C-Pulse® Heart assist system for heart failure

TIMEFRAME: Estimated earliest commercial availability in the UK

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

C-Pulse® Heart assist system, developed by Sunshine Heart, is an extra-aortic balloon cuff placed around the aorta, which inflates and deflates to assist the heart's left ventricle by reducing the workload required to pump blood throughout the body. It also increases blood flow to the coronary arteries. C-Pulse® is designed to treat the symptoms associated with Class III and ambulatory Class IV (moderate to severe) heart failure.

Heart failure is a serious condition caused by the heart failing to pump enough blood around the body at the right pressure. It usually occurs because the heart muscle has become too weak, scarred, or stiff to work properly. The C-Pulse® system is designed to improve blood circulation and oxygen delivery to both the heart and the body.

C-Pulse® can be implanted via a small incision through the ribs, sternum (mini-sternotomy), or through a traditional full sternotomy. A pre-sutured cuff is wrapped around the outside of the ascending aorta above the aortic valve. Epicardial sensing leads are attached to the left ventricle. The tubing is brought out via an exit site in the abdominal area and connected to a computer that sits outside the body. According to the company, the procedure takes around one hour to perform, followed by one day in post-operative care in ICU. The anticipated total length of stay in hospital is around 8 days (range 4-14 days). The balloon counter-pulsation inflation and deflation is synchronised to the patient’s ECG (heart rhythm), in a similar way to a pacemaker. During inflation of the balloon, blood flow is increased to the coronary arteries, thereby providing additional oxygen. During deflation, the workload or pumping required is reduced.

The C-Pulse® Heart assist system is CE marked and the company is planning to commercialise the product in the UK.
POTENTIAL FOR IMPACT

Heart failure is a common disease affecting approximately 900,000 people in the UK. Patients with Class III and ambulatory Class IV heart failure are typically unable to engage in normal activities, compromising their quality of life. The incidence and prevalence of heart failure increases with age. The prognosis is poor, 30-40% of patients die within the first year after diagnosis, although this has improved over the past decade. Heart failure accounts for 2% of all NHS bed days and 5% of emergency admissions. With an ageing population the burden of heart failure on NHS services is projected to rise. NICE guidance for chronic heart failure was updated in 2010. Standard treatment includes a range of drugs such as beta blockers and ACE inhibitors. Some patient groups can benefit from invasive procedures such as valve surgery and cardiac resynchronisation therapy. Patients with end stage heart failure may be eligible for heart transplantation. Intra-aortic balloon pumps and ventricular assist devices are circulatory assist devices that may be used as a bridge to recovery or transplant.

C-Pulse® is intended to be used in addition to current pharmacotherapy. The company states that C-Pulse® is less invasive than existing surgical treatments for heart failure which may mean reduced recovery times and shorter in patient stays.

According to the company, the potential patient benefits of C-Pulse® include relief of symptoms such as shortness of breath, increased physical activity, and improved cardiac function and quality of life. The company states that the patient has the ability to disconnect from the system for brief periods of time, enabling them to walk and perform other activities independent from the system. In addition, as the cuff portion of the C-Pulse® device is placed outside the bloodstream (unlike intra-aortic balloon pumps and left ventricular assist devices), the risk of stroke and blood clots may be reduced and patients may not require anti-clotting drugs such as heparin or warfarin (unless other medical conditions require this). The company claims that some patients treated with C-Pulse® will be able to stop using the device due to sustained improvement in their condition as a result of the therapy. This could prevent the need for later-stage heart failure interventions.

If clinical and cost effectiveness can be demonstrated, C-Pulse® may offer an additional treatment option for select patients with heart failure.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


ONGOING STUDIES


INFORMATION FROM

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