Lung Transplantation with the OCS™ (Organ Care System) Lung System

Bringing Breathing Lung Preservation to Transplant Patients

A Guide for You and Your Family

TransMedics®

ABOUT THIS BOOKLET

This booklet was created for patients like you who have been diagnosed with end-stage lung failure and are candidates for a lung transplant. It contains information that will help you and your family learn about options available to you for a transplant. This booklet includes information on your lungs, how they function, and respiratory failure. In addition, you will learn about a new way to preserve lungs before transplantation, called ***breathing lung preservation***.

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.

The booklet explains:

- Breathing lung preservation with the ***OCS™ Lung System***
- How the OCS™ Lung System works
- Who is eligible for the OCS™ Lung System
- Lung transplant complications
- How the lungs function
- What is respiratory failure and the treatment options
- What to expect during your treatment
- Summary of clinical data for the OCS™ Lung System
- Contact Information

Please read this booklet carefully and share it with your family and caregivers. For your convenience, a glossary is provided in the front of this booklet. Terms in the text in ***bold italics*** are explained in the glossary.

If you have questions about the OCS™ Lung System that are not answered in this booklet, please ask your physician.

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.

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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
Acute respiratory distress syndrome (ARDS)	A condition that prevents enough oxygen from getting to the lungs and into the blood
Adverse events	Unwanted and usually harmful outcomes; they can be classified as serious or non-serious
Alveoli	Tiny sacs within the lungs that allow oxygen and carbon dioxide to move between the lungs and bloodstream
Amyotrophic lateral sclerosis	Sometimes called Lou Gehrig's disease, this is an irreversible, fatal disease that attacks the part of the body (nerve cells or neurons) responsible for controlling muscle action, such as movement in the arms, legs, and face
Breathing Lung Preservation	A method for preserving donor lungs using the OCS™ Lung System. While on the OCS™ Lung System, the donor lungs are warm, breathing, and nourished with oxygen- and nutrient-rich blood as the lung is being transported to the recipient (the person who receives the transplant)
Bronchial Anastomotic Complication	A type of problem that may occur after lung transplantation at the location of the anastomosis, the surgical connection made during the transplantation
Bronchiolitis Obliterans Syndrome (BOS)	Lung disease characterized by airway blockage. With this disease, inflammation (swelling) and scarring occurs in the airways of the lung, resulting in severe shortness of breath and dry cough
Composite	Made up of several parts; for example, a study result that includes both patient survival and absence from PGD
Chronic Obstructive Pulmonary Disease (COPD)	An irreversible lung disease that makes it difficult to breathe
Chronic Respiratory Failure	Long-term (chronic) failure of the process in which oxygen passes from the lungs into the blood (denying the body's organs, such as the heart and brain, of the oxygen-rich blood that they need to perform well)
Cold Storage 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
Cystic Fibrosis	A disorder that affects mostly the lungs but also the pancreas, liver, kidneys and intestine. Long-term issues include difficulty breathing as a result of build-up of mucus in the lungs and frequent infections
Incidence	The number of times something happens or develops; for example, the number of times that PGD occurs
Intensive Care Unit (ICU)	A special department of the hospital that provides intensive care medicine
Ischemia	A medical term to describe a lack of blood supply to an organ or part of the body; this can cause a shortage of oxygen needed to keep tissue alive.

Term	Meaning
ISHLT	International Society of Heart and Lung Transplantation, a not-for-profit, organization dedicated to improving the care of patients with advanced heart or lung disease
Lung Transplantation	Surgical procedure in which a patient's diseased lungs are partially or totally replaced by lungs from an organ donor
Medical Device	A machine or instrument used to prevent or treat disease
Muscular Dystrophy	A group of diseases that cause increasing weakness and loss of muscle mass, as well as difficulty breathing in some people
Nasal Cannula	Two small plastic tubes, or prongs, that are placed in the nostrils
OCS™ Lung System	A system designed to preserve and ventilate donated lungs outside of the human body from the time of placement on the system to transplant into the recipient.
Pneumonia	An infection of one or both lungs
Primary Graft Dysfunction (PGD)	A severe form of damage to the lungs that is a major cause of early disease and death after lung transplantation. PGD is assigned an ISHLT (see above) grade, and Grade 3 is the most severe
Pulmonary Embolism	A blockage of one of the major arteries (the pulmonary artery) of the lungs
Respiratory Distress	Difficult breathing and the anxiety (distress) that often accompanies it
Respiratory Failure	A condition in which not enough oxygen passes from the lungs into the blood. This denies the body's organs, such as the heart and brain, of the oxygen-rich blood that they need to perform well
SAE	Serious adverse event
Severe donor lung injury with air leak	Damage to the donor lung observed by doctors by using x-ray, or by examining the lung in the donor's chest to confirm an air leak
Tracheostomy	A surgical incision in the trachea (windpipe) that is created when there is something blocking the ability to breathe
Ventilator	A machine that breathes for a person unable to breath on his or her own

1. WHO IS ELIGIBLE FOR THE OCS™ LUNG SYSTEM (INDICATIONS FOR USE)

The TransMedics® Organ Care System™ Lung System is a portable organ perfusion, ventilation, and monitoring ***medical device*** intended to preserve donor lungs in a near physiologic, ventilated, and perfused state for transplantation.

