TRAFERX

TorEx Lung Perfusion System

Patient Information Guide

English

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

What is the TorEx Lung Perfusion System?

The TorEx Lung Perfusion System is a medical device used to help doctors evaluate and preserve donated lungs before they are transplanted. This system allows doctors to test how well the lungs are working outside the body to decide if they are safe for transplantation.

It is part of a special process called Ex Vivo Lung Perfusion (EVLP), which keeps the lungs warm, filled with fluid, and gently ventilated (breathed) after donation. This process gives doctors more time to examine the lungs before transplanting them into a patient like you.

Why is this System Used?

Not all donated lungs are ready to be transplanted right away. Some may be slightly injured or not clearly functioning well. The TorEx Lung Perfusion System helps by:

- Allowing doctors to carefully test and monitor lung function
- Helping more patients receive a transplant by making more lungs usable

Using this system may increase the chances of a successful transplant by ensuring that only healthy, well-functioning lungs are chosen.

Indications for use: The TorEx Lung Perfusion System is indicated for use in continuous normothermic machine perfusion of donor lungs, initially deemed unsuitable for transplantation, during which time the ex vivo function of the lungs can be reassessed for transplantation in adults. The TorEx Lung Perfusion System includes a mobile cart with embedded software, single-use sterile Organ Chamber and Cannulae set and is used with TorEx Lung Perfusate solution to perform ex vivo lung perfusion for up to 6 hours.

Note: The TorEx System is used to evaluate the quality of donated lungs, but the final determination of the suitability of the lungs for transplant remains with the transplanting surgeon.

How Does the System Work?

After the lungs are removed from a donor, they are connected to the TorEx system. The TorEx system allows one to perform the Toronto Technique for lung perfusion. The Toronto EVLP technique is a clinically validated method used to evaluate donor lungs before transplantation. This technique was first developed at Toronto General Hospital and has been extensively studied in Canada, the United States, and internationally. It allows doctors to keep donor lungs functioning outside the body in a warm, oxygen-rich environment so that they can better assess the lung's condition and help recover lungs that may not have been usable otherwise.

In clinical studies, the Toronto EVLP technique has been shown to safely expand the use of the donor lung pool. A landmark study published in the *New England Journal of Medicine* (Cypel et al., 2011) demonstrated that lungs evaluated using the EVLP method had similar outcomes after transplant compared to standard donor lungs, even when the donor lungs were initially considered higher-risk.

Patients who received lungs through this technique experienced similar survival rates and overall lung function after transplant.

Since its initial success, the Toronto EVLP technique has become an accepted standard of care at many leading transplant centers around the world. It has helped increase the number of available lungs for transplant and has been used safely in hundreds of lung transplant procedures.

This device:

- Gently warms the lungs to body temperature (around 37°C or 98.6°F)
- Pumps a special fluid (called TorEx Lung Perfusate) through the lungs to mimic blood flow
- Provides oxygen and ventilation, similar to breathing
- Allows doctors to take fluid samples, perform X-rays, and measure lung function

This process usually lasts a few hours. If the lungs perform well during this evaluation, they can be transplanted into a recipient.

What Are the Benefits?

The TorEx Lung Perfusion System may:

- Allow doctors to use lungs that might otherwise be discarded
- Improve transplant outcomes by selecting higher-quality lungs
- Help avoid the use of lungs that are not functioning well
- Increase the total number of lungs available for patients

This technology has already helped many people receive successful lung transplants.

Are There Any Risks?

Patients are not exposed to the system itself. It is used before transplantation. General transplant risks still apply, such as rejection, infection, and surgical complications.

What Should You Know?

- You will not feel anything from the use of this system—it is only used before the surgery.
- If lungs are selected using this system, your transplant team will inform you.
- The system is approved for clinical use and has been used in transplant centers outside of the United States.
- Ask your transplant team if you have questions about how the system is used in your case.

Contact Information

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