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

Bringing Breathing Lung Preservation to Transplant Patients

A Guide for You and Your Family

TransMedics®
Bringing new life to organ transplant

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, called breathing lung preservation 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.

The booklet explains:

- Who is Eligible for the OCS™ Lung System
- How the OCS™ Lung System Works
- Risks and Benefits of Using the OCS™ Lung System
- What to Expect During Your Treatment
- Summary of Clinical Data for the OCS™ Lung System
- Contact Information

Please read this booklet. 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.

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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
Adverse Events	Unwanted and usually harmful outcomes; they can be classified as serious or non-serious
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
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
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
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
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
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

Term	Meaning
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
Ventilator	A machine that breathes for a person unable to breath on his or her own

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

The TransMedics® Organ Care System (OCS™) Lung System is a portable organ perfusion, ventilation, and monitoring medical device indicated for the preservation of standard criteria donor lungs in a near physiologic, ventilated, and perfused state for double lung transplantation.

Standard criteria donor lungs are those that are commonly transplanted in US transplant centers today. Any adult who has been registered on the transplant waiting list for double lung transplant 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.

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

Any patient on the lung transplant waiting list for double lung transplantation is eligible to receive their donor lungs preserved with the OCS™ Lung System.

The use of the OCS™ Lung System is contraindicated for donor lungs that have moderate to severe lung injury resulting air leak, as this could result in leakage of fluid and air at the injured area, which will compromise the ability of the OCS™ Lung System to maintain the donor lungs in good condition.

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 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 "breath" 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-transplant clinical outcomes.

OCS™ Lung System

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 of the system are described below.

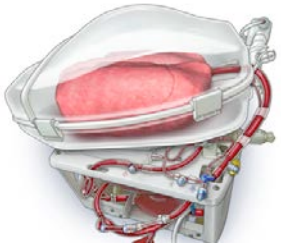
OCS™ Lung Console

The Lung Console is a portable medical device that contains the mechanical and electrical elements required to warm, pump, ventilate, and manage the gas content of the solution that is pumped through the lungs. In addition, it contains software to collect information on the condition of the donor lungs being preserved.

OCS™ Wireless Monitor

The 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 preservation and 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, maintain sterility, and provide nourishment with warm, oxygenated, nutrient-rich blood during preservation. In addition, the module contains all the important sensors to monitor the donor lung function during preservation.

OCS™ Lung Solution

The OCS™ Lung System also includes 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 preservation.

RISKS AND BENEFITS

Potential Risks of using the OCS™ Lung System

WARNING: Safety and effectiveness of the OCS™ Lung System for marginal/extended criteria lungs, including donor lungs subjected to extended preservation times, have not been studied in the INSPIRE Trial.

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. 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 your transplant procedure may be cancelled. In this case, you will have to wait for another donor lung to become available.

In the unlikely event that the system begins to perform poorly or fails, the transplant team will try to resolve the issue immediately. It is also possible that they will not be able to resolve the problem and the OCS™ Lung System will not be used to preserve the donor lungs. In this case, you will most likely receive lungs preserved using cold storage.

The OCS™ Lung System performance will be continuously monitored by a team of 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. In the clinical study of the OCS™ Lung System, this occurred in 1 out of 153 (0.7%) donor lungs preserved on OCS™. If this occurs, your transplant surgery may be cancelled and you may have to wait for new donor lungs to become available. It is 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, in which case the surgeon will most likely preserve the organ with standard cold storage (i.e., placed on ice in a cooler) and you will still receive a transplant.

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 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. In addition, clinicians can monitor the overall condition of the donor lungs throughout preservation and up to the point that the transplantation procedure is initiated.

The results of the OCS™ Lung INSPIRE Trial demonstrated several clinical benefits that were associated with using the OCS™ Lung System to preserve donor lungs as compared to cold storage. Key benefits included:

- Reduction in the rate of the most severe form of patient complication that occurs immediately after lung transplantation - Primary Graft Dysfunction (PGD) Grade 3 (or PGD3) within the first 72 hours following the transplant.
- In addition, the clinical study also showed that the OCS™ Lung System may be associated with: (1) lower duration of post-transplant mechanical ventilation (using a machine for breathing); (2) shorter length of initial post-transplant ICU stay; and (3) shorter post-transplant hospital admissions.
- The clinical study of the OCS™ Lung System also showed that patients who received their lungs preserved on OCS™ Lung System had slightly higher survival without the development of Bronchiolitis Obliterans Syndrome (BOS) at 2 years after transplantation. Additional follow-up is underway to assess this finding.

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 the donor lung 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.

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.

OCS™ LUNG SYSTEM CLINICAL STUDY RESULTS

Study Overview

A large clinical trial was conducted to study the safety and effectiveness of the OCS™ Lung System. This trial, called the OCS™ Lung INSPIRE Trial, was conducted to evaluate donor lung preservation on the OCS™ Lung System compared to the cold storage method. The INSPIRE Trial is the largest clinical study to-date that evaluated breathing lung transplant and its impact on transplant outcomes.

The study involved patients who had a lung transplant across 21 centers in the U.S., Canada, Europe, and Australia.

The study results showed that the OCS™ Lung System is safe and effective in preserving donor lungs for transplantation.

