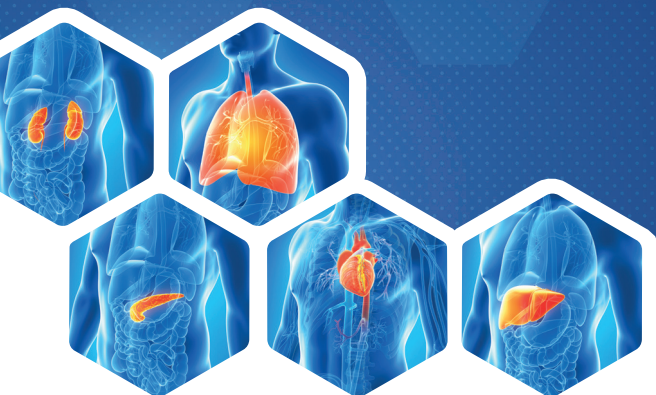


The IGL logo is a dark blue square with rounded corners, featuring the letters 'IGL' in a white, serif font. A thin, light blue vertical line runs down the center of the square, passing through the 'I' and 'L'.

IGL



# PRODUCTS

## CATALOGUE



## IN THE BEGINNING THERE WAS A PATIENT...

*Since then our mission is to support transplant teams in lifesaving transplantation, providing advanced solutions and systems to expand the pool of transplantable organs and improve transplant outcomes.*

**IGL presents its product catalog, a range of solutions for the care of explanted organs and tissues.**

We have gathered all our expertise in these pages, with the desire that they can help you on a daily basis. Whether you use our solutions for flushing, storage or transport, you will find here concisely a lots of practical information (composition, packaging, recommended volumes of use, bibliography, etc.).

Do you need more information? Do not hesitate to find all our contact details at the end of the catalog, whether for technical documentation (IFU/technical sheet) or for an exchange with your regional sales representative.

Our mission is to support the transplant teams, we hope that this document will accompany you in this.

Good reading!



  
D. Allard



The IGL logo is a dark blue square with the letters "IGL" in white, serif font. It is centered within a white shield-like shape that has a blue border and a blue background with a hexagonal pattern.

# STATIC PRESERVATION



Our static preservation systems, comprised of specially formulated solutions and insulated shippers, provide safe and consistent method for cold ischemic storage and transport of donor organs. Our systems are adequate for all type of abdominal and thoracic organs.

IGL

# IGL-1<sup>®</sup>

**COLD STORAGE SOLUTION  
FOR ABDOMINAL ORGANS:  
LIVER, KIDNEY, PANCREAS.**



- Extracellular solutions – low K<sup>+</sup>
- Flushing & Storage
- Ready to use, no filtration
- Manufacturing on a pharmaceutical production site and according to ISO 13485



## ● COMPOSITION

*IGL-1 has the following composition:*

Lactobionic acid	35,8 g/L
Adenosine	1,336 g/L
Allopurinol	0,136 g/L
Glutathione	0,922 g/L
Polyethylene glycol (PEG 35000)	1 g/L
Potassium dihydrogen phosphate	3,402 g/L
Raffinose pentahydrate	17,84 g/L
Magnesium sulfate heptahydrate	1,232 g/L
Sodium Hydroxide qs pH	7,4

## ● ORGAN / SUGGESTED MINIMUM VOLUMES

IN SITU AORTIC FLUSH	
Adults, 2 000 ml-4 000 ml	
Children, 50 ml/kg	
EX VIVO INFUSION	
Liver	Adults, 1200 ml Children, 50 ml/kg
Kidney/ Pancreas	Adults, 300-500 ml Children, 150-250 ml/kg

## ● PACKAGING

*Box of 10 x 1000ml bag.*

*Box of 6 x 2000ml bag.*



Please read carefully the IFU.



0459 - Class III Medical Device.



# Celsior®



**Celsior is intended for flushing and cold storage of thoracic organs (heart and lung) and abdominal organs (kidney, liver, pancreas) during transplantation: from removal from the donor as well as during storage, transportation and until transplantation into the recipient**



- Extracellular solutions
- Ready to use - no filtration
- Impermeants to reduce swelling during cold storage
- Provision of a buffering capacity, which prevents tissue acidosis<sup>1</sup>
- Substrates to help the production of energy in anaerobic conditions<sup>1</sup>

## ● COMPOSITION

*CELSIOR has the following composition (active ingredients):*

Glutathione	<b>0,921 g</b>	<b>3 mmol</b>
Mannitol	<b>10,930 g</b>	<b>60 mmol</b>
Lactobionic acid	<b>28,664 g</b>	<b>80 mmol</b>
Glutamic acid	<b>2,942 g</b>	<b>20 mmol</b>
Sodium hydroxide	<b>4,000 g</b>	<b>100 mmol</b>
Calcium chloride dihydrate	<b>0,037 g</b>	<b>0,25 mmol</b>
Potassium chloride	<b>1,118 g</b>	<b>15 mmol</b>
Magnesium chloride hexahydrate	<b>2,642 g</b>	<b>13 mmol</b>
Histidine	<b>4,650 g</b>	<b>30 mmol</b>

## ● SUGGESTED VOLUMES

ORGAN	SUGGESTED MINIMUM VOLUMES
Heart adult	1-2 litres
Lung	4-6 litres
Heart Infants	30 ml/kg
Liver	6-8 litres
Kidney	4-5 litres
Pancreas	4 litres
Multi-organ	in accordance with the appropriate organs

## ● PACKAGING

**Box of 4 x 1000ml bag.**

## CLINICAL STUDIES

1. Menasche P, Termignon JL, Pradier F, et al. Experimental evaluation of Celsior, a new heart preservation solution. Eur J Cardiothorac Surg 1994;8(4):207-13.



