

Organ Care System (OCS™) Lung

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



The TransMedics Organ Care System (OCS™) Lung Technology

The TransMedics OCS Lung System was developed to improve upon the limitations of cold storage preservation to increase donor Lung utilization for transplantation.

OCS Lung is Designed to:



Create conditions similar to the human body

The lungs are kept warm and oxygenated during preservation from the donor to the recipient



Optimize the donor Lung environment

OCS allows for the evaluation of the donor lungs by the transplant team during the transport of the lungs from the donor to the hospital



OCS Lung Monitor

Allows continuous monitoring & evaluation of the lungs by the transplant team

OCS Lung Perfusion Module

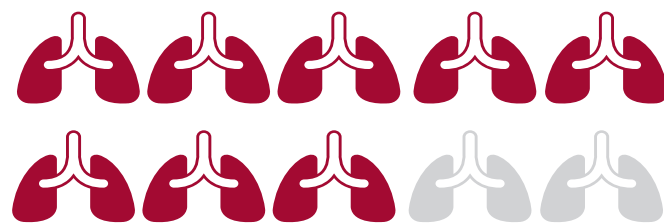
Sterile, protective chamber that houses the breathing lung and circulating blood during preservation

OCS Lung Console

Compact, highly portable device that fits in all modes of transportation for donor Lungs

OCS™ LUNG BENEFITS

- ✓ Reduction of time without blood supply on donor lungs
- ✓ Optimize donor lung environment
- ✓ Allows for continuous evaluation of donor lungs



**8 out of every 10 Donor Lungs
Preserved on OCS were
Successfully Transplanted**

Potential Risks

All surgical procedures have potential risks. The potential risks of a transplant with 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.

Potential Risks Associated with OCS Lung:

- It is possible that after preservation on the OCS Lung, transplant doctor may decide that the donor lung is not good enough to be transplanted. If this happens, the transplant surgery may be canceled, and the patient will retain their status on the lung transplant waiting list for another donor lung to become available.
- The OCS Lung is continuously monitored by a trained team during preservation on the OCS System. Like with many medical technologies, it is possible that the OCS Lung may not work properly. This could lead to the organ being converted to cold storage or may damage the organ.

There are some serious risks associated with lung transplantation, regardless of the method used to preserve the donor lung. Patients receiving donor lungs preserved with the OCS Lung System may experience the following side effects, which could be experienced with any lung transplant:

- Death
- Kidney failure or dysfunction
- Respiratory dysfunction/infection
- Primary graft dysfunction (PGD)
- Acute rejection
- Cardiac arrhythmia
- Bronchiolitis Obliterans Syndrome (BOS –obstructive lung disease of the small airways)
- Bronchial stenosis/dehiscence (restricted airways)



Organ Care System (OCS™) Lung Part Numbers

OCS Lung Console

REF Number	Device Name
2000	OCS Lung Console
<i>OCS Lung Console subcomponents that can be ordered separately:</i>	
1404	OCS Data Card
1408	OCS Battery
1411	OCS Mobile Base
1423	OCS 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
2460	Lung Preservation Gas Cylinder
2461	Lung Monitoring Gas Cylinder
2464	OCS Lung Monitoring Gas Regulator Kit

OCS Lung Perfusion Set

REF Number	Device Name
2200	OCS Lung Perfusion Set
<i>OCS Lung Perfusion Set subcomponents that can be ordered separately:</i>	
2401	OCS Lung Instrumentation Tool Set
2402	OCS Lung Perfusion Initiation Set
2403	OCS Lung Perfusion Termination Set

OCS Lung Solution Set

REF Number	Device Name
2300	OCS Lung Solution



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



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