

## **PRESERVATION SOLUTION**

# **X°Port Lung Preservation Solution**

**Container filled with solution for perfusion  
or preservation of organs intended  
for transplantation**

### **INSTRUCTIONS FOR USE**

**EN**

**TRAFER**  **X**

**Traferox Technologies Inc.**  
3505 Laird Rd. Unit 16  
Mississauga ON L5L 5Y7, Canada

Manufactured by

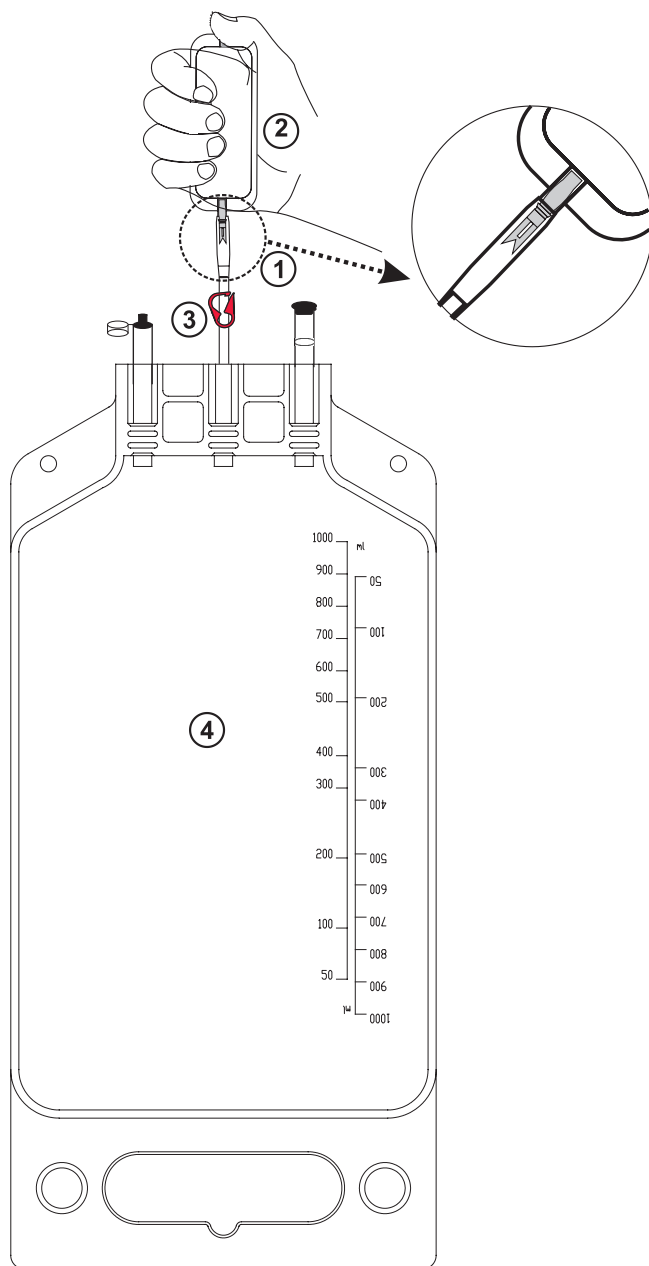
 **carnamedica**

Caution: Federal law restricts this device to sale by or on the order of a physician.

IFU/910-0003/US/2025/04/30

**Carnamedica Sp. z o.o.**  
Olszynki Grochowskiej 21 str. apt. U6  
04-281 Warsaw, Poland

- 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 X°Port Lung Preservation Solution

## COMPOSITIONAL DESCRIPTION

Composition 1000 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 chloride	8.0 g	137 mmol/l
Potassium chloride	0.4 g	5.5 mmol/l
Water for injection		to 1000 ml
THAM buffer:		
THAM	0,121 g (1 mmol)	
Water for injection		to 25 ml

X°Port Lung Preservation Solution has a calculated osmolality of about 295 mOsm/kg. pH: 5.4 (pH 7.4 after addition of THAM). The X°Port Lung Preservation Solution must be supplemented with additional 0.5 mmol/l Calcium Chloride prior to use.

## DEVICE DESCRIPTION

X°Port Lung Preservation Solution is a clear to slightly yellow, sterile, non-pyrogenic, colloid based "extracellular" low potassium dextran solution used primarily for flushing, static cold storage, and preservation of lungs intended for transplantation.

## INTENDED USE

Organ storage and preservation for transplantation.

## INDICATION FOR USE

The solution is indicated for the flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient. 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°C 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 at 4°C to 10°C. X°Port Lung Preservation Solution is not intended to be used with continuous machine perfusion. Administration of X°Port Lung Preservation Solution 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 micro vessels 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. The product should be transparent to slightly yellow (no more yellow than Y6 according to the coloration scale in the current edition of Eur. Ph.) with no signs of turbidity. If the product is slightly yellow along with signs of turbidity, it should not be used.

**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 X°Port Lung Preservation Solution container) with the 1 mmol THAM buffer. In order to open the circuit, break the bag's valve labelled number ② and by squeezing the bag, pump its contents into the X°Port Lung Preservation Solution liquid container. Next, in order to prevent reverse flow, close the tube with the red clamp labeled number ①.



Into the bag injection port, inject an additional 0.5 mmol/l Calcium Chloride solution. After thoroughly mixing the buffer and calcium with the liquid in the container, the solution should be 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 flushing and cold static preservation and transport depends on the size of organ to be preserved. For the perfusion in lung transplantation 50-75 ml of X°Port Lung Preservation Solution 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.

## 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.

Do not use if contamination is evident in the solution. Use only clear solutions in undamaged containers.

X°Port Lung Preservation Solution is intended for single use only and **MUST NOT BE REUSED**. Reuse of X°Port Lung Preservation Solution is not allowed due to the risk for infection.

Do not use X°Port Lung Preservation Solution if the 'use by' date has expired.

X°Port Lung Preservation Solution is not intended for intravenous administration in the human body.

Do not use the injection port for administration.

## PRECAUTIONS

The use of X°Port Lung Preservation Solution cannot improve an already damaged lung. Recovery of healthy lungs under proper conditions is essential.

Treatment of children: There is no data on the use of X°Port Lung Preservation Solution on children.

Pregnancy: There is no data on the use of X°Port Lung Preservation Solution during pregnancy.

Lactation: It is not known to what extent X°Port Lung Preservation Solution passes into breast milk.

## ADVERSE REACTIONS


















When administered systemically, dextran has been associated with rare allergic reactions.

## PACKAGING AND STORAGE

Secondary package contains of 10 one-liter (1000 ml) or 5 two-liter (2000 ml) EVA bags of X°Port Lung Preservation Solution. Store X°Port Lung Preservation Solution at a temperature controlled between +2°C and +25°C away from direct sunlight. 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!		Medical device
	Use-by date		Consult instruction for use.		Do not use if package is damaged and consult instructions for use.
	Batch code		Temperature limits		Sterilized using aseptic processing techniques. Single sterile barrier system with protective packaging outside.
	Catalogue number		Non-pyrogenic		Sterilized using steam or dry heat. Single sterile barrier system with protective packaging outside.
	Keep away from sunlight.		Do not re-use		Prescription only
	<b>Traferox Technologies Inc.</b> 3505 Laird Rd. Unit 16 Mississauga ON L5L 5Y7, Canada		<b>Manufacturer</b>	Manufactured by Carnamedica for Traferox <b>Carnamedica Sp. z o.o.</b> Olszynki Grochowskiej 21 str. apt. U6 04-281 Warsaw, Poland	

**TRAFER**  **X**

**Traferox Technologies Inc.**

3505 Laird Rd. Unit 16  
Mississauga ON L5L 5Y7, Canada  
sales@traferox.com

Manufactured by

 **carnamedica**

**Carnamedica Sp. z o.o.**

Olszynki Grochowskiej 21 str. apt. U6  
04-281 Warsaw, Poland  
Email: office@carnamedica.com