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UroMems Announces First-Ever Smart Artificial Urinary Sphincter Implant in a Female Patient

Initial clinical study results will inform pivotal clinical trial in U.S. and Europe

GRENOBLE, France & MINNEAPOLIS, Minnesota (July 20, 2023) – [UroMems](#), a global company developing innovative, mechatronics technology to treat stress urinary incontinence (SUI), announced today that it has successfully completed the first-ever implant of the UroActive™ smart, automated artificial urinary sphincter (AUS) in a female patient. This milestone indicates a new era for millions of women suffering from SUI, and results of this clinical study will contribute to the design and implementation of UroMems' pivotal clinical trial in Europe and the U.S.

“This is a unique accomplishment for UroMems and SUI in women,” said Hamid Lamraoui, UroMems chief executive officer and co-founder. “We are addressing the observations by so many physicians that there is a vast unmet need for a better way to definitively treat this female population.”

The robotic-assisted procedure for the first female recipient was successfully completed at La Pitié-Salpêtrière University Hospital (AP-HP, Sorbonne University, Paris, France) by Professor Emmanuel Chartier-Kastler, Dr. Aurélien Beaugerie and Dr. Christophe Vaessen. This first-in-female procedure was approved by the National Agency for the Safety of Medicines and Health Products (or ANSM, the French equivalent to the U.S. Food and Drug Administration).

“It’s magic,” the patient stated, as the first woman to activate the novel UroActive device. “I am so glad I can again do simple things in my daily life I was not able to do any more.”

UroActive is the first smart active implant that treats SUI, powered by a MyoElectroMechanical System (MEMS). This innovative system is placed around the urethral duct and is adjustable based on the patient’s activity, intending to provide patients with ease of use and a better quality of life than current options. The first-in-human (male) UroActive implant was announced in [November 2022](#), and UroMems recently received the [Safer Technologies Program \(STeP\) designation](#) from the U.S. Food and Drug Administration (FDA) for UroActive. STeP is a collaborative program intended to help reduce the time it takes to develop and obtain marketing authorization for eligible devices.

“It’s unacceptable that women today don’t have a better option for treating their stress incontinence,” said Professor Pierre Mozer, UroMems chief medical officer and co-founder. “Ultimately, we hope UroActive will become the therapy of choice for both physicians and their patients.”

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. While mild SUI is addressed by pelvic floor re-education and bulking agents, moderate and severe SUI historically have only had two options: mesh sling or manually-operated artificial urinary sphincter.

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.

About UroMems

Founded in 2011 by Professor Pierre Mozer, Hamid Lamraoui and Stéphane Lavallée, UroMems aims to restore the quality of life, dignity and self-esteem of millions of men and women worldwide suffering from untreated 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. The first challenge for the company will be applying embedded mechatronics methods and smart systems for treating urinary incontinence. Designed by urologists and collaborating scientists and engineers, UroActive intends to provide a new standard of care combining safety, efficacy, durability and ergonomics fitting any individual's lifestyle and anatomy.

Since the inception of the company, significant investments have been made for the development of UroMems' first product. This includes two financing rounds totaling 46 million euros, led by Wellington Partners, Bpifrance, Supernova Invest, b-to-v Partners AG, Cita Investissement, Hil-Invent, Financière Arbevel and the founders. The company has received several awards for innovation, including the Prix Galien Award Medstart'up and the Worldwide Innovation Challenge initiated by the French government. For more information, please visit www.uromems.com.

