

PRESERVATION SOLUTION

✓ **LungProtect®**

**Container with perfusion and preservation solution
for organs intended for transplantation**

INSTRUCTIONS FOR USE

EN

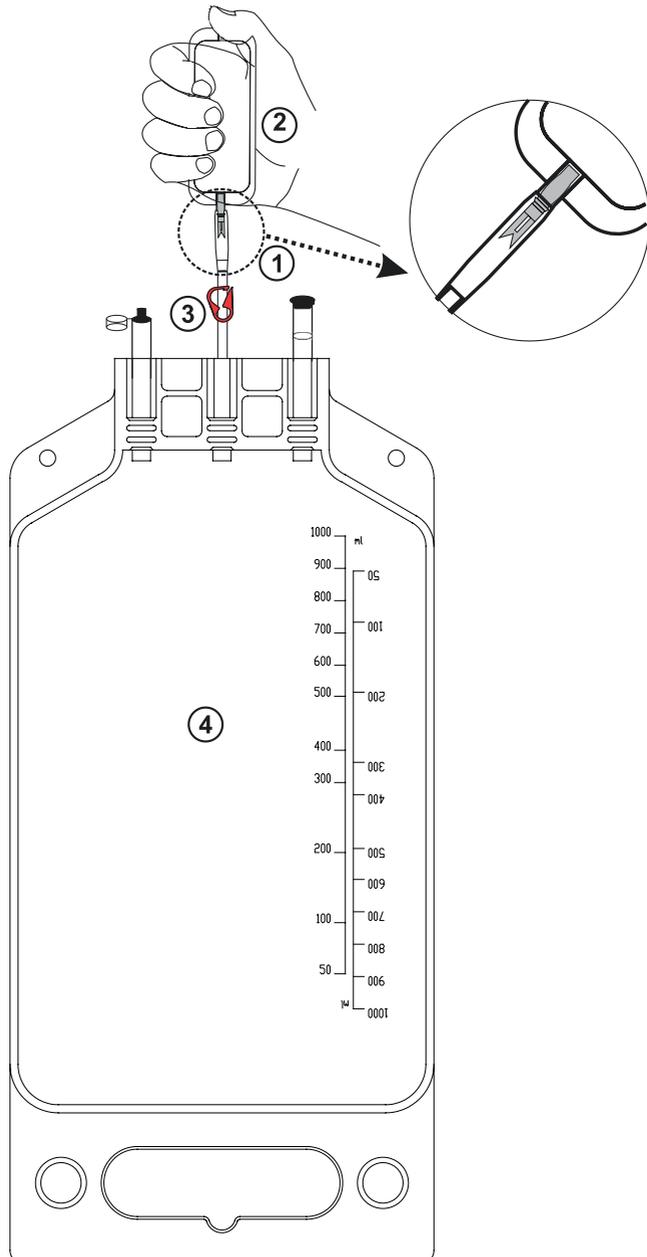
 **carnamedica**

ifU/LPRT/en/2020/01/07

Carnamedica Sp. z o.o.
ul. Olszynki Grochowskiej 21 lok. U6
04-281 Warsaw, Poland

 **2274**

- ① Break the valve.
- ② Squeeze the THAM bag.
- ③ Close the red clamp.
- ④ Mix the solutions gently.



Container contents:

Solution for perfusion and cold storage of organs for transplantation LungProtect®

DESCRIPTION

Composition 1.000 ml solution contains:

Dextran 40	50.0 g	50 g
Monopotassium Phosphate	0.063 g	0.5 mmol/l
Glucose monohydrate	1.0 g	5 mmol/l
Magnesium sulfate anhydrate	0.098 g	0.8 mmol/l
Disodium phosphate anhydrate	0.046 g	0.32 mmol/l
Sodium dichloride	8.0 g	137 mmol/l
Potassium chloride	0.4 g	5.5 mmol/l
Water for injection		to 1.000 ml

Pirkimo dalis Nr. 11 - Tirpalas donorinių plaučių hipotermiam laikymui (1000ml: 50g Dextran 40, 8g Natrii chloridum, 1g Glucosae monohydratum, 0,4g Kalii chloridum etc.), sterilus, ne didesnėje nei 3000ml pakuotėje.

