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

TEMPERATURE CONTROL
OXYGENATED
PULSATILE FLOW
FUNCTIONAL VIABILITY ASSESSMENT
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) (HMP)
- Initially rejected kidneys deemed suitable after perfusion (12) (HMP)
- Prediction of renal function upon reperfusion (13) (COR)
- Could serve as a platform for delivery of therapeutics (14) (HMP)

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

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

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.

- Table top with sterile drape to allow back table work.
- Dedicated disposable organ chamber; kidney submerged in perfusion medium.
- Ergonomic working height.
- Sampling port: to sample perfusate allowing functional assessment.
- Thermo Unit: Control perfusion temperature.
- Easy to operate.
- Trolley: Allows for easy in hospital transportation.
- Renal Artery Pump Unit: Pressure controlled rotary pump generating pulsatile perfusion.
- 360° rotating wheels with brakes.
# SPECIFICATIONS

**TOTAL SYSTEM:**
- Dimensions total system: 1120 mm x 925 mm x 625 mm
- Weight total system: 66 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 450 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 (nu)
- 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

**DISPOSABLE SET:**
- Pump: Deltrastream DP2, rotary pump
- Oxygenator: Hili 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

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**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

<table>
<thead>
<tr>
<th>CLINICAL CHALLENGE</th>
<th>PRECONDITIONING</th>
<th>PRESERVATION</th>
<th>RECONDITIONING</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Restore abdominal circulation</td>
<td>• Reduce cold ischaemic injury</td>
<td>• Reduce end ischaemic injury</td>
<td></td>
</tr>
<tr>
<td>• Reduce warm ischaemic time</td>
<td>• Better time management</td>
<td>• Decrease time pressure in transplant hospital</td>
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<tr>
<td>• Maintain biological conditions of the donor body</td>
<td>• Improve donor-organ quality</td>
<td>• Functional viability assessment</td>
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<tr>
<td>• Increase use of DCD donors</td>
<td>• Support metabolism by full oxygenation</td>
<td>• Reduce discard rate</td>
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</tbody>
</table>

### PORTFOLIO
- DONORASSIST
- KIDNEYASSIST
- LIVERASSIST
- LUNGASSIST
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.

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

ORGAN INTERESTED? PLEASE CONTACT US.

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