alternative is surgery that removes or reduces the amount of prostate tissue to open the blocked urethra. While current surgical options can be very effective in relieving symptoms, they can also leave patients with permanent side effects such as urinary incontinence, erectile dysfunction and retrograde ejaculation (dry orgasm).

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. Patients also experienced a significant improvement in quality of life. More than 45,000 men worldwide have been treated with the UroLift System. 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 UroLift System is available in the U.S., Europe, Australia, Canada, Mexico and South Korea. Learn more at www.UroLift.com.

About NeoTract | Teleflex Interventional Urology

A wholly owned subsidiary of Teleflex Incorporated, the NeoTract 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. 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.

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[1] Roehrborn et al. Can J Urol 2017

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