3.4. Contraindications
There are no known contraindications when used as directed.

3.5. Special warnings and precautions for use
NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

3.6. Adverse reactions
Vascular complications (thrombosis, fibrin, primary non-functions, graft rejections, akinesia, necrosis) have been reported with clinical use of IGL-1®. However, these post-transplantation reactions could not be attributed solely to IGL-1®.

3.7. Cautions
Federal and international laws restrict the sale of this device to or on the order of a physician or licensed practitioner.

4. ACTIONS
IGL-1® Solution, cooled at +2°C and +4°C is used for flushing the isolated organ immediately before removal from the donor and/or immediately after removal from the donor. The solution is then left in the organ vascular system during hypothermic storage and transportation. IGL-1® is not intended to be used for cold storage of the organ and is not acceptable for continuous machine perfusion. Administration of IGL-1® at the recommended temperature, with effectiveness, the organ and lower its metabolic requirements.

5. SPECIAL PRECAUTIONS FOR STORAGE
Do not freeze the solution, and do not use if frozen.

Store away from direct sunlight
Store solution between +2°C and +4°C

6. MARKETING AUTHORISATION HOLDER
Manufactured by:
IGL Spain
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Fax +34 935 677 078
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welcome
@groupe-igl.com

Please contact us for a complete list of references and authorizations Available in 1-liter and 2-liter bags

IGL-1® includes components (allopurinol) which individually have caused hypersensitivity reaction in patients. Physicians should be alert to treat possible reactions.

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Please contact us for a complete list of references and authorizations Available in 1-liter and 2-liter bags
3.1. Intended use

IGL-1® is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor and preparation for storage, transplantation and eventual transplantation into a recipient.

3.2. Preparation

Cool the solution to +2°C to +6°C. Remove overwrap prior to use. Do not refrigerate. If a leak is found, discard solution bag. With the overwrap removed, perform a visual inspection of the solution for particulate matter. Do not use the solution if obvious particulate matter, precipitants, or contamination are evident in the solution.

Use an administration set to filter the organ with IGL-1® solution. Prior to connection to the organ, the solution container should be suspended from a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 ml/min during flushing. Flushing should be continued until the organ is uniformly pale and the effluent is clear.

Suggested minimum volumes:

Ex-vivo infusion:
- Liver (bila portal vein and bila trends)
  Adults, 1200 ml
  Infants, 150 ml/kg

- Pancreas or Kidney
  Adults, 350–500 ml
  Infants, 150–350 ml

3.3. Packaging and storage

1200 ml of IGL-1® Solution in one-litre bags shelf-life of 10, or 2800 ml IGL-1® Solution in two-litre bags shelf-life of 6. Store IGL-1® at a temperature between +2°C and +8°C away from direct sunlight. Do not freeze the solution, and do not use if frozen.

Additional solution should be dispensed into the container holding the organ. Seal the container aseptically. The organ storage container should be maintained within a well-insulated transport container, at a temperature between +2°C and +8°C. Do not store in direct sunlight. Do not open the transport container, but should be insulated in the container, where the ice could come into direct contact with the organ. Donor organs must be flushed with IGL-1® prior to transplantation according to transplantantation centers protocols. These operations must be done by qualified operators.
PUBLICATIONS

ORGAN FUNCTION

2. PHARMACEUTICAL FORM

IGL-1® is a clear to light yellow, dry, non-pyrogenic solution intended for hypothermic flushing and storage of organs (kidney, liver, pancreas). IGL-1® has an osmolality of 290 mOsm/kg.

3. CLINICAL PARTICULARS

3.1. Intended use

IGL-1® is intended for the flushing and the hypothermic storage of kidney, liver and pancreas organs at the time of organ removal from the donor and for preparation for storage, transplantation and eventual transplantation into a recipient.

3.2. Preparation

Cool the solution to 2°C to 6°C, Remove wrapping prior to use. Check each bag for leaks by squeezing the container firmly. If it leaks, discard the solution bag. With the overwrap removed, perform a visual inspection of the solution for particulate matter. Do not use the solution if obvious particulate matter, precipitates, or contamination are evident in the solution. Use an administration set to flush the organ with IGL-1® solution.

Prior to connection to the organ, the solution container should be suspended from a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 ml/min. Flushing should be continued until the organ is uniformly pale and effluent is clear.

Suggested minimum volumes: Ex situ aortic flush: Adults, 2000-4000 ml/kg; Infants, 50 ml/kg

Ex vivo infusion:
- Liver (via portal vein and biliary tree): Adults, 1200 ml; Infants, 150-300 ml/kg
- Pancreas or kidney: Adults, 1200 ml; Infants, 150-300 ml/kg

3.3. Packaging and storage

1200 ml of IGL-1® Solution in one litre bags shelf life of 13 or 2800 ml IGL-1® Solution in two litre bags shelf life of 8. Store IGL-1® at a temperature between 0°C and 24°C away from direct sunlight. Do not freeze the solution and do not use if frozen.

Additional solution should be dispensed into the container holding the organ. Seal the container aseptically. The organ should be maintained within a well-insulated transport container. Ice should be used to surround the organ storage container, but it should not be used within the container, where the ice could come into direct contact with the organ. Donor organs must be flushed with IGL-1® prior to transplantation according to transplantcenter protocols. These operations should be done by qualified operators.
3.6. Contraindications

There are no known contraindications when used as directed.

3.7. Special warnings and precautions for use

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

3.8. Adverse reactions

Vascular complications (thrombosis, fibrinolytic, primary non-functions, graft rejections, bile duct complications after transplantation) have been reported while testing clinically. IGL-1®. However, these post-transplantation reactions could not be attributed solely to IGL-1®.

3.7. Cautions

Federal and international laws restrict the sale of this device to or on the order of a physician or licensed practitioner.

4. ACTIONS

IGL-1®, Solution, cooled at +2°C and +4°C is used for flushing the isolated organ immediately before removal from the donor and/or immediately after removal from the donor. The solution is then left in the organ vascular districts during hypothermic storage and transportation. IGL-1® is not intended to be used for cold storage of the organ and is not acceptable for continuous machine perfusion. Administration of IGL-1®, at the recommended temperature, will effectively cool the organ and lower its metabolic requirements.

5. SPECIAL PRECAUTIONS FOR STORAGE

Do not freeze the solution, and do not use it if frozen.

Store away from direct sunlight

Store solution between +2°C and +6°C

6. MARKETING AUTHORISATION HOLDER

IGL Spain

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Class III Medical Device

Br.IGL-1.EN.Rev03 2016/06/29

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3.6. Contraindications
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3.7. Special warnings and precautions for use

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3.8. Adverse reactions

Vascular complications (thrombosis, fistulas, primary non-functions, graft rejection, allopurinol, cytokine reactions after transplantation) have been reported while treating clinically IGL-1®. However, these post-transplantation reactions could not be attributed solely to IGL-1®.

3.9. Cautions

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4. ACTIONS

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5. SPECIAL PRECAUTIONS FOR STORAGE

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READ ATTENTIVELY THE INSTRUCTIONS FOR USE