



LifePort® Kidney Transporter Background Information

Created with the challenges of organ recovery and transport in mind, the LifePort® Kidney Transporter is designed to provide improved kidney preservation, evaluation and transport prior to transplantation. When a human kidney becomes available for transplantation it needs to be preserved and often transported from the donor to recipient in hospitals that can be many miles apart. Traditionally kidneys are packed in ice in a cool box, known as static storage.

The LifePort provides a sealed, sterile, protected environment where a solution is gently pumped through the kidney at cold temperatures to minimize damage while the organ is outside the body. The LifePort is lightweight and portable allowing organs to be perfused from the time of recovery until transplant. It can travel unaccompanied by land or air, safely transporting the kidneys across town or between countries. While the kidney is being perfused, the LifePort records data on temperature, flow rate, vascular resistance and pressure every 10 seconds, providing surgeons with additional data prior to transplantation.

Using LifePort to machine preserve kidneys could improve the long-term survival of transplanted kidney grafts. Machine preservation (MP) reduces delayed graft function (DGF) when compared with traditional static storage.¹ DGF is a delay in the recovery of renal function requiring use of dialysis in the first week post transplantation. It gives rise to the need for continuing dialysis, the requirement for biopsies, longer hospitalization and is associated with poorer long term outcome.^{2 3} In addition it has adverse psychological and medical effects on the patient.³ DGF can increase the risk of acute and chronic allograft rejection.² It occurs in up to 40%³ of transplanted kidneys, which means they do not function independently immediately following transplantation and the patient will require dialysis treatments post transplant.

A number of key studies have demonstrated the effectiveness of MP in reducing DGF compared with cold storage (CS) with reductions in the incidence of DGF ranging from 5.7% to 43%.^{4 5 6 7}

The Machine Preservation Trial

In January 2009, results of the first prospective landmark study demonstrating the merits of machine perfusion were published in the *New England Journal of Medicine*. The Machine Preservation Trial was the first international, randomised, controlled, multicenter trial to investigate the efficacy and cost effectiveness of continuous hypothermic machine perfusion on the LifePort versus static storage in cadaveric donor kidneys.

The trial compared outcome in pairs of cadaveric kidneys, one preserved by machine perfusion on the LifePort and the other by static storage. The trial was conducted in collaboration with Eurotransplant and the Deutsche Stiftung Organtransplantation. Beginning in November 2005, all cadaveric kidney donors over 16 years of age from Belgium, The Netherlands and the DSO Region Nordrhein-Westfalen Germany were considered for enrollment in the trial. 338 pairs of kidneys were enrolled and outcomes monitored and reported at 3, 6 and 12 months.

Results demonstrated that the odds for experiencing a delay in recovery of kidney function are 43% lower in the kidneys that were preserved in a LifePort and that these kidneys are 48% less likely to fail within a year compared to those stored in the traditional box of ice.⁸

Machine Preservation – Potential Benefits

With a continuing global shortage of organs for transplantation, it is important to find ways of increasing not just the number of kidneys available but also the quality of organs for transplantation to improve the long-term outcome for recipients. More than 1.5 million people worldwide suffer from end stage renal disease, for which a kidney transplant is the preferred treatment option, yet only 29,000 cadaveric kidneys are recovered annually.

MP could make more kidneys available for transplantation and potentially reduce the waiting list by allowing transplant surgeons to use kidneys that might otherwise be discarded, such as those from extended criteria donors (ECDs). Such donors include deceased donors over age 60 years or those over age 50 with health conditions such as high blood pressure, stroke or elevated levels of a protein called creatinine as well as those from non-heartbeating donors.

Since receiving FDA clearance and CE Marking in 2004, over 240 LifePorts have been installed in transplant programs throughout Europe and North America treating over 12,000 kidneys.

The LifePort has been recognized for excellence in design by *Popular Science* (Best of What's New 2003), the Industrial Designers Society of America (Silver Award IDEA2004), the Medical Design Excellence Awards (Gold Winner 2004), the Museum of Modern Art (SAFE: Design Takes on Risk 2005-2006), and the Smithsonian Cooper-Hewitt National Design Museum (National Design Triennial 2006-2007).

The LifePort Kidney Transporter is made by Organ Recovery Systems. Medical devices for *ex vivo* preservation of the heart, lung, pancreas and liver are in pre-clinical development.

Organ Recovery Systems is a business division of Lifeline Scientific Inc, a Chicago-based global medical technology company. Its European headquarters are located in Brussels.

References

¹Schold JD et al. Are we frozen in time? Analysis of the utilization and efficacy of pulsatile perfusion in renal transplantation. *Am J Transpl* 2005; 5: 1681-1688.

²Daly PJA, Power RE, Healy DA et al. Delayed graft function: a dilemma in renal transplantation. *BJU International* 2005; 96: 498-501.

³Perico N, Cattaneo D, Sayegh MH, Remuzzi G. Delayed graft function in kidney transplantation. *Lancet* 2004; 364: 1814

⁴Wight JP, Chilcott CB, Holmes MW, Brewer N. Pulsatile machine perfusion vs. cold storage of kidneys for transplantation: a rapid systematic review. *Clin Transplant* 2003; 17: 293-307

⁵Matsouka L, Shah T, Aswad S et al. Pulsatile perfusion reduces the incidence of delayed graft function in expanded criteria donor kidney transplantation. *Am J Transplant* 2006;6: 1473-1478

⁶Plata-Munoz J, Contractor H, Muthusamy A et al. Central role of pulsatile perfusion on preservation of kidneys from controlled non-heart-beating donor. Abstract 188. *American Transplant Congress 2007* San Francisco.

⁷Stratta RJ, Moore PS, Farney AC et al. Influence of pulsatile perfusion preservation on outcomes in kidney transplantation from expanded criteria donors. *J Am Coll Surg* 2007; 204: 873-884

⁸Koning OH, Ploeg RJ, van Bockel JH et al. Risk factor for delayed graft function in cadaveric kidney transplantation: a prospective study of renal function and graft survival after preservation with University of Wisconsin solution in multi-organ-donors. European Multicenter Study Group. *Transplantation* 1997; 63: 1620-8.

⁹Moers C, Smits JM, Maathuis M-HJ et al. Machine perfusion or cold storage in deceased-donor kidney transplantation. *N Engl J Med* 2009; 360: 7-19.