

The IGL logo is a dark blue square with rounded corners, featuring the letters 'IGL' in a white, serif font. A thin white lightning bolt graphic is positioned vertically behind the letters. The background of the top of the page is a teal gradient with several water droplets on a reflective surface.

IGL



Waves™

**The transportable kidney perfusion system
which inherits four decades of experience**

WAVES was designed by Waters Medical Systems, LLC to:

- Provide a single kidney transportable device alternative for the perfusion market
- Meet increased preservation demand due to changing donor demographics (Expanded Criteria Donors, Donation After Cardiac Death)
- Improve the clinician's ability to monitor perfusion trends in real time by providing clinical trending data via a network to a remote location and trending graphs to assist with viability assessment
- Continue to improve Delayed Graft Function rates, long term graft survival rates for patients and decrease organ discard rates
- Minimize setup and training time



User interface

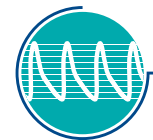
WAVES is equipped with a large multilingual color touchscreen technology to walk the user through setup, to control the perfusion parameters, and to monitor and address alarms.



Complete and active perfusion evaluation

WAVES continuously monitors and displays systolic, mean, and diastolic pressure, flow, temperature, and renal resistance. Data allow the user to compare perfusion trends over a period of time.

- Temperature of the perfusate is measured just before the solution is pumped into the organ.
- Pressure is measured by a pressure monometer in the WAVES cassette.
- Flow is measured by a ultrasonic Flow Probe in the arterial port onto which the kidney's artery is connected.
- Renal Resistance (RR) is calculated using the measured systolic and diastolic pressures and measured flow.



Connected device

WAVES, as a fully connected device, can be:

- connected to the local computer network which allows for off-site or remote monitoring
- plugged to a memory stick for data transfer
- WIRELESSLY monitored on a PC, tablet, or mobile phone



Physiologic pulsatile design

WAVES employs a piston pump-head design which produces a "physiology based systolic and diastolic pressure" to generate flow. The device produces a "true" systolic (or pumping) pressure during pump-head compression and a "true" diastolic (or resting pressure) during the pumphead filling phase. The pump-head (compressing the ventricle of the cassette) expels the perfusate during the systolic phase and refills the ventricle of the pump-head during the diastolic phase.



Transport Performance

WAVES allows the donor paperwork, tissue typing materials, biopsy slides, and organ to be transported together in a safe, secure transport enclosure. Kidney is completely immersed in the solution. Protection is guaranteed even if the machine shuts down. WAVES is validated for 24 hours with extra ice filling.

Oxygenation membrane

WAVES cassette is equipped with an oxygenation membrane. Oxygenation of the perfusate minimizes Ischaemic effects and allows a better buffer effect.

Specifications

Environment of Use

- Organ Procurement Organizations (OPO), hospitals.

User

- Used by OPOs, hospitals, and in other clinical environments.
- Operators should be specially trained in organ preservation.

Product life

- Control unit: 10 years after manufacturing release
- Disposable Cassette: 2 years shelf-life after sterilization

Associated products

- Machine preservation solution for kidneys;
- Clamp and cannula for attaching kidneys;
- Sterile drape and specimen containers;
- Devices for network connectivity such as: wireless routers, USB memory devices for transporting preservation history data;
- Wheeled transport bag.

Portability

- Yes. 24 hours operation on battery.

Environmental limits

- Temperature: 0°C to +40°C ■ Humidity: 0% to 95% non-condensing
- Pressure: 94 kPa to 101 kPa ■ Elevation: sea level to 2000 m

Hypothermic kidney operation

- Temperature controlled +3°C to +10°C
- Operation on ice: 24 hours (+10°C max at +21°C ambient) with an extra ice filling
- Power failure fail-safe hypothermic preservation for 12 hours

Perfusion

- Pulsatile. ■ 60 pulses per minute fixed.
- Pressure regulated or fixed.
- 0 to 250 ml/min perfusion flow.

Air pump

- Ambient air for oxygenation. 1.5 to 2 l/min
- External gas inlet port available (local approved protocol)

Display user interface

- Low power LCD 4.3" colour display. LED backlight
- Integrated touch panel

Cooling

- Ice and water circulated in a closed circuit using thermal transfer to perfusate.
- Ice/water compartment capacity: 5 litres
- Easy ice entry access. Easy drainage using integrated reservoir pump
- Coolant container sealed to prevent leakage.
- Coolant pump: 12 volts DC non-submersible.

Weight

- WAVES System: 26 kg (or 57 lb) fully loaded



Manufactured by
Waters Medical Systems, LLC.
Rochester, Minnesota, United States of America
Cleared by US FDA.
CE marked medical device



 Read attentively the instruction for use

IGL:
a key player
in the world
of organ transplantation.



GROUPE IGL
Institut Georges Lopez

Parc Tertiaire du Bois Dieu
RN6 | 1, allée des Chevreuils
F-69380 Lissieu | France
Tel. +33 (0)4 37 64 63 32
Fax +33 (0)4 37 64 60 09

IGL América Latina

Rua Comendador Tavares, 118
Bairro Navegantes
CEP 9023 020
Porto Alegre-RS | Brasil
Tel. +55 51 30 86 35 75
Fax +55 51 30 86 35 75

Waters Medical Systems

2112 15th St. NW,
Rochester
MN 55901 | USA
Tel. +1 507 288 7777
Fax +1 507 252 3700

www.groupe-igl.com
welcome@groupe-igl.com



Federal and international law restrict the sale of this device to or on the order of a physician or licensed practitioner.
Please contact us for a complete list of references and authorizations.