LUNGGUARD®

DONOR LUNG PRESERVATION SYSTEM

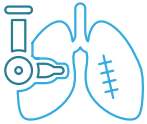
PARAGONIX®

Introduction

At Paragonix our mission is to create a new standard for organ preservation and transport that improves patient outcomes worldwide. We strive to protect the ultimate donation with the dignity and safety it deserves to give patients every possible advantage to thrive.

The Paragonix LUNGguard® Donor Lung Preservation System is a leading FDA cleared and CE marked preservation device for donor lung transportation. Paragonix LUNGguard® provides a sterile and temperature controlled environment for organs traveling between operating rooms. The product is designed to be easy-to-use in stressful, clinically demanding environments where there is no room for mistakes.

Temperatures are monitored throughout the organ journey via the Bluetooth® connected Paragonix App and Web Portal. The Paragonix LUNGguard® provides a secure transport system that provides predictable, repeatable, and measurable results.



A NEW STANDARD OF CARE

1 in 3 U.S. lungs were transported in the LUNGguard® Donor Lung Preservation System so far in 2024[10]

ISHLT 2024 PRESENTATION ON DONOR LUNG PRESERVATION

Data supports growing evidence that elevated temperature reduces post-transplant complications[1]

UNPREDICTABLE HISTORIC STANDARD OF CARE STORAGE

Clinical data has shown temperatures can reach <1°C in less than an hour, potentially exposing donor lungs to freezing conditions[2]

DELIVERING A NEW STANDARD IN LUNG PRESERVATION & TRANSPORT

HISTORIC STANDARD OF CARE STORAGE

PROBLEM

Unpredictable Lung Tissue Cooling

CAUSE

Rapid Temperature Decrease to Below 2°C

RESULT

- Multi-center clinical study found average organ temperature during ice cooler transportation (n=186) was below 2°C and below 0°C after 6 hours[3]
- Organ surface rapidly cools to near freezing temperatures, with significant gradients between the surface and interior of the organ[4,5]

The International Society for Heart and Lung Transplantation has published a consensus statement that warns

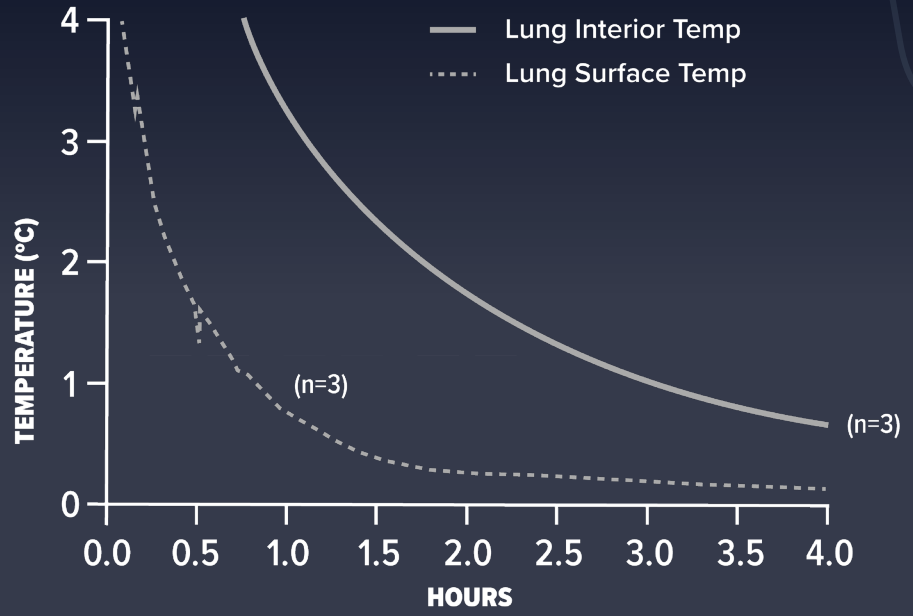
"...freezing and thawing causes irreversible cellular damage."[6]

KNOWN RISKS BELOW 2°C[7,8]

- Local damage to pulmonary endothelium
- Potential for primary graft dysfunction after transplantation

ICE IS NOT 4°C: THERMODYNAMIC CHARACTERIZATION OF LUNGS AND HEARTS PRESERVED ON ICE[2]

F. Rega, P. Patel, B. Bulka, L. Churchill, M. Tajima, L. Anderson.



Average lung surface temperature decreased from an initial 6.7°C to 0.8°C (1 hr) to 0.1°C (4 hrs)

