



Momentum growing for Sunshine Heart clinical trials - fifth patient receives implant -

Key Points

- Monash Medical Centre implants first patient
- Five investigational sites actively screening for patients in Australia and New Zealand
- Five people implanted with the C-Pulse™ heart assist device

Sydney, Australia. 11 September 2006. Sunshine Heart (ASX: SHC) has today announced its unique heart assist pump called C-Pulse™ has been successfully implanted into a fifth patient as part of the company's Australian and New Zealand clinical trial program.

Successful 5th implant in current Pilot Clinical Trial

Melbourne-based Monash Medical Centre, part of the Southern Health network, confirmed it has successfully implanted the C-Pulse™ into its first patient this week. Southern Health joined the clinical trial program earlier this year.

The C-Pulse™, developed by Australian company Sunshine Heart, improves the heart function of patients with heart failure by increasing blood supply to the heart muscle and reducing the heart's pumping work. It is uniquely designed as a non-blood contacting heart-assist device, reducing the risks of clotting and bleeding complications and making it safe to turn the device on and off.

Professor Julian Smith, Principal Investigator and Head of Cardiothoracic Surgery at Southern Health, said: "The C-Pulse™ was successfully implanted this week and the patient continues to recover post operatively. We are encouraged with these initial results."

Victor Windeyer, Chief Operating Officer of Sunshine Heart added: "The clinical program is gaining momentum as four of the five investigational sites actively screening patients for inclusion in the trial now have implanted, and have experience with, the C-Pulse™."

In all, eleven people have been implanted with the C-Pulse™, six in a previous short term intra-operative study and now a further five people in the current Pilot Clinical Trial.

This implant is part of a multi-centre trial in Australia and New Zealand involving up to ten patients being conducted at Auckland City Hospital (Auckland), the Alfred Hospital (Melbourne), Southern Health Monash Medical Centre (Melbourne), St Vincent's Hospital (Sydney) and Royal Perth Hospital (Perth).

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Sunshine Heart (ASX: SHC) (www.sunshineheart.com) is a global medical device company, committed to the commercialisation of the C-Pulse™ an implantable, non-blood contacting, mechanical heart assist device for the treatment of people with heart failure. Sunshine Heart listed on the ASX in September 2004 and has a presence in Australia, New Zealand and the United States of America.

Heart failure is a progressively worsening condition characterised by shortness of breath with mild exercise, fatigue, dizziness and fluid retention. Heart failure is caused by the inability of the heart to pump sufficient blood around the body to meet its oxygen requirement. An estimated 325,000 people in Australia have symptomatic heart failure and that there are 22,000 admissions to hospital for heart failure each year. Heart failure is believed to contribute to over 1.4 million days of hospitalisation annually at a cost of more than \$1 billion. In excess of 5 million people in the US have heart failure.

The C-Pulse™ is an implantable, non-blood contacting mechanical heart assist device powered by an external driver unit.

The implantable cuff consists of a wrap and a balloon which is placed around the aorta just above the heart. The balloon is inflated and deflated to the rhythm of the heart to improve blood supply to both the body and the heart muscle, while reducing the workload on the heart.

The wearable **external driver** is linked by an air tube to the cuff and detects the heart's natural rhythm and controls inflation and deflation of the balloon in rhythm with the heart.

Implantation of the C-Pulse™ involves wrapping the cuff around the aorta. No incisions are needed so that the device never comes into contact with the patient's bloodstream. The C-Pulse™ balloon inside the cuff is designed to inflate in a way that rolls the wall of the aorta inward in a gentle 'thumb printing' manner. The balloon is inflated and deflated rhythmically to improve blood supply to the heart and body as well as reduce the workload of the heart.

Artist's rendition of C-Pulse with a wearable driver that is in development

