

# Wireless Cardiac Stimulation System for chronic heart failure

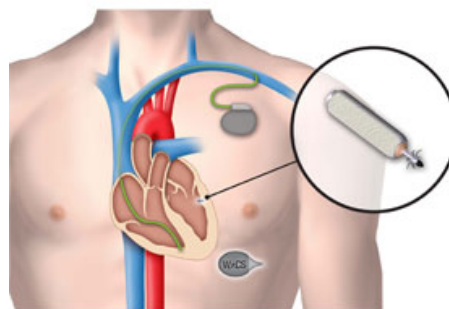
TIMEFRAME: Estimated earliest commercial availability in the UK



## TECHNOLOGY

Wireless Cardiac Stimulation system for the left ventricle (WiCS-LV) is being developed by [EBR Systems](#). It is a leadless pacing system that works with a conventional pacemaker and/or defibrillator for patients with chronic heart failure who require cardiac resynchronisation therapy.

A conventional single or dual chamber pacemaker delivers electrical stimulation through leads running into the right side of the heart to pace the right ventricle. Then to upgrade a conventional pacing system to cardiac resynchronisation (biventricular pacing), a lead is passed through the coronary sinus vein from the right atrium to the left outside surface of the heart. This is a complex procedure, which can cause complications and may not be successful.



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WiCS-LV comprises a pulse generator implanted subcutaneously near the heart that senses the conventional pacemaker's pacing pulse. WiCS-LV then wirelessly transmits ultrasound energy to a receiver electrode implanted inside the left ventricle. The receiver electrode converts the ultrasound energy, then delivers electrical stimulation to the heart sufficient to pace the left ventricle synchronously with the right.

The company anticipates CE marking and UK launch during Q3 2015.

## POTENTIAL FOR IMPACT

Heart failure is 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 or stiff to work properly. Symptoms of heart failure include breathlessness, tiredness and ankle swelling. In most cases heart failure cannot be cured. A combination of management options

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is often required including lifestyle changes, medicines, and devices or surgery that will improve heart function.

People with an abnormal heart rhythm may also be able to have cardiac resynchronisation therapy (CRT), also called biventricular pacing. CRT may be helpful if the electrical impulses that control the heart muscle's contraction and relaxation do not travel through the heart rapidly and evenly. The left ventricle may contract a fraction of a second after the right ventricle instead of simultaneously. This lack of co-ordination affects the ability of the heart to pump effectively. CRT not only functions as a pacemaker but also coordinates or resynchronises the beating of the two ventricles by pacing both simultaneously, improving contraction of the left ventricle. CRT therefore differs from typical pacemakers that only pace the right ventricle and control heart rate. CRT devices may not only improve the symptoms of heart failure, but have been shown to prolong long-term survival.

Current CRT pacemakers or defibrillators require the implantation of up to three leads into the heart, one of which is threaded through a complex route from the right to the left side of the heart via the coronary sinus vein. A pacemaker and/or defibrillator device is connected to the leads, which sense heart activity and deliver electrical stimulation through electrodes into the heart. Added to the difficulty of the procedure itself is the chance of lead failure and infection.

According to the company, the benefits of WiCS-LV for patients include lower risk complications such as lead dislodgement. The company states that benefits for the NHS include shorter procedure times and reduced length of stay in hospital.

If clinical and cost effectiveness can be demonstrated, WiCS-LV may offer an additional treatment option for select patients with chronic heart failure.

### EVIDENCE

#### PUBLISHED PAPERS AND ABSTRACTS

Auricchio A, Delnoy PP, Regoli F, *et al.* First-in-man implantation of leadless ultrasound-based cardiac stimulation pacing system: novel endocardial left ventricular resynchronization therapy in heart failure patients. *Europace*. 2013 Aug;15(8):1191-7. doi: 10.1093/europace/eut124. Epub 2013 May 23.  
<http://www.ncbi.nlm.nih.gov/pubmed/23703364>

Lee KL, Tse H-F, Echt DS, *et al.* Temporary leadless pacing in heart failure patients with ultrasound-mediated stimulation energy and effects on the acoustic window. *Heart Rhythm*. 2009 Jun;6(6):742-8. doi: 10.1016/j.hrthm.2009.02.025. Epub 2009 Feb 24.  
<http://www.ncbi.nlm.nih.gov/pubmed/19427274>

Lee KL, Lau C-P, Tse H-F, *et al.* First human demonstration of cardiac stimulation with transcutaneous ultrasound energy delivery: implications for wireless pacing with implantable devices. *Journal of the American College of Cardiology*. 2007 Aug 28;50(9):877-83. Epub 2007 Aug 13.  
<http://www.ncbi.nlm.nih.gov/pubmed/17719475>

Lee KL, Lau C-P, Tse H-F, *et al.* First acute demonstration of leadless pacing in patients using acoustic energy. *Heart Rhythm* 2006;3:S102.  
[http://www.heartrhythmjournal.com/article/S1547-5271\(06\)00503-0/abstract](http://www.heartrhythmjournal.com/article/S1547-5271(06)00503-0/abstract)

### COMPLETE UNPUBLISHED STUDIES

No completed, unpublished trials were identified.

### ONGOING STUDIES

ClinicalTrials.gov. Wireless stimulation endocardially for cardiac resynchronization therapy (WiSE-CRT)

<http://clinicaltrials.gov/show/NCT01294527> Accessed 18<sup>th</sup> December 2013.

ClinicalTrials.gov. Safety and performance of electrodes implanted in the left ventricle (SELECT-LV).

<http://clinicaltrials.gov/ct2/show/NCT01905670?term=SELECT-LV&rank=1> Accessed 18<sup>th</sup> December 2013.

### INFORMATION FROM

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