

Lung Transplantation with the Organ Care System (OCS™) Lung System: Patient Information

A Guide for You and Your Family



GLOSSARY

Term	Meaning
Acute Rejection	When a patient's body has problems accepting the new, transplanted organ, typically within the first year after transplantation; treatment for acute rejection may include a high dose of corticosteroids, a type of medication
Cardiac arrhythmia	Irregular heartbeat
Cold Storage Preservation/Cold Static Preservation	A method that preserves donor lungs on ice in a cooler during the time that the lung is retrieved from the donor and transported to the recipient. Cold temperatures are used to preserve the organ before it is transplanted
Donor after Circulatory Death (DCD)	A DCD is a donor from whom organs were procured after medical support of the heart was withdrawn and death is declared. Most organs in the U.S. today are procured from donors after brain death (DBD) in whom the heart is still beating when brain death is declared.
ET	Endotracheal (within the trachea or airway)
Ex vivo	Outside of the living body
Normothermic	Normal body temperature
Perfusion	The passage of fluid through the organ
Preservation	The effort of keeping the lungs from injury or loss
Procurement	The surgical procedure that removes an organ from a donor for transplantation (organ harvesting)
Primary Graft Dysfunction (PGD)	A severe form of damage to the lungs that is a major cause of early disease and death. Grade 3 is the most severe
Ventilation	A ventilator is a machine that breathes for a person unable to breath on his or her own. Ventilation is the movement of air through the lungs by a ventilator.

ABOUT THIS BOOKLET

This booklet was created for patients like you who are on the lung transplant waiting list. It contains information that will help you and your family learn about a new way to preserve lungs before transplantation using the FDA approved OCS™ Lung System.

Your doctor is the best person to explain your treatment options and their risks and to help you decide which option is right for you. If you have questions about the OCS™ Lung System that are not answered in this booklet, please ask your doctor.

This booklet is intended for general information only. It is not intended to tell you everything you need to know about a lung transplant. Your doctor should always be your primary source of information about your general health, your condition, and a lung transplant.

WHAT IS THE OCS™ LUNG SYSTEM?

The TransMedics® Organ Care System (OCS™) Lung System is a portable organ perfusion, ventilation, and monitoring medical device that may be used to preserve both standard criteria donor lungs and donor lungs that are deemed initially unacceptable for transplantation based on limitations of cold storage. Reasons why donor lungs are deemed initially unacceptable for procurement and transplantation could include donors with advanced age, reduced lung function, prolonged preservation time and DCD. Talk to your doctor about whether the OCS™ Lung System may be the right option for you.

HOW THE OCS™ LUNG SYSTEM WORKS

The OCS™ Lung System is a new method of donor lung preservation.

Instead of being placed on ice in a cooler, donated lungs are placed in the OCS™ Lung System, which keeps them warm and breathing as in the human body. The system circulates oxygenated, nutrient-rich blood through the breathing lungs from the time they are placed on the machine at the site of donation until they are removed from the machine for transplant into the recipient.

The system is designed to:

- Keep the lungs warm and oxygenated during preservation from the donor to the recipient
- Ventilate the lungs so they continue to “breathe” during preservation
- Allow your doctor to assess and continuously monitor the condition of the lungs prior to transplantation.

Because lungs are kept oxygenated and breathing, the OCS™ Lung System reduces the injurious time during which there is a lack of oxygenated blood supply to the lungs. An extended period of lack of blood supply to the lungs is associated with injuries to the lungs that could negatively impact post-operative healing and recovery.

The OCS™ Lung System is fully contained and portable. Everything needed to keep the lungs warm and breathing is contained within the system, including an oxygen tank. The system runs on battery power for easy transportation in a car, helicopter, or airplane. The major components are pictured below.

Figure 1: OCS™ Lung System Components



Indication for Use

The TransMedics Organ Care System (OCS) Lung is a portable normothermic organ perfusion, ventilation and monitoring medical device indicated for preservation of standard criteria donor lung pairs and for preservation of donor lung pairs initially deemed unacceptable for procurement and transplantation based on the limitations of cold static preservation. The device allows for ex vivo assessment of donor lungs prior to transplantation.

Who is eligible to receive donor lungs preserved using the OCS™ Lung System?

Any adult aged 22 or over who has been registered on the transplant waiting list for double lung transplant is eligible to receive donor lungs preserved using the OCS™ Lung System.

When Should the OCS™ Lung System Not be Used (Contraindication)

The use of the OCS™ Lung System is contraindicated (should not be used) for donor lungs that have moderate to severe lung injury with air leak, as this could result in leakage of fluid and air at the injured area, which will impair the ability of the OCS™ Lung System to maintain the donor lungs in good condition.

