

Affluent Medical announces that the clinical results of the Artus robotic urinary sphincter were presented at the international conferences of the Urological Association of Asia (UAA) and the International Continence Society (ICS)

Aix-en-Provence, September 29, 2025 – 5.45 p.m. CEST – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME – “Affluent”), a French clinical-stage medical technology company specialized in the international development and industrialization of innovative implantable medical devices, is today announcing that the presentation of the Artus robotic urinary sphincter and the results of the pilot phase clinical trial attracted strong interest from the medical community during both conferences.

At the 22nd Urological Association of Asia (UAA) Congress in Taiwan, Véronique Phe, Professor of Urology at Tenon Hospital and member of Affluent Medical’s Scientific Advisory Board, presented the results of the pilot phase of the European multicenter clinical trial in humans which was completed in May 2025. She took this opportunity before an audience of US and Asian healthcare professionals to outline again the differentiating characteristics of the Artus device.

The trial demonstrated the safety profile of the device, the ease with which it can be implanted by surgeons and the ease of use by implant patients thanks to the remote control. Preliminary performances observed show an average improvement of 87% in the reduction of urinary leakage in implant patients.

Véronique Phe, Professor of Urology at Tenon Hospital and member of Affluent Medical’s Scientific Advisory Board, says: *“Discussions with the medical community attending the UAA Congress revealed a keen interest in the Artus next-generation urinary sphincter. With no real innovation over the past several decades to address a medical need that has become a real public health issue, Artus has the potential to provide a very promising therapeutic solution for all male and female patients suffering from moderate to severe urinary incontinence.”*

Meanwhile, Prof. Roman Zachoval, MD, PhD, Head of the Department of Urology at Thomayer University Hospital in Prague and one of the trial investigators, also presented these results at the International Continence Society (ICS) annual meeting held in Abu Dhabi, UAE on September 17, 2025. Prof. Zachoval performed the first implantation of the artificial urinary sphincter in a patient in the Czech Republic in March 2024. The results were also very well received by the community of healthcare professionals at that event.

Artus is the first robotic urinary sphincter of its kind, involving a fully implantable device designed to treat moderate to severe stress urinary incontinence (SUI) that can be adjusted according to each patient’s needs and which is easy to use. These very promising clinical results and recent clinical performances will also be presented during forthcoming international urology conferences and events in order to increase visibility around the Artus device.

As a reminder, Affluent Medical received approval from the Data Safety Monitoring Boards (DSMB) last May to move into the pivotal phase for Artus. This European multicenter clinical trial, DRY, will seek to validate the efficacy of Artus in reducing urinary leakage by at least 50%; the recruitment of several dozen patients in leading urology centers for this purpose is under way, and new investigation centers will be added by the end of the year in Italy, Spain and France, in addition to the countries already approved for the pilot study.



With two new investigation centers opened in France, Affluent Medical is currently working to recruit new patients with the aim of implanting a male and female patient in France, potentially by the end of 2025.

Urinary incontinence is a major public health problem for over 400 million people worldwide for which there has been no breakthrough in the last 40 years. Patients suffer a reduced quality of life associated with the psychological disorders related to the disease.



About Affluent Medical

Affluent Medical is a French medical technologies company, founded by Truffle Capital, that aims to become a global leader in the treatment of structural heart diseases, one of the world's leading causes of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation implants that are minimally invasive, innovative, adjustable and biomimetic, designed to restore essential physiological functions. The candidate products developed by the Company are all undergoing clinical studies in humans.

For more information, please visit www.affluentmedical.com

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