KIDNEYASSIST

THE ONLY TEMPERATURE CONTROLLED OXYGENATED PERFUSION SYSTEM
DESIGNED TO PRESERVE AND RECONDITION KIDNEY GRAFTS

TEMPERATURE CONTROL

OXYGENATED

PULSATILE FLOW

FUNCTIONAL VIABILITY ASSESSMENT

ORGAN ASSIST

BENEFITS

IMPROVED DONOR ORGAN QUALITY

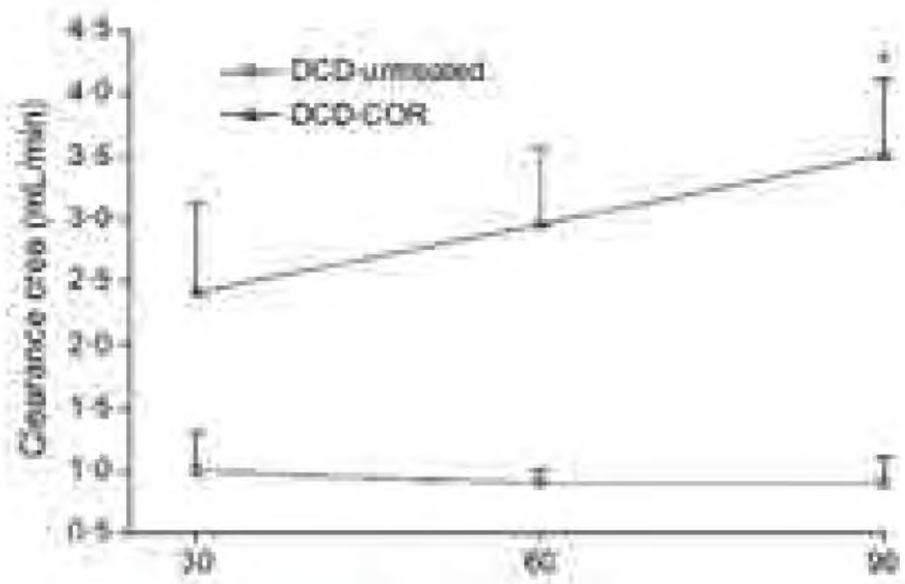
- Reduced risk and duration of DGF in all kidney donor types [1-4] (HMP)
- Improved 1 to 3 year graft survival [5] (HMP)
- Reduced number of patients returning to dialysis [6] (HMP)
- Superior HMP effect in DBD and DCD kidneys after oxygenated perfusion[7-9] (HMP)
- Improved kidney function, lower oxidative damage and reduced inflammatory gene expression after gradually oxygenated rewarming [10] (COR)

HIGHER ORGAN UTILIZATION RATE

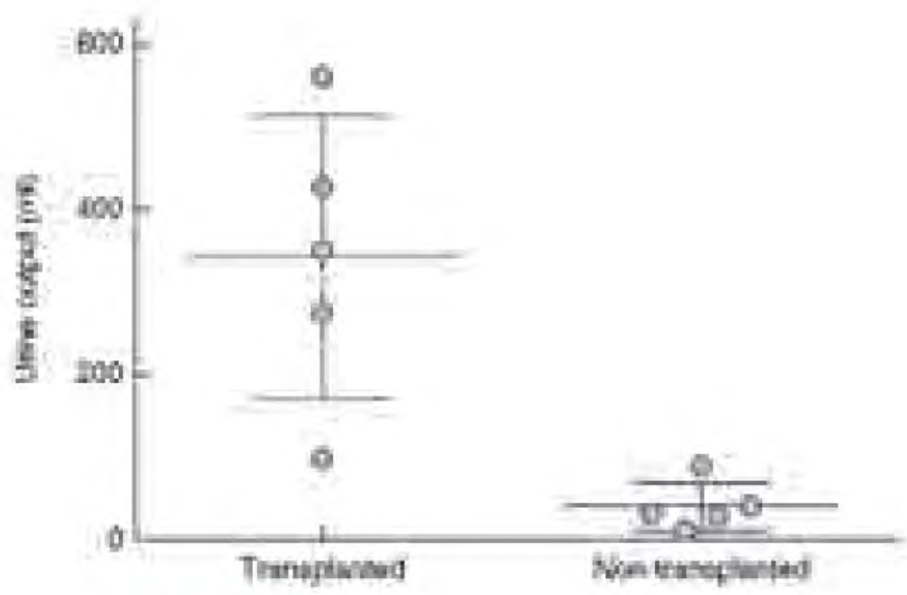
- Allows for viability assessment [11] (NMP)
- Initially rejected kidneys deemed suitable after perfusion [12] (NMP)
- Prediction of renal function upon reperfusion [13] (COR)
- Could serve as a platform for delivery of therapeutics [14] (NMP)

EASY TO USE AND IMPLEMENT

- Different cannulation approaches available
- Ergonomic working height
- Better time management of personnel and OR availability; by making the Tx procedure semi-elective
- Modular system design and interface allows for rapid and easy implementation; supported by our training and education program



Improved Function
In DCD kidneys, renal clearances of creatinine is significantly improved, when controlled oxygenated rewarming was performed prior to reperfusion [10]



Viability Assessment
During NMP the total urine output can be used quality assessment parameter [12]

HMP = Hypothermic Machine Perfusion, **COR** = Controlled Oxygenated Rewarming and **NMP** = Normothermic Machine Perfusion.

