TransMedics®

Bringing new life to organ transplant

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

Patient Information

A Guide for You & Your Family

transmedics.com

About this brochure

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

Donor Heart Preservation for Transplantation

Every donor heart needs to be preserved from the time it is removed from the donor until it is implanted into the recipient. Patients who receive a heart transplant may experience early heart related complications like donor heart dysfunction. This is when the donor heart doesn't function well immediately after transplantation and the patient requires additional care and support in the hospital and intensive care unit to recover. Therefore, it is important to protect the donor heart from potential damage through preservation before it is transplanted.

Cold Storage Donor Heart Preservation

Historically, donor hearts are preserved using cold storage on ice. The donor heart is flushed with a cold preservative solution to stop the heart from beating. The heart is then removed from the donor body and is placed in a plastic bag filled with the same cold preservative solution and packed in an igloo cooler filled with ice. During this time it is kept cold, not beating or functioning and is not perfused with blood or nutrients.

Although cold storage has been used for donor heart preservation over the years, it has major limitations. Because of these limitations, only 3 out of every 10 donor hearts available are actually used for transplantation.

COLD STORAGE LIMITATIONS

- Time-related injury due to lack of blood supply
- No organ optimization capabilities
- No assessment of organ viability

Only 3 out of 10 donor hearts used[1]

1. 2019 OPTN Database for U.S. Heart Transplants

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

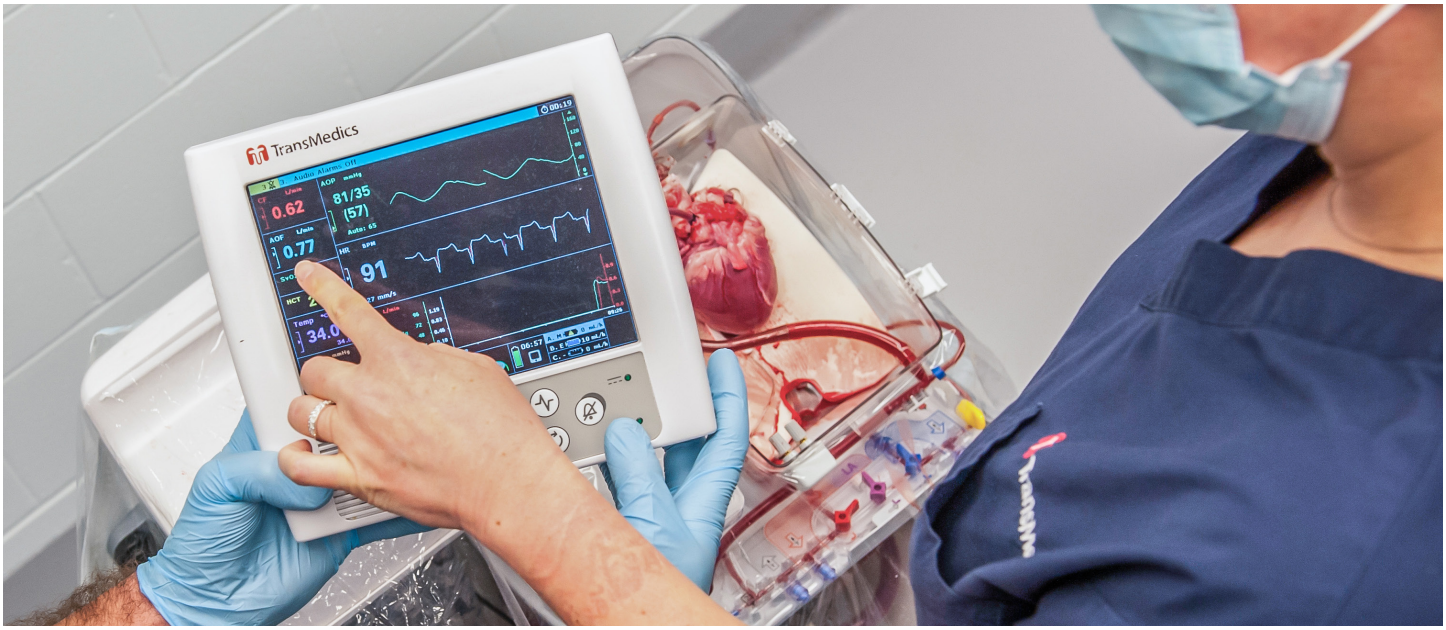
Optimize the donor heart environment

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

OCS Heart Monitor
Allows continuous monitoring & evaluation of the heart by your 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 for donor hearts



Overall Clinical Experience with OCS™ Heart System

For the FDA-approved clinical use, the OCS Heart System was evaluated in two clinical studies: the EXPAND Study and the associated EXPAND Continued Access Protocol (CAP). The EXPAND and EXPAND CAP were single arm studies that enrolled donor hearts that are seldom used for transplant with cold storage due to its limitations. Below is a summary of the clinical findings of EXPAND and EXPAND CAP Studies:

