TransMedics®

Bringing new life to organ transplant

## Organ Care System (OCS™)

# Redefining What's Possible in Organ Transplantation


Supporting lung, heart and liver transplant therapy

# The Only Fully-Integrated, Compact, Portable Organ System. Shown to Improve Clinical Outcomes.

The TransMedics Organ Care System (OCS™) is a fully-portable, multi-organ, normothermic preservation and assessment technology that mirrors human physiology, minimizes ischemia, and provides the ability to optimize organs during transport.

- Only multi-organ platform used with donor lungs, hearts and livers
- Largest user base at 70 leading US and global transplant centers
- Largest body of literature and clinical evidence in warm perfusion
- Most extensive training program including 24/7 clinical support


**Wireless Monitor**
controls and displays physiologic and functional parameters of the donor organ

**Perfusion Module**
sterile, protective, biocompatible chamber that houses the organ and circulating perfusate

**Batteries**
everything needed for independent operation is carried on board of the system

**OCS Console**
portable, integrated perfusion & assessment system, fits in all standard modes of transportation for donor organs

# Revolutionary Technology

This revolutionary technology allows physicians and institutions to maximize the potential of donor lungs, hearts and livers while monitoring each organ throughout the entire process, ensuring transplant teams can preserve organs in an optimal condition.

## THE OCS™ PLATFORM IS DESIGNED TO:

### Mimic the human body

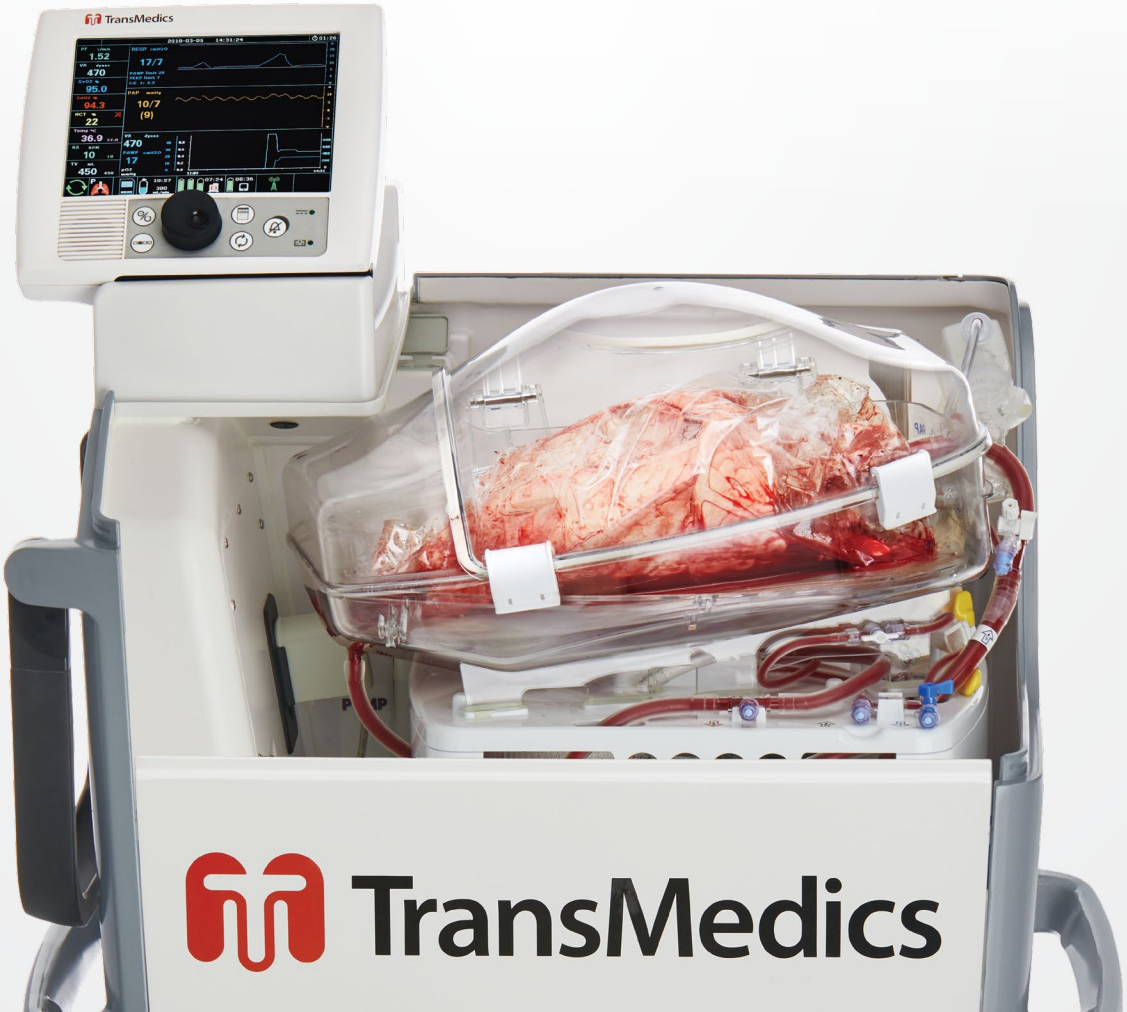
Warm, oxygenated blood perfusion allows transplant teams to maintain organs in a living, functional state. As a result, the lung breathes, the heart beats, and the liver produces bile.

