

NOW READY  
TO USE



## PERFADEX® Plus

THE GOLD STANDARD IN LUNG  
PRESERVATION MADE READY TO USE

Combines safety and efficacy of PERFADEX® with easier use

**XVIVO**  
PERFUSION

# PERFADEX® Plus

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## PERFADEX® Plus – a new solution for optimal cold static preservation of donor lungs

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 safer and 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. As an added safety feature, you can also see clearly whether the bag has been tampered or if the sterility barrier has been broken through the ports.

**04**

**Ports are made of stronger plastic** – no risk of perforating the bag during injection.

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.**

## 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, particularly protects the microvasculature against post-ischemic reperfusion injury, primarily by preventing pathological leukocyte-endothelial interaction.<sup>12,13</sup> It also prevents edema formation during preservation.<sup>14, 15, 20</sup>

Numerous studies have shown that PERFADEX® enables safe preservation of lungs up to 12 hours, depending of status of the organ during retrieval.<sup>1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11</sup>

## Using PERFADEX® Plus

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 so that it is ready to use whenever you need it.

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

## Current best practice <sup>21</sup>

*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 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 lumenally or abuminally.<sup>16</sup>

### 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.<sup>17,18</sup>

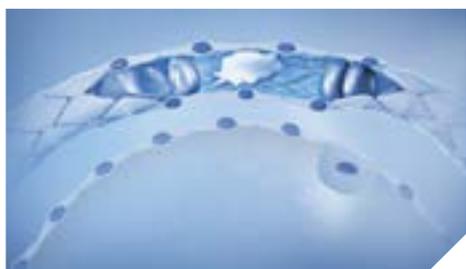
### The importance of an intact endothelium

Experimental and clinical evidence indicates 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.<sup>18</sup> 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.<sup>19</sup>

### 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



Excess 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.

CE marked

**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 so that it is ready to use whenever you need it. PERFADEX® Plus is supplied in 1000ml and 3000ml bags. PERFADEX® Plus should always be administered through a high flow filter:

**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.

### References

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### Supply information:

Reference:	Packaging:
19800	10 x 1000 ml bags with PERFADEX® Plus
19900	2 x 3000 ml bags with PERFADEX® Plus