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 an 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. The LUNGguard™ Donor Lung Preservation System provides a secure transport system that provides predictable, repeatable, and measurable results.
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 hours1

• Organ surface rapidly cools to near freezing temperatures, with significant gradients between the surface and interior of the organ.2,3

The International Society for Heart and Lung Transplantation has published a consensus statement that warns4

“...freezing and thawing causes irreversible cellular damage.”4

KNOWN RISKS BELOW 2°C5
• Local damage to pulmonary endothelium
• Potential for primary graft dysfunction after transplantation
**PGD PREVALENCE & RISK FACTORS**

**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

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**ISHLT DONOR LUNG PROCUREMENT CONSENSUS**

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

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**PRESERVATION SOLUTION MANUFACTURER REQUIREMENTS**

- Manufacturer’s 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
KNOWN RISKS FOR PULMONARY ENDOTHELIUM DAMAGE

Hypothermic induced cellular damage is a known risk of pulmonary endothelial damage. This is precipitated by prolonged total ischemic times and low storage temperatures below 2°C.

- Prolonged total ischemic times
- Low storage temperatures below 2°C
- Violates IFU of preservation solutions
- Leads to incorrect solution pH levels

CHAIN REACTION

Local damage to pulmonary endothelium
Activation of inflammatory cascade
Expanded damage to pulmonary endothelium
Edema, atelectasis, reperfusion injury
Primary graft dysfunction after transplantation
ADVANCING LUNG PRESERVATION

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

Predictable, Repeatable, Measurable.

Based on proven cardiac preservation system architecture

Control over organ preservation environment that is currently unachievable with ice storage

Connectivity and data reporting for the entire transplant team

Standardization of protocols and process
<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>SECURE &amp; RIGID OUTER SHELL</strong></td>
<td>Secure vault to maintain the shape of the lungs and prevent physical trauma during transport</td>
</tr>
<tr>
<td><strong>TRIPLE BAG SYSTEM</strong></td>
<td>Utilizes industry standard best-in-care bagging system</td>
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<tr>
<td><strong>TEMPERATURE PROBE</strong></td>
<td>Continuous monitoring of temperature</td>
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<tr>
<td><strong>PARAGONIX SHERPACOOL® RIBBONS AND POUCH</strong></td>
<td>Consistent storage environment validated to maintain temperature over 44 hours</td>
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<tr>
<td><strong>SHIPPER WITH TELESCOPING HANDLE AND WHEELS</strong></td>
<td>Light-weight, easy to handle system design to fit in standard aircraft and ground vehicles</td>
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<tr>
<td><strong>DISPLAY AND BLUETOOTH® DATA TRANSMISSION</strong></td>
<td>Real-time monitoring and data reporting via Bluetooth® connected devices</td>
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</table>
FOLLOW YOUR TRANSPLANT'S JOURNEY FROM BEGINNING TO END

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 to track organ conditions

**LOCATION**
GPS tracking of procurement team en route from the donor center

**COMMUNICATION**
HIPAA compliant messaging and communications to keep the procurement team, OPO, donor hospital, and recipient team informed

**CASE STATUS**
At-a-glance graphic status trackers provide a snapshot summary of timing of key events in the transplant
STABLE AND HOMOGENIUS TEMPERATURE PROFILE

Stable temperatures for each lung for extended preservation times (n=4)

Validated to maintain temperatures between 4-8°C for over 40+ hours
GUARDIAN-LUNG CLINICAL REGISTRY

Multi-Center, Post-market, Observational Registry
ClinicalTrials.gov Identifier: NCT04930289

Objective

The objective of GUARDIAN-LUNG is to collect and evaluate various clinical effectiveness parameters in patients with transplanted donor lung that were preserved and transported within the Paragonix LUNGguard™.

Synopsis

GUARDIAN-LUNG will include transplant centers across the U.S. and Europe. The primary objectives of the post-market registry study are to evaluate short term post-transplant outcomes (within the first 48 hours), intermediate term outcomes (3- and 6-month follow-up) and long-term outcomes (1-year follow-up).

Design

The GUARDIAN-LUNG study is a post-market, observational registry of adult and pediatric lung transplant recipient patients whose donor lung(s) was preserved and transported using the Paragonix LUNGguard™ Donor Lung Preservation System. The data are being collected retrospectively from medical records of patients already transplanted before the initiation of the registry and any new patients who meet the eligibility criteria.
References

1. Horch et al., Transplant Proceed 2002
2. Validation data on file with Paragonix Technologies
4. Copeland et al. ISHLT Donor Heart and Lung 2020 Consensus Statement
7. 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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