

## TransMedics™ Organ Care System

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TransMedics has developed the world's first commercial, portable, warm blood perfusion system that allows a new type of organ transplant, called a living organ transplant. This new technology, called an Organ Care System, is designed to maintain organs in a warm, functioning state outside of the body to optimize their health and allow continuous clinical evaluation.

Through the use of proprietary technology, the Organ Care System is designed to increase the amount of time that an organ can be maintained outside the body in a condition suitable for transplantation by reducing time dependent ischemic injury, provide surgeons the opportunity to assess the function of the organ outside the body, and enable resuscitation of the organ and potentially improve function after removal from donor. The system integrates a compact wireless monitor, an organ specific perfusion module, and proprietary solutions for organ maintenance.

The OCS optimizes the organ's health and allows for continuous clinical evaluation. Physicians can perform visual, functional and metabolic assessment of the organ to reduce the risk of organ rejection and increase the number of organs accepted for transplant. Current cold ischemic preservation and transportation methods – which essentially consist of transporting the organ in an ordinary beverage cooler – create severe time limitations, as well as potential injury to the organ, resulting in significant underutilization of the current pool of consented, donated organs.

The number of people requiring a life-saving transplant continues to rise faster than the number of available donors. Of the 96,000 people in the U.S. currently waiting for a donor organ, only a third will receive a transplant, while nearly 7,000 will die each year while waiting for an organ. This means

approximately 19 transplant candidates die each day while waiting to receive a donor organ.

The PROTECT trial is the PROspective multi-center European Trial to Evaluate the safety and performance of the Organ Care System for Heart Transplants. In this non-randomized, multi-center European study, 20 consented patients received donated hearts that were maintained by the OCS in a perfused and physiologic beating state for a mean time of 3.7 hours. The study met the primary endpoints, and achieved 30-day patient and graft survival of 100 percent. Additionally, the OCS resulted in rapid time to recovery for patients as evidenced by the median length of time patients spent on a ventilator and in the ICU, which were 10.7 hours and 24.3 hours, respectively. The trial sites participating in the PROTECT I study included the Clinic for Thoracic & Cardiovascular Medicine, Bad Oeynhausen, the German Heart Institute in Berlin, Germany, Papworth Hospital in Cambridge, UK and Harefield Hospitals, NHS Trusts in Middlesex, UK.

“These data show the Organ Care System is safe in maintaining human hearts for transplant in near physiologic conditions, reducing ischemic injury, to improve patient outcomes,” said Dr. Gero Tenderich from the Thoracic and Cardiovascular Surgery, Heart Center North Rhine-Westphalia, Bad Oeynhausen, Germany. “The OCS represents a significant advancement in organ transplant surgery over current standards of care.”

[1]"Journal of Heart & Lung Transplantation." Journal of Heart & Lung Transplantation 25 (1997): 1510-595.

[2] "Organ Care System: , Inc." TransMedics. 20 Feb. 2009  
<[http://www.transmedics.com/wt/page/organ\\_care](http://www.transmedics.com/wt/page/organ_care)>.