Any adult who has been registered on the transplant waiting list by his or her doctor is eligible to receive a donor lung preserved using the OCS™ Lung System. Talk to your doctor about whether the OCS™ Lung System may be the right option for you.

2. HOW THE OCS™ LUNG SYSTEM WORKS

The OCS™ Lung System allows for 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 ventilated. The system pumps oxygenated, nutrient-rich blood through the ventilated 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:

- Reduce damage to the lungs by keeping them warm and nourished during transport from the donor to the recipient
- Ventilate the lungs so they continue to "breath" during transport
- Allow your doctor to continuously monitor and assess the lungs to ensure suitability for transplantation

Because lungs are kept warm and ventilated, they may be better able to withstand longer periods outside of the body and be less vulnerable to damage during transportation.

Section 5 below provides background information about the lungs.

OCS™ Lung System

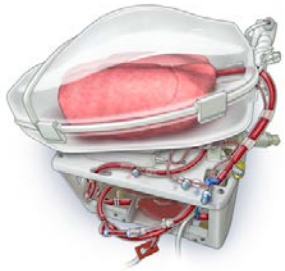
The OCS™ Lung System is fully contained and portable. Everything needed to keep the lungs warm and breathing is stored on board, including oxygen. The system runs on battery power for easy transportation in a car, helicopter, or airplane.

Major components of the OCS™ Lung System:

OCS™ Wireless Monitor

A wireless monitor displays and controls the system's functions. The monitor also provides important information to allow the doctor to assess the lungs with a variety of parameters during transport. Monitoring starts as soon as the lungs are placed on the OCS™ Lung System and ends when the lungs are removed from the system, just before transplant.

OCS™ Lung Perfusion Module



Within the OCS™ Lung System is a clear, sterile chamber called a Lung Perfusion Module. This module, which houses the lungs, is designed to provide protection and nourishment with warm, oxygenated, nutrient-rich blood during transport.

OCS™ Lung Solution

The OCS™ Lung System also contains OCS™ Lung Solution. Because the lungs are kept warm and ventilated outside of the body, they continue to use nutrients just as they would inside of the body. The OCS™ Lung Solution is designed to deliver nutrients required to keep the lungs healthy during transport.

3. WHO SHOULD NOT RECEIVE THE OCS™ LUNG SYSTEM (CONTRAINDICATION)

Use of the OCS™ Lung System is contraindicated for moderate to ***severe donor lung injury with air lea***k to avoid:

- Leakage of fluid at the injured area. If fluid leaks into the airways, it could cause edema (swelling).
- Problems caused by the air leak when trying to re-expand a collapsed donor lung.

4. BENEFITS AND RISKS

4.1. Benefits - How the OCS™ Lung System Can Help You

Because the OCS™ Lung System keeps the lungs warm and ventilated, they may be better able to withstand longer periods outside of the body and be less vulnerable to damage during transportation.

The clinical benefits are demonstrated by the clinical results summarized in Section 7 below. In the OCS™ Lung INSPIRE Study, several benefits were associated with using the OCS™ Lung System together with the OCS™ Lung Solution to preserve donor lungs as compared to cold storage. Key benefits included significantly greater patient survival in the 30 days following the transplant together with a significant reduction in the rate of ***Primary Graft Dysfunction (PGD) Grade 3*** in the first 72 hours following the transplant.

Numerous studies have shown a relationship between PGD and early disease and death after lung transplantation. Some researchers believe that PGD may be related to the development of ***bronchiolitis obliterans syndrome (BOS)***, which affects long-term survival of lung transplant recipients and lacks treatment that works all of the time. No other system or method of lung preservation has demonstrated an impact on the rate of PGD in lung transplant recipients.

4.2. Potential Risks of Lung Transplantation

All surgical procedures have potential risks. The potential risks of a transplant with breathing lung preservation on the OCS™ Lung System are the same as those with a normal transplant procedure using cold storage preservation.

It is important that you understand the potential risks associated with lung transplantation.

