TransMedics®
Bringing new life to organ transplant

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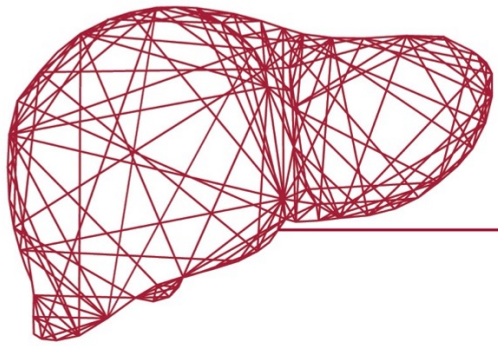
Liver Transplantation with the **Organ Care System (OCS™) Liver System:**

Patient Information

A Guide for You & Your Family



GLOSSARY

Term	Meaning
Cold Storage Preservation/Cold Static Preservation	A method that preserves donor livers on ice in a cooler during the time that the liver is retrieved from the donor until it is transplanted in the recipient. Cold temperatures are used to preserve the organ before it is transplanted.
Early Allograft Dysfunction (EAD)	Delay in the return of normal functionality of the organ post-transplant procedure.
Ex vivo	Outside of the living body
Extracorporeal	Outside of the body
FDA	Food and Drug Administration
Graft	Transplanted donor liver
Ischemic Biliary Complications	Injury to bile ducts due to lack of blood flow
LGRSAE	Liver graft-related serious adverse event
Normothermic	Normal body temperature
Near-physiologic	Similar to conditions in the human body
OCS	Organ Care System
Oxygenated	Carrying oxygen to the liver
Perfusion	The passage of fluid through the liver
Preservation	The effort of keeping the liver from injury or loss

ABOUT THIS BOOKLET

This booklet is for patients like you who are on the liver transplant waiting list. It contains information that will help you and your family learn about a new way to preserve livers before transplantation using the FDA-approved TransMedics® OCS™ Liver System.

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

This booklet is for general information only. It is not intended to tell you everything you need to know about a liver transplant. Your doctor is the best person to ask about your general health, your condition, and about liver transplant.

WHAT IS THE OCS™ LIVER SYSTEM?

The OCS™ Liver System is a portable organ perfusion and monitoring medical device intended to preserve a donated liver in a near-physiologic, bile-producing, functioning and perfused state, while continually monitoring and optimizing liver function for eventual transplantation into the recipient.

The OCS™ Liver System is fully contained and portable. Everything needed to keep the donated liver in a near-physiologic state is within the system. The system runs on AC (plugged in), as well as battery power, for easy transport in a car, helicopter, or airplane.

HOW DOES THE OCS™ LIVER SYSTEM WORK?

The OCS™ Liver System involves a new way of donor liver preservation. Instead of putting the donated liver on ice in a cooler, it is placed in and connected to the OCS™ Liver System. This system keeps the organ warm and perfused as in the human body. The system circulates blood that is oxygenated and nutrient-rich through the liver from the time it is put on the system until it is taken out of the system to be transplanted into you, the patient. The system allows your doctor to continuously monitor how the donor liver is working before it is transplanted into you.

Because the liver is kept warm and oxygenated, this reduces the amount of time during which there is no oxygenated blood flow to the liver. A long amount of time without blood flow can cause injury to the liver that may negatively impact your healing and recovery after surgery.

INDICATIONS FOR USE

The TransMedics® Organ Care System (OCS™) Liver is a portable extracorporeal liver perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of liver allografts from donors after brain death (DBD) or liver allografts from donors after circulatory death (DCD) ≤55 years old in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.

Who is Eligible to Receive a Donor Liver Preserved using the OCS™ Liver System?

Any adult who is has been registered on the transplant waiting list for a liver transplant is eligible to receive a donor liver preserved using the OCS™ Liver System.

When Should the OCS™ Liver System Not be Used (Contraindications)

The use of the OCS™ Liver System is contraindicated (should not be used) to preserve

- Livers with moderate or severe traumatic injury
- Livers with active bleeding (e.g., hematomas)
- Split livers.

