XPS™
THE FLEXIBLE
COMPREHENSIVE
EVLP PLATFORM
Humanitarian Device. Authorized by Federal law in the U.S for use in 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. The effectiveness of this device for this use has not been demonstrated.

More than 70% of donor lungs worldwide are deemed unusable and not used for transplantation.

Increase your lung donor pool with a fully flexible and comprehensive platform for EVLP

- Proven clinical protocol and extensive clinical practice
- Developed with daily clinical challenges in mind
- Based on expertise and experience from clinicians

First FDA approved device for EVLP

The XVIVO Perfusion System™ (XPS™) is CE-marked and FDA approved for ex vivo lung perfusion of initially unacceptable donated lungs*. The NOVEL Study in U.S was designed to establish the safety of the method.

The NOVEL Study – Establishing the safety of the method

The NOVEL study was the first prospective, multicenter clinical trial designed to evaluate the safety of Ex Vivo Lung Perfusion (EVLP) as a method to screen and identify good quality lungs that have been unused or rejected for transplantation.

The one-year follow up of the study showed that EVLP with XPS™ and STEEN Solution™ is a safe tool to increase the percentage of transplanted lungs by screening the unused donor pool.

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EXPANDING THE LUNG DONOR POOL

Normothermic EVLP, ex vivo lung perfusion, is a technique to assess and evaluate donor lungs by providing optimal conditions of reperfusion and protective ventilation.

Normothermic EVLP attempts to simulate the in vivo environment of a donor lung using ventilation and perfusion of the isolated lung to assess and continuously evaluate lung function.

EVLP provides clinicians and transplant teams an ideal setting for donor lung evaluation and allows lung treatment:
- Objective assessment of marginal/extended or DCD donor lungs
- More time to choose optimal treatment strategy
- Opportunity to reassess prior to transplant

The ultimate objective of EVLP is to expand the pool of transplantable organs and thus minimize mortality and morbidity on the transplant waiting list. More than 300 transplantations have been performed using this new unique technique. EVLP is not only the ideal setting for donor-lung assessment and evaluation, it also opens up the possibility for future treatment of the lungs.
Introducing new features and upgrades!

- XMAT™ - Remote monitoring system*
- Barcode PGM calibration
- Improved user interface
- Integrated smart sequencing
- Weight sensor

XPS™ developed with daily clinical challenges in mind

The system was developed together with clinicians with genuine experience and knowledge from normothermic EVLP using STEEN Solution™. Understanding the clinical needs and challenges transplant teams encounter in daily work, the XPS™ facilitates the clinical decision making process and offers a flexible comprehensive platform for EVLP.

XPS™ – The first FDA HDE approved and clinically proven EVLP Technology on the market

- Gives you control of the entire EVLP process
- Supported by clinical experience and knowledge
- All required EVLP components integrated
- In-line gas monitoring
- Continuous data recording – evaluate for safety and control

*Currently not approved by the FDA.
Operational benefits on-site
• Barcode scanning of PGM calibration data
• Integrated smart sequencing features
• Flexible and comprehensive platform for normothermic EVLP

Integrated system for innovative technique
• CardioHelp XVIVO Centrifugal Pump – Quadrox-iR next generation oxygenator
• Separate sterile area and perfusionist non-sterile area
• Heater/Cooler (15-39°C)
• Hamilton ICU Ventilator
• In-line gases (pO2, pH)
• User remains in control as the EVLP process is performed on-site
• Continuous data recording – evaluate for safety and control
• User-friendly system

Flexibility
• Touchscreen user interface
• Extract and analyse data
• Configured to allow X-ray and CT-scan of lungs
• Integrated weight sensor platform allowing measurement throughout the EVLP
• Adjustable to preferred clinical protocol
• Adjustable flow to preferred clinical protocol
• Adjustable ventilation
• Supported by clinical experience and knowledge
• X-ray and CT-scan possibilities

Integrated system for innovative technique
• STEEN Solution™ pump – Perfusion management system with integrated pumps to enable the addition, subtraction and recycling of STEEN Solution™ in the perfusion circuit. XPS™ is equipped with peristaltic pumps for convenient management.

Platform for gas cylinders – one containing medical grade (100%) oxygen for membrane oxygenation and the other containing a mixture of medical grade gases (6% O2, 8% CO2, 86% N2) for membrane deoxygenation.

