

## Excellent valve performance at 1 year follow up and rising recognition of Epygon biomimetic mitral valve

- Case study of the first successful human implantation published in an American peer-reviewed journal
- One-year follow up transesophageal echocardiography examination confirms excellent prosthetic performance
- Interventional cardiologist community increasingly recognizes hemodynamic value proposition of Epygon

Aix-en-Provence, 29 February 2024 – Affluent Medical (ISIN: FR0013333077 – Ticker: AFME), a French clinical-phase MedTech company specializing in the international development and industrialization of innovative medical prostheses, today reported supportive findings on the clinical value of Epygon, its cutting-edge device being developed to replace mitral valves in patients suffering from mitral insufficiency.

An article on the successful first human implantation of its transcatheter mitral valve, Epygon, entitled, “A Mono-Leaflet, Low-Profile Transcatheter Mitral Prosthesis – First-in-Human Implantation”, was published in the highly respected, peer-reviewed *Journal of the American College of Cardiology: Cardiovascular Interventions*. The first implantation of Epygon was conducted in February 2023 via a minimally invasive transcatheter procedure by **Prof. Stefano Salizzoni, MD, PhD, cardiac surgeon and co-investigator of the Minerva pilot clinical study**, and his team, at the Molinette Hospital of Health and Science in Torino, Italy. The article summarizes the procedure and the follow up at 6 months, which showed continued good prosthetic performance.

Recently, the patient reached the 1-year follow up. Examination through a transesophageal echocardiogram revealed excellent valve performance, with neither mitral regurgitation nor paravalvular leak.

These promising results are in line with a survey conducted with up to 60 interventional cardiologists and cardiac surgeons. 70% of the interventional cardiologists surveyed stated they would refer patients to cardiac surgeons if the Epygon valve was available and based on the potential value of excellent hemodynamic properties.

**Mohammad Sarraf, MD, Interventional Cardiologist at the Mayo Clinic, top ranked hospital in the US, stated:** “The Epygon valve’s unique design, focusing on replicating the natural anatomy and physiology of the native mitral valve, sets it apart from other mitral valve designs. Its asymmetrical profile and large mono leaflet aim to mimic the natural vortex of bloodstream flow. This design innovation holds promise for improving left ventricle function, particularly in frail patients. By closely emulating the natural structure and flow dynamics of the mitral valve, the Epygon device may enhance overall cardiac performance and contribute to better patient outcomes.”

Epygon is the first biomimetic transcatheter mitral valve to mimic the native mitral valve and restore the natural vortex of blood flow in the left ventricle. Its transcatheter implantation makes it a fast and minimally invasive procedure, avoiding open heart surgery.

Mitral valve regurgitation is a serious and potentially fatal disease affecting 2% of the world’s population, or approximately 160 million people. However, fewer than 4% of patients with a severe form can receive open heart surgery, which poses a high risk of death and hospitalization. The market for mitral valve repair surgery is estimated to be worth \$1.5 billion in the U.S.-Europe region in 2023, growing at 3.5% per year.



The publication, entitled “A Mono-Leaflet, Low-Profile Transcatheter Mitral Prosthesis – First-in-Human Implantation”, can be accessed online here: <https://www.jacc.org/doi/abs/10.1016/j.jcin.2023.09.033>.



### About Affluent Medical

Affluent Medical is a French MedTech company, founded by Truffle Capital, with the ambition to become a global leader in the treatment of structural heart diseases, which are the world's leading cause of mortality, and urinary incontinence, which currently affects one in four adults.

Affluent Medical develops next-generation, mini-invasive, innovative, adjustable, and biomimetic implants to restore critical physiological functions. The product candidates developed by the Company are currently in preclinical and clinical studies.

Kalios, the first mitral adjustable annuloplasty ring, should be the first Affluent Medical device to be marketed.

Subject to raising the necessary funds to finance its strategy and to positive results from ongoing clinical studies, the Company's ambition is to gradually commercialize its products early 2026.

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

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