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Horizon Scanning Technology

Prioritising Summary

LifePort® kidney transporter: A portable donor kidney transporter/ perfuser

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PRIORITISING SUMMARY

REGISTER ID: **000091**

NAME OF TECHNOLOGY: **LIFEPORT® KIDNEY TRANSPORTER**

PURPOSE AND TARGET GROUP: **PORTABLE DONOR KIDNEY TRANSPORTER/ PERFUSER**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☒	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

The LifePort® device was given US Food and Drug Administration approval in 2003 and received the European CE mark in 2004 (Dove 2007).

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Russia	✓		
Netherlands	✓		

IMPACT SUMMARY:

Organ Recovery Systems markets the LifePort® kidney transporter with the aim of providing machine perfusion to ensure the viability of kidneys which need to be transported from one location to another. This technology would be made available through specialist transplant hospitals for patients who require kidney transplantation.

BACKGROUND

Kidney transplantation is both cost-effective and an ideal treatment option for patients with end-stage renal failure. However the number of patients on the transplant waiting list outweighs the number of organs available. A number of ways of increasing the donor pool available have been examined including the use of non-beating heart donors and increasing the use of related or unrelated donors.

The deprivation of oxygen and nutrients caused by ischaemia may lead to permanent damage, therefore preservation of kidney viability between retrieval and implantation is important. To preserve function two strategies have been used: cold storage (CS) and machine perfusion (MP). Damage is reduced during CS by slowing the metabolic rate. The kidney is flushed through with a perfusion or preservation fluid and then kept on ice. MP uses a machine to pump a cold perfusion solution through the kidney, and provides oxygen and nutrients, allowing the kidney to continue metabolism. During the 1970s, the majority of kidneys made available for transplantation would have undergone MP, however several studies found that there was no clear clinical benefit gained from the use of the more expensive and labour intensive MP and CS became the system of choice in kidney transplantation during the 1980s. However, MP may result in a reduced rate of delayed graft function (the delay in normal renal function post-transplantation). Although delayed graft function is observed in 23-33 per cent of kidneys transplanted from beating heart donors, it is more common following transplantation from non-beating heart donors. Delayed graft function is associated with poorer long term outcomes and requires short-term dialysis (Wight et al 2003).

The LifePort® device is a portable machine perfusion unit that is designed to contain and perfuse a transplantable kidney under cold and asceptic conditions (Figure 1). Although relatively compact (dimensions 61x37x36cm) the unit weighs 20.4 kg and would therefore require two people to transport it. The unit can be used for up to 24 hours before battery replacement and ice replenishment is required. The LifePort® device may have the potential to increase the number of organs able to be transplanted by increasing the viability of transported kidneys (Organ Recovery Systems 2003).

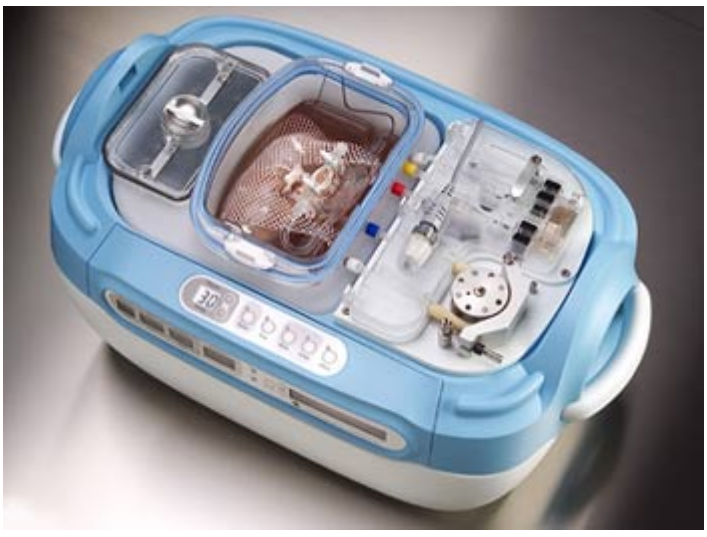

Figure 1 The LifePort® kidney transporter (Medgadget 2005)

