PERFADEX® Plus

THE GOLD STANDARD IN LUNG PRESERVATION MADE READY TO USE

Combines safety and efficacy of PERFADEX® with easier use

XVIVO PERFUSION

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THE GOLD STANDARD IN LUNG PRESERVATION MADE READY TO USE

PERFADEX® Plus is an extracellular, low potassium, dextran-based electrolyte preservation solution for rapid cooling, perfusion and cold static storage of donor lungs **pre supplemented with calcium ions and THAM so that it is ready to use whenever you need it.**

PERFADEX® Plus with click port - a new ready to use solution for optimal cold static preservation of donor lungs in a bag which connects spike free.

XVIVO Perfusion have developed PERFADEX® Plus a new generation of PERFADEX®. To save you time and effort, we have pre-supplemented the solution with calcium ions and THAM, so it is always ready to use. Calcium ions have been added to further mimic the composition of plasma.

PERFADEX® Plus has several design features that make it even easier to handle.

01

Strong, reinforced hanger – for safety and convenience.

02

Free from PVC, latex and phthalates – for patient safety.

03

New double, twist-off sterile ports are easy to grip and easy to open.

04

Injection port is made of stronger plastic – no risk of perforating the bag during injection.

05

New easy to use click port – connect tubing spike free to the bag with one simple click using the XVIVO Click Adapter. Once connected, the tubing can rotate on its own axis for flexibility during handling.

How PERFADEX® Plus works

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. The colloid component, dextran 40, protects the microvasculature against post-ischemic reperfusion injury, primarily by preventing pathological leukocyte-endothelial interaction.[12,13] It also prevents edema formation during preservation.[14, 15, 20] Calcium is important to maintain endothelial and epithelial cell integrity and endothelial contractility.[23] It is also crucial to maintain tight junctions between cells (to avoid cell disintegration).[22, 24]

Numerous studies have shown that PERFADEX® enables safe preservation of lungs up to 12 hours, depending on the quality of the donor lung being retrieved.[1 ,2 ,3 ,4 ,5 ,6 ,7 ,8, 9, 10, 11]

Using PERFADEX® Plus with click port

PERFADEX® Plus must be stored between 2-25 °C. The solution must not be supplemented with calcium ions or THAM – PERFADEX® Plus is pre-supplemented and ready to use whenever you need it.

PERFADEX® Plus now comes in a bag that allows for easier handling - with only one click, without the use of a spike, the bag is connected to XVIVO Click Adapter. PERFADEX® Plus with click port gives you full flexibility during the perfusion process as it can rotate around its own axis.

Once opened the solution should be kept chilled and used within 24 hours.

Current best practice [21]

According to Munshi et al, 2013

Current best practice based on the latest research on potential lung donor and lung-preservation techniques advises the use of an extracellular, dextran-based solution.

Lung preservation techniques

- Extracellular solution consisting of dextran 40, glucose and low potassium
- Anterograde and retrograde flushing of 60 mL/kg and max 30 cm height
- Temperature during lung preservation 2-8 °C
- Inflation to 50% of total lung capacity, fraction of inspired oxygen 50%
- Pharmacological additives: prostaglandin E1, heparin, glucocorticoids
- Cold ischemic times generally less than 8 h
- Normothermic ex-vivo lung perfusion based on lung assessment and therapeutics.

The Endothelium - a vulnerable tissue

The lung is primarily composed of endothelial cells which line the enormous surface area of the capillaries (equivalent to an entire tennis court) and a similar surface area of types I and II epithelial cells which line the alveoli and secrete surfactant respectively. The endothelium is the most vulnerable tissue and plays a critical role for the structure and function of a normal vessel wall. Endothelial cells produce a variety of biologically active substances that control vascular permeability, vessel tone, coagulation, fibrinolysis and inflammatory responses. Some of these substances, such as proteins which seal the junctions between cells (adhesion molecules), are integral parts of the cell structure. Others, such as nitric oxide (NO), prostacycline, chemokines, or factors involved in coagulation and fibrinolysis, are produced and then released by the endothelial cells either luminally or abluminally.[16]

Consequences of an injured endothelium

Injuries to the endothelium can induce platelet and leukocyte sticking. This can trigger inflammatory cascades including increased permeability of the capillary wall, which in turn increases tissue edema and the risk of Primary Graft Dysfunction (PGD). A well preserved endothelium is antithrombogenic, yet promotes platelet aggregation and coagulation if injured. [17,18]

The importance of an intact endothelium

Experimental and clinical evidence indicate that early ischemia-reperfusion injury to the endothelium, within the very first few hours of reperfusion, is a key trigger for cytokine cascades which eventually lead to PGD and subsequent graft failure often months or years later.[18] This early injury can be prevented or mitigated by minimizing physical injury in manipulation and storing the lungs in a protective solution under optimal temperature conditions.[19]

What causes damage to the endothelium?

A number of factors can injure the pulmonary endothelium during the manipulation and temporary storage involved in the retrieval of donor lungs;

- Traumatic manipulation during retrieval, evaluation and transplantation
- Excessive pressure
- Low temperature – particularly below 2°C
- Storage solution – e.g. intracellular type (high K+) solutions
- Prolonged cold ischemia
- Ischemia-reperfusion – free radical injury

Oncotic pressure retains water in capillaries and prevents loss into the extravascular (interstitial) space, thus preventing lung edema. The coating of the endothelium with dextran 40 prevents excessive leucocyte interaction.

Supply information:	
Reference:	Packaging:
19850	10 x 1000 ml bags with PERFADEX® Plus
19950	2 x 3000 ml bags with PERFADEX® Plus

US - FDA 510(k) clearance

Usage: PERFADEX® Plus must be stored between 2-25°C (36-77°F). Must not be supplemented with calcium ions or THAM – PERFADEX® Plus is pre-supplemented and ready to use whenever you need it. PERFADEX® Plus is supplied in 1000ml and 3000ml bags.
Intended use: PERFADEX® Plus solution for lung perfusion is indicated for flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

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