Average left inferior lung lobe temperature decreased from 6.1°C to 3.4°C (1 hr), 1.8°C (2 hrs), and 0.7°C (4 hrs)

PGD PREVALENCE & RISK FACTORS[8]

PGD Prevalence

- Study of 1,225 patients across 10 US centers
- Severe PGD in up to 30% of recipients within 72 hours

Ischemic Time as a Risk Factor

- Likelihood of Severe PGD increases with total ischemic time

2017 Allocation Change Policy

- Allocation change has led to an increase from 5.30 to 5.66 mean ischemic time between pre- and post-eras

ISHLT DONOR LUNG PROCUREMENT CONSENSUS[6]

- Avoid close proximity to ice because of irreversible cell damage
- Freezing injury is an under-appreciated cause of graft failure

"Avoid close proximity to ice because of irreversible cellular damage"[6]

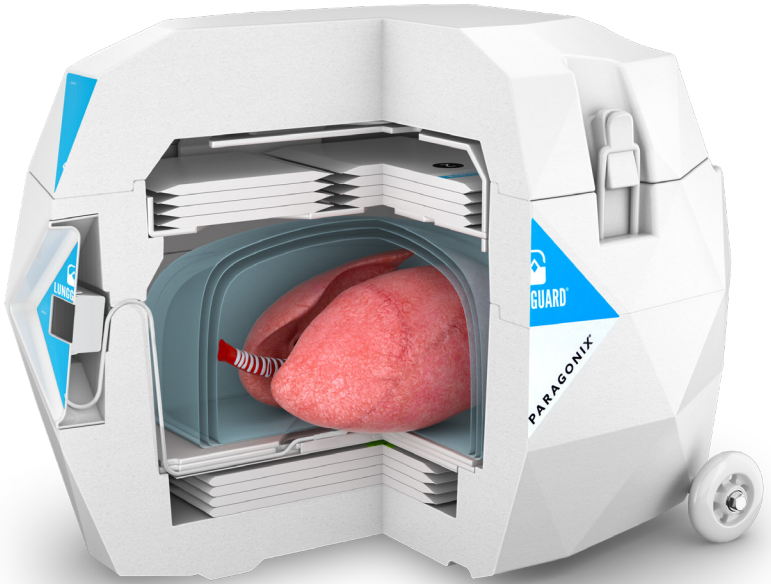
PRESERVATION SOLUTION MANUFACTURER REQUIREMENTS

- Manufacturer instructions call for a storage and transportation temperature range between 2°C to 8°C during storage and transportation
- Guidance from Lung Preservation Solution Manufacturers states to avoid low temperatures below 2°C and prolonged cold ischemia

ADVANCING LUNG PRESERVATION

Move on from Ice and Unpredictable Results with the **LUNGguard** Donor Lung Preservation System

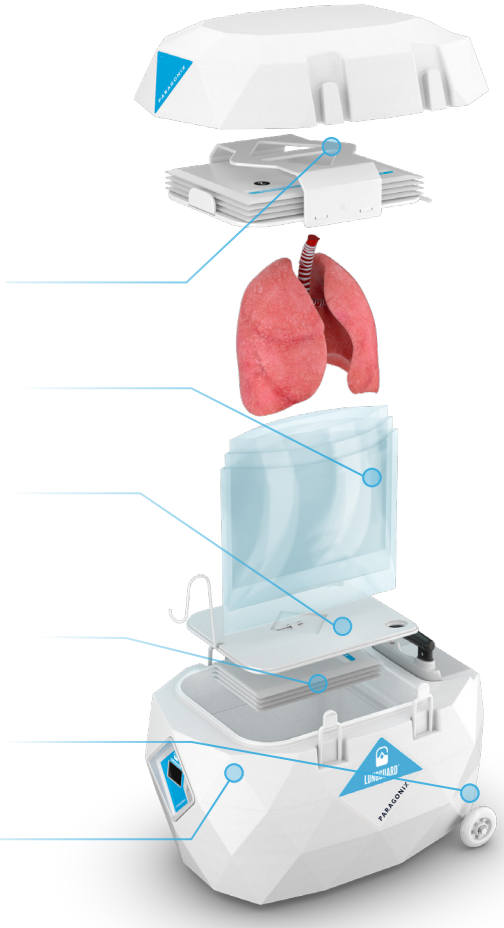
- Predictable, Repeatable, Measurable
- Control over organ preservation environment that is currently unachievable with ice storage
- Elevated hypothermic preservation has been shown to reduce post-transplant complications[1]
- Connectivity and data reporting for the entire transplant team
- Standardization of protocols and process