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, the waiting list for kidney transplantation has slightly decreased from 1,488 in 2003 to 1,388 in 2007. This corresponds to a slight increase in the number of

kidney transplantations performed, up from 325 in 2003 to 342 in 2007. However, in New Zealand the number of patients awaiting kidney transplantation has increased markedly from 370 in 2003 to 559 in 2007. The number of kidney transplantation procedures performed in New Zealand has remained almost static with 67 in 2003 and 65 in 2007. In Australia during 2007 there were 198 kidney donors with 349 kidneys transplanted. In New Zealand during the same period there were 38 kidney donors with 65 kidneys transplanted. A number of organs are sent and retrieved between Australian States and New Zealand each year (Table 1), indicating the need for ideal transportation conditions of organs. Although no kidneys were transplanted in Australia from New Zealand donors during 2006-2007, since 1989 a total of 21 kidneys have been exchanged and transplanted. Patient and graft survival rates are shown in Figure 2 (ANZOD 2008).

Table 1 Exchange of kidneys between Sates and New Zealand 2007, 2006 (ANZOD 2008)

	NZ	Q'land	NSW	ACT	Vic	Tas	SA	NT	WA
Sent	0, 0	9, 19	12, 20	2, 6	7, 17	2, 14	6, 11	6, 4	7, 11
Received	0, 0	8, 9	19, 35		7, 29		11, 22		6, 7

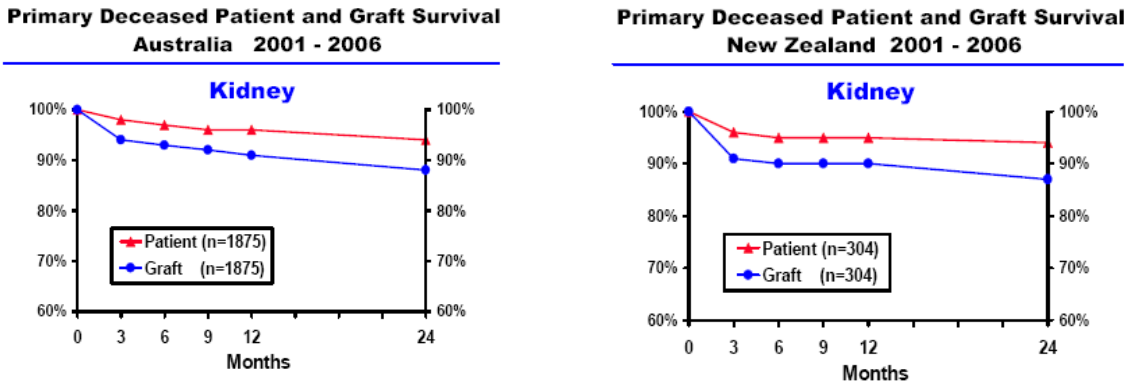

Figure 2 Patient and graft survival rates for Australia and New Zealand (ANZOD 2008)

DIFFUSION

There is no evidence that the LifePort® machine perfusion device is in use in Australia.

COMPARATORS

Cold storage or conventional machine perfusion would be used to maintain and preserve viability between retrieval and transplantation of the donated kidney (Wight et al 2003).

SAFETY AND EFFECTIVENESS ISSUES

A recent study attempted to transplant 44 kidneys from 22 non-beating heart donors. Each pair of kidneys from one donor were divided by the type of preservation with

one kidney preserved using conventional cold storage whilst the other was preserved using the LifePort® machine perfusion device (level III-2 intervention evidence). The characteristics of the recipients are summarised in Table 2.