So, if you are unclear about any of these risks, please discuss them with your doctor.

The following potential serious risks are associated with lung transplant procedures and have been noted within the first 30 days after lung transplant:

- Acute rejection
- Arrhythmia
- Bleeding (major)
- Hemodynamic instability
- Death
- Fever
- Primary Graft Dysfunction (PGD) as defined by ISHLT during the first 72 hours post-lung transplant
- Respiratory failure
- Graft failure
- Focal or systemic major infection (bacterial, viral, fungal)
- Sepsis
- Emphysema
- Tracheobronchitis/pneumonitis/pneumonia
- Renal dysfunction
- Hyperammonaemia
- Malignancy (post-transplant lymphoproliferative disorder (PTLD))
- Multiple organ failure
- Myocardial infarction
- Neurological dysfunction
- Hepatic dysfunction
- Pancreatitis, peptic ulceration
- Gastroesophageal reflux disease (GERD)
- Aspiration
- Pneumothorax
- Hemothorax
- Pleural bleeding

- Pleural effusion
- Airway anastomotic complications (focal infection, necrosis/dehiscence, stenosis)
- Venous thromboembolism (deep venous thrombosis [DVT])
- Pulmonary embolism (PE)
- Pulmonary infarction
- Wound dehiscence
- Organ deemed not transplantable after retrieval

In addition, regardless of the method used to preserve the donor lungs, there is a risk of receiving a lung that does not function properly. As with any medical device, there is also a risk of side effect that may be extremely rare or unknown prior to treatment.

5. ABOUT THE LUNGS

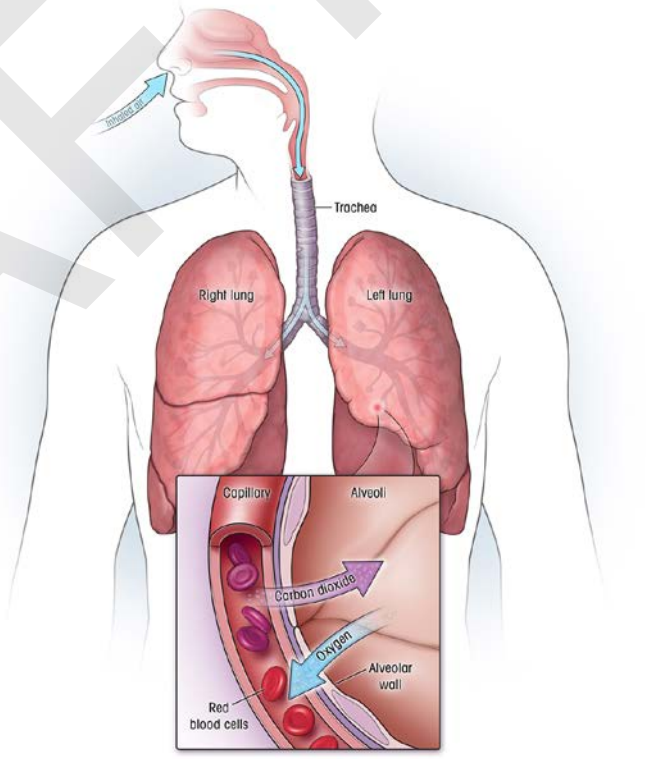
5.1. How the Lungs Work

The air that you breathe in through your nose or mouth travels down through your trachea (windpipe) into two tubes in your lungs called bronchial tubes or airways.

The windpipe and the bronchial tubes look like an upside down tree. The windpipe is the trunk. The airways look like the tree branches.

The two bronchial tubes split into thinner tubes called bronchioles. The bronchioles end in tiny air sacs called ***alveoli***. When the air that you have breathed in reaches these air sacs, the oxygen in the air passes through the air sac walls into the blood in small blood vessels called capillaries. At the same time, carbon dioxide (a waste gas) moves from the capillaries into the air sacs. This process is called gas exchange.

The oxygen-rich blood in the capillaries then flows through larger veins to the heart. Your heart pumps the oxygen-rich blood to all of your body's organs, which cannot function without oxygen.



5.2. Respiratory Failure

If you or someone you love is living with ***respiratory failure***, you are not alone. According to the National Institutes of Health (NIH), approximately 12 million adults in the U.S. are thought to be living with ***Chronic Obstructive Pulmonary Disease (COPD)***, the most common cause of respiratory failure, and an additional 12 million adults in the U.S. are thought to have undiagnosed COPD. Lung diseases cause an estimated 235,000 deaths each year.

5.3. What Causes Lungs to Fail?

A number of conditions can lead to respiratory failure. These conditions, and examples of each, are included below.

