

Innovative therapy for treating heart failure

# ThePulse

News and Views Regarding the C-Pulse Clinical™ Trial

## FIRST U.S. C-PULSE™ IMPLANTS



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Photos from first U.S. implants at OSUMC



The OSUMC surgical team as C-Pulse™ Cuff is being prepared for implant



Don Rohrbaugh, CEO

### CEO Update

Since our FDA approval in September, the team of Sunshine Heart and the six investigational sites have been addressing start-up activities such as IRB approvals, agreements, surgical training and many other important details. Currently, all 6 Sites are approaching the finish line towards patient enrollment.

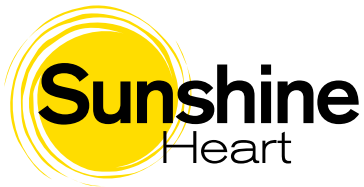
I am pleased to announce that April 15 and 16 marked the first two United States implants of the C-Pulse™ heart assist system. Of course, this is a major Company achievement. This milestone also represents the start of the first FDA sanctioned clinical study specifically targeting heart assist therapy for Class III, moderate heart failure patients.

The implants were performed by Benjamin Sun M.D., Chief, Division of Cardiothoracic Surgery and Director, Cardiac Transplantation and Mechanical Support, at The Ohio State University Medical Center

(OSUMC). Many of you know Ben Sun and will join me in congratulating him and his outstanding team at OSUMC. The OSU Heart Failure program is a world-class example of collaboration with the CT Surgeons, Cardiologists, Clinical Coordinators, VAD Coordinators, Perfusionists, Ross Heart Nurses, Nurse Practitioners and countless others playing vital team roles. Cardiologists Bill Abraham, MD, our co-national PI and Garrie Haas, MD, were both attending physicians for the first two C-Pulse implant patients. We look forward to having a clinical conference call in coming weeks so our entire US clinical team can discuss the OSUMC experience. Details to follow.

I look forward to progressing to first implants at all of the remaining sites. Keep screening Class III patients for the study and let us know what we can do to provide all the support you need. ●

Don



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Perfusionist Chad Poulton works on C-Pulse™ programmer with Doug Lohmann, Vital Engineering, Dr. Peters, and Rodney Parkin, Sunshine Heart engineer



Drs. Sun (right) and Peters at The Ohio State University Medical Center after the first U.S. C-Pulse™ patient implant

## Medical Director Update

*William S. Peters M.D., company co-founder, C-Pulse™ inventor and Medical Director*

It was an honor for me to join Benjamin Sun, M.D. for the first two United States implants of the C-Pulse™ heart assist system. This milestone represents a culmination of many years of development and clinical study. Dr. Sun, director of the Cardiac Transplantation and Mechanical Support and Chief, Division of Cardiothoracic Surgery at The Ohio State University Medical Center and his expert surgical team implanted C-Pulse into two moderate heart failure patients. Like the Australia-New Zealand pilot study patients and families, these first U.S. C-Pulse patients and families are true pioneers. It is humbling to experience the hope and gratitude of these patients as they seek symptom relief from this progressive disease.

By the time a moderate heart failure patient would be considered as a candidate for C-Pulse, their symptoms are no longer relieved

by medications and many patients have already tried heart failure pacemakers to improve their cardiac function. While the pacemakers correct electrical problems, Sunshine Heart's C-Pulse is designed to improve heart pumping function by increasing the heart's own coronary blood supply +65% and by reducing the load against which the heart pumps blood. A key to safety and patient convenience is that C-Pulse can be turned on and off and is disconnectable.

The first two C-Pulse system implants went exactly as planned. All trained clinical team members performed flawlessly as did the system. I look forward to seeing many of you again and meeting those I haven't yet as I travel to each site for first implants and any presentations you'd like me to give. I will gladly share our pilot experience, discuss patient selection and give more details of the OSUMC experience. ●



Sunshine Heart thanks the outstanding clinical coordinator team from OSUMC (L to R: Laura Yamokoski, Kelly MacBrain, Rodney Parkin and Nicole O'Bleness)