PARAGONIX LUNGGUARD®

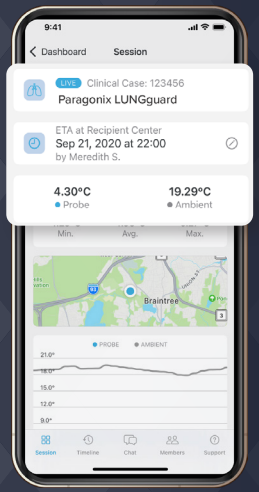
DONOR LUNG PRESERVATION SYSTEM

SECURE & RIGID OUTER SHELL	Secure vault to maintain the shape of the lungs and prevent physical trauma during transport
TRIPLE BAG SYSTEM	Utilizes industry standard best-in-care bagging system
TEMPERATURE PROBE	Continuous monitoring of temperature
PARAGONIX SHERPACOOL® RIBBONS AND POUCH	Consistent storage environment validated to maintain temperature
SHIPPER WITH TELESCOPING HANDLE AND WHEELS	Lightweight shipper system is validated to maintain a consistent thermal environment for up to 40 hours
DISPLAY AND BLUETOOTH® DATA TRANSMISSION	Real-time monitoring and data reporting via Bluetooth® connected devices



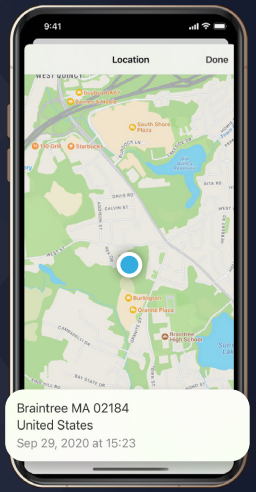
FOLLOW YOUR TRANSPLANT'S JOURNEY FROM BEGINNING TO END

The Paragonix App and Web Portal provides real-time, centralized, secure coordination for transplant teams including pairing with the Paragonix organ transport systems to share organ status with the entire team



ORGAN STATUS

Bluetooth® pairing

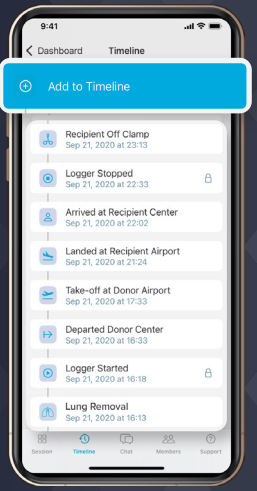


LOCATION

GPS tracking

COMMUNICATION

HIPAA compliant messaging



CASE STATUS

Snapshot summaries

GUARDIAN CLINICAL RESULTS[1]

GUARDIANLUNG

Largest Real-World Multi-Center Study Outcomes Reported with Controlled Hypothermic Preservation of Donor Lungs

J. Haney, M. Hartwig, N. Langer, P. Sanchez, P. Carrott, H. Huang, L. Ceulemans, J. Kukreja, E. Bush

KEY FINDINGS

- In this multi-center, real-world analysis, LUNGguard® showed notable statistically significant improvements of:
  - 38% reduction of PGD 3 at 24 hours (p=0.024)
  - 39% reduction of ECMO post transplant (p=0.027)
  - 51% reduction in need for dialysis at discharge (p=0.025)
- These data support growing evidence that avoiding cold or near freezing injury through elevated hypothermic preservation has a meaningful impact on outcomes