Conditions that affect the flow of air in and out of the lungs:

- ***COPD***
- ***Cystic Fibrosis***

Conditions that affect gas exchange in the alveoli:

- ***Acute respiratory distress syndrome (ARDS)***
- ***Pneumonia***

Conditions that affect the flow of blood into the lungs:

- ***Pulmonary embolism***

Conditions that affect the nerves and muscles that control breathing:

- ***Muscular dystrophy***
- ***Amyotrophic lateral sclerosis (ALS)***
- Spinal cord injuries
- Stroke

Conditions that affect the areas of the brain that control breathing:

- Stroke
- Drug or alcohol overdose

5.4. Symptoms of Respiratory Failure

The signs and symptoms of respiratory failure depend on its underlying cause and the levels of oxygen and carbon dioxide in the blood. Accordingly, people in ***respiratory distress*** or failure experience some combination of the following:

- Shortness of breath
- Air hunger (feeling like you cannot breathe in enough air)
- Bluish color on the skin, lips, and fingernails
- Rapid (fast) breathing
- Confusion
- Sleepiness
- Loss of consciousness
- Arrhythmias (irregular heartbeats)

5.5. Treating Respiratory Failure

Chronic respiratory failure typically develops over a long period of time and requires long-term treatment. A key objective of treating respiratory failure is to deliver oxygen to your lungs and other organs and to remove carbon dioxide from your body. To this end, a number of options exist.

Treatment options are described below.

5.5.1. Oxygen Therapy

Oxygen is delivered through a ***nasal cannula*** (two small prongs or tubes), or through a mask that fits over your nose and mouth.

5.5.2. Tracheostomy

Oxygen can also be delivered through a ***tracheostomy***. In this case, a breathing tube is placed in the hole to help you breathe.

5.5.3. Ventilation

If the oxygen level in your blood does not increase, or if you are still struggling to breath, your doctor may recommend ***ventilator*** support. A medical professional will control the ventilator to ensure your lungs get the proper supply of oxygen and to prevent injury to your lungs.

5.5.4. Lung Transplantation

If your condition is severe, your doctor may consider ***lung transplantation***, which replaces one or both lungs with a healthy lung or lungs from a donor. Lung transplantation has become the standard therapy for those who have irreversible respiratory failure and who are likely to benefit most from donor lungs. Lung transplantation is the only lasting treatment for the late stages of respiratory failure.

Lung transplantation can be very successful. Compared with patients who receive only medical treatment, transplant recipients have fewer hospitalizations, better quality of life, more gainful employment, and longer survival. About 87 out of 100 people who have a lung transplant survive for at least 1 year. About 69 people out of 100 survive 3 years.[1]

Unfortunately, the number of donor lungs is limited. In the United States, approximately 4,000 people are currently waiting for a lung or lungs while fewer than 2,000 lung transplantation procedures are performed annually.[2]

Because of this difference, a waiting list for a lung transplant has been established. Unfortunately, it is difficult to predict how long a patient will remain on the waiting list before a donor lung becomes available. The waiting time is dependent on several factors including the urgency for transplantation, size of the lungs, and blood type. The waiting time may vary from several days when a lung is needed immediately, to months or even years.

The gap between the number of people who could benefit from a transplant and the available number of donor lungs is a significant challenge for transplant programs worldwide.

[1] ISHLT Transplant Registry Quarterly Reports for Lung in North America. Survival Rates for Transplants performed between April 1, 2010 and March 31, 2014. ISHLT data as of January 15, 2016.

[2] Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients(SRTR). OPTN/SRTR 2013 Annual Data Report. Rockville, MD: Department of Health and Human Services, Health Resources and Services Administration; 2014.

5.6. Different Types of Donor Lung Preservation for Transplantation

Transplantation with ***cold storage preservation*** of donated lungs is used most commonly today. In this scenario, once the lungs are removed from the donor, they are cooled and preserved on ice, usually in a cooler, until they arrive at the hospital. In the absence of nutrient-rich, oxygenated blood, cooling the lungs helps reduce damage. The lungs are then gradually warmed before placement in the recipient. While cold storage helps preserve the lungs during transport, not all lungs can withstand the effects of cold storage and, thus, cannot be used for transplant. Cold storage is described in more detail below.

Another option for donor lung preservation is ***breathing lung preservation for transplantation***. This type of preservation is obtained with the OCS™ Lung System. Instead of cooling the donated lungs on ice, the organs are placed on the OCS™ Lung System – a machine that keeps them warm and supplies them with oxygenated, nutrient-rich blood during transport. Because the lungs are warm and ventilated with oxygen, they continue to "breath." Lungs preserved in this manner can be kept outside of the body with less impact to their function than with cold storage. Additionally, because the lungs are breathing, a doctor can assess their function and suitability for transplant.

