OPTIMIZER™ system for chronic heart failure

TECHNOLOGY

The OPTIMIZER™ is a three-component system developed by Impulse Dynamics N.V., for use in adult patients with symptomatic heart failure due to left ventricular systolic dysfunction, despite appropriate medical therapy.

The OPTIMIZER™ system is designed to modulate the strength of contraction of the heart muscle rather than the rhythm. It delivers non-excitatory electrical signals called Cardiac Contractility Modulation (CCM) signals to the heart during the absolute refractory period. The application of these non-excitatory signals in moderate to severe heart failure can modify the properties of the heart, including enhancing the force of contraction, in a predictable and reproducible manner.

The OPTIMIZER™ system consists of: (i) the Optimizer IVs implantable pulse generator unit, which senses the heart’s electrical activity and delivers CCM signals at regular intervals throughout the day via two electrodes placed in the septal region of the heart’s right ventricle, (ii) the Optimizer IVs Mini Charger which allows patients to recharge the implantable pulse generator at home (typically for 60 minutes on a weekly basis) and (iii) the OMNI II programmer system, which allows healthcare professionals to customise the CCM signal parameters according to individual patient need.

Although it does not have a pacemaker function, the Optimizer IVs device physically resembles a cardiac pacemaker and is implanted under local anaesthetic, into the right side of the heart. It is connected to three pacemaker leads that are implanted transvenously into the right side of the heart: one lead senses atrial activity and the other two sense ventricular activity and deliver the CCM signals.

The OPTIMIZER™ system received a CE mark in December 2002. The company anticipate launch in the UK for private and NHS clinical use in 2015.
POTENTIAL FOR IMPACT

Heart failure is a condition in which the heart pumps blood inadequately. In systolic dysfunction, the heart contracts less forcefully and pumps out less blood than it receives. A range of treatments are utilised to slow or halt the progression of heart failure, including lifestyle modifications, pharmacological treatments and surgical interventions.

Pacemakers, defibrillators and cardiac resynchronisation therapy devices all work to resolve cardiac rhythm management problems or cardiac dyssynchrony. Although cardiac resynchronisation therapy devices improve cardiac performance, they are beneficial in only 30-40% of patients with chronic heart failure.

The key innovative feature of the OPTIMIZER™ system is the application of CCM technology, which may offer an alternative therapy for patients with symptomatic heart failure due to left ventricular systolic dysfunction. The company claim there are currently no other devices that provide evidence based therapy similar to the OPTIMIZER™ system.

Research has shown that the application of non-excitatory CCM signals to the heart significantly improves the heart’s contractility by modifying the function and expression of certain proteins in the heart muscle. CCM therapy has undergone clinical testing in randomised controlled trials, and the company state the results suggest the therapy is safe and effective at improving left ventricular function and exercise tolerance.

Further benefits for patients, as claimed by the company, may include a potential reduction in morbidity, improvements in quality of life and potentially better health outcomes for patients with symptomatic chronic heart failure in the future.

The company state that using the OPTIMIZER™ system may provide opportunities for resource savings, in the form of staff time and finances, due to a reduced need to treat complications. If clinical and cost effectiveness can be demonstrated, the OPTIMIZER™ system may offer an additional treatment option for selected patients.

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS


FIX-CHF-4

Neelagaru SB, Sanchez JE, Lau SK et al. Non-Excitatory, Cardiac Contractility Modulation (CCM) Electrical Impulses: Feasibility Study for advanced Heart Failure in Patients with Normal QRS Duration. Heart Rhythm 2006;3(10),1140-1147.

COMPLETED UNPUBLISHED STUDIES

Results of the FIX-HF-7, FIX-HF-10, FIX-CHF-12 and FIX-CHF-13 studies are planned for publication.

ONGOING STUDIES


INFORMATION FROM

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