RISKS AND BENEFITS

Potential Risks of using the OCS™ Liver System

All surgical procedures have potential risks. The potential risks of a transplant with the OCS™ Liver System are the same as those with a normal transplant procedure using cold storage preservation (stored on ice). There is a risk of receiving a liver that does not function properly after transplant. Although it has never happened during clinical trials, there may be a possible risk that the donor liver may be damaged during preservation. It is possible that after preservation on the OCS™ Liver System, your doctor may decide that the donor liver should not be transplanted. If this happens, your transplant surgery may be cancelled, and you will have to wait for another donor liver to become available.

The OCS™ Liver System will be continuously monitored by a trained team during the preservation time on the OCS™. However, it is possible that the OCS™ Liver System will not work properly, or the medical team may make an error which could lead to damage of the donor liver.

Your doctor can discuss with you the potential risks of your liver transplant surgery.

Benefits - How the OCS™ Liver System Can Help You

The OCS™ Liver System was designed to overcome the clinical limitations of cold storage in the following key areas:

- The OCS™ Liver System reduces the time during which there is a lack of blood supply to the liver by keeping it supplied with oxygenated blood. An extended period of lack of blood supply to the liver is associated with injuries to the liver during preservation which could result in clinical complications or graft failure after transplant.
- The OCS™ Liver System allows the medical team to assess how well the donor liver is working and the overall condition of the donor liver during preservation, up to the point that the donor liver is ready to be transplanted into you. This helps to be sure that the liver is suitable for transplantation.
- The OCS™ Liver System gives the transplant team more time to prepare you to receive the liver and more time to make sure that the liver is clinically acceptable before transplantation.

A large clinical trial, OCS Liver PROTECT trial, was conducted in major liver transplant centers in the U.S. that enrolled 300 patients. The results of the OCS Liver PROTECT trial demonstrated several clinical benefits that were associated with using the OCS™ Liver System to preserve donor livers as compared to cold storage. Key benefits included:

- Reduction in Early Allograft Dysfunction (EAD), a serious post-transplant complication. In turn, the clinical study showed that patients who did not have EAD had the following additional clinical benefits:

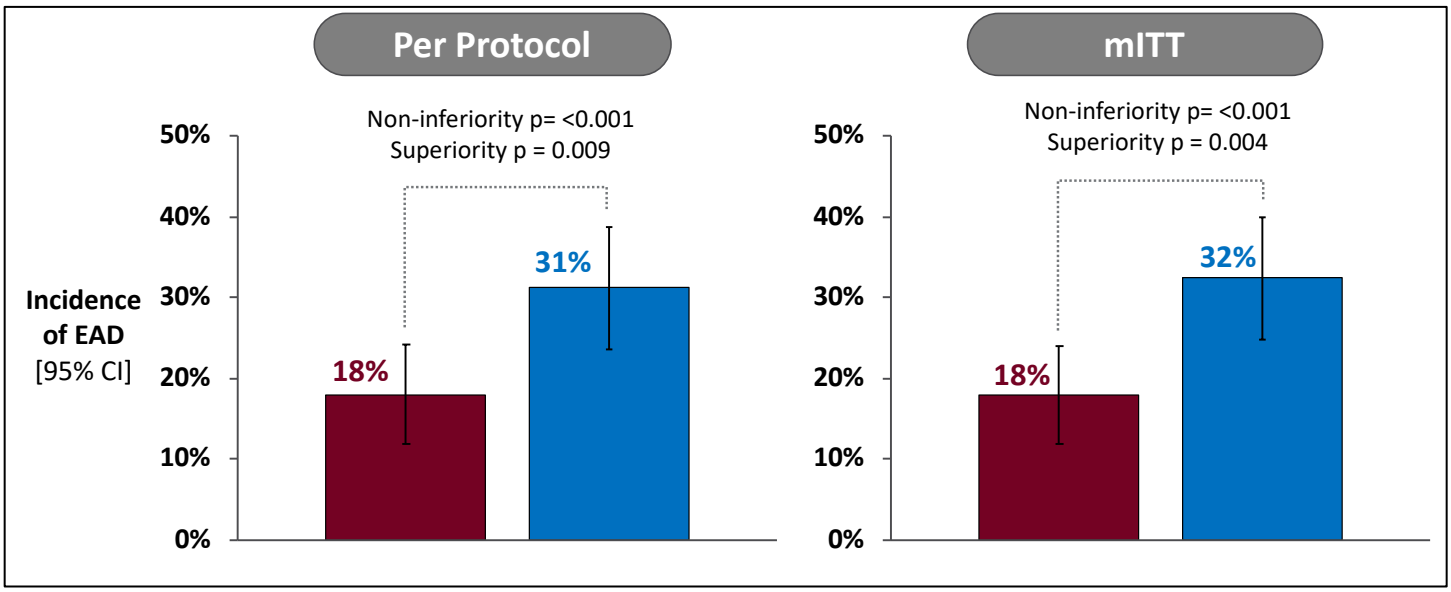
  - Lower risk of graft failure
  - Shorter ICU stays
  - Shorter hospital stays.
- Reduction in ischemic biliary complications, a potential serious longer term complication after liver transplant.
- The donor livers preserved and assessed on OCS Liver System were found to have less evidence of preservation injury on histological examination.