5.6.1. What is Cold Storage?

Since the arrival of organ transplantation, the foundation of organ preservation has been cold storage preservation, which, as we stated above, is placing organs on ice for transport to the recipient. Although this method is intended to reduce the extent of organ damage during transport, significant deterioration of the donated organ may still occur.

The Narrow Window of Time for Safe Transport

The longer the organ is kept on ice, the greater the potential for damage. If too much time passes, the organ will become unusable. Therefore, most lung transplants are performed within six hours of removal from the donor. This restricts the geographic distance allowed between donor and recipient. In some cases, healthy donor organs go unused because there are no matching recipients located close enough to receive the organ in time.

The Possibility of Compromised Lung Function

Even when an organ can be transplanted within the narrow time frame for safe storage on ice, the organ may suffer some degree of damage.

Your doctor will carefully consider accepting a lung for transplantation, weighing many factors, including how well the organ will tolerate cold storage. If the potential for damage is too great, your doctor will decline to transplant that organ. In fact, many organs are not used for this reason.

Inability to Test the Organ for Function

Because lungs transported using cold storage are not breathing, assessing organ function and suitability for transplant can be very difficult.

Given the limitations of cold storage, it is estimated that only about 20% of consented donor lungs in the U.S. are transplanted despite being donated for this purpose.[3]

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

6.1. Before the Lung Transplant Procedure

As the recipient, you do not have to do anything differently to undergo transplantation with the donated lungs preserved using the OCS™ Lung System as compared to the donated lung preserved using cold storage. Be prepared to travel to the hospital as soon as you are notified of a potential donor. Once at the hospital, you will begin preparation for surgery. You will undergo a physical exam, your blood will be drawn, and you will be asked to provide a urine sample. Your chest will be cleaned and shaved in order to reduce the risk of infection. An intravenous line will be placed in your arm for easy administration of medications. You will be given general anesthesia so that you will sleep through the surgery as well as immunosuppressant medications to prevent your body from rejecting your new lungs.

Before your surgery, a transplant team will retrieve the donor organ. The donor lungs will be placed in the OCS™ Lung System and hooked up to receive a supply of warm, oxygenated, nutrient-rich blood. The donor lungs will begin breathing, and remain on the OCS™ Lung system as they are transported to the hospital. The transplant team will monitor the function of the lungs for the duration of the trip. If the lungs are deemed suitable, the transplant procedure will begin.

6.2. During the Procedure

Lung transplantation with lungs preserved using the OCS™ Lung System is very similar to a transplant in which the donor lungs are preserved using cold storage.

During surgery, your chest will be opened and your main arteries will be connected to a heart-lung bypass machine to pump your blood and a ventilator to help you breathe. Then, your diseased lungs will be removed.

The donor lungs will be disconnected from the OCS™ Perfusion Module and placed in your chest. Your trachea and pulmonary artery will then be connected to your new lungs. As this point, the heart-lung bypass machine will be removed and your incisions will be closed. The procedure usually takes four to six hours.

[3] OPTN 2011/Scientific Registry of Transplant Recipients (SRTR) 2011 Annual Report: Transplant data 2011.

6.3. After the Procedure

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.

Your doctor and nurses will move you to the Hospital's ***Intensive Care Unit (ICU)***, where you will be closely monitored. You will remain on medication to manage pain, and may remain on a ventilator to help you breathe. You may have tubes inserted into your chest to drain any fluids that accumulate around your lungs and heart.

Most patients remain in the hospital for one to two weeks following the transplant procedure. After leaving the hospital, you will be monitored at your outpatient transplant center for about three months. During this time, you will have regular tests to measure how your new lungs are functioning.

You will also need to take daily medication to prevent the body from rejecting the new lungs. These drugs decrease the activity of your immune system to prevent it from attacking your new lungs. Because your immune system may never completely accept the new organ, you'll take some of these medications for the rest of your life.

6.4. What Happens if the OCS™ Lung System Works Poorly or Fails?

Since the OCS™ Lung System will be continuously under the care of a transplant team from the donor to the hospital, this team will monitor its performance. If the system begins to perform poorly or fails, the transplant team will try to make changes to resolve the problem.

7. OCS™ LUNG SYSTEM CLINICAL STUDY RESULTS

7.1. Study Overview

A clinical study was conducted to study the safety and effectiveness of the OCS™ Lung System. This study, called the OCS™ Lung INSPIRE Study, was conducted to evaluate donor lung preservation on the OCS™ Lung System compared to the cold storage method.

