

PRESS RELEASE

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Successful first post-operative adjustment of Kalios™ mitral ring

Affluent Medical (ISIN: FR0013333077 – ticker: AFME), a French medtech specialising in the international development and industrial scale-up of innovative medical prostheses, at a clinical stage, to treat urinary incontinence and cardiac mitral insufficiency, today announces the success of the first ever Kalios™ mitral ring adjustment on a patient suffering from post-operative recurrence of severe mitral insufficiency.

Prof. Alberto Albertini (GMV Maria Cecilia Hospital de Cotignola, Italy) successfully performed the percutaneous adjustment of the original Kalios™ annuloplasty ring 11 months after its implantation following a recurrence of severe mitral insufficiency.

Following successful implantation of a Kalios™ adjustable mitral ring, a simple trace of residual leakage was observed in a patient, who was operated in August 2020 for major mitral insufficiency (4+)¹, following a myocardial infarction.

Following a period of stability, a major mitral incompetence (regurgitation) of grade 4+ and NYHA IV occurred as a result of deterioration and dilation of the left ventricle requiring further intervention in order to absorb the leak and improve the patient's prognosis.

The adjustment was carried out in July 2021 without surgery by inserting balloons into the subcutaneous line in order to reduce the size of the ring under ultrasound control, thereby substantially reducing the leak to its initial level (1+) and allowing the immediate result to be verified.

The patient, who is under programmed medical monitoring, is currently classified NYHA I² and is therefore not limited with regard to everyday activities.

Prof. Alberto Albertini confirmed: *“The Kalios™ device allowed a simple and efficient intervention via the transcatheter route, offering the patient a solution that avoided further, more complex open-heart surgery involving a longer hospital stay, along with all the associated risks.”*

Affluent Medical's Chief Medical Officer Prof. François Laborde confirmed that the Kalios™ device was a major breakthrough in treating mitral regurgitation and its recurrence, which happens between 30% and 40% of the redo mitral incompetence as reported in the medical literature. This also underlines the innovative nature of the Kalios™ device, which combines an established surgical technique with a potential future transcatheter adjustment depending on how mitral regurgitation develops in the patient. *“Kalios™ is a unique future solution unrivalled on the current market for both the patient and the healthcare system, in that it is expected to offer major medico-economic benefits that should help understand mitral regurgitation better and improve its treatment in the future.”*

1 (4+): Graduation allowing to define the importance of the mitral leak following an ultrasound examination - 4+ being the most important level.

2 NYHA: The NYHA classification is a scale of diagnostic, prognostic and therapeutic interest that expresses the clinical severity of heart failure.

About Kalios™

Kalios™ is the only ring designed for mitral valve repair optimised for minimally invasive cardiac surgery and allowing multiple post-operative readjustments via the transcatheter route - without invasive reoperation. It is therefore a unique hybrid technology.

A pivotal study is currently underway in Austria, Germany, Switzerland and Italy and a number of patients have already been recruited.



About Affluent Medical

Affluent Medical is a French medtech company founded by Truffle Capital with the aim of becoming a global leader in the treatment of cardiovascular diseases, which are the leading cause of death worldwide, and of urinary incontinence, which today affects one in four adults. Affluent Medical develops innovative, next-generation minimally invasive implants to restore essential physiological functions in these areas. The four main technologies developed by the company are currently at the stage of preclinical and clinical studies. The first medical device is expected to go to market by 2023 with Kalios™ in Europe.

Read more: www.affluentmedical.com