LIVER ASSIST

A UNIQUE SYSTEM THAT ALLOWS FOR PRESSURE AND TEMPERATURE CONTROLLED DUAL OXYGENATED PERFUSION DESIGNED TO PRESERVE AND RECONDITION LIVER GRAFTS

FUNCTIONAL VIABILITY ASSESSMENT
TEMPERATURE CONTROL
OXYGENATED
PRESSURE CONTROLLED PULSATILE & CONTINUOUS FLOW
**BENEFITS**

**IMPROVED DONOR ORGAN QUALITY**
- Lower allograft dysfunction in DCD Livers and similar to DBD Livers (1)(HMP)
- Lower peak AST (1,2,3) and ALT (1,2) (HMP)
- Lower peak Bilirubin (1,2) (HMP)
- Improved 1-yr graft survival in machine perfused livers (1,2) (HMP)
- Improved 5-yr patient & graft survival in HOPE-treated livers (3) (HMP)
- Lower biliary complications (1)(HMP)
- Less Ischemia Reperfusion Injury after oxygenated perfusion (4,5) (HMP)

![Graph showing graft survival](image)

**HIGHER ORGAN UTILIZATION RATE**
- Allows for viability assessment (6,7,8,10)(HMP)
- Initially rejected livers deemed suitable after perfusion (6,7,8,10)(HMP)
- Increase in the safe use of DCD Donors (1,2,5,6,8,9,10)(HMP)

**EASY TO USE AND IMPLEMENT**
- Better time management of personnel and OR availability; by making the Tx procedure semi-elective
- Total Tx cost of machine perfused DCD grafts lower than standard DBD Tx (9)(HMP)
- Modular system design and interface allows for rapid and easy implementation; supported by our training and education program
- Ergonomic working height
- With over 700 clinical Liver Tx the Liver Assist is the Machine Perfusion System of choice; Key opinion leaders around the world are our reference

HMP = Hypothermic Machine Perfusion, NMP = Normothermic Machine Perfusion.

Assess function and viability of the liver grafts by perfusion and perfusate characteristics as well as bile production.

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

Oxygenated dual vessel perfusion by two hollow fiber oxygenators with integrated heat exchangers.

True pulsatile perfusion pattern (60 bpm) through Hepatic Artery and continuous perfusion through Portal Vein, generated by two dedicated pressure controlled pump units.

Table top facilitating an ergonomic working height.

Hollow fiber oxygenators.

Easy to operate: Single button control.

Thermo Unit: Control perfusion temperature.

Hepatic Artery Pump Unit with Pressure controlled rotary pump generating pulsatile perfusion.

Trolley: Allows for easy in hospital transportation.

360° rotating wheels with brakes.

Dedicated disposable organ chamber with sterile drape to allow back table work.

Sampling port to sample perfusate allowing functional assessment.

Portal Vein Pump Unit with Pressure controlled rotary pump generating continuous perfusion.

- Hepatic Artery (amplitude = 20%)
- Portal Vein
### SPECIFICATIONS

#### TOTAL SYSTEM:
- **Dimensions total system**: 1120 mm x 925 mm x 625 mm
- **Weight total system**: 81 kg (combined weight Pump Units, Thermo Unit and Trolley)
- **Power total system**: 110-230 VAC, 50 Hz, 880 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
- **Patent**: EP2009986, US287580, CA2647629
- **Certification**: CE, certificate CE63647 (issued by BSI Netherlands)
- **Operating conditions**: +18 °C to +24 °C ; 30-85 % RH
- **Storage conditions**: +5 °C to +40 °C ; 30-85 % RH

#### PUMP UNITS (Portal Vein & Hepatic Artery):
- **Dimensions/weight**: 426 mm x 140 mm x 460 mm; 13.5 kg
- **Sensors**: PV: flow (1 x), temperature (2 x), pressure (1 x)
  - HA: flow (1 x), temperature (1 x), pressure (1 x)
- **Connections**: mains, USB type B, data 12 pin, IP68
- **Pulsatility**: PV: continuous flow
  - HA: 60 BPM (1 Hz), amplitude ± 20% of mean pressure
- **Flow**: PV: continuous flow 0 - 2.5 L/min (temperature dependent)
  - HA: pulsatile flow 0 - 1.0 L/min
- **Pressure**: PV: max 16 mmHg
  - HA: max 110 mmHg
- **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 (u)
- **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**: Deltastream DP2, rotary pump 2 x
- **Oxygenator**: Heite 2800 with integrated venous bubble trap and heat exchanger 2 x
- **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 LIVER ASSIST is intended to be used for temperature & pressure controlled oxygenated machine perfusion of donor livers for a period up to 6 hours.
### Pathway Organ Donation

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

INTERESTED?
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