The study involved patients who had a lung transplant across 21 centers in the United States, Canada, Europe, and Australia. There are a total of 319 patients in the "safety" population and a total of 306 patients in the "per-protocol" population. The "per-protocol" patients are the safety patients minus those removed from the dataset because of major protocol violations (e.g., did not meet study inclusion criteria).

The study patients fell into one of the following groups:

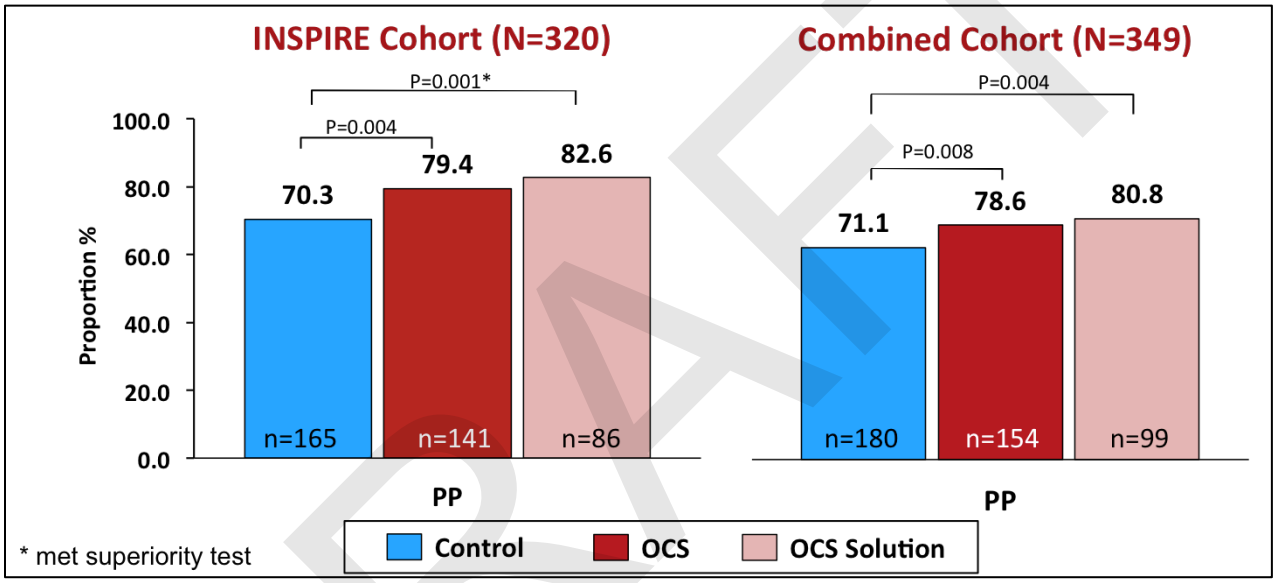
- **Control Group**: These are patients who received lungs preserved using standard cold storage.
- **OCS Group**: These are patients who received lungs preserved with the OCS™ Lung System. There were two solutions used as part of the OCS Group in this clinical study:
  - Commercially available Low Potassium Dextran (LPD) Lung Storage Solution – This was the solution used at the beginning of the study.

– OCS Lung Solution – This is the solution that will be sold as part of the OCS™ Lung System. This subgroup is the most important one, so results will be shown for this subgroup in addition to the Control Group and the OCS Group.

7.2. Primary Effectiveness Endpoint

The primary effectiveness was a ***composite*** of patient survival at day 30 post-transplantation and the absence of PGD Grade 3 in the first 72 hours (between 0-72 hours) hours post-transplantation. The results are shown in Figure 1 below for the Control Group (i.e., Cold Storage), the OCS Group (as a whole), and the OCS Lung Solution subgroup for the per-protocol population.

Figure 1: Primary Effectiveness Endpoint Results for PP Population for INSPIRE Cohort (N=320) and Combined Cohort (N=349)



7.3. Safety Endpoint

The safety endpoint was the average number of the following types of serious lung graft-related s***erious adverse event (SAE)*** up to 30 days post-transplantation:

- ***Acute rejection*** (biopsy proven)
- ***Respiratory failure***
- ***Bronchial anastomotic complication***
- Major pulmonary-related infection.

The results are shown in Table 1 below for the Control Group (i.e., Cold Storage), the OCS Group (as a whole), and the OCS Lung Solution subgroup for the per protocol population. There was a lower average number of lung-graft related SAEs for both the OCS Group and the OCS Lung Solution subgroup as compared to the Control Group.

