



**International Society for Heart & Lung Transplantation**  
[www.isHLT.org](http://www.isHLT.org)

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**FOR IMMEDIATE RELEASE**

**Proceed II International Heart Transplant Trial Results Revealed**  
Organ Care System as Effective as Standard of Care Method

**SAN DIEGO – April 10, 2014** – The Proceed II international heart transplant trial results will be announced today at the International Society for Heart and Lung Transplantation (ISHLT) 34<sup>th</sup> Annual Meeting and Scientific Sessions in San Diego, Calif. This trial indicates that heart transplant recipients whose donor hearts were preserved on Organ Care System (OCS™) had similar survival as recipients whose hearts were preserved on ice, the current standard of care. Trial results also indicated no differences between the OCS™ and ice preservation in reference to incidences of cardiac adverse events, rejection and time spent in ICU. The Proceed II trial also met the primary effectiveness and safety endpoints and success criteria for the FDA approval process.

The Proceed II trial was an international multicenter trial designed to test the efficacy and safety of OCS™ heart technology as compared to the standard of care organ preservation method. Donor harvesting teams randomly chose an envelope that stated whether the team was to utilize an OCS™ system or traditional ice method. 128 heart transplants were performed as part of this trial. Proceed II is the largest prospective international clinical program for heart preservation for transplantation to date.

This non-inferiority study was not designed to attempt to repair the hearts currently deemed unacceptable, only to compare the modality of preservation. However, these results could pave the way for such technology. “Proceed II provides a platform for OCS™ technology improvements that allow for the assessment and improvement of hearts previously deemed unacceptable,” said Dr. Abbas Ardehali, Director of Heart and Lung Transplant Programs at UCLA Medical Center; “thus potentially increasing the possible donor pool.”

The TransMedics OCS™ system is a portable warm blood perfusion system designed to preserve an organ outside of the human body, allowing it to function at a near physiologic state for an extended period of time.

*The International Society for Heart and Lung Transplantation (ISHLT) is a not-for-profit professional organization with more than 2,700 members from over 45 countries dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies via research, education and advocacy. For more information, visit [www.isHLT.org](http://www.isHLT.org).*

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