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4. Treckmann J et al. Machine perfusion versus cold storage for preservation of kidneys from expanded criteria donors after brain death.Transpl Int. 2011;24(6):548-54.
5. Moers C, Pirenne J, Paul A, Ploeg RJ. Machine perfusion or cold storage in deceased-donor kidney transplantation. N Engl J Med 2012; 366:770–771.
6. Kwiatkowski A, Wszola M, Kosieradzki M, et al. Machine perfusion preservation improves renal allograft survival. Am J Transpl 2007; 7: 1942
7. Thuillier R, Allain G, Celhay O, et al. Benefits of active oxygenation during hypothermic machine perfusion of kidneys in a preclinical model of deceased after cardiac death donors. J Surg R 2013; 184:1174–1181.
8 Patel K, Smith TB, Neil DAH, et al. The Effects of Oxygenation on Ex Vivo Kidneys Undergoing Hypothermic Machine Perfusion. Transplantation. 2019;103(2):314-322.
9. Hofker, HS, Jochmans I, Brat A, et al. Oxygenated hypothermic machine perfusion of kidneys donated after circulatory death: an international randomised controlled trial. Best Abstract Bootcongress March 2019. Presentation S. Hofker
10. Minor T, Sutschet K, Witzke O, et al. Prediction of renal function upon reperfusion by ex situ controlled oxygenated rewarming. Eur J Clin Invest 2016; 46:1024–1030.
11. Hosgood SA, Barlow AD, Hunter JP, Nicholson ML. Ex vivo normothermic perfusion for quality assessment of marginal donor kidney transplants. Br J.Surg 2015; 102:1433–1440.
12. Hosgood SA, Thompson E, Moore T, Wilson CH, Nicholson ML. Normothermic machine perfusion for the assessment and transplantation of declined human kidneys from donation after circula death donors.Br J Surg. 2018.105(4):388-394.
13. Minor T, Sutschet K, Witzke O, et al. Prediction of renal function upon reperfusion by ex situ controlled oxygenated rewarming. Eur J Clin Invest 2016; 46:1024–1030.
14. Casiraghi F, Perico N, Cortinovis M, Remuzzi G. Mesenchymal stromal cells in renal transplantation: opportunities and challenges. Nat Rev Nephrol 2016; 12:241–253.

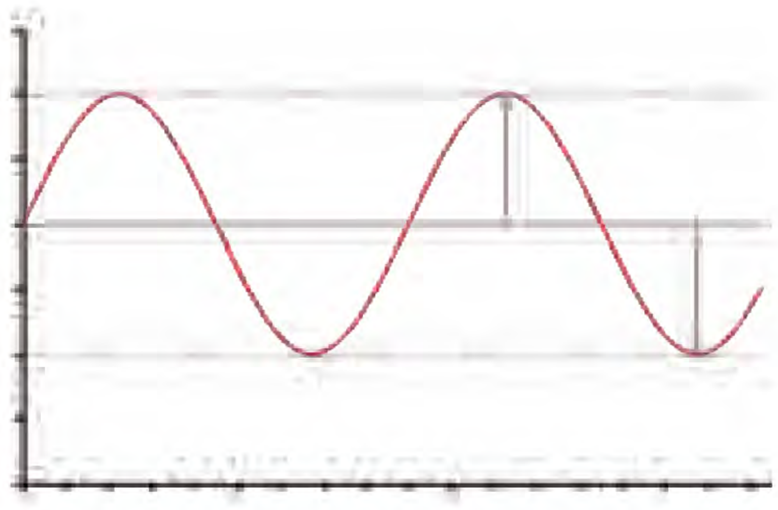
DEVICE FEATURES

Assess function and viability of the kidney graft by perfusion and perfusate characteristics as well as urine production

The only commercially available device that is capable of perfusion at a flexible temperature range (12 – 37 °C)

Hollow fiber oxygenator for efficient oxygenated perfusion with integrated heat exchanger

True pulsatile perfusion pattern (60 bpm) through renal artery, generated by dedicated pressure controlled pump unit