THAM buffer:

THAM	0,121 g (1 mmol)	
Water for injection		to 25 ml

Solution LungProtect® has a calculated osmolality of about 295 mOsm/kg. pH: 5.4 (pH 7.4 after addition of THAM).

TYPE OF DEVICE

Sterile pyrogen-free solution for organ preservation. The solution is clear, colorless or slightly yellow.

INTENDED USE

The solution is used for organ perfusion and hypothermic preservation of lungs. The device can only be used by medical staff adequately trained in its use, in accordance with established operating protocols.

MECHANISM OF ACTION

The solution cooled to 4° to 8°C is used to perfuse the isolated organ immediately before its removal from the donor and/or immediately after its removal. The solution is then left in the organ vasculature during hypothermic storage and transportation. LungProtect® is not intended to be used with continuous machine perfusion. Administration of LungProtect® at recommended temperatures will effectively cool the organ and will reduce its metabolic requirements. Dextran in the solution prevents edema, the formation of thrombi and additionally protects microvessels from damage during reperfusion.

PREPARATION:

Cool the solution to 4°C to 8°C. Check the bag for leaks by squeezing the container firmly. If a leak is found, discard the solution bag. With the overwrap removed, perform a visual inspection of the solution for visible particulate matter. Do not use the solution if particulate matter, precipitates, or contamination are evident in the solution.

Adjust the pH of the solution to 7.4 before use. To do so, squeeze the **entire** contents of the bag connected to the container (or of two bags in the case of the 2-litre LungProtect® container) with the 1 mmol THAM buffer (Technical drawing 1). In order to open the circuit, break the bag's valve labelled number **2** and by squeezing the bag, pump its contents into the LungProtect® liquid container. Next, in order to prevent reverse flow, close the tube with the red clamp labeled number **1**.

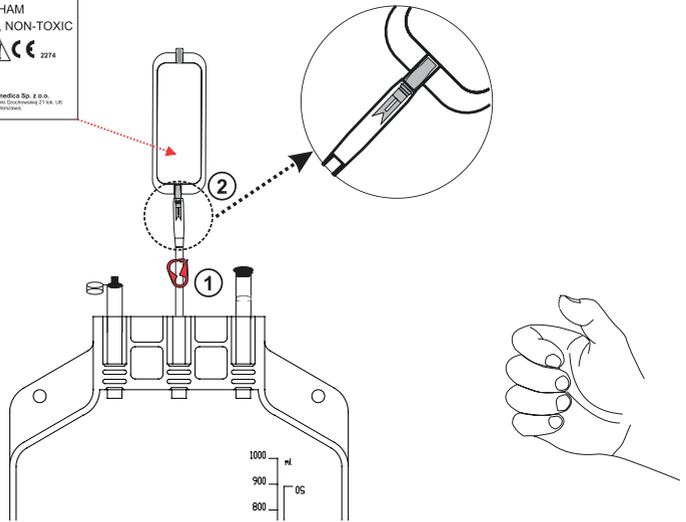
THAM Solution
 for adjusting pH of LungProtect
 contains 1 mMol of THAM
 STERILE, NON-PYROGENIC, NON-TOXIC