CLINICAL EXPERIENCE WITH THE OCS™ LIVER SYSTEM

The OCS Liver PROTECT trial was a prospective, multi-center, randomized trial of 300 patients. The clinical objective of the trial was to compare the safety and the effectiveness of the OCS™ Liver System for liver transplantation compared to the standard of care, which is cold storage.

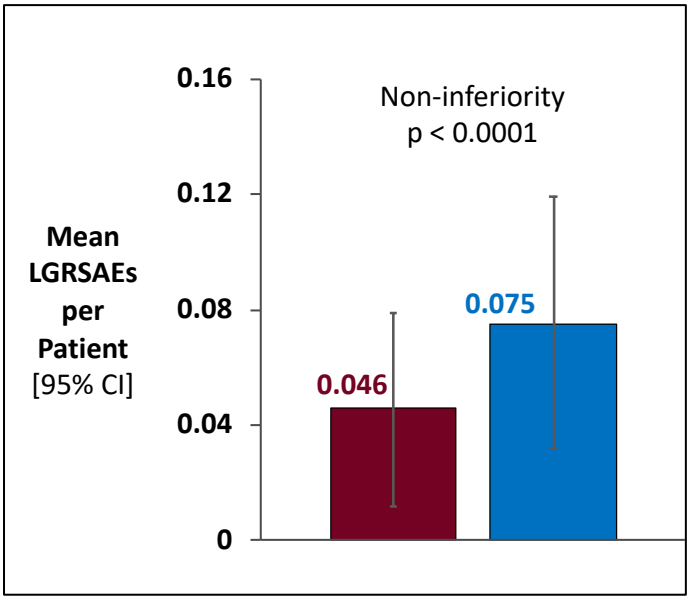
The OCS Liver PROTECT trial results showed that the OCS™ Liver System was superior to standard cold storage for the primary endpoint of the study, EAD for the Per Protocol (PP) population and the modified Intent to Treat (mITT) population, as shown in Figure 1 below. EAD is the most common severe complication after liver transplantation and is associated with patients' spending a longer time in the ICU and in the hospital post-transplant and is associated with a lower graft survival rate.