Table 1: Safety Endpoint

Safety Endpoint	Control Group (N= 169)	OCS Group (N=150)	OCS Lung Solution Subgroup (N=89)
Average number of lung graft-related SAEs up to 30-days post-transplantation	0.28	0.23	0.26

The events that make up the primary safety endpoint are described in more detail in Table 2 below for the safety population. The results are shown for the Control Group (i.e., Cold Storage), the OCS Group (as a whole), and the OCS Lung Solution subgroup. The results show that 24% of the Control Group suffered a lung graft-related SAE (LGR SAE) as compared to 20% in the OCS Group and 21% in the OCS Lung Solution subgroup. The most common LGR SAE in the OCS Group was respiratory failure (13%), while the most common LGR SAE in the Control Group was major pulmonary related infection (15%).

Table 2: Safety Endpoint Details

	Safety Population					
Parameter	**Control Group**		**OCS Group**		**OCS Solution Group**	
	Patients (n=169)	**Events (n=48)**	**Patients (n=150)**	**Events (n=37)**	**Patients (n=89)**	**Events (n=25)**
Lung-graft-related serious adverse events -30 days *(combination of individual SAEs below)*	40 (23.7%)	48 (100%)	33 (22%)	37 (100%)	21 (24%)	25 (100%)
Acute Rejection[1]	4 (2%)	4 (8%)	2 (1%)	2 (5%)	2 (2%)	2 (8%)
Respiratory Failure[2]	14 (8%)	14 (29%)	19 (13%)	20 (54%)	11 (12%)	12 (48%)
Bronchial Anastomotic Complications	4 (2%)	4 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Major Pulmonary-Related Infection	25 (15%)	26 (54%)	14 (9%)	15 (41%)	10 (11%)	11 (44%)

[1]Biopsy proven moderate to severe according to the ISHLT working formulation of pathology grading
[2] Impairment of respiratory function requiring re-intubation, tracheostomy or the inability to discontinue invasive ventilatory support within 4 days (96 hours) post-transplant.

7.4. Other Study Findings

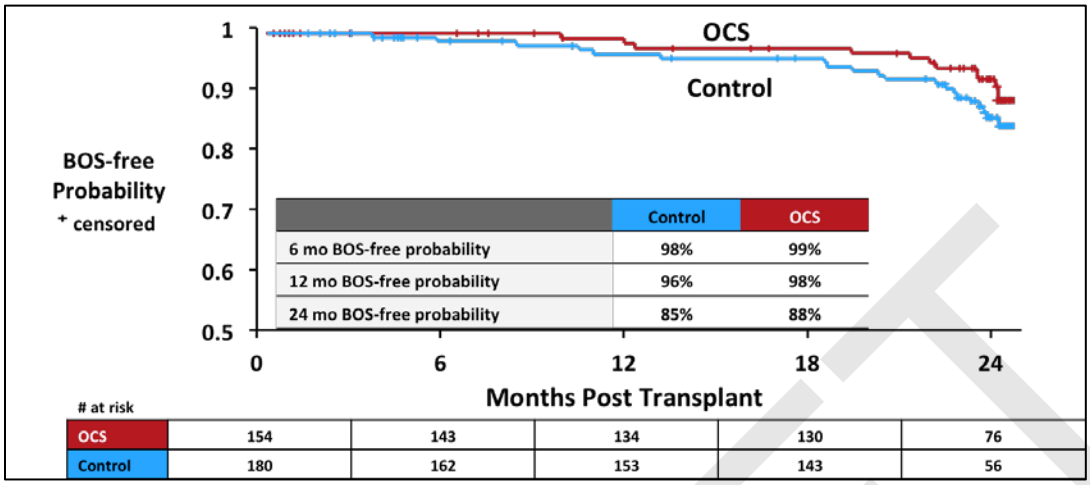
In addition to the primary effectiveness and safety endpoints discussed above, other important results from the study for the per-protocol population include the following.

Bronchiolitis Obliterans Syndrome (BOS)

BOS is the most common long-term complication after lung transplantation and is the leading cause of long-term graft failure in lung transplantation. Figure 2 below demonstrates the results of the overall 24-month KM freedom from BOS analysis. The OCS arm showed a numerically

higher percentage of patients who were free from BOS as compared to the Control arm at 24 months (88% for OCS compared to 85% for the control group).