The study patients fell into one of the following groups:

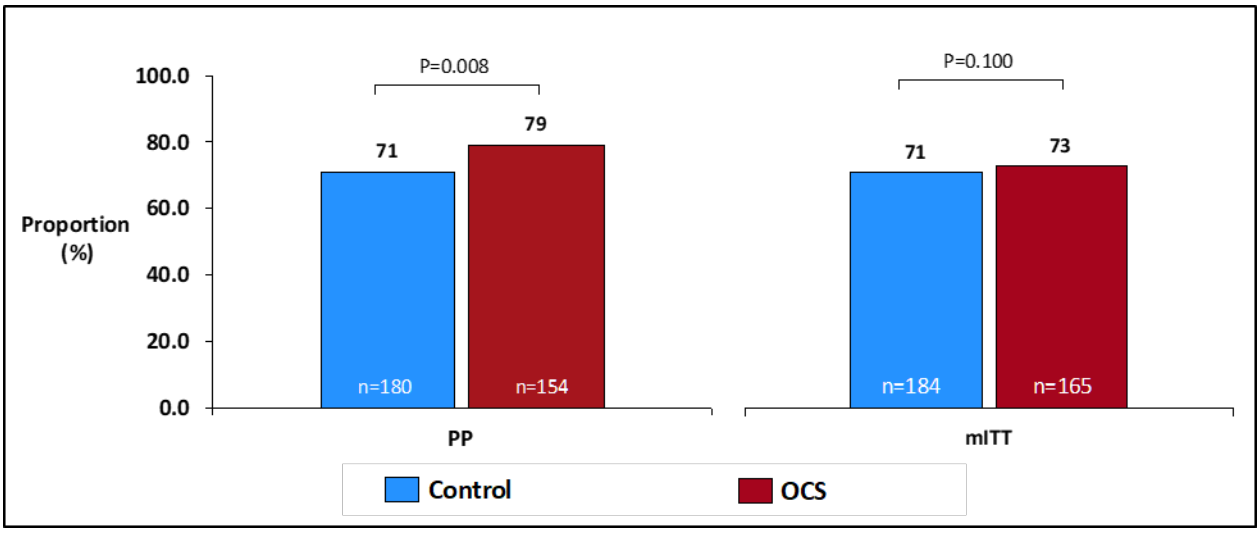
- **Control Group**: These are patients who received lungs preserved using standard cold storage.
- **OCS Group**: These are patients who received lungs preserved with the OCS™ Lung System. The INSPIRE Trial was approved to allow the use of two perfusion solutions in the OCS Group– the OCS™ Lung Solution, made by TransMedics and a commercially available, Low Potassium Dextran solution. Data are presented for the entire OCS Group (patients for whom the OCS™ Lung Solution or the commercially available solution was used). In addition, data are presented for the OCS Solution subgroup. These are patients for whom only the TransMedics OCS™ Lung Solution was used for lung preservation. The OCS™ Lung Solution is the solution that is FDA-approved for exclusive use with OCS™ Lung System perfusion of donor lungs in the U.S.

The data are presented for the per-protocol (PP) population; the "modified Intent-to-Treat" (mITT) population and safety population. The results are also displayed for the OCS Solution subgroup, since it is the FDA-approved product to be exclusively used with OCS™ Lung System.

Primary Effectiveness Endpoint

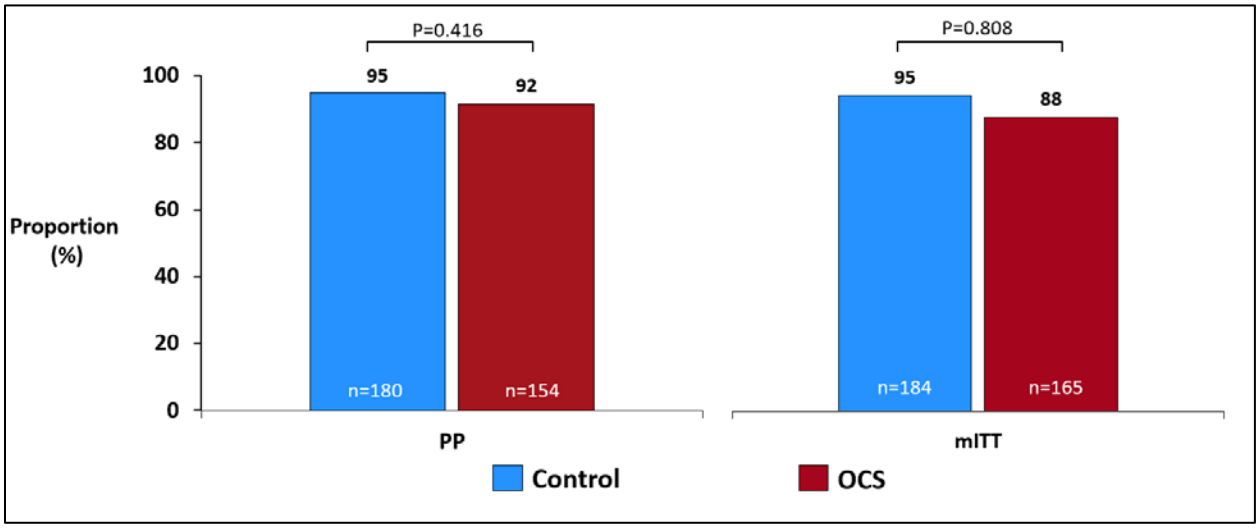
The amended primary effectiveness endpoint was the combination of patient survival at day 30 post-transplantation and being free from the most severe form of PGD (Grade 3) throughout the entire initial 72 hours post-transplantation. The results are shown in Figure 1 below for the Control Group (i.e., Cold Storage) and the OCS Group, for both the mITT and PP populations. The results show that the percentage of patients achieving this endpoint was similar in both groups. The OCS™ Lung System met the statistical test in the PP population but not in the mITT population.

