



ISHLT

A Society that Includes Basic Science, the Failing Heart, & Advanced Lung Disease

Media Contact: Nancy Mays

Phone: +1 (913) 568.3605

Email: nk.mays@ishlt.org

New system to preserve donor hearts could expand donor pool by using organs outside of standard scope

Heart EXPAND Trial results show potential to expand donor pool with excellent results

- *Research presented at ISHLT2019*

ORLANDO, Fla. April 4, 2019– A study showed that maintaining the heart alive and beating outside the donor body in the OCS Heart perfusion system – instead of the standard cooler of ice currently used in the U.S. – allowed surgeons to safely and effectively use hearts that would otherwise go unused because of limitations inherent in ice storage. The Heart EXPAND Trial results were presented today at the 39th Annual Meeting of the International Society for Heart and Lung Transplantation in Orlando, Fla. by Jacob Schroder MD, Duke University Medical Center in Durham, North Carolina.

One of the major risks for primary graft dysfunction, a devastating complication that can occur post-transplant, is the amount of time the donor heart is out of circulation, known as ischemic time. Current practice calls for an ischemic time of no more than four hours. However, researchers found that using a portable Organ Care System (OCS) Heart perfusion system that keeps the heart in a beating, perfused state throughout transport can safely preserve hearts for longer -- and it enables physicians to assess the condition of the donor heart until transplantation. This could significantly expand the geographic area for heart retrieval, allowing travel to almost anywhere in the U.S., the researchers said.

“The Heart EXPAND study showed that using the OCS perfusion system is safe, effective --- and can significantly expand our current donor pool of hearts for transplantation,” said Schroder. The study was part of a U.S. pivotal FDA trial to evaluate the safety and effectiveness of the portable Organ Care System (OCS™) for preserving and assessing expanded criteria donor hearts for transplantation. The study included 12 U.S. transplant centers. The OCS is made by TransMedics, Inc. a Massachusetts-based medical technology company.

The study found that:

- If the ischemic time was between two and four hours, hearts with additional risk factors could be safely preserved using OCS, including from donors 55 years and older, donors with minor coronary artery blockages, or moderately thicker hearts, all of which would likely be ruled out for

transplantation if used on ice storage. Specifically 81 percent of those donor hearts used in the EXPAND trial were transplanted successfully into a recipient as compared to approximately 35 percent when ice storage is used for preserving donor hearts.

- Using OCS resulted in excellent short-term post-transplant outcomes, most notably a low rate of primary graft dysfunction.

The OCS™ Lung System is approved by FDA and OCS™ Heart System is currently under review by FDA for use in the U.S. Both OCS Lung and Heart Systems are in clinical use in leading transplant centers in Europe, Australia and Canada, and more than 1200 patients were successfully transplanted worldwide with the OCS technology. The new OCS™ Liver system is in clinical trials in the US and Europe, and the OCS™ Kidney technology is in development.

About ISHLT

The International Society for Heart and Lung Transplantation is a not-for-profit, multidisciplinary professional organization dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies. With more than 3,800 members in more than 45 countries, ISHLT is the world's largest organization dedicated to the research, education and advocacy of end-stage heart and lung disease. ISHLT members represent more than 15 different professional disciplines. For more information, visit www.isHLT.org.