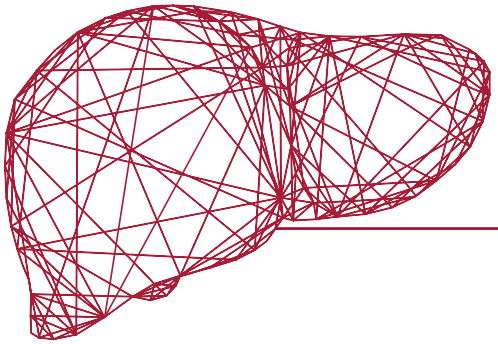
TransMedics®

Bringing new life to organ transplant

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

Patient Information

A Guide for You & Your Family



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About this brochure

This brochure is for patients who need a liver transplant and are listed on the U.S. liver transplant waiting list. It will help you learn more about the traditional cold storage liver preservation method and the new TransMedics Organ Care System (OCS™) Liver perfusion technology for donor liver preservation. Please discuss any questions with your liver doctor or liver transplant team.

Donor Liver Preservation for Transplantation

Every donor liver needs to be preserved from the time it is removed from the donor body until it is implanted into the recipient. This is important to protect the donor liver from potential damage that may negatively impact liver function after it is transplanted into the recipient.

Current Method of Donor Liver Preservation

The current standard of care is to preserve donor livers using a cold storage preservation solution. The donor liver is flushed with a cold preservative solution to stop the liver from functioning. The liver is then removed from the donor body and is placed in a plastic bag filled with the same cold preservative solution and packed in a cooler filled with ice. During this time it is kept cold, not functioning and is not perfused with blood or nutrients.

Cold storage has been used to successfully preserve livers for transplantation for many years, however, it has major limitations that play a role in why many donor livers available for transplant may not be used for transplantation. In addition, these limitations can contribute to post-transplant complications like early allograft dysfunction (EAD). EAD is when the donor liver doesn't function well immediately after transplantation and the patient requires additional care and support in the hospital and intensive care unit to recover. In a few cases, EAD has been shown to be associated with liver graft failure and the patient may need a second liver transplant to survive.

COLD STORAGE LIMITATIONS

- Prolonged time without blood supply can lead to organ damage
- No ability to monitor or assess organ function during storage

Early Complications After Transplant (EAD)

1. Hudcova et al. *Clin Transpl* 2017

The TransMedics Organ Care System (OCS™) Liver Technology

The TransMedics OCS Liver was developed to improve upon the limitations of cold storage preservation.

OCS LIVER IS DESIGNED TO:

Create conditions similar to the human body

The liver is kept warm, functioning, and perfused with oxygenated and nutrient enriched blood

Allow the liver transplant team to observe & adjust donor liver environment

The OCS Liver measures hemodynamic parameters and evaluate the donor liver during the transport of the liver from the donor to your hospital before it is transplanted.

OCS Liver Monitor
Allows continuous monitoring & evaluation of the liver by your transplant team

OCS Liver Perfusion Module
Sterile, protective chamber that houses the functioning liver and circulating blood during preservation

OCS Liver Console
Compact, highly portable device that fits in all modes of transportation for donor livers for transplant

OCS™ LIVER BENEFITS

- Reduction of time the liver is without blood flow *(from ~6 hours to ~3 hours)*
- Allow transplant team to adjust donor liver environment outside of the body
- Allow for continuous monitoring and evaluation of donor livers

OCS had Lower Rate of EAD Compared to Cold Storage

Overall Clinical Experience with OCS™ Liver

For the FDA-approved clinical use, the OCS Liver was evaluated in the OCS Liver PROTECT Trial. The PROTECT Trial compared the clinical results of 153 transplanted patients who received OCS livers to 146 patients who received livers preserved by cold storage (Control). Whether the patient received an OCS or control liver was determined randomly (like a coin toss) to either OCS or cold storage. Due to the nature of donor liver procurement, whether a patient received a cold storage or OCS liver was known to the transplant team.

The PROTECT Trial results showed that the OCS Liver was superior to cold storage in reducing the number of patients with EAD after liver transplantation. There was no difference between OCS and control in the number of patients with grafts that failed, or the amount of time that patients spent in the ICU or hospital.

The OCS patients had a similar average number of liver related complications in the first 30 days after liver transplant compared to cold storage. The overall patient survival was high and there was no difference between the groups through 1 and 2 years after transplant.