Figure 1: Results for Amended Primary Effectiveness Endpoint: (Survival at 30 Days and Freedom from PGD3 Within 72 Hours Post-Transplant), INSPIRE Combined Cohort



The initial primary effectiveness endpoint consisted of a composite of survival at Day 30 and PGD3 at a single late timepoint - at 72 hours after transplant. The percentage of patients achieving this endpoint was similar in both groups. The statistical test for either the PP or mITT population was not met for this data analysis. (See Figure 2.)

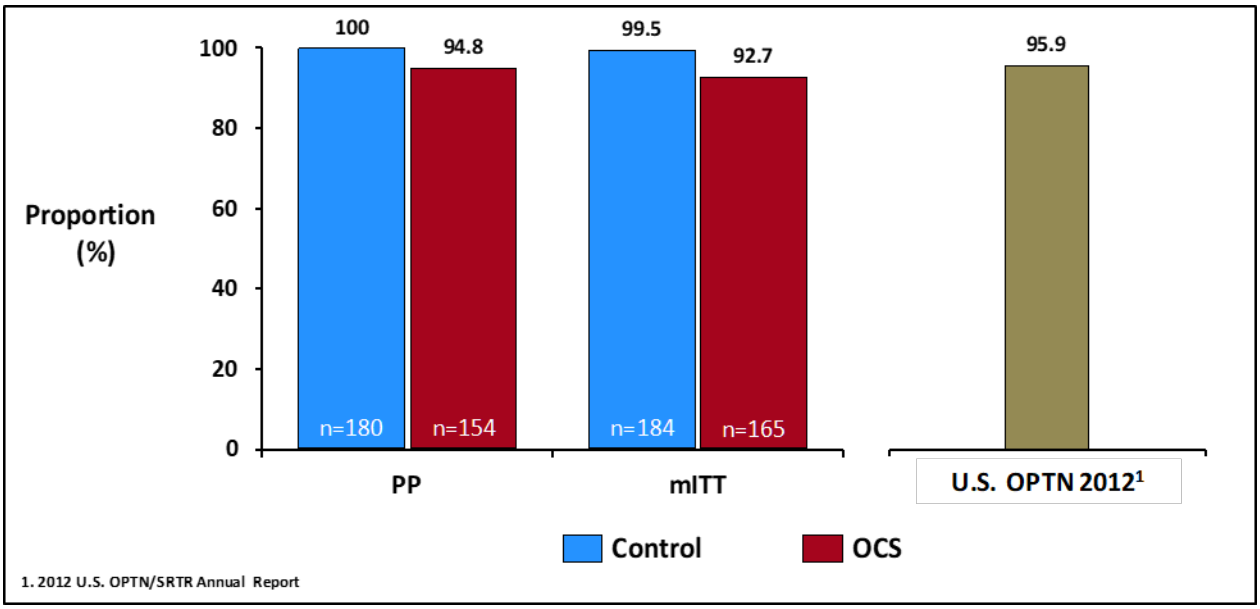
Figure 2: Results for Initial Primary Effectiveness Endpoint: (Survival at 30 Days and Freedom from PGD3 at 72 Hours Post-Transplant), INSPIRE Combined Cohort



Patient Survival

As shown in Figure 3 below, patient survival at 30 days was lower in the OCS group in comparison to the Control group. The green bar in this figure shows the national average 30-day all-cause mortality in lung transplant patients reported in the US in 2012, which is 4.1%. Survival throughout transplant hospital admission, even if longer than 30 days, was similar for the two groups. At 6, 12, and 24 months the survival rate was the same for both groups.

Figure 3: 30-Day Patient Survival in OCS™ and Control patients compared to the National Average in the United States.

