

Company

XVIVO Perfusion

Drug or Device Name

XPS with STEEN Solution

Category

Biotechnology

Compound/Technical Name

XPS with STEEN Solution

Trade Name

XPS with STEEN Solution

Date of Approval

04/26/2019

Therapeutic Categories

Lung transplant Lung failure

Indications

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

Background

Lung transplantation remains the only known life-saving treatment for end-stage lung disease, but many patients die while waiting for suitable lungs to become available for transplant. On average, only 15 percent of lungs obtained from deceased donors are suitable for transplantation. This is because the physiological function of a large number of donor lungs is questionable due to, for example, poor lung quality or possible injury, or there is inadequate time to find a suitable donor-recipient match.

Development

Dr. Stig Steen began developing a normothermic organ perfusate back in the late 1990's in his laboratory, which would later become known as STEEN Solution™. The XPS was developed in 2008 to be used with STEEN Solution and went into first-in-human clinical trials in 2010 in the USA. This was the first normothermic perfusion device for this indication developed.

Innovation

The XPS with STEEN Solution Perfusate was the first medical device that was approved for EVLP of initially unacceptable donated lungs. This unique platform allows for lungs to be maintained for an extended period of time outside the body, allowing for therapeutics deliveries, broad research and

evaluation applications, and even potential rehabilitation and recondition of organs. Researchers are currently using this device for testing of therapeutics for reversal of lung injury, and researchers in Toronto are using STEEN Solution and EVLP to be able to transplant lungs from Hepatitis C donors which previously have been unused as well as to deliver chemotherapy isolated to the lungs to reduce systemic toxic effects.

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