**Operational benefits on-site**

**Integrated system for innovative technique**

**Flexibility**

*Currently not approved by the FDA.*
ICU-type Hamilton Ventilator with modes designed to provide protective ventilation of the ex vivo lung.

CardioHelp XVIVO centrifugal pump with integrated temperature and pressure sensors for monitoring of safety during the procedure.

Thermoelectric heater/cooler device that uses water to maintain perfusate temperatures at any set point between 15–39°C.

The XPS™ is equipped with two in-line gas sensors, which enables real-time trending of pH and pO2 during EVLP.

The XPS™ is specifically configured and designed for allowing X-ray and CT-scan while doing normothermic EVLP.

Touchscreen computer display for the perfusionist and a display-only screen for the surgeon that displays data from the hardware components as well as trends important lung function parameters graphically.
**NEW FEATURE AND UPGRADES INCLUDE THE FOLLOWING:**

- Added barcode scanner for Perfusate Gas Monitor Calibration - Improves usability and accuracy.
- Integrated smart sequencing feature to guide perfusionist through EVLP protocol and ventilation settings.
- Improved User Interface and Operation based on customer feedback.

**XVIVO MONITORING AND ANALYSIS TOOL XMAT™**

Introduction of XMAT™ (XVIVO Monitoring and Analysis Tool™). Integrates data from XPS™, video cameras, bronchial scope images, x-ray images, ventilator information into single system for analysis and remote monitoring.

**ALL REQUIRED EVLP COMPONENTS INTEGRATED**

XPS™ is a fully integrated off-the-shelf cardiac bypass system that includes all components needed to safely run normothermic EVLP. The XPS™ system is based on innovative technology from leading companies and includes a centrifugal pump (MAQUET CardioHelp), Hirtz heater/cooler and ICU-ventilator (Hamilton).

**READ MORE ON XVIVOPERFUSION.COM**

XPS™ was developed to provide transplantation teams with a consistent and easy-to-use method of performing EVLP in the hospital. The objective was to develop an automated perfusion system that would allow for standardization of EVLP without interfering with the need for clinical flexibility.

The donor lungs are transported in regular manner, in a cooler box from the procurement site. The donor lungs are flushed thoroughly with PERFADEX® or PERFADEX® Plus and then put on the EVLP platform. After warming up according to a detailed protocol, it is up to the EVLP team to set preferred ventilation and perfusion strategies depending on the requirements of each donor lung. Integrated inline perfusate gas monitors (PGM™) enables for real-time trending of pH and pO2 during the entire EVLP procedure. The XPS™ also enables precise continuous monitoring of EVLP performance metrics, all pre-set by the EVLP team.

The XPS™ is intended to be used with STEEN Solution™ for flushing and temporary continuous normothermic perfusion of initially unacceptable excised donor lungs, during which time the function of the lungs can be evaluated and assessed as viable transplantable organ (FDA HDE approval August 2014).

The XVIVO Perfusion System (XPS™) is intended for flushing and temporary continuous normothermic machine perfusion of isolated lungs, during which time the function of the lungs can be assessed for transplantation (for all other countries).

- Video cameras
- Bronchial scope images
- Ventilator information
- X-ray images

*Currently not approved by the FDA.
The use of EVLP has after extensive experimental research been successfully transformed into clinical practice. Published reports from several centers show favorable clinical outcomes and clinical trials confirm these results.

The NOVEL study was the first prospective, multicenter clinical trial designed to evaluate the safety of Ex Vivo Lung Perfusion (EVLP) as a method to screen and identify good quality grafts from lungs that have been unused or rejected for transplantation. The participating centers in the NOVEL study used PERFADEX®, STEEN Solution™ and the XPS™ system to evaluate and assess rejected donor lungs.

The one-year follow up of the study showed that EVLP with XPS™ and STEEN Solution™ is a safe diagnostic tool to increase the percentage of transplanted lungs by screening the unused donor pool.

Supporting data – clinically proven

Good interim results presented – The NOVEL study

The XPS™ is specifically designed to facilitate X-ray while performing normothermic EVLP. If a mobile X-ray unit is not available, XPS™ may be transported at shorter distances within the hospital as it has a battery built-in that could support up to 20 min. This allows for simultaneous X-ray without interrupting the EVLP process.