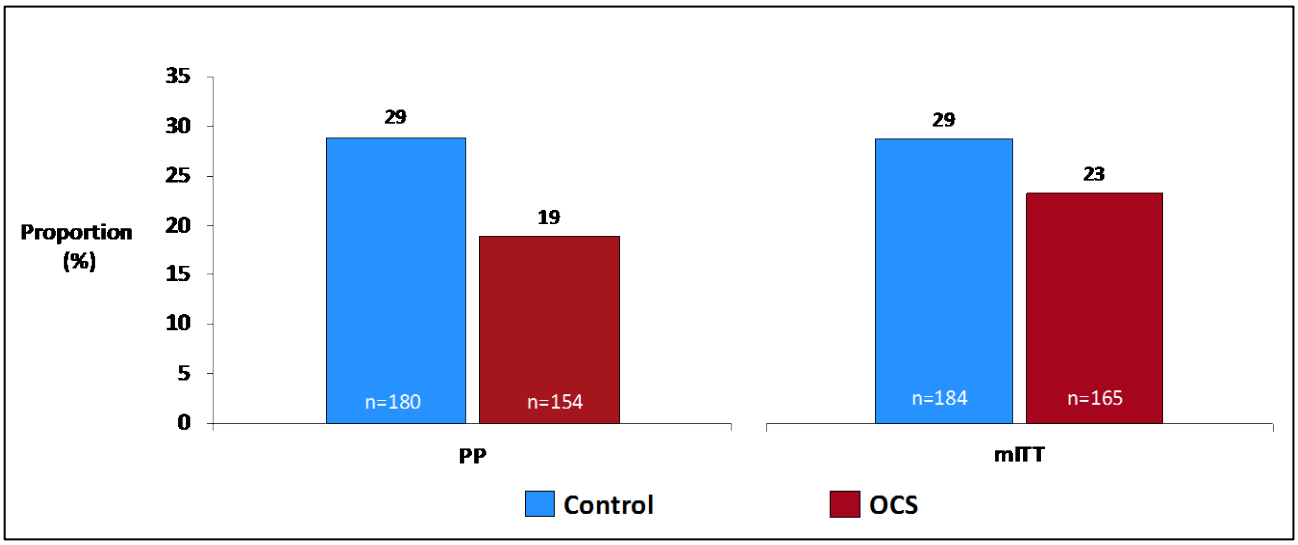


PGD3 Component of the Primary Composite Endpoint – PGD3 within 72 Hours and PGD3 at T72

Figure 4 below provides the results for the other component of the amended composite primary endpoint, i.e., the incidence of PGD3 throughout the entire initial 72 hours post-transplantation.

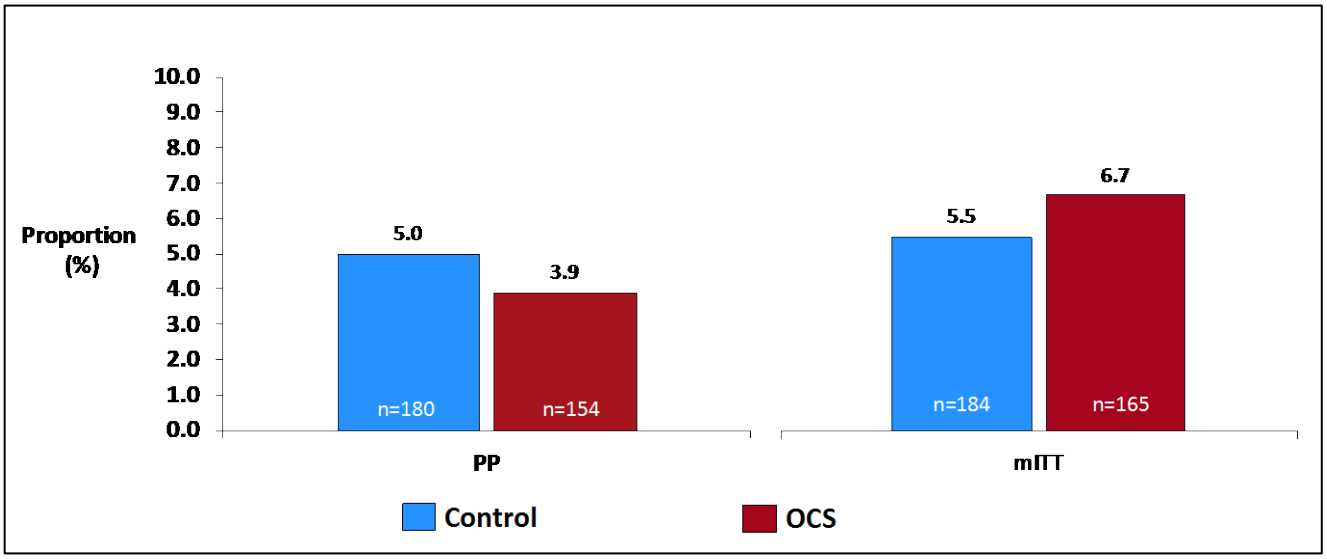
The OCS group experienced less PGD3 within the initial 72 hours as compared to the Control group in the PP and mITT populations. The highest reduction in PGD3 occurred at time zero and there was no difference between the groups in PGD3 at the late timepoint, 72 hours after transplant.

Figure 4: Percentage of Patients with PGD3 within 72 hours (INSPIRE Combined Cohort - PP Population and mITT population)



The results for the other component of the initial composite primary endpoint, i.e., the incidence of PGD3 at T72 are shown in Figure 5 below. The percentage of patients with PGD3 at T72 hours was similar between both groups and was low overall.

Figure 5: Percentage of Patients with PGD3 at T72 hours (INSPIRE Combined Cohort - PP Population and mITT population)



Secondary Endpoints

The study included three secondary endpoints:

- The percentage of patients experiencing PGD3 at 72 hours after transplant (T72)
- The percentage of patients experiencing either PGD grade 2 (PGD2) or PGD3 at 72 hours after transplant (T72)
- Survival at 30 days after transplant.

The percentage of patients experiencing either PGD2 or PGD3 at T72 hours was similar for both groups and was low overall. The statistical test was not achieved for these analyses. The results for survival at 30 days after transplant and PGD3 at T72 were described in the previous sections.

Safety Endpoint

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

- Biopsy proven acute rejection
- Respiratory failure
- Bronchial anastomotic complication
- Major pulmonary-related infection.

The results are shown in Table 1 below for the Control group and the OCS group. The average number of LGRSAEs for the OCS group and the Control group was similar.

The events that make up the safety endpoint are also shown in Table 1. The most common LGRSAE in the OCS group was respiratory failure (14%), while the most common LGRSAE in the Control group was major pulmonary related infection (16%).

