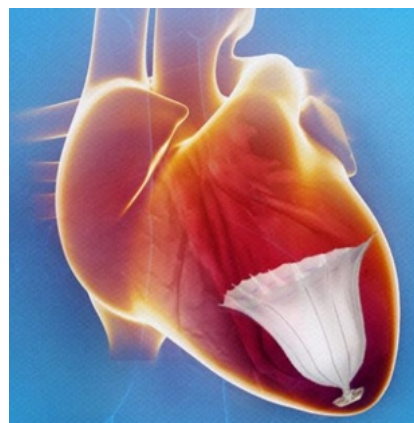


Parachute[®] Implant System for ischaemic heart failure

TECHNOLOGY

The Parachute[®] Implant System is a ventricular partitioning device developed by [CardioKinetix Inc.](#) It is used to isolate damaged heart muscle in patients with symptoms of heart failure due to ischaemic heart disease.

After a heart attack, the damaged heart muscle can become over stretched as it has less resistance than undamaged muscle and is unable to contract. The left ventricle in the heart then enlarges as healthy muscle tries to compensate for lost function. This progressive enlargement eventually overloads the heart, causing a decrease in cardiac output and resulting in symptoms of heart failure such as fatigue, shortness of breath and fluid accumulation.



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The Parachute[®] device is delivered via a catheter through the femoral artery into the left ventricle and attaches to the walls of the heart, isolating the non-functional muscle segment from the functional segment. This decreases the overall volume and restores the shape and function in the left ventricle as the viable heart muscle is properly stretched. The device may be suitable for around 20-30% of patients with heart failure, which equates to around 300,000 patients in the UK.

The device received its CE mark in June 2011 and is entering late phase clinical trials at five centres within the UK. Commercialisation in the UK is anticipated by mid 2013.

POTENTIAL FOR IMPACT

The company state this is the first minimally invasive device that can delay the progression of ischaemic heart failure and lead to a reduction in repeat hospitalisations and mortality in a condition where there are limited treatment options. Compared with surgical ventricular restoration, the company state that the Parachute[®] device has not been shown to cause arrhythmias and its percutaneous approach is associated with lower risks than open heart surgical techniques. The procedure, which takes approximately 75 minutes, is performed in a catheterisation laboratory setting with patients under conscious sedation. The company therefore do not anticipate any additional costs compared to other percutaneous devices.

The device is intended for use in addition to current therapies for heart failure such as beta blockers and bi-ventricular pacing where treatment is currently inadequate. The company claim it may also delay the need for end-stage heart failure options such as left ventricular assist devices and heart transplants.

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EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS

Bozdag-Turan, I., Bermaoui, B. and Turan, R.G. *et al.* Left ventricular partitioning device in a patient with chronic heart failure: Short-term clinical follow-up. *International Journal of Cardiology*. 2013, 163 (1): e1-e3.

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Mazzaferri, E.L. Jr., Gradinac, S. and Sagic, D. *et al.* Percutaneous Left Ventricular Partitioning in Patients with Chronic Heart Failure and a Prior Anterior Myocardial Infarction: Results of the PARACHUTE Trial. *American Heart Journal*. 2012, 163 (5): 812-820.

<http://www.ncbi.nlm.nih.gov/pubmed/22607859>

Sagic, D., Otasevic, P. and Sievert, H. *et al.* Percutaneous Implantation of the Left Ventricular Partitioning Device for Chronic Heart Failure: A Pilot Study with 1-Year Follow-Up. *European Journal of Heart Failure*. 2010; 12 (6): 600-606.

<http://www.ncbi.nlm.nih.gov/pubmed/20400453>

ONGOING STUDIES

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<http://www.clinicaltrials.gov/ct2/show/NCT01286116?term=Parachute&rank=1>. Accessed 28 February 2013.

ClinicalTrials.gov. Safety Study of the Ventricular Partitioning Device (VPD) Implant System in Heart Failure Patients (PARACHUTE) NCT00573560.

<http://www.clinicaltrials.gov/ct2/show?term=Parachute&rank=3>. Accessed 28 February 2013.

ClinicalTrials.gov. A Multinational Trial to Evaluate the Long-term Safety of the Parachute Implant System (PARACHUTE III) NCT01297296.

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INFORMATION FROM

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