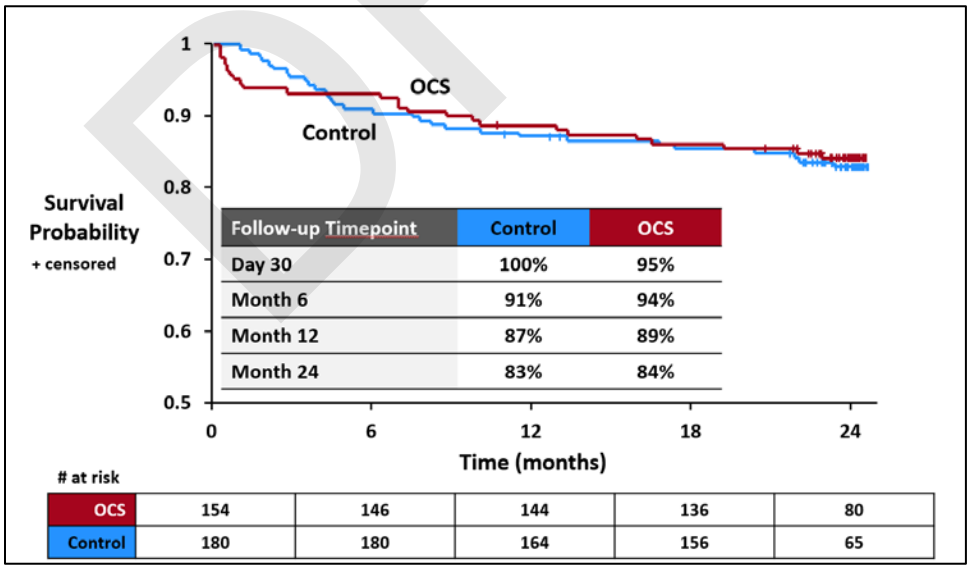
Figure 2: BOS-Free Probability through 24 Months (PP, Combined Cohort)



Long-Term Patient Survival

The study also looked at the longer-term survival of patients up to 2 years after lung transplantation. Patients who undergo a lung transplant are generally very sick before the transplantation. As described earlier, in general about 87 out of 100 people who have a lung transplant (87%) survive for at least 1 year.[4] Figure 3 below demonstrates the results of the Kaplan-Meier (K-M) survival analyses through 24 months for the Combined Cohort (PP Population), with the point estimates for each of the assessment timepoints below the graph. The long-term survival of the OCS and Control arms were similar after 24 months of follow-up.

Figure 3: K-M Survival for OCS and Control groups at 24 Months (Combined Cohort PP Population)



[4] ISHLT Transplant Registry Quarterly Reports for Lung in North America. Survival Rates for Transplants performed between April 1, 2010 and March 31, 2014. ISHLT data as of January 15, 2016.

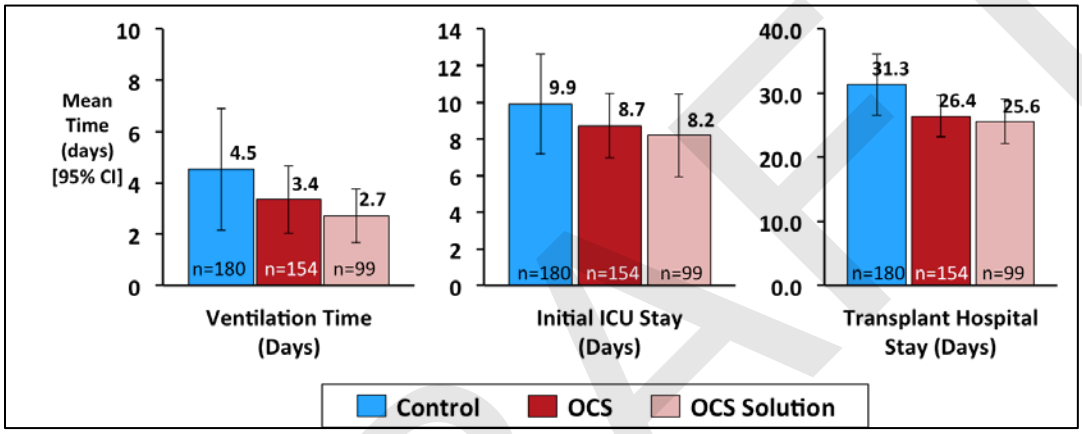
Other Findings

The study also showed the following trends for both the OCS Group and the OCS Lung Solution subgroup versus the Control Group (i.e., Cold Storage)**:**

- Lower duration of post-transplant mechanical ventilation (a method to help patients breathe by using a ventilator, or pump)
- Shorter length of initial post-transplant ICU stay
- Shorter additional post-discharge hospital admissions (if any) within 6-months post-transplant

These trends are shown in Figure 4 below.

Figure 4: Improvements in Ventilation Time, ICU Time and Hospitalization (PP, Combined Cohort)



8. 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

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. See instructions for use for indications, contraindications, warnings, precautions, and adverse events.

Please address any questions you have about the OCS™ Lung System to your doctor.

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