



Organ Recovery_{systems}

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FDA CLEARS LIFEPORT KIDNEY TRANSPORTER DEVICE

Lack of Transplantable Kidneys a Public Health Crisis

Organ Recovery Systems' Device May Offer Significant Improvement over Static Storage of Transplant Kidneys

CHICAGO, Ill.—AUGUST 5, 2003—Organ Recovery Systems, a developer of technologies and services to improve the quality and quantity of organs, cells, and tissues for transplantation, announced today a major milestone. The U.S. Food & Drug Administration (FDA) has given the company clearance to market its LifePort™ Kidney Transporter, an automated device designed to assess and treat donated kidneys. Portable, durable, and easy to use, the LifePort™ Kidney Transporter is the first in a new generation of mobile perfusion devices specifically designed to establish a continuum of organ care that spans the critical time between recovery and transplantation. The LifePort™ Kidney Transporter provides a new high-tech alternative to the conventional static method of organ storage and transportation—a cooler filled with ice. Perfusion is the gentle pumping of an organ with a physiologic solution as a pre-treatment for transplantation.

The nation faces an organ donation crisis. According to the United Network of Organ Sharing (UNOS), approximately 55,000 Americans are waiting to receive kidneys. Less than 20 percent of these patients may ever receive the organs they need. The United States Renal Data System (USRDS) predicts the kidney waiting list could double in the next 10 years, creating an acute need for new technology to increase the quality and number of organs available for transplant.

Machine perfusion with the LifePort Kidney Transporter holds the promise of increasing the organ pool and improving outcomes. Perfusion has the potential to enable the use of more kidneys and to reduce the number of discarded kidneys. A retrospective review of US kidney transplant data indicates that perfused kidneys function better after transplant than statically stored kidneys. If perfusion was the standard of care nationwide, the resulting combination of more organs and improved outcomes could save the healthcare system more than \$1 billion annually.

“Perfusion technology had not changed for the last 30 years. This device significantly advances the state of the art, especially in the areas of portability, ease of use, and kidney treatment and assessment,” said Dr. Stephen C. Jensik, associate director of the renal transplant program at Rush-Presbyterian St. Luke’s Medical Center. “This could enable us to make more kidneys available for transplant and ensure better outcomes.”

The LifePort Kidney Transporter gently perfuses, or pumps, the kidney with a cold liquid solution to improve its condition before transplantation. Research shows that machine perfusion can safely prolong the average cold storage time for kidneys from the current 18 hours to 35 hours or more. With the extra time afforded by this technology, kidney transplants may soon become more elective-style as opposed to emergency-style procedures, resulting in improved outcomes and decreased hospital costs. LifePort is designed for perfusion transport between donor hospitals, organ procurement organizations (OPOs), and transplant centers, both within a service area or across the country. The device also provides critical data to monitor and evaluate kidneys during transport. As a result, physicians and organ procurement professionals can better ensure the proper match between donor and recipient.

“Although surgical techniques have improved over the last few years, the packaging and transportation of organs from the donor site to the waiting recipient have not advanced much,” said Marion Borowiecki, chief executive officer of the Transplant Resource Center of Maryland. “Perfusion gives us the luxury of more time—more time to spend matching the donated organ to the recipient, more time to spend getting the recipient ready for surgery without having to rush the process.”

“As a company we are dedicated to providing new tools like the LifePort Kidney Transporter to preserve, evaluate, treat, and transport organs before transplantation. We hope that these devices will make an important contribution in expanding the number of organs available,” said David Kravitz, CEO of Organ Recovery Systems. “Our company looks forward to further refining its technology to introduce new, life-saving devices for the transplant community. LifePort Perfusion Transporters for liver, pancreas, and heart are in late-stage development,” Kravitz added.

About Organ Recovery Systems

Organ Recovery Systems is a privately held company developing technologies and services to improve the quality and quantity of organs, tissues, and cells for transplantation. The company is organized into three operating groups: the Perfusion Services Group helps leading transplant centers and organ procurement organizations (OPOs) by employing proprietary perfusion techniques for evaluation and therapy of traditional, expanded criteria, and nonheartbeating donor kidneys prior to transplant; the Medical Devices Group develops perfusion-based devices to improve the preservation, assessment, and treatment of organs for transplantation; and the Charleston Research Center develops new technologies for cell and tissue preservation and conducts basic and applied research to support the company's platform of organ therapy products. For more about Organ Recovery Systems visit <http://www.organ-recovery.com>.

Note to producers and editors: For print media, color graphics are included in a press kit. For television, B-Roll is available with patients, medical professionals, and animation of the technology with close-ups of the device: