

en: Instructions for Use

PERFADEX® Plus

Buffered, calcium containing solution for lung perfusion.

Description

PERFADEX® Plus is an extracellular electrolyte solution containing dextran 40. The solution is prebuffered with 2mM THAM and supplemented with 0.5 mM CaCl₂. PERFADEX® Plus is used for rapid cooling, perfusion and cold static storage of lungs in connection with transplantation.

Administration of the solution at the recommended temperatures will effectively cool the lung to reduce its metabolic requirements.

Composition and ionic concentrations are shown in Table 1.

Intended Use

PERFADEX® Plus 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.

Contraindications

None known.

Warnings

Do not use if contamination is evident in the solution. Use only clear solutions in undamaged containers. PERFADEX® Plus is intended for single use only and **MUST NOT BE REUSED**. Reuse of PERFADEX® Plus is not allowed due to the risk for infection. Do not use PERFADEX® Plus if the 'use by' data has expired.

PERFADEX® Plus is not intended for intravenous administration in the human body.

Ensure that the PERFADEX® Plus bag is not in direct contact with ice.

Do not use the injection port for administration.

PERFADEX® Plus is pre-buffered and pre-supplemented with calcium-ions. Additional buffer, such as THAM and calcium-ions, **MUST NOT** be added.

Do not use a pressure cuff or add external pressure on the PERFADEX® Plus bag since an elevated pressure might introduce damage to the vasculature or cause the bag to rupture.

Precautions

No additives are necessary as PERFADEX® Plus is pre-buffered and pre-supplemented with calcium ions. The solution should be kept chilled and used within 24 hours after the container is opened. If any other additives are used, chill solution as directed prior to adding any additives and mix thoroughly immediately prior to use.

The use of PERFADEX® Plus cannot improve an already damaged lung. Recovery of healthy lungs under proper conditions is essential.

The safety and efficacy of PERFADEX® Plus for marginal lungs has not been evaluated in a clinical study by FDA.

Treatment of children: There are no data on the use of PERFADEX® Plus on children.

Pregnancy: There are no data on the use of PERFADEX® Plus during pregnancy.

Lactation: It is not known to what extent PERFADEX® Plus passes into breast milk.

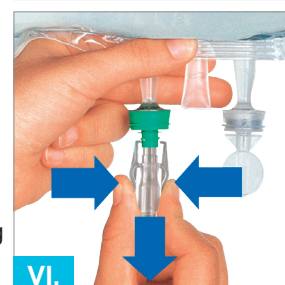
Adverse Reactions

When administered systemically, dextran has been associated with rare allergic reactions (<1 in 1000) such as urticaria, fever, chills, pruritus and anaphylaxis. However, no such reactions have been reported for any of XVIVO Perfusion's Dextran containing solutions when used for lung preservation. Any invasive procedure carries a risk of infection.

Directions for use

Use aseptic technique throughout the procedure.

1. Cool the solution to about 2–10 °C (36–50 °F), avoid freezing.
2. Once the container is opened the contents should be kept chilled and used within 24 hours. If additives are used, they should be thoroughly mixed with the solution immediately prior to use.
3. Suspend the PERFADEX® Plus bag at a height, 12 inches or 30 cm is usually enough, to produce a sufficient flow.
4. Instruction on how to connect the bag to the XVIVO Click Adapter
 - I. Remove the XVIVO Click Adapter from its sterile packaging.
 - II. Connect the XVIVO Click Adapter to a tubing set.
 - III. Clamp the tubing set.
 - IV. Twist off the closing cap of the green port on the bag.
 - V. Remove the protective cap of the XVIVO Click Adapter and connect it to the green click port on the bag until it is locked.
 - VI. For change to new bag, press the side-wings of the XVIVO Click Adapter, to disconnect. Connect to a new PERFADEX® Plus bag by following instruction steps IV-V.
5. Flush the lung with gravity flow until the PERFADEX® Plus exiting the lung is clear. For optimal preservation a combination of retrograde and antegrade flushing is recommended. This procedure usually requires 50-75 ml/kg body weight of the donor or from three (3) to eight (8) litres of PERFADEX® Plus.
6. Partially fill a sterile storage container with chilled PERFADEX® Plus and immerse the lung immediately after removal and in situ flushing.
7. Dispense the remainder of the solution into the organ storage container and seal the container with a sterile closure.
8. Maintain the organ storage container well insulated at about 2–10 °C (36–50 °F), avoid freezing.
9. The lung may be stored up to 12 hours, depending on the condition of the lung and/or the established routines at the hospital.
10. Dispose any residual solution after the procedure according to the hospital's standard routines.



How Supplied

PERFADEX® Plus is supplied as:
1000 ml bags packed 10 per carton
3000 ml bags packed 2 per carton
Store between 2-25 °C.

Symbols

	Sterilized using steam
	Contains dextran 40
	Do not re-use, discard after procedure
	Do not use if the package is damaged and consult instructions for use
	Use-by date
	Temperature limitation
	Do not resterilize
	Consult instructions for use
	Catalog number
	Batch code
	Date of manufacture
	Manufacturer
	Medical Device
	Caution: Federal US law restricts this device to sale by or on the order of a physician.
	Insertion Port
	Injection Port
	Single sterile barrier system with protective packaging outside

Composition and Ionic Concentrations

Composition g/l		Ionic Concentration mmol/l	
Dextran 40	50.00	Sodium	138
Sodium Chloride	8.000	Potassium	5.83
Potassium Chloride	0.400	Magnesium	0.81
Magnesium Sulfate	0.098	Glucose	5.30
Disodium Phosphate	0.046	Chloride	143
Monopotassium Phosphate	0.063	Sulfate	0.81
Glucose Monohydrate	1.050	Total phosphate	0.79
Tromethamine	0.242	Calcium	0.50
Calcium Chloride	0.056	Tromethamine	2.00
Water for Injection	qs		

Contact information

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This product may be covered by one or more patents.
See xvivogroup.com/patents

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