

Affluent Medical announces promising performance results for its Artus artificial urinary sphincter and receives approval to initiate pivotal phase of its clinical trial

- Clearance to initiate the pivotal phase was granted following a review of the positive safety profile from the clinical pilot phase.
- Preliminary performance data show an 87% improvement in reducing urinary leakage.
- Pivotal phase will start in the coming weeks with additional centers in Spain and Italy and will continue to expand beyond currently active centers.

Aix-en-Provence, May 15, 2025 – 5:45 p.m. CEST – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME – “Affluent”), a French clinical-stage medical technology company specializing in the development and industrialization of innovative implantable medical devices, today announced that the external Data and Safety Monitoring Board (DSMB) has granted clearance to proceed to the pivotal phase of its clinical trial evaluating Artus, the Company’s artificial urinary sphincter (AUS) for the treatment of stress urinary incontinence (SUI).

The multicenter European clinical study, DRY, aims to validate the performance of Artus in reducing urinary leakage by at least 50% and will enroll several dozens of patients across leading urology centers in Italy, Spain, France, and Belgium in addition to the countries already approved for the pilot study.

10 male patients were successfully implanted with the Artus device during the pilot phase. Procedures had an average duration of approximately 40 minutes; 100% of devices were successfully activated six weeks post-surgery. The pilot phase allowed the company to evaluate in real conditions the safety features embedded into the device, which have proven effective. The learnings from the pilot phase will be implemented during the pivotal phase. Additionally, training will be reinforced for surgeons and extended to hospital staff and patients to support both the surgical procedure and the use of the device.

The panel of patients includes subjects from 67 to 79 years of age with a BMI ranging from 22.7 to 32.3. At baseline, the urine leakage ranges from 207ml to 1992ml per day representing highly severe stress incontinence. Preliminary available efficacy data are promising as they show an 87% average reduction in urinary leakage, measured by pad weight test three months after activation of the device.

“The safety profile demonstrated in the pilot study is good, and the ease of use has been highlighted both for the surgical implantation and for patients with the use of the remote control. Preliminary results are promising and will be confirmed at a larger scale in the pivotal phase. Artus has the potential to significantly improve the quality of life for patients living with SUI,” said **Prof. Nicolas Barry Delongchamps, Prof. of Urology, Cochin Hospital, Paris, and member of the Scientific Board of Affluent Medical.**

SUI is highly prevalent and significantly under-addressed condition, impacting the quality of life of more than 400 million individuals globally.

Artus is the first mechanic-electronic urinary sphincter of its kind, designed to treat moderate to severe SUI through a fully implantable, adjustable device that patients can easily operate via a remote control. The technology offers a minimally invasive and effective alternative to existing treatment option.

“For decades, patients living with SUI have faced limited innovation and inadequate solutions, leaving millions to cope with compromised quality of life and the emotional burden of the condition. Artus aims to change that,” added **Sébastien Ladet, CEO of Affluent Medical.** “With promising early results, DSMB clearance, and the



pivotal phase now underway, we are one step closer to delivering a next-generation, less invasive alternative to existing systems - one that could significantly enhance continence, comfort, and day-to-day confidence for a large and underserved patient population, both for men and women.”

The global market for urinary incontinence devices—including slings, neurostimulators, and artificial sphincters is projected to reach \$4.3 billion by 2027, growing at 11% annually [Optima Insights]. The economic burden of incontinence is estimated at \$7 billion annually in Europe and up to \$66 billion in the United States¹.



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.

Artus is a unique mechanico-electronic sphincter designed to reduce moderate to severe stress urinary incontinence, both for men and women. Controlling the opening and closing of the urethra, the device is managed via a remote control to adapt to patients' daily activities.

For more information, please visit www.affluentmedical.com

References:

[1] Source: State of the art Artus - Thomas Jefferson university hosp. Dr. Shenot – 2023

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