



HEMO₂life[®]

User Manual

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

MOL-INST-008.v1



Maximum storage time after defrosting: 16 hours at 5°C +/-3°C

DO NOT REFREEZE - DO NOT HEAT - DO NOT REUSE

Before preparation...

Thawing

Use 1 vial per litre preservation solution for kidney transplant (concentration 1 g/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 5°C ± 3°C and used within 16 hours. HEMO₂life[®] can be used as soon as it is thawed.



HEMO₂life[®] is composed of haemoglobin of animal origin (extracted from the marine invertebrate *Arenicola marina*), which gives it its **blood-red colour**.

The thawed HEMO₂life[®] 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 HEMO₂life[®] is completely thawed (visual inspection). If not, do not perform the extraction and wait until complete thawing at room temperature.

Do not heat.



HEMO₂life®

Instructions for use

 Refer to the instructions for use

A 5-step approach

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 HEMO₂life® 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 stopper and carefully extract the HEMO₂life® 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

Preparation time: 1 to 2 min

- Introduce the needle of the syringe containing the HEMO₂life® into the septum of the preservation solution bag and slowly inject the HEMO₂life® at a ratio of **1 g per litre** of solution - **figure 1**.
- Carefully mix the supplemented bag - **figure 2**.
- Check that the mixture is homogeneous (the final solution for preservation is now red) - **figure 3**.

The solution is ready to use.



Figure 1



In case of a bag capacity exceeding 1 L, please respect the concentration of 1 g/L.

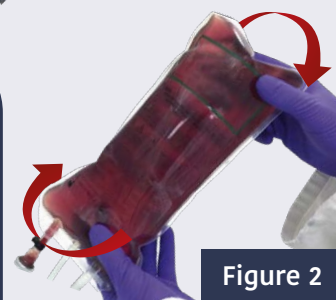


Figure 2

Step 4

Use

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



Figure 3

Step 5

Rinsing

At the end of the preservation period and prior to transplantation, **the graft must be rinsed with a HEMO₂life® free solution**. The graft is considered rinsed when the liquid draining from it is **colorless**.