Table 1: Safety Endpoint

INSPIRE Combined Cohort (n=349)	Control N=184	OCS N=164
Lung-graft related SAEs, n (%)	45 (24.5)	40 (24.4)
Mean ± SD	0.29 ± 0.54	0.26 ± 0.48
Non-Inferiority p-value		0.042
Type of Lung-graft related SAEs, n (%)		
Acute Rejection	4 (2)	2 (1)
Respiratory Failure*	16 (9)	23 (14)
Bronchial Anastomotic Complication	4 (2)	0
Major Pulmonary-Related Infection	29 (16)	18 (11)

* Need for re-intubation, tracheostomy or the inability to discontinue ventilator support within 4 days post-transplant

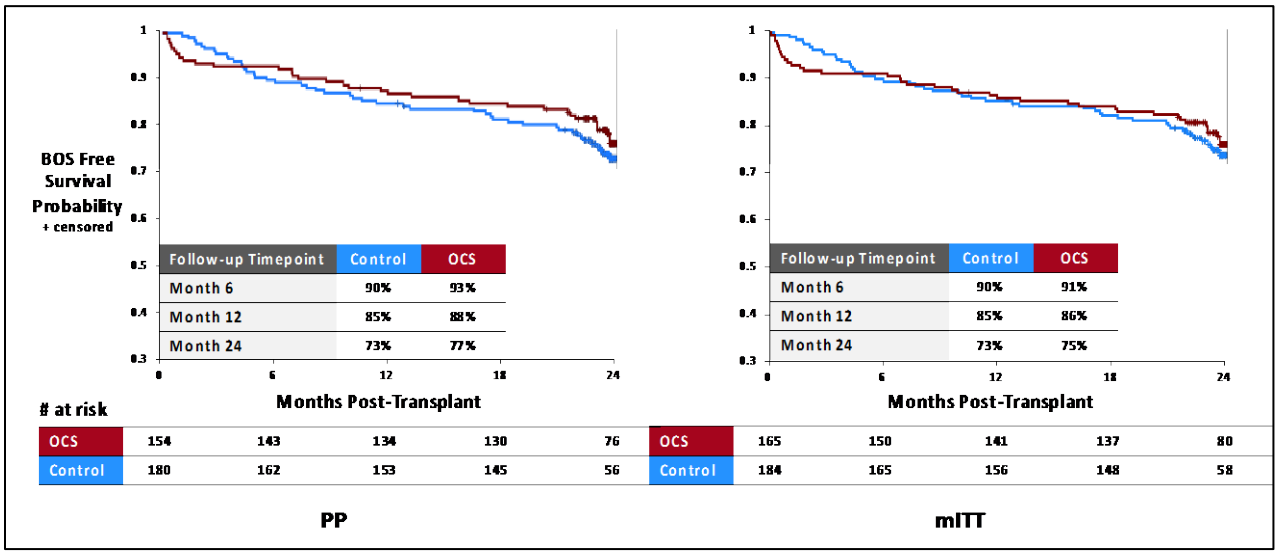
Other Study Findings

In addition to the primary effectiveness and safety endpoints discussed above, other important results from the study 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. The results for patients who survived and were free from BOS were generally similar for both groups. The OCS™ Lung System showed slightly higher BOS-free survival at 24 months after transplantation compared to the cold storage standard of care. These results are shown in Figure 6 below. BOS is a chronic condition that develops between 2 and 5 years following lung transplantation. TransMedics will evaluate this trend for 5 years post-transplant in our post-market study.

Figure 6: BOS-Free Survival Probability through 24 Months (PP and mITT, INSPIRE Combined Cohort)



Other Findings

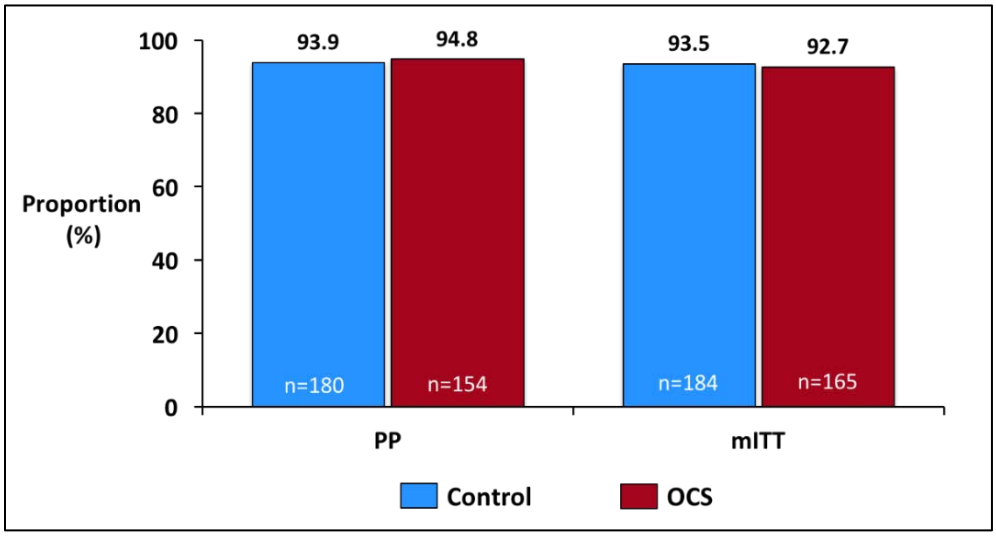
The study also showed the following trends for the OCS group versus the Control group:

- Lower duration of post-transplant mechanical ventilation (using a machine to breathe for the patient)
- Shorter length of initial post-transplant stay in the Intensive Care Unit (ICU)
- Shorter initial post-transplant hospital stay.