Pulse amplitude ±20% of mean pressure

SPECIFICATIONS

TOTAL SYSTEM:	
Dimensions total system	1120 mm x 925 mm x 625 mm
Weight total system	68 kg (combined weight Pump Unit, Thermo Unit and Trolley)
Power total system	230 VAC, 50 Hz, 740 VA
Battery capacity	Max. 20 minutes (fully charged batteries)
Battery charging	Automatic while connected to mains, 8 hours empty-full
Application period	6 hours
Product Life time	7 years
Certification	CE, certificate CE663647 (issued by BSI Netherlands)
Operating conditions	Temperature 18 to 24°C, 30 - 85% RH
Storage conditions	Temperature 5 to 40°C, 30 - 85% RH
PUMP UNIT:	
Dimensions/weight	425 mm x 140 mm x 460 mm; 13,5 kg
Sensors	Flow (1 x), temperature (2 x), pressure (1 x)
Connections	Flow: 16 pin, IP68
	Pressure: 6 pin, IP68
	Temperature: 4 pin, IP68
	USB: type B
	Mains
Pulsatility	60 BPM (1 Hz), amplitude ± 20% of mean pressure
Flow	Pulsatile flow, up to 1000 ml/min
Pressure	Up to 50 mmHg @12°C
	Up to 110 mmHg @37°C
Measurement/display	Perfusion time (hh:mm:ss)
	Flow: mean perfusion flow (ml/min)
	Pressure: mean perfusion pressure (mmHg)
	Temperature: arterial and venous perfusion temperature (°C)
	Vascular resistance: pressure/flow (ru)
Alarms	Pressure, flow, temperature, sensor (disconnect) mains (disconnect), perfusion level, battery level, thermo water level
THERMO UNIT:	
Dimensions/weight	425 mm x 224 mm x 460 mm; 29 kg
Sensors	temperature (1 x), level (1 x)
Connections	Mains, data 12 pin, IP68, water 2 x
Thermal performance	12 - 37 °C ; Heating T = 0.3 °C/min
Priming volume	2000 ml
TROLLEY:	
Dimensions	1120 mm x 925 mm x 600 mm
Weight	25,5 kg
Safety	Rotating wheels with parking brakes 4 x
DISPOSABE SET:	
Pump	Deltastream DP2, rotary pump
Oxygenator	Hilite 2800 with integrated venous bubble trap and heat exchanger
Arterial filter	Arterial Filter 32 µm
Tubing	PVC, silicon
Solution	Any certified machine perfusion solution
Priming volume	min. 2000 ml
Sterility	Single use, shelf life 3 years from manufacturing date
Certification	CE, certificate Z/11/02608

INTENDED USE

The KIDNEY ASSIST is intended to be used for isolated temperature-controlled ex-vivo pulsatile oxygenated machine perfusion of donor kidneys, for a period up to 6 hours.

PATHWAY ORGAN TRANSPLANTATION

	PRECONDITIONING	PRESERVATION	RECONDITIONING
CLINICAL CHALLENGE	• Restore abdominal circulation • Reduce warm ischaemic time • Maintain biological conditions of the donor body • Increase use of DCD donors	• Reduce cold ischaemic injury • Better time management • Improve donor-organ quality • Support metabolism by full oxygenation	• Reduce end ischaemic injury • Decrease time pressure in transplant hospital • Functional viability assessment • Reduce discard rate
PORTFOLIO	 **DONORASSIST**	 **KIDNEYASSIST** TRANSPORT	 **KIDNEYASSIST** **LIVERASSIST** **LUNGASSIST**

Organ Assist Headquarters

ORGAN ASSIST: WHEN TIME COUNTS AND QUALITY SAVES LIVES

Organ Assist has been active in the field of oxygenated machine perfusion since 2005. Ever since, together with partners, Organ Assist is fully dedicated to expanding the quality and availability of donor organs.
To achieve this goal our unique portfolio enables oxygenated machine perfusion at all different time points in the pathway of organ donation; during preconditioning, preservation and reconditioning.

Organ Assist Academy

TRAINING AND EDUCATION

Organ Assist is facilitating theoretical and practical training sessions at the Organ Assist Academy at our headquarters in Groningen. Training programs at the academy will be tailored to your specific needs and wishes.
Courses can vary from one to multiple days and may include:

- theoretical basics and background of machine perfusion
- hands-on technical use of devices
- hands-on clinical use and procedure simulation
- device maintenance

HELPDESK: 24/7 technical helpdesk service
SERVICE: maintenance services for your device
ONLINE SUPPORT: access all details about our devices (e.g. instruction videos) on your mobile device through the dedicated Organ Assist App

R2

INTERESTED?

PLEASE CONTACT US.

For more information:
scan the QR code
or visit www.organ-assist.nl

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