



LifePort® Kidney Transporter

Frequently asked questions

Q. What is LifePort?

A. 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 different hospitals that can be many kilometres 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 transplantation. 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 which would not be available with cold storage.

Q. Why do we need it? Doesn't the current method work OK?

A. With a continuing global shortage of organs available 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.

Using LifePort to machine preserve kidneys could improve the long-term survival of transplanted kidneys. Machine preservation reduces delayed graft function (DGF) when compared with traditional static storage.¹ DGF is a delay in the recovery of renal function in the first week post transplantation. It gives rise to the need for continuing dialysis, the requirement for biopsies, longer hospitalisation and is associated with poorer long term outcome.^{2,3} In addition it has adverse psychological and medical

effects on the patient³ DGF can increase the risk of acute and chronic allograft rejection.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 transplantation.

A number of key studies have demonstrated the effectiveness of MP in reducing DGF (defined as the requirement for dialysis in the first week post-operatively) compared with cold storage (CS) with reduction in the incidence of DGF ranging from 5.7% to 43%.^{4,5,6,7}

Until recently however no prospective studies have investigated the merits of machine preservation. Results from the landmark Machine Preservation Trial published in the New England Journal of Medicine in January 2009 demonstrated for the first time that in transplanted kidneys preserved and transported in a specially designed machine (LifePort Kidney Transporter) the odds for experiencing a delay in recovery of kidney function are 43% lower 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 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.

A kidney may be stored in the LifePort for 35 hours or more. Because LifePort can support the kidney outside of the body (*ex vivo*) for longer time periods, it allows more time for doctors to get the recipient ready for surgery, and allows kidneys to be transported long distances.

Q. Isn't machine preservation expensive compared with static storage?

A. The clinical benefits of MP are associated with significant cost savings. The initial cost outlay for a machine is balanced by the improvement in outcomes which in turn result in a decreased need for dialysis, a reduction in length of stay post implantation and an improved rate of utilization compared with CS.^{5, 9,10,11,12} When compared to CS these cost savings result in MP becoming the cheapest technology after a period of only 2 months following transplantation. In addition the use of MP reduces the number of patients returning to dialysis in the long- term,^{11, 12}

Q. What are the advantages over the current method of transporting kidneys?

A. The LifePort Kidney Transporter is designed to provide improved kidney preservation, evaluation and transport prior to transplantation. The LifePort is lightweight and portable allowing organs to be perfused from the time of recovery until

transplantation. 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 which would not be available with the use of cold storage.

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health conditions such as high blood pressure, stroke or elevated levels of a protein called creatinine as well as those from non-heartbeating donors.

Q. What evidence is there to show machine preservation is better than cold static storage?

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Until recently however no prospective studies have investigated the merits of machine preservation. Organ Recovery Systems sponsored the first prospective clinical trial which aimed to determine which preservation method is best. The Machine Preservation Trial is the first international, prospective, randomised, controlled, multicentre trial to investigate the efficacy and cost effectiveness of continuous hypothermic machine perfusion versus static storage in cadaveric donor kidneys. The trial compares outcome in pairs of 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. Since 1 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 enrolment in the trial. 338 pairs of kidneys were enrolled and outcomes monitored and reported at 3, 6 and 12 months.

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Q. What evidence do you have that LifePort reduces delayed graft function?

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Q. What evidence do you have to show machine preservation allows the use of kidneys from higher risk donors and non-heartbeating donors?

A. Many retrospective clinical outcome studies have shown that machine preservation improves the quality of a cadaveric kidney prior to transplantation in comparison to organs statically stored in a cool box. This retrospective data demonstrates that machine perfused kidneys are more likely to function immediately after transplantation and to remain healthy for a longer time regardless of donor status.⁴

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Q. Can LifePort be used with other organs?

A. Medical devices for *ex vivo* preservation of the heart, lung, pancreas and liver are in late-stage pre-clinical development.

Q. How many LifePorts are being used by transplant centres?

A. Since the LifePort Kidney Transporter received Food and Drug Administration (FDA) clearance in the USA in late 2003 and a CE Mark in Europe in 2004, during a pilot phase more than 240 LifePorts have been used to preserve more than 12,000 kidneys worldwide

References

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