Classification: Europe : Drug / World (Outside EU) : Medical Device

In the USA, the use of CELSIOR® for preservation of organs, other than hearts, has not been approved by the FDA.

Please contact us for a complete list of references and authorizations. Legal mentions are available on [www.groupe-igl.com](http://www.groupe-igl.com). Please read carefully the IFU.



# Bel-Gen<sup>®</sup>

**COLD STORAGE SOLUTION  
FOR KIDNEY, LIVER AND PANCREAS**



- Same composition as originally formulated by F.O. Belzer, MD and James Southard, PhD, at the University of Wisconsin
- Flushing & Storage
- Ready to use, no filtration
- Manufacturing on a pharmaceutical production site and according to ISO 13485

## ● COMPOSITION

*BEL-GEN has the following composition:*

Pentafraction (Hydroxyethyl Starch)	<b>50 g/L</b>
Lactobionic Acid	<b>35,83 g/L</b>
Potassium Dihydrogen Phosphate	<b>3,4 g/L</b>
Magnesium Sulfate heptahydrate	<b>1,23 g/L</b>
Raffinose pentahydrate	<b>17,83 g/L</b>
Adenosine	<b>1,34 g/L</b>
Allopurinol	<b>0,136 g/L</b>
Total Glutathione	<b>0,922 g/L</b>
Potassium Hydroxide	<b>5,61 g/L</b>
Sodium Hydroxide/Hydrochloric Acid qs pH	<b>7,4</b>

## ● SUGGESTED MINIMUM VOLUMES

### IN SITU AORTIC FLUSH

Adults, 2 000 ml-4 000 ml

Children, 50 ml/kg

### EX VIVO INFUSION

Liver	Adults, 1200 ml Children, 50 ml/kg
Kidney / Pancreas	Adults, 300-500 ml Children, 150-250 ml/kg

## ● PACKAGING

*Box of 10 x 1000ml bag.*



Please read carefully the IFU.



0459 - Class III Medical Device.



# IGL-Box<sup>®</sup>

## ORGAN TRANSPORTER



- The insulation method maintaining the organ storage temperature between 2°C and 8°C.
- A system combining disposable and reusable components, reducing significantly the cost of organs transportation and storage
- An Easy-To-Use device minimizing setup and training time



## ● IGLBOX SYSTEM FOR KIDNEY, PANCREAS, HEART COMPRISES:

- 1 IGLBox®-TB Organ Transporter
- 1 IGLBox®-OC Organ Container
- 1 IGLBox®-IB Insulated Box
- 4 IGLBox®-GP GelPacks
- 1 Biopack-1 330 ml

## ● IGLBOX SYSTEM FOR LIVER COMPRISES:

- 1 IGLBox®-TB Organ Transporter
- 1 IGLBox®-IBXL Insulated Box XL
- 2 IGLBox®-GP GelPacks
- 1 Biopack-1 330 ml"

## ● PACKAGING

*IGLBox-TB Organ Transporter : unit.*

*IGLBox-OC Organ Container: Packaged by 4.*

*IGLBox-IB Insulated Box: Packaged by 4.*

*IGLBox-IBXL Insulated Box XL: Packaged by 4.*

*IGLBox-GP GelPacks: Packaged by 8.*

*Biopack-1 330 ml: Packaged by 12.*

## ASSOCIATED PRODUCTS



Please read carefully the IFU.



0459 - Class IIa Medical Device.

The logo consists of the letters "IGL" in a white, serif font, centered within a dark blue square. This square is positioned at the top of a white shield-like shape that has a pointed bottom and is set against a dark blue background with a subtle hexagonal pattern.

# DYNAMIC PRESERVATION



Our perfusion machines provide safe and secured environment where a physiologic solution is pumped through the explanted organ to minimize tissue damage. Perfusion parameters are controlled and recorded, offering clinicians' additional data to evaluate the organ.



# Perf-Gen<sup>TM</sup>

## MACHINE PERFUSION SOLUTION



- Same composition as originally formulated by F.O. Belzer, MD and James Southard, PhD, at the University of Wisconsin
- Ready to use, no filtration
- Manufacturing on a pharmaceutical production site and according to ISO 13485

# PERF-GEN™

## ● COMPOSITION

*PERF-GEN has the following composition:*

Calcium chloride dihydrate	0,068 g/L
Sodium gluconate	17,45g/L
Adenine	0,68 g/L
Potassium phosphate (monobasic)	3,4 g/L
Pentafraction (HES)	50 g/L
Magnesium gluconate	1,13 g/L
HEPES	2,38 g/L
Beta D (+) glucose	1,80 g/L
Glutathione	0,92 g/L
D (-) Ribose	0,75 g/L
Mannitol	5,4 g/L
Sodium hydroxide q.s. pH	7,4

## ● SUGGESTED MINIMUM VOLUMES

The recommended volume of PERF-GEN™ for one kidney is 1000 mL.

