

## Affluent Medical Announces Progress Toward European Clinical Study of Artificial Sphincter Artus for the Treatment of Urinary Stress Incontinence in Women

- SPHINX pilot study in women is set to launch across Europe in H2 2025
- Preparatory evaluations using robotic-assisted implantation confirm that the minimally invasive procedure in women is feasible.

Aix-en-Provence, April 15, 2025 – 5:45 pm. CET – 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 progress toward its upcoming SPHINX clinical study. The study, which is set to launch across Europe, in the second half of 2025, will assess the safety and performance of the Artus artificial urinary sphincter in female patients at leading medical centers in France, Spain and Belgium. This marks a significant step in expanding treatment options for women suffering from stress urinary incontinence (SUI).

In preparation for the launch of the SPHINX study, Affluent Medical successfully completed the first implantation of its Artus device in a female anatomy model. The procedure was led by Professor Véronique Phé, a leading European urologist from Tenon Hospital in Paris, and evaluated the surgical approach in women. Utilizing the Da Vinci robotic-assisted laparoscopy system, it was confirmed that the device can be implanted with precision and ease, demonstrating its suitability for minimally invasive surgery.

**Professor Véronique Phé, who will serve as principal investigator for the SPHINX study, commented:** *"The SPHINX study represents a major step forward in the treatment of female SUI. Our preparatory evaluations confirm that the Artus device offers the same ease of minimally invasive implantation in women as observed in men. Coupled with a good clinical safety profile and promising preliminary performance results, we are confident in the potential of this innovative therapy to improve the lives of more patients in need."*

**Sébastien Ladet, CEO of Affluent Medical, added:** *"Our progress toward the SPHINX study underlines our commitment to addressing unmet needs in female urology. We are working closely with leading European clinical centers and experts to bring this novel, patient-friendly solution to those living with stress urinary incontinence."*

Severe Urinary incontinence is a widespread condition that significantly affects quality of life, with women accounting for approximately 80% of the more than 400 million individuals affected globally. Artus is designed to treat moderate to severe SUI through a fully implantable, adjustable device that patients can easily operate via remote control. The technology offers a minimally invasive and effective alternative to existing treatment options and has demonstrated promising results in male patients from the recently completed DRY pilot study.



### 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 human.

For more information, please visit [www.affluentmedical.com](http://www.affluentmedical.com)



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