XPS™
THE FLEXIBLE COMPREHENSIVE EVLP PLATFORM
FIRST FDA APPROVED DEVICE FOR EVLP

The XPS™ is CE-marked and FDA approved for ex vivo lung perfusion of initially unacceptable donated lungs*. The NOVEL Study in USA 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 grafts from 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.
More than 70 % of donor lungs worldwide are deemed unusable and not used for transplantation.
Expanding the Lung Donor Pool

Normothermic EVLP, ex vivo lung perfusion, is a novel technique to assess and evaluate poorly functioning 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 evaluation and lung treatment:

- Objective assessment of marginal/extended or DCD donors
- More time to choose optimal treatment strategy
- Opportunity to reassess prior to transplant
- More time to fully assess function and HLA match
- Ex vivo treatment limits side effects of relatively toxic drugs

Increase your lung donor pool with a fully flexible and comprehensive platform for EVLP, XVIVO Perfusion System (XPS™).
The ultimate objective of EVLP is to expand the donor organ pool 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 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

INTRODUCING XVIVO ACADEMY!

- XPS Partner Training Program
- Xpert Training Program
- Master Training Program
ICU-type Hamilton C2 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.

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

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

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

NEW FEATURE AND UPGRADES INCLUDE THE FOLLOWING:

- New and improved touchscreen monitor. Improved screen sensitivity. Upgraded operating system and improved communication links.
- Added barcode scanner for Perfusate Gas Monitor Calibration- Improves usability and accuracy.
- Improved User Interface and Operation based customer feedback.
- New XPS™ monitoring and analysis tool – XMAT. Integrates data from XPS™, video cameras, bronchial scope images, x-ray images, ventilation images into single system for analysis and remote monitoring.
CardioHelp XVIVO Centrifugal Pump – Quadrox-iR next-generation oxygenator

Separate sterile area and perfusionist non-sterile area

Heater/Cooler (15-39°C)

INTEGRATED SYSTEM FOR INNOVATIVE TECHNIQUE

Adjustable to preferred clinical protocol

Adjustable flow to preferred clinical protocol

Adjustable ventilation

FLEXIBILITY

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, XPS™ facilitates the clinical decision making and offers a flexible comprehensive platform for EVLP.

OPERATIONAL BENEFITS ON-SITE

User remains in control as the EVLP process is performed on-site

Continuous data recording – evaluate for safety and control

User-friendly system

Supported by clinical experience and knowledge

X-RAY POSSIBILITIES

XPS™ is specifically designed for allowing X-ray while performing normothermic EVLP. If a mobile unit is not available, XPS™ may be transported within the hospital as it is built with a long life battery. This allows for simultaneous X-ray without interrupting the EVLP process.

IN-LINE PERFUSATE GAS MONITORS (PGM) FOR REAL-TIME TRENDING

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

INTEGRATED SYSTEM FOR INNOVATIVE TECHNIQUE

Flexible and comprehensive platform for normothermic EVLP

XPS™ – THE FIRST FDA APPROVED AND CLINICALLY PROVEN EVLP TECHNOLOGY ON THE MARKET

XMAT - For remote monitoring and analysis of EVLP data

Integrated smart sequencing features

Flexible and comprehensive platform for normothermic EVLP

IN-LINE MONITORS (PGM) FOR REAL-TIME TRENDING

The XPS™ equipment is also equipped with in-line gas monitors (PGM™). The XPS™ enables continuous real-time monitoring of important EVLP parameters.

READ MORE ON XVIVOPERFUSION.COM

ALLOWING FOR STANDARDISATION OF EVLP

XPS™ was developed to provide transplant teams with a consistent and easy to use method of performing EVLP in the hospital. The objective was to design an automated perfusion system that would standardize perfusion without interfering with the usual clinical flexibility. The design began as a research project at Malmö University Hospital. The design phase was thoroughly performed in parallel with the R&D phase.

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ALL REQUIRED EVLP COMPONENTS INTEGRATED

All required EVLP components integrated

Support by clinical experience and knowledge

In-line gas monitoring

Continuous data recording – evaluate for safety and control

The 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 C2).

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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.

GOOD INTERIM RESULTS PRESENTED – THE NOVEL STUDY

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.
The XPS Disposable Kit™ contains disposables and pre-packed products to suit your needs and requirement for sterility. The products in our disposable kit have been carefully selected from leading suppliers and brands, packaged and sterilized for your convenience.

**SELECTED FROM LEADING SUPPLIERS**

- Pressure sensor line
- Fluid level sensor
- Cannulas
- Bacterial/viral filter
- Ventilator flow sensor
- Limb-o-ventilator breathing circuit
- Sterile drape

The pre-packed kit contains all the necessary perfusion products and provides the aseptic interface between the XPS™ and the ex vivo lung. The sterile circuit includes Quadrox iR integrated centrifugal pump head/oxygenator and heat exchange membrane, pediatric hard-shell reservoir, Pall leucocyte filter, tubing and priming loop, gas sensor quick connectors and a 500 mL soft drain reservoir.

Other components included in the pre-packed kit are: pressure sensor line, fluid level sensor, cannulas, bacterial/viral filter, ventilator flow sensor, Limb-o-ventilator breathing circuit and sterile drape.
CONVENIENT TO ORDER AND EASY TO CONNECT

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

- Surgical pack and disposables for connecting the lungs to the perfusion circuit
- STEEN Solution™
- XVIVO Organ Chamber™
- PGM Disposable Sensors™

IN-LINE GAS MONITORING THE EASY WAY

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

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

CLINICALLY PROVEN AND FDA APPROVED SOLUTION

STEEN Solution™ is a buffered extracellular solution that includes human albumin to provide an optimal colloid osmotic 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.
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 have the possibility to get hands-on training on the EVLP concept. You may choose from a selection of workshops, individual or together with other international transplant teams. 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, North and South America. Contact training@xvivoperfusion.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 technician will together with your local coordinator arrange a two day installation and training session on site in the hospital. We will provide you with 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 worldwide teams in their strive to develop new applications and areas for EVOP. EVOP may in the future provide the opportunity to deliver personalized medicine for organs, i.e 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 have to die waiting for a transplant.
WE EMPOWER TRANSPLANT TEAMS TO SAVE MORE LIVES

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 firmly 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 new life.

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