Measured Preservation Temperature
LUNGguard: 6.1°C ± 2.1°C

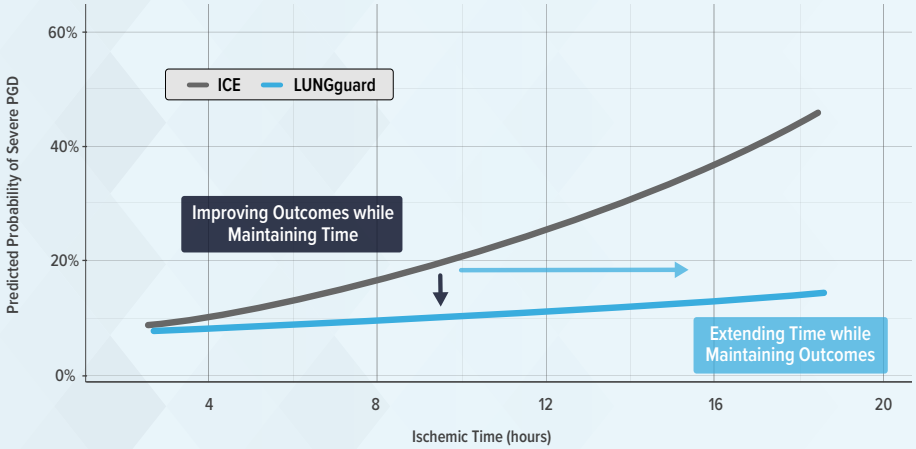
		ICE (N=259)	PARAGONIX LUNGGUARD (N=259)	P-VALUE
SURVIVAL	1-year Survival (%)	89.9%	**91.5%**	0.62
PGD	PGD 3 at 72 (%)	15.4%	**9.7%**	0.063
POST-TX MCS	ECMO Post-TX (%)	18.9%	**11.6%**	0.027
RENAL FUNCTION	Dialysis at Discharge(%)	11.2%	**5.5%**	0.025

Comparison of Paragonix System to Ice Storage, Paragonix data on file. GUARDIAN is a registered clinical study funded and administered by Paragonix Technologies. The data from the registry is descriptive, not statistically powered, and not pre-specified. The information should be interpreted accordingly.

KEY FINDING: GROWING EVIDENCE THAT ADVANCED HYPOTHERMIC PRESERVATION HAS A MEANINGFUL IMPACT ON OUTCOMES

GUARDIAN-LUNG: Improving Outcomes to All Ischemic Times[1]

Predicted Probability of Severe PGD at Ischemic Time Intervals



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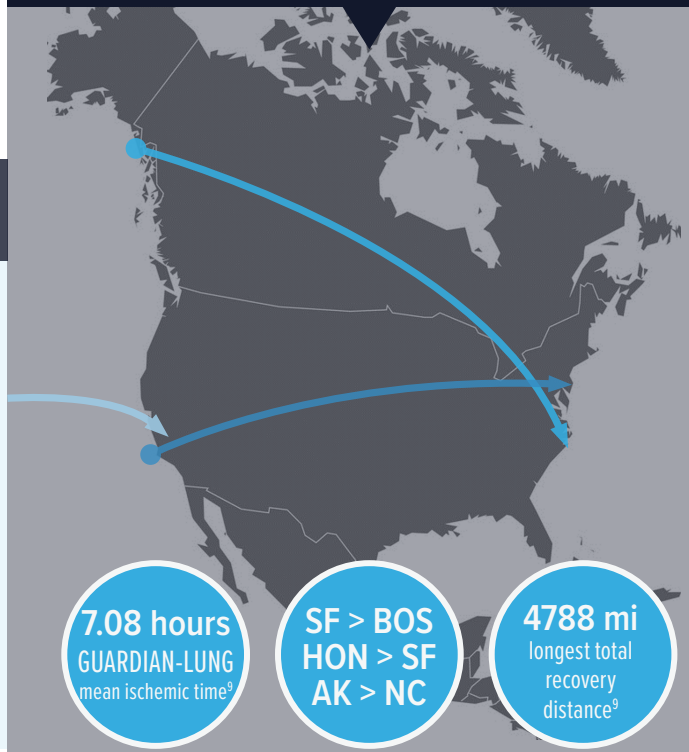
EXPANDED RANGE & ACCESS



Indications for Use: LUNGguard System is indicated for organ storage times up to 8 hours. Donor lungs exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability.

References

1. Haney et al., ISHLT Presentation 2024, Data on File.
2. Rega et al. 2023 ISHLT Presentation. Data on File.
3. Horch et al., Transplant Proceed 2002
4. Validation data on file with Paragonix Technologies
5. Hendry et al., J Thorac and Cardiovasc Surg 1989
6. Copeland et al. ISHLT Donor Heart and Lung 2020 Consensus Statement
7. Munshi, L. et al. The Lancet Respiratory Medicine 2013
8. Toborek, M. et al. et al. Basic Research in Cardiology 1999
9. Hartwig, M.. ISHLT 2023 Industry Symposium
10. Data on file

Indications for Use: The Paragonix LUNGguard® (LUNGguard®) is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the lungs. The intended organ storage time for LUNGguard® is up to 8 hours. Donor lungs exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient. Note: Partial lungs can be transported via LUNGguard® by packaging lungs per institutional protocol and UNOS guidelines.

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PARAGONIX®

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