### Enable diagnostic evaluation

Diagnostic assessment makes it possible to analyze organ function and viability.

### Optimize organ condition

Allows for therapeutic intervention through replenishing oxygen and nutrients.



# Growing Global Utilization


## 1,824 OCS™ TRANSPLANTS TO DATE*

**1043**
**OCS Heart Transplants**
(256 DCD)

**530**
**OCS Lung Transplants**
(104 DCD)

**251**
**OCS Liver Transplants**
(54 DCD)

**Data on file at TransMedics, 2021.*

# Clinical Evidence - Lung

The only FDA approved device for both standard and expanded* criteria donor lungs for transplantation.[1]

## INSPIRE TRIAL

The OCS™ Lung is FDA approved for use with standard criteria donor lungs.


**Improved post-transplant outcomes** compared to cold storage


**~50% reduction of PGD3** (Primary Graft Dysfunction grade 3)†

**Significantly expanded organ retrieval range** while limiting ischemic time

**Visit transmedics.com** to view OCS Lung publications

†*PGD3 in the first 72 hours is a severe form of acute lung injury that is a major cause of early morbidity and mortality encountered after lung transplantation. TransMedics OCS Lung significantly reduced PGD3 vs control group in the INSPIRE Trial.*

## EXPAND TRIAL

The OCS Lung is FDA approved for use with expanded* criteria donor lungs.

**Types of expanded* criteria donor lungs used**

**39%** - Older (≥55 Years) | **33%** - DCD | **32%** - Expected Ischemic Time >6 Hours | **25%** - $PaO_2/FiO_2$ Ratio ≤300mmHg

*(21 patients had 2 or more indications)*

**87% UTILIZATION**

**87% successful usage of donor lungs on OCS** that had been rejected for transplant by centers using cold storage

**91% SURVIVAL**

**Over 91% patient survival**
1 year post transplant

VS


**Declined Lungs**
UNOS data showed donor lungs used for the OCS Lung EXPAND Trial had been **declined for transplantation on average 35 times by other transplant centers** before reaching an OCS transplant center.

## LONG-DISTANCE RETRIEVAL

**20+ HOURS**

**20+ hours of cross-clamp time** in a successful retrieval and transplant from Hawaii to North Carolina

** Expanded criteria is defined as donor lung pairs initially deemed unacceptable for procurement and transplantation based on limitations of cold static preservation.*

# Clinical Trials - Heart

The only device currently under FDA review for utilized and unutilized donor hearts.[2]

**250+**
DCD HEART TRANSPLANTS

OCS™ heart is the only system used in DCD heart transplantation worldwide.