Continuous data recording – evaluate for safety and control

The touch-display monitors and software allows monitoring the procedure and components as well as data capturing. The software captures and displays key performance data in real time. Parameters displayed are PVR, delta pO₂ etc. Data can easily be downloaded via an USB port.

In-line perfusate gas monitors (XVIVO PGM Disposable Sensors™) for real-time trending

The XPS™ is equipped with two in-line gas sensors, which enables real-time trending of pH and pO₂ during EVLP.

X-ray possibilities

The XPS™ IN THE U.S
The XPS Disposable Lung Kit™ contains specially developed disposables and pre-packed products to suit your needs and requirement for sterility. The products in our disposable kit have been carefully produced and selected - packaged and sterilized for your convenience.

**ACCESSORIES**

**CONVENIENT, RELIABLE, STERILE**

The XPS Disposable Lung Kit™ contains specially developed disposables and pre-packed products to suit your needs and requirement for sterility. The products in our disposable kit have been carefully produced and selected - packaged and sterilized for your convenience.

**Selected from leading suppliers**

The pre-packed kit contains all the necessary components and tubing to run one normothermic EVLP procedure on the XPS™.

- Disposables for connecting the lungs to the perfusion circuit
- STEEN Solution™
- XVIVO Organ Chamber™
- XVIVO PGM Disposable Sensors™

**In-line gas monitoring the easy way**

XVIVO PGM Disposable Sensors™ provides in-line, easily calibrated trending of the perfusate. The sensors are single-use, disposable in-line sensors intended to be used with the XPS™ to trend the pH and dissolved pO₂ gases in STEEN Solution™ during ex vivo assessment and evaluation.

The XVIVO PGM Disposable Sensors™ come pre-calibrated to STEEN Solution™ directly out of the package.

**Clinically proven solution**

STEEN Solution™ is a buffered extracellular solution that includes human albumin to provide an optimal oncotic pressure, and Dextran 40 to coat and protect the endothelium from excessive leucocyte interaction. STEEN Solution™ is designed to facilitate prolonged evaluation and promote stability of isolated lungs ex vivo.

XVIVO Organ Chamber™ is a single-use, sterile disposable container designed to aseptically hold the lungs during the procedure.

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WE SIMPLIFY YOUR ADMINISTRATIVE WORK
DIRECT, FAST AND PRECISE

To facilitate your administrative work – simply order all items needed for an EVLP procedure directly with us. We have products in stock and arrange direct shipments from our facility. You can rely on our long experience of shipping products worldwide.

Training and workshops on-site

XVIVO Perfusion arranges workshops where transplant teams receive hands-on training on the EVLP concept. You may choose from a selection of workshops, individual or together with other international partners. On-site training can also be customized to your local team and facility. Over the years we have arranged both local and regional workshops together with leading centers in Europe, Asia, Pacific, North and South America. Contact training@xivivopерfusion.com to learn more about our curriculum and activities in your region.

Installation and Technical Support

When a customer has decided to use the XPS™ in the clinic or for research, an XVIVO Perfusion certified Technical Advisor will together with your local coordinator arrange a two day installation and training session on site in the hospital. We will provide you with a detailed manuals and check-lists. If you have any problems or need help, our dedicated staff will be happy to help you out.

Research and Future therapies

XVIVO Perfusion supports research in the field of ex vivo organ perfusion, EVOP. We currently support teams worldwide in their strive to develop new applications and areas for EVOP. May the future provide the opportunity to define specific diagnosis and deliver appropriate treatments to a metabolically active organ. Please join XVIVO Perfusion to fulfill the company’s mission to develop innovative products and solutions that will ultimately lead to the outcome that nobody should die waiting for an organ.

Article references


NOBODY SHOULD DIE WAITING FOR A NEW ORGAN

XVIVO Perfusion is a medical technology company focused on developing optimized solutions for organ, tissue and cell preservation and perfusion in connection with transplantation. The company is rooted in medical science.

XVIVO Perfusion collaborates with transplant teams to save lives. Our mission is to increase the survival rates of patients awaiting transplantation by supporting transplant teams in every way we can. We join forces with the transplant teams to give more patients a better life.

We provide our customers with solutions and systems that can improve the transplant process outcome and expand the organ donor pool.