

Organ Care System (OCS™) Liver

Safety and Performance Information
for EU Customers and Patients
Required by EU Medical Device Regulations



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 evaluates the donor liver during the transport of the liver from the donor to the hospital before it is transplanted.



OCS Liver Monitor

Allows continuous monitoring & evaluation of the liver by the 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

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, the transplant doctor may decide that the donor liver is not good enough to be transplanted. If this happens, transplant surgery may be cancelled, and the patient will retain their status on the liver transplant waiting list 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.

Potential Risks Associated with Liver Transplant Procedure:

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



Organ Care System (OCS™) Liver Part Numbers

OCS Liver Console

REF Number	Device Name
3000	OCS Liver Console
<i>OCS Liver Console subcomponents that can be ordered separately:</i>	
1404	OCS Data Card
1408	OCS Battery
1411	Mobile Base
1423	Regulator Yoke Gasket
1428	OCS Power Cord - UK
1429	OCS Power Cord - EU
1430	OCS Power Cord - Italy
1431	OCS Power Cord - Switzerland
1432	OCS Power Cord – North America
1434	OCS Power Cord - Australia/New Zealand
1436	OCS Power Cord - Denmark
3406	OCS Liver Gas Cylinder

OCS Liver Perfusion Set

REF Number	Device Name
3200	OCS Liver Perfusion Set
<i>OCS Liver Perfusion Set subcomponents that can be ordered separately:</i>	
3400	OCS Liver Perfusion Initiation Set
3401	OCS Liver Instrumentation Tool Set
3421	OCS Liver Perfusion Termination Set
3457	OCS Liver Solution Infusion Set
1467	Solution Delivery Cassettes
3450	OCS Bile Cannula, 12Fr

OCS Liver Bile Salts

REF Number	Device Name
3440	OCS Liver Bile Salts Set

Other

REF Number	Device Name
1460	OCS Console Contact Button Cleaner



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. Patients should address any questions about the OCS Liver System to their doctor.



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ONLINE: www.transmedics.com

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