Instructions for use

Please read these instructions carefully prior to use
For the attention of the surgeon
and operating theatre personnel

HEMO$_2$life® 1 g

Additive to hypothermic graft preservation solutions
Sterile medical device of animal origin

HEMARINA SA
Aéropôle centre
29600 MORLAIX – France
Tel: +33(0)2 98 88 14 02
Fax: +33(0)2 98 88 38 94
https://www.hemarina.com/

(01)03770010306016

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1.DESCRIPTION

HEMO$_2$life® is a non-pyrogenic, sterile red liquid solution for *ex-vivo* use as an additive to solutions for hypothermic preservation during kidney transplantation.
HEMO$_2$life® is composed of haemoglobin of animal origin (extracted from the marine invertebrate *Arenicola marina*), which gives it its blood-red colour.
HEMO$_2$life® is packaged in individual, non-pyrogenic, sterile glass vials sealed with a stopper and a Flip-Off cap. Each vial contains 20 ml of solution, containing 1g of M101 extracellular haemoglobin.

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

The composition of HEMO$_2$life® is as follows:

Haemoglobin M101 from *Arenicola marina*	1g
Magnesium chloride	6mg
Sodium chloride	105.2mg
Sodium gluconate	100.3mg
Sodium acetate	73.5mg
Potassium chloride	7.5mg
Calcium Chloride	7.3mg
Ascorbic acid	≤ 35.2mg
Water for injection	qsp 20 mL
pH	6.9-7.5 at 2°C-8°C

3.INDICATIONS

HEMO$_2$life® is intended to be used *ex-vivo* as an additive to preservation solutions for kidney preservation during hypothermic transportation under static or perfused conditions.
HEMO$_2$life® must be used diluted in a preservation solution at a concentration of 1 vial per litre of solution, for rinsing the graft after its collection, hypothermic storage and transport until its transplantation.

4.CONTRAINDICATIONS

There are no known contraindications other than those linked to transplantation procedures.

5.RESIDUAL RISKS

Biological Evaluation and clinical investigations have no demonstrated undesirable effects however HEMO$_2$life® is not intended for systemic administration by direct injection or intravenous infusion (the graft must be rinsed before transplantation).
To prevent degradation of the product, HEMO$_2$life® must be stored and handled in accordance with the specifications described in these instructions for use. In case of temperature excursions, please contact HEMARINA® at the following address: vigilance@hemarina.com.

6.UNDESIRABLE EFFECTS

No undesirable effect due to the product have been described during clinical investigations.

7. EXPECTED BENEFITS

The haemoglobin contained in HEMO$_2$life® solution allows continuous physiological oxygenation of the graft throughout its storage and until transplantation, thereby improving graft quality by limiting ischemia/reperfusion injuries.

8.PERFORMANCE CHARACTERISTICS

HEMO$_2$life® improves organ preservation quality by delivering sufficient oxygen to prevent and/or reduce damage linked to ischaemia/reperfusion (I/R); it thus reduces delayed graft function and improves the renal function of transplanted grafts.

9.COMPATIBILITY

HEMO$_2$life® is compatible with solutions used during hypothermic transportation under static or perfused conditions.

10.STORAGE

HEMO$_2$life® must be stored in undamaged packaging (individual box) at a temperature between -80°C ± 10°C and -20°C ± 5°C.

11.PRECAUTIONS FOR USE

HEMO$_2$life® must be prepared and used by operating theatre personnel under medical control.
HEMO$_2$life® is intended to be used for kidney preservation, it is not intended for systemic administration by direct injection or intravenous infusion (the graft should be rinsed before transplantation).
Do not use for a normo- or subnormothermic graft preservation.
Do not heat.
Do not refreeze once thawed.
Do not reuse, any open vial must be discarded.
Do not use after expiry date.
Discard if any sign of damage to the vial is detected.

Careful visual inspection of the preservation solution must be performed before injecting HEMO$_2$life® and, if there is any precipitate or contamination, the solution must be discarded.