Figure 1: Primary Effectiveness Endpoint - Incidence of Post-Transplant Early Allograft Dysfunction (PP and mITT Populations)



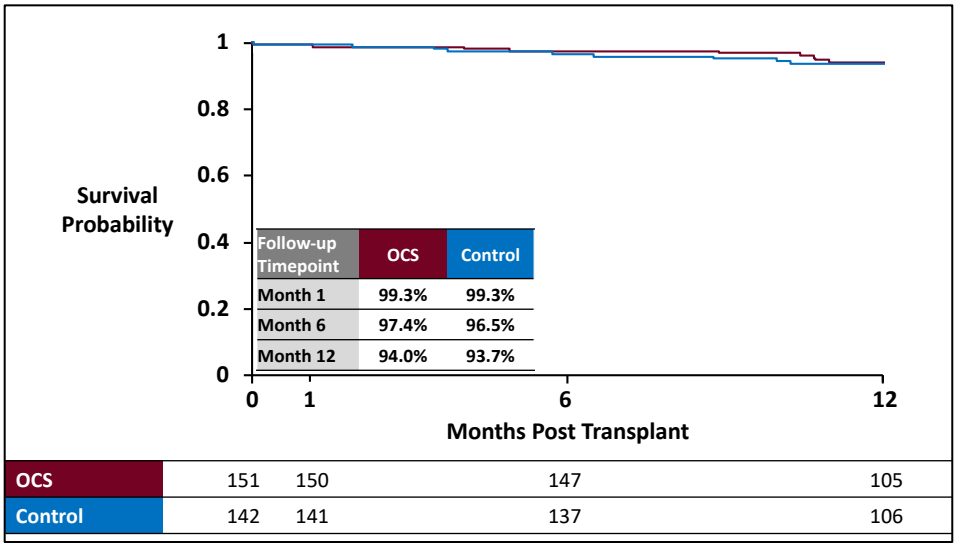
The OCS Liver PROTECT trial met the primary safety endpoint by showing that the average number of liver graft-related serious adverse events (LGRSAEs) per patient within the first 30 days after liver transplantation in the OCS™ patients was no different (non-inferior) to the cold storage control patients (see Figure 2). The LGRSAEs that were analyzed included ischemic biliary complications (that is, damage to the bile ducts caused by low blood flow), vascular complications, liver graft infections and non-functioning grafts (that is, liver grafts that do not function right after transplantation with the need for urgent re-transplantation).

Figure 2: Safety Endpoint – Average Number of LGRSAEs Per Transplanted Patient within the First 30 Days Post-Transplant



One category of LGRSAE that was shown to be higher for cold storage livers was ischemic biliary complications (damage to the biliary system of the liver). This is one of the most serious complications that can occur after liver transplant and it can lead to long-term graft failure and possible death. Twelve months after transplantation, the patients who received OCS™-preserved livers had lower rates of ischemic biliary complications compared to the patients who received livers preserved using cold storage control (3% for OCS compared to 10% for cold storage). In the OCS Liver PROTECT trial, patient survival was high and was similar for both the OCS™ and cold storage control groups (see Figure 3).

Figure 3: Overall Patient Survival at Day 30 through 12 Months Follow-up (PP Population)



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

Before the Liver Transplant Surgery

You do not have to do anything differently to have a transplant with a donor liver preserved on the OCS™ Liver System as compared to a donor liver preserved using cold storage. Your doctor and medical team will describe all steps needed for your transplant surgery.

Before your surgery, the donor liver will be put on the OCS™ Liver System and supplied with warm, oxygenated, nutrient-rich blood. The donor liver will remain on the OCS™ Liver System during preservation and transport to the hospital. The liver's condition will be monitored (checked) during the time it is on the system and the medical team will decide whether the liver is suitable for transplantation.

During and After the Liver Transplant Surgery

The liver transplant surgery and your care after surgery is no different with a liver preserved using the OCS™ Liver System compared to a donor liver that is preserved using cold storage.

PRECAUTIONS

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™ Liver System.

CONTACT INFORMATION

For more information on a liver transplant with the OCS™ Liver 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: U.S.: 978.552.0900
Online: www.transmedics.com

See the OCS™ Liver User Guide 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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200 Minuteman Road
Suite 302
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1-978-552-0900
info@transmedics.com
www.transmedics.com

TransMedics®
Bringing new life to organ transplant