

Organ Care System (OCS™) Heart

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



The TransMedics Organ Care System (OCS™) Heart Technology

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

OCS Heart is Designed to:



Create conditions similar to the human body

The heart is kept warm, beating, and perfused with blood



Optimize the donor heart environment

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



OCS Heart Monitor
Allows continuous monitoring & evaluation of the heart by the transplant team

OCS Heart Perfusion Module
Sterile, protective chamber that houses the beating heart and circulating blood during preservation

OCS Heart Console
Compact, highly portable device that fits in all modes of transportation for donor hearts



OCS™ HEART BENEFITS

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



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

Potential Risks

All surgical procedures and medical devices have potential risks. The potential surgical risks of a transplant with a donor heart are similar for OCS™ Heart System preservation and cold storage preservation. There is a risk of receiving a heart that does not function properly after transplant. There is also a risk that the donor heart may be damaged during preservation.

Potential Risks Associated with OCS Heart:

- It is possible that after preservation on the OCS Heart System, the transplant doctor may decide that the donor heart 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 heart transplant waiting list for another donor heart to become available.
- The OCS Heart System is continuously monitored by a trained team during preservation on the OCS System. Like with many medical technologies, it is possible that the OCS Heart System 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 heart transplantation, regardless of the method used to preserve the donor heart.

Potential Risks Associated with Heart Transplant Procedure:

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



Organ Care System (OCS™) Heart Part Numbers

OCS Heart Console

REF Number	Device Name
1000	OCS Heart Console
<i>OCS Heart 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
1406	OCS Heart Gas Cylinder

OCS Heart Perfusion Set

REF Number	Device Name
1200	OCS Heart Perfusion Set
1400	OCS Blood Collection Set
1401	OCS Heart Instrumentation Tool Set
1421	OCS Cardioplegic Arrest Set
1457	OCS Heart Solution Line Set
1461	OCS Small Cable Tie Tool
1466	Leukocyte Filters
1467	Solution Delivery Cassettes

OCS Heart Solution Set

REF Number	Device Name
1300	OCS Heart Solution Set

Other

REF Number	Device Name
1460	OCS Console Contact Button Cleaner



Contact Information

For more information on a heart transplant with the OCS™ Heart System, please contact TransMedics, Inc. by mail, by phone, or online as shown below. Patients should address any questions about the OCS Heart System to their doctor.



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