RISKS AND BENEFITS

Potential Risks of using the OCS™ Lung System

All surgical procedures have potential risks. The potential risks of a transplant with the OCS™ Lung System are the same as those with a normal transplant procedure using cold storage preservation. There is a risk of receiving a lung that does not function properly after transplant. There is also a risk that the donor lung may be damaged during preservation and there is a possibility that after preservation on the OCS Lung System, your doctor may decide that the donor lung is not appropriate for transplantation. In these cases, your transplant procedure may be cancelled and you will have to wait for another donor lung to become available.

The OCS™ Lung System performance will be continuously monitored by a trained clinical transplant team throughout the preservation period. However, it is possible that the OCS™ Lung System will not work properly, or the medical staff may make an error which could lead to damage of the donor lungs.

It is also possible that the OCS™ may not be available for donor lung preservation or there may not be personnel available trained in the use of the OCS™ Lung System when a donor lung becomes available for you.

Your doctor can discuss with you the potential risks that may be associated with your lung transplant surgery.

Benefits - How the OCS™ Lung System Can Help You

The ability to transplant organs that were initially deemed unacceptable for transplantation will expand the pool of available donor lungs for transplantation and may reduce the time on the waiting list for potential lung transplant recipients. The OCS™ Lung System was designed to overcome the clinical limitations of cold storage in the following key areas:

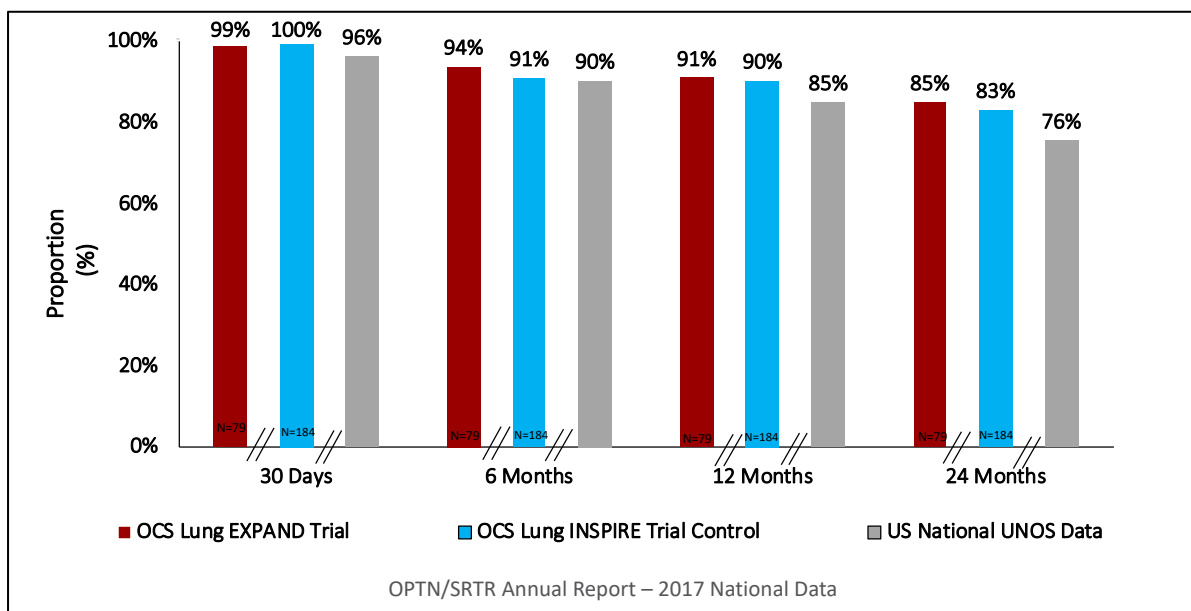
- The OCS™ Lung System reduces the injurious time during which there is a lack of blood supply to the lungs by keeping the lung supplied with oxygenated blood. An extended period of lack of blood supply to the lungs is associated with injuries to the lungs during preservation which could result in clinical complications post-transplant.
- Clinicians can assess donor lung oxygenation function and the overall condition of the donor lungs throughout preservation and up to the point that the transplantation procedure is initiated to ensure that these lungs are suitable for transplantation into a patient.
- The use of the OCS™ Lung System gives the transplant team more time to prepare you to receive the lungs and more time to make sure that the lungs are clinically acceptable before transplantation.

