

Ex Vivo Lung Perfusion(EVLP) XPS™ with STEEN Solution™

Patient Information



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Rx ONLY - PRESCRIPTION USE ONLY

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

Introduction

As a part of your upcoming lung transplant, your doctor has elected to use the XVIVO Perfusion System (XPS™) (pictured on the first page) with STEEN Solution™ Perfusate. This medical device will house your lung(s) from the time they are removed from cold preservation solution until it is time to prepare for the transplant procedure and they are implanted in you. Your lungs were initially considered to be unacceptable for transplantation prior to being placed on the XPS™ System. During the lungs' time in the device, the surgical team will have a chance to reassess the lungs and make sure that they meet the standards established for being a good lung for use in your transplant. While the donated lungs are on the XPS™ System, the doctor is able to gather information on pressures in the lung, how the lung is inflating and deflating, and how well the lung is able to oxygenate. The doctor also has more time to assess the lung and be able to view the lung prior to transplant. The doctor will use the same established standards for determining what is a good lung for transplant as they do now when determining the suitability of a lung in a donor, although it is not clear if the readings obtained from the XPS™ machine during perfusion are the same as the values obtained from lung donors. Your transplant surgeon will make the final decision as to whether the lung is able to be transplanted.

Speak to your doctor about all available options, including perfusion with the XPS™ System and STEEN Solution™, so you may make an informed choice for your treatment.

The XPS™ with STEEN Solution™ Perfusate device is indicated for use only on donor lungs removed from the donor body. There is no direct patient contact with this device; however, the device has a direct contact with the lungs that are subsequently transplanted into you. The donor lung quality after preservation has a direct effect on organ function and survival. The potential

for infection and physical trauma, due to the handling and placing of a tube in the lung airway and connecting blood vessels, may lead to complications after transplantation (e.g., infection, pneumonia, pneumothorax (collapsed lung)/hemothorax (bleeding into the chest cavity), etc.).

Patients receiving a lung treated with the XPS™ System with STEEN Solution™ Perfusate device may experience the following side effects, including those experienced with any lung transplant:

- Death;
- Kidney failure or dysfunction;
- Respiratory dysfunction/infection;
- Primary graft dysfunction;
- Acute rejection;
- Cardiac arrhythmias;
- Bronchiolitis Obliterans Syndrome (BOS) (obstructive lung disease of the small airways)
- Bronchiole stenosis/Dehiscence (restricted airways)

Product Indication for Use

The XVIVO Perfusion System (XPS™) with STEEN Solution™ Perfusate is indicated for the flushing and temporary continuous warm machine perfusion of initially unacceptable donor lungs during which time the function of the lungs outside the body can be reassessed for transplantation.

What does it do?

The STEEN Solution™ Perfusate used in the XVIVO Perfusion System has been used for about 18 years and has been used around the world including in Europe, Australia, Canada, and in the United States. The XPS™ system has been used since 2011 and was approved under a Humanitarian Device Exemption (HDE) in the USA in 2014, after showing probable benefit, for use with STEEN Solution™ Perfusate. It has now demonstrated reasonable safety and effectiveness. The system is used to pump STEEN Solution™ Perfusate through the donated lungs from the time they have been

removed from the cold preservation solution, connected to the device and re-warmed until they are cooled down again prior to being implanted in you. The perfusion solution (i.e., STEEN Solution™ Perfusate) is a combination of proteins, sugar, and soluble salts.

Previous Human Experience

The XPS™ System with STEEN Solution™ Perfusate has been used in hundreds of EVLP transplants worldwide. In the NOVEL study, a study done in the USA, 110 patients who received lungs perfused with the XPS™ System and STEEN Solution™ Perfusate were compared to patients who received standard lungs that had not been placed onto the XPS™ system. In this study, the lungs chosen to be treated with warm perfusion of STEEN Solution™ Perfusate were considered non-ideal and unsuitable for transplantation before the preservation procedure. After perfusion, they were re-evaluated and transplanted if they were found to be suitable. Post-transplantation survival was then assessed for patients transplanted with STEEN Solution™-preserved lungs and compared to patients transplanted with lungs preserved with conventional, cold storage without perfusion.

In the NOVEL study, the differences in the outcomes studied between lungs treated with ex vivo lung perfusion and those that did not undergo perfusion were not significantly different: thirty-day survival rate, one-year survival rate, lung function at one year and adverse events.

Speak to your physician about the use of the XPS™ System and STEEN Solution™ Perfusate and its previous clinical experience so you may make an informed choice for your treatment.

Advantages

The lungs will be oxygenated during this time and do not need to be transplanted into another body as quickly. This gives:

- More time to prepare you to receive them;
- More time to make sure the lungs meet the acceptability criteria required by your transplanting surgeon before being transplanted;

- Time to ensure any donor blood is flushed out of the lung;
- Increase in the organ donor pool and the utilization of donor lungs.

Typical Process

Typically, the medical device is used between 2 and 5 hours. The lungs are placed in the disposable organ dome (i.e., the bubble chamber on the front of the machine). The lungs are attached to a Lung Circuit and liquid is pumped through the lungs. The lungs are warmed to normal body temperature (37°C) and the liquid, STEEN Solution™ Perfusate, is pumped through the lungs. The lungs are ventilated and the system allows for the surgeon to do a complete evaluation of the lung while on the machine. The process is done under sterile conditions.

The manipulation required of the airway and blood vessels involved carries the potential for contamination, which may lead to infections, and mechanical trauma of the donor lungs.

Who should NOT be using this device/ Contraindications

There are currently no known contraindications of the XPS™ System with STEEN Solution™ Perfusate for patients with end-stage lung disease waiting for a lung transplant.

Speak to your lung transplant doctor about the potential benefits and risks of XPS™ System with STEEN Solution™ Perfusate for your lung transplant procedure.