Survival through Hospital Discharge

The study showed that the percentage of patients who survived at 30-days after transplant surgery or at hospital discharge after transplant surgery (if longer than 30 days) was similar for the OCS and Control group. This is shown in Figure 7 below.

Figure 7: Comparison of Survival at Day 30 after Transplant or at Hospital Discharge after Transplant (if longer than 30 days), (PP and mITT, INSPIRE Combined Cohort)



OCS Solution Subgroup Results

The OCS Solution subgroup consists of patients who received donor lungs preserved on the OCS System using the OCS™ Lung Solution. Only the OCS™ Lung Solution is approved by FDA for use with the OCS™ Lung System.

As shown in Figure 8 through Figure 11 below, the results for the OCS Solution subgroup for the amended primary endpoint, the initial primary endpoint and the percentage of patients who experienced PGD3 throughout the entire initial 72 hours and PGD3 at T72 hours are similar to the results for the entire OCS group.

Figure 8: Results for Amended Primary Effectiveness Endpoint: (Survival at 30 Days and Freedom from PGD3 Within 72 Hours Post-Transplant), INSPIRE Combined Cohort, Control, OCS Group and OCS Solution Subgroup

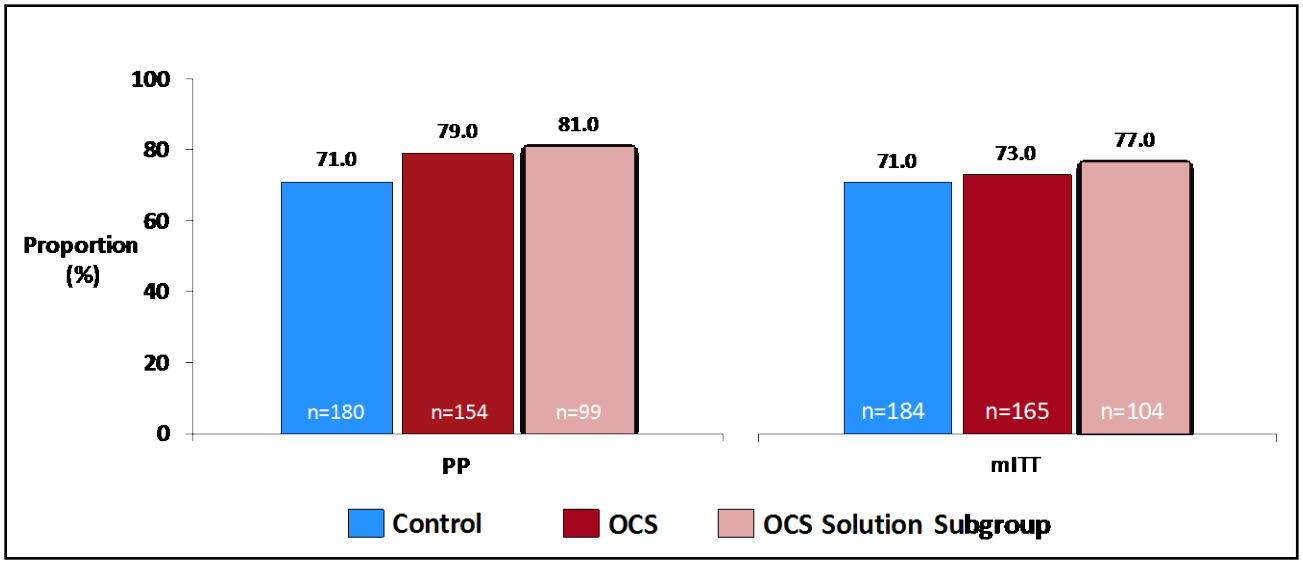


Figure 9: **Results for Initial Primary Effectiveness Endpoint: Survival at Day 30 Post-Transplantation and Absence of ISHLT PGD3 *at* 72 Hours, INSPIRE Combined Cohort, OCS Solution subgroup**