STERILE 2274

LOT

Carmedica Sp. z o.o.
 ul. Tychy 10, 41-200 Wrocław, Poland

50 x 32 mm

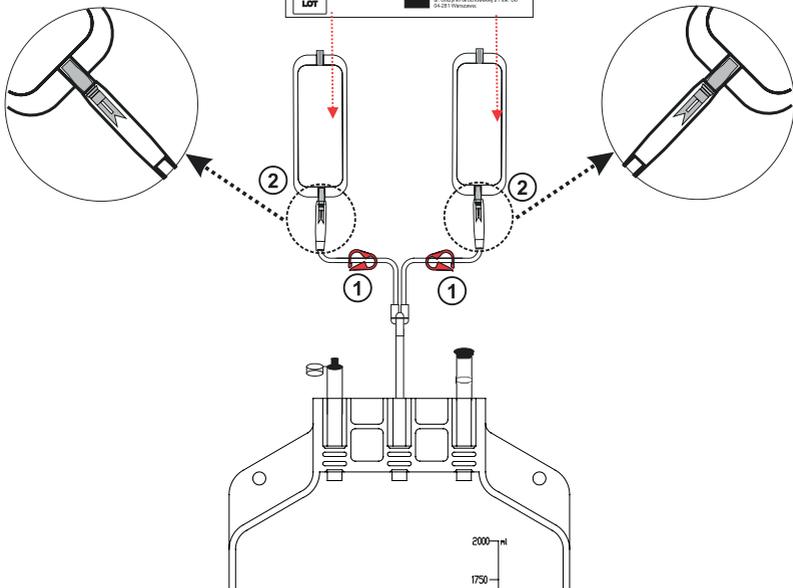


THAM Solution
 for adjusting pH of LungProtect
 contains 1 mMol of THAM
 STERILE, NON-PYROGENIC, NON-TOXIC

STERILE 2274

LOT

Carmedica Sp. z o.o.
 ul. Tychy 10, 41-200 Wrocław, Poland



After thorough mixing of the buffer with the liquid in the container, the solution should be cooled down and used within 24 hours. No need to filter the solution before use. The solution is not intended to be used in continuous machine perfusion. The device is sterile and disposable. The solution is intended for one single uninterrupted administration and any residue must be discarded to avoid risk of contamination due to loss of sterility.

INSTRUCTIONS FOR USE

The amount of solution for the perfusion procedure depends on the size of organ to be preserved. For the perfusion in lung transplantation 50-75 ml of LungProtect® per kg of body weight of the donor are used. For an adult donor approximately 3-8 liters of solution are needed.

In order to ensure a steady flow of solution, the bag is usually placed at 30 cm above the perfused organ and the flushing should continue until the organ becomes uniformly pale and the effluent is clear. The perfusion method should be chosen by the transplantation team.

During storage and transport, it is recommended to follow a commonly accepted multi-organ protection protocol. Prior to transplantation the donor organ must be flushed to remove Lung Protect according to transplantation centers' protocols.

CONTRAINDICATIONS

There are no known contraindications when used as directed.

WARNING

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION. THE PRODUCT CAN BE USED ONLY BY THE QUALIFIED MEDICAL STAFF.

PRECAUTIONS

Prior to the reperfusion the donor organ must be flushed with physiological solution to remove the LungProtect® to prevent occurrence (in the recipient) of potentially serious cardiovascular complications such as hyperkalemic cardiac arrest or bradyarrhythmia.

PACKAGING AND STORAGE

Primary container with 10 one-liter (1000 ml) or 5 two-liter (2000 ml) EVA bags of LungProtect® solution. Store at a temperature between +2°C and +25°C away from direct sunlight. Avoid excessive heat. Do not freeze the solution, and do not use if frozen or after expiry date.

ATTENTION

This medical device is to be used only by the qualified medical staff.

	Date of production		Caution! See instruction for use.		The product meets the requirements of the European Medical Devices Directive MDD. The manufacturer is certified by the Notifying Authority No. 2274
	Expiration date		Do not use if damaged.		The product includes instruction for use.
	Series number		Sterile (Aseptic filling)		Restriction of acceptable storage temperatures
	Catalog number		Single use		Non-pyrogenic
	Keep away from sunlight.		Medical Device		Carnamedica Sp. z o.o. ul. Olszynki Grochowskiej 21 lok. U6 04-281 Warsaw, Poland



Carnamedica Sp. z o.o.

ul. Olszynki Grochowskiej 21 lok. U6

04-281 Warsaw, Poland

Phone: +48 608336159

Fax: +48 22 3078113

Email: office@carnamedica.com