Table 2 Recipient characteristics

	Control cold storage (n=17)	LifePort® machine perfusion (n=21)
Male	7	10
Female	10	11
Age (years)	37.9 ± 10.2	45.2 ± 9.5
Waiting list time (years)	4.2 ± 3.7	5.2 ± 3.3
Haemodialysis	11	16
Peritoneal dialysis	6	5
Glomerulonephritis	12	16
Pyelonephritis	4	4
Other diseases	1	2

Five kidneys that were to be transplanted into the cold storage group were deemed to be non-viable and discarded as was one kidney in the LifePort® group. Viability was assessed during biopsy and degenerative changes observed resulted in the kidneys being discarded. Early clinical outcomes are summarised in Table 3 (time not stated explicitly however follow-up creatinine levels were measured at 90 days post-transplantation).

Table 3 Comparison of early post-transplant outcomes

	Control cold storage (n=17)	LifePort® machine perfusion (n=21)	p value
Immediate function	3 (18%)	10 (48%)	<0.001
Delayed graft function	14 (82%)	11 (52%)	<0.001
Haemodialysis/ 30 days	4.9 ± 3.6	2.3 ± 2.6	<0.05
Creatinine day 1	820.7 ± 112.0	700.9 ± 227.3	<0.1
Creatinine day 21	376.9 ± 106.0	213.0 ± 137.3	<0.001
Creatinine day 90	177.0 ± 26.8	139.7 ± 32.0	<0.001
Hospital stay (days)	43.8 ± 10.2	29.3 ± 8.3	<0.0001
Acute rejection	4	1	
Primary non-function transplant	3	0	
Surgical complications	3	1	

There were significant differences between cold storage and the LifePort® machine perfusion patients in all reported outcome categories. Thirty per cent more kidneys in the machine perfusion group experienced immediate function ($p<0.001$) and there was a significant reduction in the number of kidneys with delayed graft function ($p<0.001$). There were no non-functioning transplants in the LifePort® group compared to three in the cold storage group (Reznik et al 2008).

An earlier small scale study was reported by the same author. A total of 14 kidneys from seven non-beating heart donors were transplanted into 14 recipients. One kidney from each donor was preserved using conventional cold storage whilst the other was preserved using the LifePort® machine perfusion device (level III-2 intervention evidence). The average warm ischaemia time (time between declaration of death to time cold perfusion began) was 25.5 ± 13 minutes. The average cold perfusion time was the same in both groups at 18 ± 6 hours. Unfortunately the results of this initial study were omitted in the published paper. The evaluators contacted the author who is yet to respond (Reznik et al 2006).

COST IMPACT

Organ Recovery Systems quote the current price of the LifePort® Kidney Transporter, Continuous Flow and the Pulsatile Flow as US$20,160 and €14,400, equating to approximately A$25,000. The LifePort® device requires the use of several disposable, one use only, consumables which may be purchase separately or as a pack. The Perfusion Pack consists of LifePort Perfusion Circuit (closed system with in-line filter and pressure sensor), SealRing™ 7x20 cannula, and sterile drape and costs US$620 or €440 (Organ Recovery Systems 2003).

No economic studies evaluating the use of the LifePort® device were identified, however if the LifePort® was capable of maximising the number of viable kidneys able to be transported and transplanted, this may have a potential economic impact considering factors including survival of patients on waiting lists and the ongoing need for dialysis. In addition, the LifePort® device may increase the donor pool by salvaging previously rejected kidneys from deceased donors, which may have an economic impact (Dove 2007).