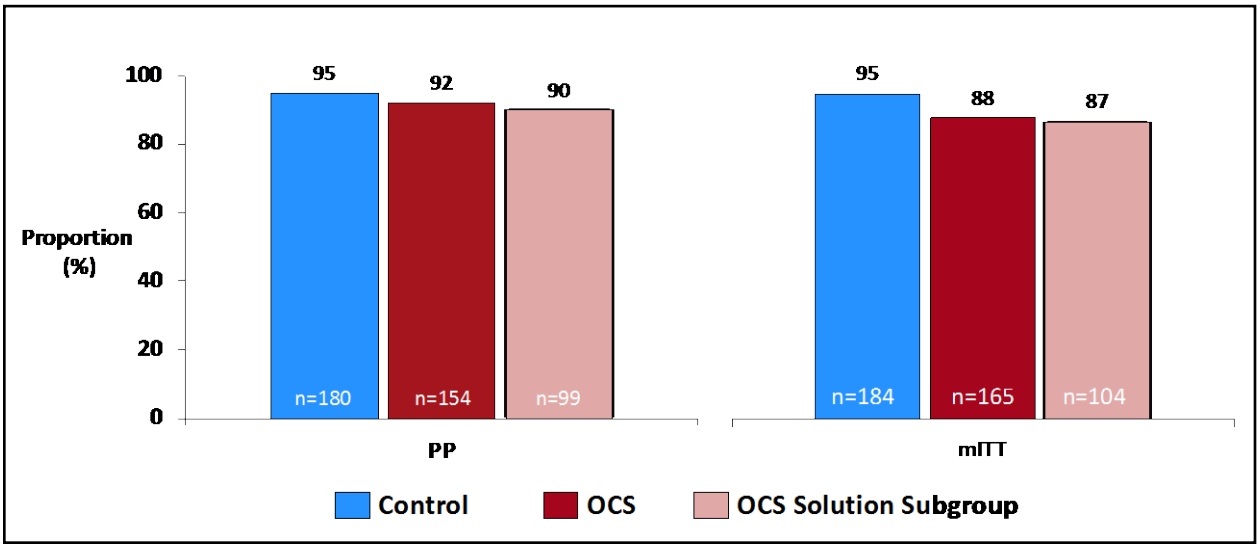


Figure 10: **Percentage of Patients with PGD3 Throughout the Entire Initial 72 hours Post-Transplant (INSPIRE Combined Cohort - PP Population and mITT population, Control, OCS Group and OCS Subgroup)**

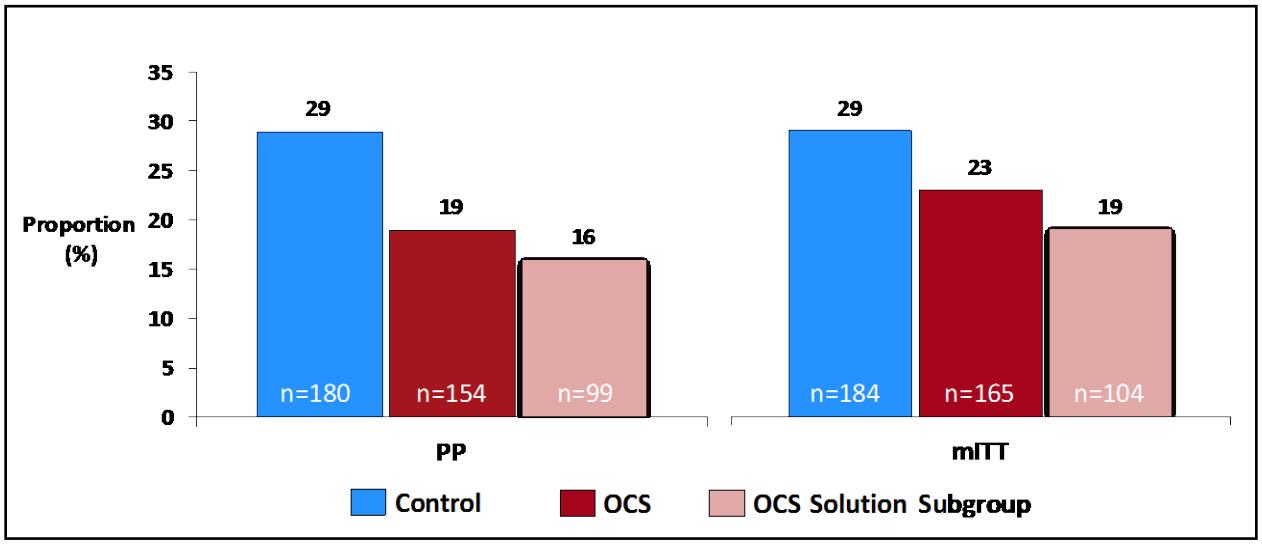
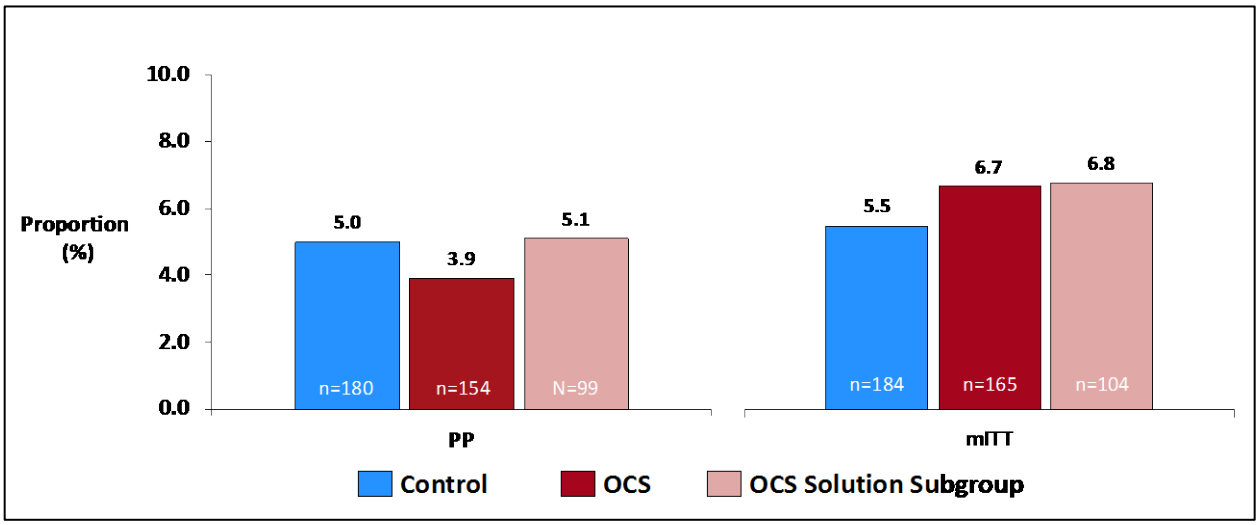