# EXPAND TRIAL

**Types of expanded criteria donor hearts used**

- **37%** - Expected ischemic time ≥4 hours
- **31%** - 20 or more mins of down time
- **28%** - LVEF of 40-50%
- **13%** - Older donors ≥55 years
- **8%** - Coronary artery disease

(*31 patients had 2 or more indications*)

ICE

**Declined Hearts**

UNOS data showed donor hearts used for the OCS Heart EXPAND Trial had been **declined for transplantation on average 66 times by other transplant centers** before reaching an OCS transplant center.

**US pivotal trial** to evaluate the Organ Care System for use with unutilized donor hearts that may not meet current standard acceptance criteria for transplantation.

**75 patients** were enrolled

**Primary effectiveness endpoints:**

- Patient survival at day-30 post transplant
- Absence of severe primary heart graft dysfunction (PGD) in the first 24 hours post-transplantation


**Visit transmedics.com** to view OCS Heart publications

*The OCS Heart is an investigational device and, therefore, limited by federal law to investigational use in the US.*

# Clinical Trials - Liver

The OCS™ Liver System is undergoing clinical trials in the US.[3] The OCS is designed to enable surgeons to transplant more organs from the available donor pool and to achieve better procedural outcomes.

## OCS LIVER PROTECT TRIAL

**US FDA pivotal trial** with the objective of evaluating the safety and effectiveness of the OCS Liver System for transplantation

**155 donor livers** including both DBD and DCD, were instrumented on the OCS Liver, of which 152 were successfully transplanted, yielding a 98% utilization rate

**98%**
**UTILIZATION**

**Primary effectiveness endpoint:**
The use of OCS Liver resulted in a significantly lower incidence of early allograft dysfunction (EAD) compared to control **(17.3% OCS vs. 30.5% Control p=0.009)** across both the donors after brain death (DBD) and donors after circulatory death (DCD) cohorts in the trial.

**43%**
**LOWER EAD**

**Secondary effectiveness endpoint:**
The use of OCS Liver resulted in a significantly lower incidence of ischemic biliary complications at 6 months post-transplantation **(1.4% OCS vs. 8.5% Control p=0.005).**

**84%**
**REDUCTION**


**ClinicalTrials.gov**
**NCT02522871**

*The OCS Liver is an investigational device and, therefore, limited by federal law to investigational use in the US.*

# Designed to improve clinical outcomes, with the potential **to save more patients' lives.**


Time is everything. My surgery was very challenging, it lasted 11-hours. Without the OCS, I feel that I wouldn't be here now.

-SILVANO, OCS LUNG PATIENT

It's like taking the donor lungs and putting them in a nice, cozy warm environment and taking care of them and nurturing them.

-LEE ANN, OCS LUNG PATIENT


**Let our expertise help you redefine transplant care.**

*The OCS Lung, OCS Heart and OCS Liver are all CE marked devices.*
*The OCS Lung is an FDA-approved device for standard and expanded* criteria donor lungs.*
*The OCS Heart and OCS Liver devices are investigational devices and, therefore, are limited by federal law to investigational use in the US.*
**Expanded criteria is defined as donor lung pairs initially deemed unacceptable for procurement and transplantation based on limitations of cold static preservation.*

**References:**
1. U.S. Food & Drug Administration. Premarket Approval (PMA), P160013/S002. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160013S002. Accessed July 17, 2019.
2. U.S. National Library of Medicine. International EXPAND Heart Pivotal Trial (EXPAND Heart), NCT02323321. https://clinicaltrials.gov/ct2/show/NCT02323321. Accessed October 19, 2018.
3. U.S. National Library of Medicine. International PROTECT Liver Trial: Preserving and Assessing Donor Livers for Transplantation. https://www.clinicaltrials.gov/ct2/show/NCT02522871. Accessed October 19, 2018.

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TransMedics®
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