OCS Heart EXPAND Study Results

EXPAND Trial enrolled 75 heart transplant patients in 9 U.S. heart transplant centers. The main study results are listed below:

81% (81 out of 100) of donor hearts perfused on OCS Heart System were successfully transplanted despite having factors that make them unlikely to be preserved with cold storage or used for heart transplants

6.4 hours average preservation time from donor to recipients

95% (95 out of 100) of patients were alive at 1 month after transplant

89% (89 out of 100) of patients did not experience severe donor heart dysfunction after transplant

11 out of 75 patients experienced a serious heart related complication after transplant

- **1 patient** had donor heart failure immediately after transplant requiring a second transplant
- **11 patients** had moderate or severe donor heart dysfunction

82% (82 out of 100) of patients survived at 2 years after their transplant. Most of the patient deaths were not related to their transplanted heart

OCS Heart EXPAND CAP Study Results:

EXPAND CAP Study enrolled 41 heart transplant patients in 8 U.S. heart transplant centers. The main study results are listed below:

91% (91 out of 100) of donor hearts perfused on OCS Heart System were successfully transplanted despite having factors that made them unlikely to be preserved with cold storage

6.3 hours average preservation time from donor to recipients

100% (100 out of 100) of patients were alive at 1 month after transplant

98% (98 out of 100) of patients did not experience severe donor heart dysfunction after transplant

7 out of 41 patients experienced a serious heart related complication after transplant

- **NO patients** had graft failure immediately after transplant
- **7 patients** had moderate or severe donor heart dysfunction

93% (93 out of 100) of patients survived at 1 year after their transplant

OCS HEART CAPABILITIES

- 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

Earlier Clinical Experience with OCS™ Heart System – PROCEED II Trial

The PROCEED II trial was a study that was done before the EXPAND Heart study. It was carried out using an earlier version of the OCS Heart System. PROCEED II focused on types of donor hearts that are routinely preserved using cold storage preservation. These donor hearts are not included in the current approved use of the OCS Heart System in the U.S. PROCEED II compared the clinical results of patients who received OCS hearts to those patients who received hearts preserved by cold storage.

PROCEED II Trial Summary Results	OCS Heart Perfusion	Cold Storage Control
Total Preservation Time from Donor to Recipient	**5.4 Hours**	**3.2 Hours**
Patient Survival at 30 Days After Transplant Without Early Complications	**93.5% (93 out of 100)**	**97% (97 out of 100)**
Patient Experiencing at Least 1 Heart Related Complication After Transplantation	**12.9% (12 out of 100)**	**13.6% (13 out of 100)**
Overall Patient Survival at 2 years	**75%* (75 out of 100)**	**90% (90 out of 100)**

* Most of these deaths were not related to the transplanted hearts.

Who Can Receive a Donor Heart Perfused on OCS™ Heart System

Any adult heart transplant candidate who has been registered on the waiting list for a heart transplant may be eligible to receive a donor heart preserved using the OCS Heart System. You should fully discuss the different preservation methods and your alternatives with your heart transplant team.

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

The OCS Heart System is approved to be used for certain hearts from donors after brain death. These donor hearts are not considered to be suitable for cold storage preservation at initial evaluation by the transplant team due to the limitations of cold preservation, for example expected long preservation time (greater than 4 hours).

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

The OCS Heart System should not be used to preserve donor hearts with moderate or severe leakage of the aortic valve (the heart valve between the main pumping chamber of the heart and the main artery to the body), observed bruising of the donor heart muscle, or known unrepaired holes between the left and right heart chambers. Your heart transplant team will examine the donor hearts for these issues.

What to expect during your treatment using the OCS™ Heart System

Before the Heart Transplant Procedure

You do not have to do anything differently whether you will receive a donor heart preserved using the OCS Heart System or a donor heart preserved using cold storage. Your heart transplant team will describe all steps necessary for your transplant procedure.

Before your surgery, a trained team will retrieve the donor heart. The donor heart will be placed in the OCS Heart System for preservation. The donor heart will begin beating and remain on the OCS Heart System while its being transported to your hospital. The team will monitor the condition of the heart throughout the preservation period and report to your Surgeon.

During and After the Heart Transplant Procedure

Your surgery and care after surgery is the same whether you receive a heart preserved on OCS or a heart 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 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, your doctor may decide that the donor heart is not good enough to be transplanted. If this happens, your transplant surgery may be cancelled, and you will retain your 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. Your doctor can discuss with you the potential risks that may be associated with your heart transplant surgery.

Potential Risks Associated with Heart Transplant Procedure:

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

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.

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 Heart System to your doctor.

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TransMedics®
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