Figure 11: Percentage of Patients with PGD3 at 72 hours after transplant (INSPIRE Combined Cohort - PP Population and mITT population, Control, OCS Group and OCS Subgroup)



PATIENT DECISION CHECKLIST

In Appendix 1, we have provided a patient decision checklist to provide additional understanding of the benefits and risks of lung transplantation with the OCS™ Lung System. Please review this checklist and discuss any questions with your doctor.

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.

TransMedics, Inc.
200 Minuteman Road
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TransMedics®
Bringing new life to organ transplant

APPENDIX 1. PATIENT DECISION CHECKLIST

This document provides additional understanding of the benefits and risks of lung transplantation with the OCS™ Lung System. After reviewing the information in this brochure, please read and discuss the items in this checklist with your doctor. You should not initial or sign the document if you do not understand each of the elements listed below.

Donor Lung Preservation Options

I understand that the OCS™ Lung System allows for a new method of donor lung preservation.

I understand that transplantation with cold storage has been the traditional method for preservation of donor lungs. With the cold storage method, once the lungs are removed from the donor, they are flushed with cold preservation solution and placed on ice, in a cooler, until they arrive at the transplant hospital.

I understand that instead of being placed on ice in a cooler, donated lungs are placed on the OCS™ Lung System, which keeps them at body temperature, oxygenated, and breathing. The system circulates oxygenated, nutrient-rich blood based fluid through the breathing lungs from the time they are placed on the machine at the donor site until they are removed from the machine for transplant into the recipient.

Patient Initials _____

Limitations and Risks of Preservation of Cold Storage

I understand:

- That the cold storage technique has significant limitations that may negatively impact the function and/or viability of the donor lungs.
- In the U.S., based on annual published statistics, once harvested, 6-7% of donor lungs retrieved for transplantation are not used due to preservation and other clinical reasons. (U.S. Scientific Registry for Transplant Recipients – 2015 Annual Report). If this occurs, my transplant surgery may be cancelled and I may have to wait for another donor organ. In the INSPIRE clinical study, none of the organs in the cold storage group were turned down for transplantation after cold storage.

Patient Initials _____

Limitations and Risks of Preservation with the OCS™ Lung System

I understand that I may not receive the organs preserved with the OCS™ Lung System under certain conditions, including:

- Certain donated lungs may not be able to be preserved with the OCS™ Lung System if there is an extensive injury to the donor lung that caused air or blood leak during perfusion.
- The OCS™ Lung System may not work properly, or there may not be personnel available trained in the use of the OCS™ Lung System, in which case the surgeon will most likely preserve the organ with standard cold storage (i.e., placed on ice in a cooler).
- 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. In the clinical study of the OCS™ Lung System, this occurred in 1 out of 153 (0.7%) donor lungs preserved on OCS™. If this occurs, your transplant surgery may be cancelled and you may have to wait for new donor lungs to become available.

Patient Initials _____

Potential Benefits of OCS™ Lung System

I understand that the clinical study demonstrated the following benefits of the OCS™ Lung System:

- There is a reduction in the time during which the donor lungs could be injured from a lack of oxygenated blood supply.
- There is a reduction in the incidence in the most severe complication after lung transplantation – PGD3 throughout the entire initial 72 hours post-transplant - as compared to cold storage.
- The donor lungs are breathing and perfused throughout the preservation period on the OCS™ Lung System which allows the doctor to continuously monitor the condition of the lungs through preservation and up to the point of transplantation.
- In addition, the clinical study also showed that the OCS™ Lung System may be associated with: (1) lower duration of post-transplant mechanical ventilation (using a machine for breathing); (2) shorter length of initial post-transplant ICU stay; and (3) shorter post-transplant hospital admissions.

Patient Initials _____

What to Expect During the Transplant Procedure and the Days Afterwards

I understand that, as the recipient, I do not have to do anything differently to undergo transplantation with donated lungs preserved using the OCS™ Lung System as compared to transplantation with donated lung preserved using cold storage.

I understand that my care after surgery is exactly the same as it would be if I had received lungs that were preserved using the standard approach of cold storage.

Patient Initials _____

Other Study Results

I understand that the clinical study of the OCS™ Lung System showed that the mortality 30 days after surgery was higher in the OCS™ group. However, there was no difference at initial transplant hospital discharge and survival at two years after surgery was similar for patients who received organs preserved on OCS™ and cold storage.

I understand that there is a trend towards lower BOS rates for patients who received lungs preserved with the OCS™ Lung System. BOS is the most common long-term complication after lung transplantation and is the leading cause of long-term graft failure in lung transplantation. This trend will continue to be evaluated by TransMedics in a post-approval registry study.

Patient Initials _____

CONFIRMATION

Patient: I acknowledge that I have received and read the patient information brochure for the OCS™ Lung System, and that I have had time to discuss the items in it and in this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of the device and procedure, and I understand that alternative methods of organ preservation are available.

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Patient Signature and Date