Mitralign percutaneous annuloplasty system for functional mitral regurgitation

TIMEFRAME: Estimated earliest commercial availability in the UK

Currently unclear  Now  6 months  1 year  18 months  2 years  Over 2 years

TECHNOLOGY

The Mitralign annuloplasty system is a percutaneous mitral valve repair system being developed by Mitralign Inc, for patients with mitral regurgitation who have failed medical therapy and continue to present with symptoms of heart failure.

The Mitralign system involves delivery of a pair of surgical implants directly into the mitral annulus (a ring surrounding the mitral valve opening, involved in valve closure) to reduce the circumference of the mitral valve opening and improve the seal upon valve closure. The Mitralign system uses crossing wires and a set of six catheters, including a pledget-delivery catheter pre-loaded with sutured pledget (a small compress of soft polyester material), a plication (folding) catheter pre-loaded with a steel lock, and also a cutting catheter.

The procedure is guided by echocardiography and requires general anaesthesia. It involves femoral access to the left ventricle using a guide catheter. A bident (two-pronged) catheter delivers the crossing wires which guide pledget delivery at the annulus. It is designed in different spans of 14mm and 17mm to allow for variations in heart sizes. Half of the pledget is secured on the atrial side of the mitral annulus and the other half on the ventricular side. A second pledget is delivered in the same way at another nearby location on the mitral annulus. The plication catheter pulls the pair of pledgets together, which reduces the circumference of the mitral valve opening. The tightened pledget sutures are locked in place with a steel lock, which completes the procedure. Up to two pairs of pledgets can be implanted in one procedure.

Mitralign is currently undergoing feasibility assessments for treatment of mitral regurgitation in two clinical trials. Results are yet to be published. The company anticipate a CE mark in early 2015 with launch for research and private clinical use in September and December 2015, respectively.

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POTENTIAL FOR IMPACT

Mitral valve regurgitation occurs when the mitral valve fails to close properly, resulting in the backward flow of blood into the left atrium. It may arise as a consequence of rheumatic heart disease, cardiomyopathy, left ventricular enlargement or abnormalities in the mitral valve. Mitral regurgitation is one of the most common forms of valvular heart disease affecting the elderly. If left untreated, moderate to severe mitral regurgitation can cause progressive heart failure and eventually lead to death.

Surgery is recommended in severe cases of mitral regurgitation and includes valve repair or valve replacement. Where feasible, valve repair is preferred over valve replacement. Mitral valve repair can be performed using one of three main techniques: i) the Carpentier approach, ii) the David approach and iii) the Alfieri technique. Surgical procedures are however, associated with high procedural risk and physiological stress; hence older patients are often considered unsuitable candidates.

Percutaneous techniques for mitral valve repair are considered a less invasive alternative. Current percutaneous procedures include those based on the Alfieri technique and others involving device implantation in the coronary sinus (a large vein that collects blood from the heart muscle). All techniques aim to improve the seal of the mitral valve upon closure.

The company claim the key innovative feature of the Mitralign system is the percutaneous implantation of polyester pledgets that do not directly affect the mechanisms of the valve or the mitral annulus. The company add that pledget location, number of pledgets and reduction in the circumference of the mitral valve opening can potentially be customised according to patient need. The company claim that following the procedure, other surgical and therapeutic options also remain possible. Benefits for patients include a reduction in mitral regurgitation and an improved quality of life.

The company state that the NHS may benefit from fewer resources spent on repeat procedures. If clinical and cost effectiveness can be demonstrated, the Mitralign annuloplasty system may offer an additional treatment option for select patients with mitral regurgitation.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


**ONGOING STUDIES**


**INFORMATION FROM**

This Alert is based on information from the company and a time-limited internet search.