12.STERILIZATION

HEMO$_2$life® is sterilized by filtration. Resterilization is not permitted.
It is important to check the expiry date shown on the vial and the individual packaging box.

13.REUSE / DISPOSAL

HEMO$_2$life® IS A SINGLE-USE MEDICAL DEVICE.
Any product not used during the procedure cannot be kept for later use and must be discarded.
In case of re-use, HEMO$_2$life® could be inefficient and could provoke undesirable effects on graft and/or on patient.
Any expired product should be discarded directly by the hospital establishment in accordance with the protocols in effect or can be returned to HEMARINA®.
After use, the vial should be discarded in accordance with the hospital's procedures for disposal of biological products.

14.PREPARATION AND UTILIZATION

Thawing

Use 1 vial per litre of preservation solution for kidney transplant (concentration 1g/L of haemoglobin).
Carefully remove the vial from its individual packing box to thaw it (1.5 hours at room temperature of 20°C ± 5°C). If not used immediately after thawing, the **unopened** vial must be stored at a temperature of 5°C ± 3°C and used within 16 hours. HEMO$_2$life® can be used as soon as it is thawed.

The thawed HEMO$_2$life® solution must be extracted from its original vial and transferred in the preservation solution bag immediately prior to use and in **aseptic conditions,** using a sterile syringe and needle chosen by the operating theatre personnel.

Before extracting it from the vial, check that the HEMO$_2$life® is completely thawed (visual inspection). If not, do not perform the extraction and wait until complete thawing at room temperature. **Do not heat**.

Step 1 - Preparation

- Place the items on a clean, flat surface.
- Remove the Flip-Off cap from the vial and disinfect the stopper.

Step 2 - Extracting the HEMO$_2$life® solution

- Use a sterile syringe with a capacity of 20 ml or greater and a sterile single-use needle.
- Insert the needle into the bromobutyl septum and carefully extract the HEMO$_2$life® solution in one go.
- Extract the volume of solution desired to obtain a concentration of 1 g/L. If an entire vial is not used, the rest must be discarded.

Step 3 - Reconstitution and mixing

- Introduce the needle of the syringe containing the HEMO$_2$life® into the septum of the bag of solution for preservation and slowly inject the HEMO$_2$life® at a ratio of **1 g per litre** of solution.
- Carefully mix the supplemented bag.
- Check that the mixture is homogeneous (the final solution for preservation is now red).

A careful visual inspection of the mixture must be performed and, if there is any precipitate or contamination, the solution must be discarded.

Step 4 - Use

Use the mixture according to the protocol for use and preservation solution manufacturer's recommendations for either static or machine-perfused **hypothermic preservation**.

Step 5 - Rinsing
At the end of the preservation period and prior to transplantation**, the graft must be rinsed with a HEMO$_2$life® free solution.** The graft is considered rinsed when the liquid draining from it is colorless.

15.INFORMING THE PATIENT
The patient should be informed of the animal origin of the HEMO$_2$life® medical device.

16.VIGILANCE
This product is subject to the vigilance rules in effect. Any incident or undesirable effect that is or may be connected to the use of this product must be reported to HEMARINA® and to the competent authority in the State where the user or the patient is based.

17.MEANING OF SYMBOLS USED FOR LABELING

SYMBOL	MEANING
	DO NOT REUSE
	CAUTION
	DO NOT RE-STERILIZE
	EXPIRY DATE
	BATCH NUMBER
	STERILIZED USING ASEPTIC PROCESSING TECHNIQUES
	CATALOGUE REFERENCE
	DO NOT USE IF PACKAGING IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER
	DATE OF MANUFACTURE
	FRAGILE
	TEMPERATURE LIMIT
	MEDICAL DEVICE
	NON-PYROGENIC
	CONTAINS BIOLOGICAL MATERIAL OF ANIMAL ORIGIN
	SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
	UNIQUE DEVICE IDENTIFIER