A clinical trial of the OCS™ Lung System called the Lung EXPAND study evaluated 79 patients who received donor lungs that were preserved using the OCS™ Lung System. These donor lungs were deemed initially unacceptable for transplant for one or more of

the following reasons: older age (≥ 55) donors, donor lungs with expected prolonged preservation time > 6 hours, donor lungs with decreased capacity to exchange oxygen with the blood, and DCD. After perfusion on the OCS™ Lung System, the donor lungs were evaluated and to determine whether they met acceptance criteria for transplantation. The 79 patients who received OCS™-preserved lungs were followed, and data are available through 24 months after transplantation. The Lung EXPAND study demonstrated the following:

- The OCS™ Lung System was used to preserve and assess 93 donor lungs that were initially deemed unacceptable for procurement and transplantation based on the limitations of cold static preservation. Eighty-five percent (85% or 79 of 93) of these donor lungs were transplanted.
- PGD Grade 3 was increased in patients who received lungs initially deemed unacceptable for procurement and transplantation following preservation on the device. PGD Grade 3 is correlated to long-term lung function.
- Outcomes such as 30-day survival rate, lung function at one year and adverse events were similar between OCS™-preserved lungs and standard criteria lungs that were preserved using cold storage.
- Patient survival at 6, 12, and 24 months was similar to the survival observed for patients who received standard criteria donor lungs preserved using cold storage in TransMedics' previous trial of the OCS™ Lung System (called the INSPIRE trial) as well as the U.S. national average statistics for lung transplant recipients.

Figure 2: Post-transplant Patient Survival Comparison for Patients in the Lung EXPAND Trial with OCS™-Preserved Lungs and Control Patients in the INSPIRE Trial (Standard Criteria Lungs on Cold Storage) at 30 Days, 6 Months, 12 and 24 Months after Transplantation



WHAT TO EXPECT DURING YOUR TREATMENT USING THE OCS™ LUNG SYSTEM

Before the Lung Transplant Procedure

As the recipient, you do not have to do anything differently to undergo transplantation with the donor lungs preserved using the OCS™ Lung System as compared to donor lungs preserved using cold storage. Your doctor and care team will describe all steps necessary for your transplant procedure.

Before your surgery, a transplant team will retrieve the donor organ. The donor lungs will be placed in the OCS™ Lung System and supplied with warm, oxygenated, nutrient-rich blood-based solution. The donor lungs will begin breathing and remain on the OCS™ Lung System during preservation and transportation to the hospital. The transplant team will monitor the lungs' condition throughout the preservation period and will decide whether the lungs are suitable for transplantation.

During and After the Lung Transplant Procedure

Lung transplantation with lungs preserved using the OCS™ Lung System is identical to a transplant in which the donor lungs are preserved using cold storage. Your care after surgery is exactly the same as it would be if you had received lungs that were preserved using the standard approach of cold storage.

Patients receiving donor lungs preserved with the OCS™ Lung System may experience the following side effects, including those experienced with any lung transplant:

- Death
- Kidney failure or dysfunction
- Respiratory dysfunction/infection
- Primary graft dysfunction (PGD)
- Acute rejection
- Cardiac arrhythmia
- Bronchiolitis Obliterans Syndrome (BOS – obstructive lung disease of the small airways)
- Bronchial stenosis/dehiscence (restricted airways).

PRECAUTIONS

The safety and effectiveness of the OCS™ Lung System is based upon clinical evaluations ≤ 5 years after organ preservation and transplantation. The impact of OCS™ Lung System organ preservation on longer-term clinical outcomes (e.g., incidence of bronchiolitis obliterans syndrome (BOS) and longer-term post-transplantation survival) is unknown. Users are advised to carefully review the available clinical data in Appendices A and B of the Clinical User Guide when considering use of the OCS™ Lung System for any donor organs and recipients.

Safety and effectiveness of the OCS™ Lung System for the preservation of isolated single-lung donor organs has not been evaluated. The Clinical User Guide only includes instructions intended for the preservation of en-bloc double-lung donor organs.

The safety and effectiveness of the OCS™ Lung System has not been studied in recipients with the following:

- Single lung transplant
- Prior solid organ or bone marrow transplant
- Multi-organ transplants
- Chronic use of hemodialysis or diagnosis of chronic renal failure requiring dialysis.

Safety and effectiveness of the OCS™ Lung System has not been studied for donor organs with:

- Hepatitis B and Hepatitis C
- Presence of confirmed active pneumonia or persistent purulent secretions on repeated bronchoscopy evaluation or ET suction.

A device malfunction or user error could lead to a potential loss of a donor organ.

Only trained users are allowed to use the OCS™ Lung System.

CONTACT INFORMATION

For more information on a lung transplant with the OCS™ Lung System, please contact TransMedics, Inc. by mail, by phone, or online as shown below.

By Mail: TransMedics, Inc.
200 Minuteman Road
Suite 302
Andover, MA 01810

By Phone: In the United States: 978.552.0900

Online: www.transmedics.com

See instructions for use for indications, contraindications, warnings, precautions, and adverse events.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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