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UroMems Announces Results of First-Ever Smart Artificial Urinary Sphincter Implant in Female Patient to Treat Stress Urinary Incontinence

Positive results demonstrate promising new option for women seeking better, personalized treatment

GRENOBLE, France & MINNEAPOLIS, Minnesota (Feb. 14, 2024) – [UroMems](https://www.uro-mems.com), a global company developing innovative, mechatronics technology to treat stress urinary incontinence (SUI), announced today that it has successfully met the six-month primary endpoint for the first-ever female patient implanted with the UroActive™ System, the first smart automated artificial urinary sphincter (AUS) to treat SUI. This milestone indicates a new era for millions of women suffering from SUI, and signals an exciting transition for surgeons treating SUI not only in France, where the female patient was treated, but also across Europe and the U.S. It also follows closely on the heels of the successful results of the complete treatment cohort of the first-in-man clinical feasibility study. Results of this clinical study will contribute to the design and implementation of UroMems' pivotal clinical trial in Europe and the U.S.

“On behalf of the medical team who implanted the UroActive System in the first female patient, Drs. Christophe Vaessen, Aurelien Beaugier and I are over the moon to see our first patient has returned to living life fully after years of struggling with SUI,” said Professor Emmanuel Chartier-Kastler. “This promising therapy is a breakthrough technology in treating SUI in both women and men.”

The primary outcome measures include the successful device activation and the rate of explants and revisions at six months. The first female patient has not only met the study's primary endpoints by remaining revision-free but is also experiencing restored social continence. Follow-up on secondary measures, including leak rate values, has been extremely positive.

“As the leading advocacy organization in the U.S. supporting patients and caregivers with urinary incontinence, we hear from patients weekly looking for information on the safety and efficacy of artificial sphincters. Unfortunately, we have little to report back and support their requests as no one in the U.S. actively promotes this option for women,” said Steven Gregg, Ph.D., executive director of the National Association for Continence. “These results of the first UroActive System implanted in a female represent a promising development to treat stress urinary incontinence in both women and men. We're excited about this first-of-its-kind development and look forward to UroMems' pivotal trial results.”

Pending those results, the potential for U.S. surgeons to offer this new option is now on the horizon; skilled surgeons performing robotic-assisted surgeries such as sacrocolpopexies and hysterectomies may soon be able to add implanting UroActive to their standard practices. UroActive is the first smart active implant that treats SUI, powered by a MyoElectroMechanical System (MEMS). This innovative system is placed around the urethra in men and the bladder neck in women, controlled based on the patient's

activity, without the need for manual adjustments, intending to provide patients with ease of use and a better quality of life than current options.

“We are elated to reach this critical achievement contributing to the demonstration of the feasibility of the UroActive System to successfully treat women suffering from debilitating SUI,” said Hamid Lamraoui, UroMems chief executive officer and co-founder. “The compelling results of this first-in-female implant show the high potential of our technology, bringing us one step closer to delivering on the massive unmet need for women and physicians desperately seeking a better SUI treatment option.”

SUI, or involuntary urinary leakage, affects an estimated 40 million Americans and 90 million Europeans, and occurs when the pressure in the bladder exceeds that of the muscle (the sphincter) around the urethra, caused by activities involving high intra-abdominal pressure, like coughing, laughing and exercising. SUI significantly impacts quality of life, as it can be debilitating, and often leads to depression, low self-esteem and social stigma.

UroMems aims to restore the quality of life, dignity and self-esteem of millions of men and women worldwide suffering from poorly treated chronic conditions by the commitment to change the perception that these disorders are inevitable as one grows older and is simply something to endure with no real solution. UroMems is revolutionizing the treatment of SUI with smart active implants, using the latest technological advances in the field of embedded systems and micro-technologies for the development of its groundbreaking solutions.

About UroActive

UroActive is an active implantable electronic artificial urinary sphincter that is being developed to compensate for sphincter insufficiency in patients, both men and women, with SUI. It is based on a unique bionic platform using embedded smart, digital and robotic systems which, based on data collected from a patient, create a treatment algorithm that is specific for each patient's needs. The UroMems technology platform is protected by more than 120 patents and is designed to overcome the limitations of current solutions by optimizing safety and performance, patient experience and surgeon convenience. STeP participation does not imply product authorization. UroActive has not received marketing authorization from the FDA and is not available for sale in the United States or in the EU.

For more information, please visit www.uromems.com.