A systematic review conducted in the United Kingdom examined the clinical and cost-effectiveness of MP compared to CS as a means of preserving kidneys to be transplanted and donated from beating and non-beating heart donors. It has been suggested that MP may reduce delayed graft function and increase the size of the donor pool by extending the criteria for donor recruitment. A reduction in delayed graft function would be considered a cost saving. The meta-analysis suggests that the use of MP compared to CS is associated with a relative risk of delayed graft function of 0.804 (95%CI [0.672, 0.961]). There was no evidence indicating that this effect would be different in kidneys obtained from either beating or non-beating heart donors. One year graft survival data showed no significant effect, however the

included studies were underpowered. The published economic evidence was considered to be poor and it was considered unlikely in the UK that complete cost recovery from the use of MP would be gained from a reduction in delayed graft function. However, a baseline analysis indicated that in the long-term MP would be expected to be cheaper and more effective than CS for both beating and non-beating heart donors (Wight et al 2003).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There is an ethical imperative to increase the number of potential organs available for donation to patients on the transplantation waiting list.

OTHER ISSUES

A large multi-centre European study with 338 participants was due to conclude in 2007. When the results of this study are due to be published is unknown despite contacting the primary investigator and Organ Recovery Systems. A large multi-centre European study investigating the efficacy and cost-effectiveness of machine versus static (CS) preservation in 600 patients was due to be finalised in November 2006. No results have been reported. Two other studies are currently underway. A randomised controlled trial in the United Kingdom began in August 2006 and is looking at outcomes from non-beating heart donor kidneys. The remaining study which also commenced in August 2006 in Brazil, expects to run for 24 months and recruit 148 patients (Organ Recovery Systems 2003).

SUMMARY OF FINDINGS

The LifePort® appears to be effective in increasing the donor pool for kidney transplantation to enable the use of beating and non-beating heart donors. Only one small scale study was assessed, comparing the use of two different preservation methods on kidneys received from the same donor. Significant differences in viability were observed when the LifePort® was used compared to conventional cold storage. The portability of the LifePort® may result in a larger number of transplants being achieved between states and New Zealand.

HEALTHPACT ACTION:

Based on the good quality, albeit small evidence base and the obvious benefits to the patient of receiving a viable, functioning kidney transplant, and the possibility of increasing the number of organs exchanged between countries and states, HealthPACT recommended that this technology be monitored.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level III-2 intervention evidence	2

REFERENCES:

ANZOD (2008). *Annual Report of The Australia and New Zealand Organ Donation Registry (ANZOD)* [Internet]. Australia and New Zealand Organ Donation Registry. Available from: http://www.anzdata.org.au/anzod/ANZODReport/anzodreport.htm#2008 [Accessed 9th September, 2008].

Dove, A. (2007). 'Nifty transport device doubles durability of donor organs', *Nat Med,* 13 (4), 390.

Medgadget (2005). *LifePort kidney transporter* [Internet]. Available from: http://www.medgadget.com/archives/img/kidney_trans_big.jpg [Accessed 9th September, 2008].

Organ Recovery Systems (2003). *LifePort kidney transporter operations manual* [Internet]. Available from: http://www.organ-recovery.com/pdfs/Kidney_Transporter/LifePort_Operators_Manual.pdf [Accessed 9th September, 2008].

Reznik, O. N., Bagnenko, S. F. et al (2008). 'Machine perfusion as a tool to select kidneys recovered from uncontrolled donors after cardiac death', *Transplant Proc,* 40 (4), 1023-1026.

Reznik, O. N., Bagnenko, S. F. et al (2006). 'Increasing kidneys donor's pool by machine perfusion with the LifePort--pilot Russian study', *Ann Transplant,* 11 (3), 46-48.

Wight, J., Chilcott, J. et al (2003). 'The clinical and cost-effectiveness of pulsatile machine perfusion versus cold storage of kidneys for transplantation retrieved from heart-beating and non-heart-beating donors', *Health Technol Assess,* 7 (25), 1-94.

SEARCH CRITERIA TO BE USED:

Graft Survival/*physiology
*Kidney
Kidney Transplantation/*physiology
Organ Preservation/*methods
Perfusion/*methods
*Tissue Donors
Kidney Transplantation/*instrumentation
Reperfusion Injury/*prevention & control
Tissue Donors