## ● PACKAGING

*Box of 10 x 1000ml bag.*

## ASSOCIATED PRODUCT



Please read carefully the IFU.



0459 - Class III Medical Device.

IGL



# Waves<sup>®</sup>

## TRANSPORTABLE HYPOTHERMIC MACHINE PERFUSION FOR DONOR KIDNEY



- **Physiologic**
  - Arterial pressure waveform
  - Active oxygenation of the perfusate (ambient air or oxygen cylinder possible)
- **Convenient**
  - Touchscreen & Guided Interface
  - Remote monitoring of perfusion
  - Bubble Trap integrated to Perfusion Circuit
  - Ice replacement without stopping the perfusion
- **Safe transport**
  - Unaccompanied transport
  - Insulated protection
  - Active temperature regulation

## ● PERFORMANCE

- Automatic pressure regulation to maintain user-set pressure
- Maintain organ temperature at 2°C to 8°C

## ● PUMP

- Pulsatile pump with systolic pressure range user settable from 10 to 70 mmHg
- Fixed pulse repetition rate, 60 beats per minute (BPM)

## ● BATTERIES

- 4 lithium ion batteries. Drop-in, hot swappable
- Rapid recharge (5 hr) via mains
- Battery life 24 hr

## ● INTERFACE

- Organ Information (Organ ID, Kidney side, Clamp time)
- Device Information (Time, Date, Device ID, Battery status, Language selection, Network status)
- Display
  - Systolic, Mean, and Diastolic Pressure
  - Flow rate
  - Renal Resistance
  - Perfusate temperature
  - Ice temperature

## ● SIZE AND WEIGHT

- 64.8 cm (25 ½") x 41.3 cm (16 ¼") x 33.7 cm (13 ¼")
- WAVES® system: 26 kg (57 lb) fully loaded

## ● ACCESSORIES

- Organ Connectors (Cannula, Clamp, Trident Artery Cannula)
- Sterile drape (for control unit covering)
- Specimen containers
- Wheeled transport bag

## ASSOCIATED PRODUCT



Please read carefully the IFU.



0459 - Class IIa Medical Device.



# RM4

## HYPOTHERMIC MACHINE PERFUSION OF EITHER ONE OR TWO DONOR KIDNEYS

RM4 Kidney Perfusion System is in the process of securing US and European regulatory registrations, and is not yet approved for clinical use.



- **Physiologic**
  - Arterial pressure waveform
  - Active oxygenation of the perfusate (ambient air or oxygen cylinder possible)
- **Economic**
  - The dual perfusion is an obvious cost saving and convenient procedure for centers with high volume of transplant
- **Convenient**
  - RM4 is equipped with a large touchscreen interface to walk the user, minimizing significantly setup and training time.
  - Ice replacement without stopping the perfusion



# RM4

## ● PERFORMANCE

- Automatic pressure regulation to maintain user-set pressure
- Maintain organ temperature at 2°C to 8°C

## ● PUMP

- Pulsatile pump with systolic pressure range user settable from 10 to 70 mmHg
- Fixed pulse repetition rate, 60 beats per minute (BPM)

## ● BATTERIES

- 4 lithium ion batteries. Drop-in, hot swappable
- Rapid recharge (7 hr) via mains
- Battery life 14 hr

## ● INTERFACE

- Organ Information (Organ ID, Kidney side, Clamp time)
- Device Information (Time, Date, Device ID, Battery status, Language selection, Network status)
- Display
  - Systolic and Diastolic Pressure
  - Flow rate for each kidney
  - Renal Resistance for each kidney
  - Perfusate temperature
  - Ice temperature

## ● SIZE AND WEIGHT

- 50 cm (19,7") x 37 cm (14,5") x 20 cm (7,8")
- RM4 system: 20 kg (44 lb) system fully loaded

## ● ACCESSORIES

- Organ Connectors  
(Cannula, Clamp, Trident Artery Cannula)

## ASSOCIATED PRODUCT



Lire attentivement la notice.

# CONTACT



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International Business Developer

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## **ADMINISTRATIVE INFORMATION**

***Price inquiry: commercial.services@groupe-igl.com***

***Orders: orders@groupe-igl.com***

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## **QUALITY COMPLAINTS**

***complaints@igl-transplantation.com***

## **SAFETY INCIDENTS AND ADVERSE EVENTS**

***safety@groupe-igl.com***

Find all the product documentation (IFU, technical sheet or brochure), as well as various Quality / ISO certificates, in PDF to download directly, on our website **[www.groupe-igl.com](http://www.groupe-igl.com)**



Waters  
Medical  
Systems

IGL  
France

IGL  
América  
Latina

## **GROUPE IGL**

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our headquarters in France.