Below is a summary of the clinical results demonstrated in the PROTECT Trial:

PROTECT Trial Summary Clinical Results	OCS Liver Perfusion	Cold Storage Control
Patients with Liver Early Allograft Dysfunction (EAD)	**18%** 18 out of 100	**31%** 31 out of 100
Success rate for OCS Liver to Assess Liver Function Outside of Body	**94%** 94 out of 100	--
Patient Survival at Day 30 Post-transplant	**99%** 99 out of 100	**99%** 99 out of 100
Average Number of Liver Related Complications Within 30 Days of Transplant per Patient	**0.046** Less than 1 per patient	**0.075** Less than 1 per patient

Other Findings which were Observed in the PROTECT Trial

In the PROTECT trial, the percentage of livers from a particular type of donor (called a DCD) was higher for the OCS (51% or 51 out of 100 donor livers were used) compared to the control (25% or 25 out of 100 donors were used). Across the US, 25% (or 25 out of 100) DCD livers are normally used for transplantation using cold storage preservation.

A substantially lower number of OCS patients with a certain kind of complication of the biliary system was observed in the PROTECT Trial compared to control. These complications can happen after a liver transplant and are caused by lack of blood supply (called ischemic biliary complications). The number of patients with ischemic biliary complications at 6 months was observed to be 1.3% (about 1 out of 100) for OCS compared to 8.5% (about 9 out of 100) for control, while the number of patients ischemic biliary complications at 12 months was observed to be 2.6% (about 3 out of 100) for OCS compared to 9.9% (about 10 out of 100) for control.

The number of patients with other complications of the biliary system that are not caused by lack of blood supply (called non-ischemic biliary bomplications) at 30 days after transplant was observed to be 8.5% (about 9 out of 100) for OCS patients and 4.1% (about 4 out of 100) for control patients, while the number of patients with a complication of leaking bile ducts observed at 30 days after transplant was 2.6% (about 3 out of 100) for OCS compared to 7.5% (about 8 out of 100) for control.

Patient Survival though 12 months after transplant was the same at 94% (94 out of 100) for both OCS and the control.

Who Can Receive a Donor Liver Perfused on OCS™ Liver

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

When is the OCS Liver an Option to Use (Indication):

The TransMedics® Organ Care System (OCS™) Liver is a portable extracorporeal liver perfusion and monitoring system indicated for the preservation and monitoring of hemodynamics and metabolic function which allows for ex vivo assessment of liver allografts from donors after brain death (DBD) or liver allografts from donors after circulatory death (DCD) ≤55 years old and with ≤30 mins of warm ischemic time, macrosteatosis ≤15% in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.

When is the OCS Liver Not an Option to Use (Contraindications)

The OCS Liver should not be used to preserve donor livers if certain problems or conditions with the donor liver exist, such as major liver injury or anatomical abnormality with the liver blood supply.

What to Expect During Your Treatment Using the OCS™ Liver

Before the Liver Transplant Procedure

You do not have to do anything differently to be transplanted with a donor liver preserved using the OCS Liver as compared to the donor liver preserved using cold storage. Your liver transplant team will describe all steps necessary for your transplant procedure.

Before your surgery, a trained team will retrieve the donor liver. The donor liver will be placed in the OCS Liver and supplied with warm, oxygenated, nutrient-rich blood-based solution. The donor liver will begin functioning and will remain on the OCS Liver while it is being transported to your hospital. The team will monitor the condition of the liver throughout the preservation period and report to your Surgeon.

During and After the Liver Transplant Procedure

Your surgery and care after surgery is the same whether you receive a liver preserved on OCS or a liver preserved using cold storage.

Potential Risks

All surgical procedures and medical devices have potential risks. The potential surgical risks of a transplant with a donor liver preserved on the OCS Liver are the same as those with a normal transplant procedure using cold storage preservation. There is a risk of receiving a liver that does not function properly after transplant. There is also a risk that the donor liver may be damaged during preservation.

Potential Risks Associated with OCS Liver:

- It is possible that after preservation on the OCS Liver, your doctor may decide that the donor liver is not good enough to be transplanted. If this happens, your transplant surgery may be cancelled, and you will wait for another donor liver to become available.

- The OCS Liver is continuously monitored by a trained team during preservation on the OCS. Like with many medical technologies, it is possible that the OCS Liver may not work properly, or the medical team may make an error which could lead to the organ being converted to cold storage or may damage the organ.

There are some serious risks associated with liver transplantation, regardless of the method used to preserve the donor liver. Your doctor can discuss with you the potential risks that may be associated with your liver transplant surgery.

Potential Risks Associated with Liver Transplant Procedure:

- Death
- Donor liver rejection
- Bleeding
- Infections
- Trouble or inability to breathe
- Kidney function problems
- Severe blood infection
- Malignancy (cancer)
- Liver function problems
- Stroke or other brain injuries
- Blood clots in arteries and veins
- Fluid collection around the liver
- Abnormal liver function
- Surgical wound opening
- Digestive system problems
- Fever

Contact Information

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

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

PHONE: US: 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 Liver to your doctor.

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TransMedics®
Bringing new life to organ transplant