



FDA Grants De Novo Request for PROCEPT BioRobotics AQUABEAM® System

System's Aquablation® Technology Offers Heat-free Robotic Alternative for the Minimally Invasive Treatment of Benign Prostatic Hyperplasia (BPH)

REDWOOD SHORES, Calif. – Dec. 21, 2017– [PROCEPT BioRobotics](#), a Silicon Valley surgical robotics company developing novel and disruptive technologies to treat prostate disease, announced that the U.S. Food and Drug Administration (FDA) has granted a De Novo request for the company's [AQUABEAM® System](#) for the resection and removal of prostate tissue for the treatment of lower urinary tract symptoms (LUTS) as a result of benign prostatic hyperplasia (BPH), or enlarged prostate.

The AQUABEAM System, delivering Aquablation therapy, is the first FDA granted surgical robot providing autonomous tissue removal for the treatment of BPH. Aquablation therapy is the only treatment for BPH that combines the following three key elements to remove prostate tissue safely, quickly and precisely:

1. The clarity of **real-time, multi-dimensional imaging** for improved decision-making and treatment planning
2. The accuracy of **an autonomous robot** for precise treatment execution according to the surgeon's plan
3. The power of a **heat-free waterjet**, which eliminates the possibility of complications arising from thermal injury

The AQUABEAM System's commercial access to the U.S. market was supported by the results of the global WATER (**W**aterjet **A**blation **T**herapy for **E**ndoscopic **R**esection of prostate tissue) study, a 181-patient, double-blind, randomized clinical trial comparing Aquablation therapy with the AQUABEAM System with Transurethral Resection of the Prostate (TURP) for the treatment of LUTS caused by BPH. When compared to TURP, the surgical gold standard, Aquablation therapy demonstrated equivalent efficacy outcomes with a superior safety profile, including a reduction in sexual side effects by a ratio of four to one.

"Until today, with current BPH treatment options, men have had to choose between significant symptom relief with a high risk of sexual side effects or a lower risk of sexual complications with less than adequate symptomatic benefit. For this reason, many men have avoided treatment altogether," said Co-Principal Investigator Claus Roehrborn, M.D., Chair of the Department of Urology at [University of Texas, Southwestern](#) in Dallas. "Aquablation therapy breaks this trade-off in favor of the patient. Men can now benefit from significant symptom improvement alongside a low risk of sexual complications."

Additional data from the WATER study demonstrated that Aquablation therapy resulted in statistically superior symptom improvements compared to TURP in a pre-specified subgroup analysis of men with larger prostate volumes.



“The AQUABEAM System allows surgeons to determine an optimal tissue removal plan for each individual patient and achieve predictable, reproducible results, even in the case of larger prostates and prostates with obstructive median lobes,” said Co-Principal Investigator Peter Gilling, MD, professor of surgery at the [University of Auckland, Bay of Plenty Clinical School Tauranga](#). “Additionally, the easy-to-use system coupled with autonomous robotic resection paves the way to the future of surgery by enabling consistent results, independent of surgeon experience.”

The AQUABEAM System is commercially available in Canada, Australia, New Zealand and select European markets. In the U.S., the device will be commercially available in early 2018.

“FDA granted the De Novo request just two years after treating the first patient in our U.S. pivotal trial. This is a remarkable achievement, and I congratulate our talented and dedicated team of employees, physicians and researchers, and everyone who worked tirelessly to make this significant milestone for our organization possible,” said Nikolai Aljuri, Ph.D., PROCEPT BioRobotics chief executive officer and principal architect of the AQUABEAM System and its core Aquablation technology. “We believe Aquablation therapy is poised to fundamentally transform the way physicians treat men suffering from BPH.”

About Benign Prostatic Hyperplasia (BPH)

BPH is a highly prevalent condition affecting approximately 50 percent of men age 60 or older and 90 percent of men age 85 or older.^[1] In the United States, there are over 12 million men being actively managed for their condition, of which two million have failed medical management and are looking for alternative treatment options. Today’s treatment options range from surgical treatments such as TURP and lasers that remove the excess prostate tissue using extreme heat, to minimally invasive clips that simply push the prostate tissue to the side. Unfortunately, the treatments that offer the most significant symptom relief also have the highest complication rates, forcing the patient to choose between the two.

About PROCEPT BioRobotics

Based in Silicon Valley, PROCEPT BioRobotics is a privately held surgical robotics company enabling better patient care by developing transformative solutions in urology. With an initial focus on benign prostatic hyperplasia (BPH), the company’s first product, the AQUABEAM System delivering Aquablation therapy, is the world’s first commercially available minimally invasive surgical robot providing autonomous tissue removal to safely and effectively treat BPH. Aquablation therapy offers predictable and reproducible outcomes, independent of prostate anatomy or surgeon experience. <http://www.procept-biorobotics.com>

1. <http://emedicine.medscape.com/article/437359-overview#a2>

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