



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 LIVERguard® Donor Liver Preservation System is a leading FDA cleared and CE marked preservation device for donor liver transportation. Paragonix LIVERguard® provides advanced hypothermic preservation for livers along their journey from donor to recipient. Intentionally designed to fit directly into donor, transport, and transplant workflows, the product is easy to use in stressful, clinically demanding environments where there is no room for mistakes.

Tightly controlled temperatures are securely monitored throughout preservation via the Bluetooth® connected Paragonix App. The LIVERguard® Donor Liver Preservation System provides a secure transport system that delivers predictable, repeatable, and measurable results.



UNPREDICTABLE HISTORIC STANDARD OF CARE STORAGE⁵

Current standard of care utilizing ice for donor organ preservation can result in unpredictable liver tissue cooling



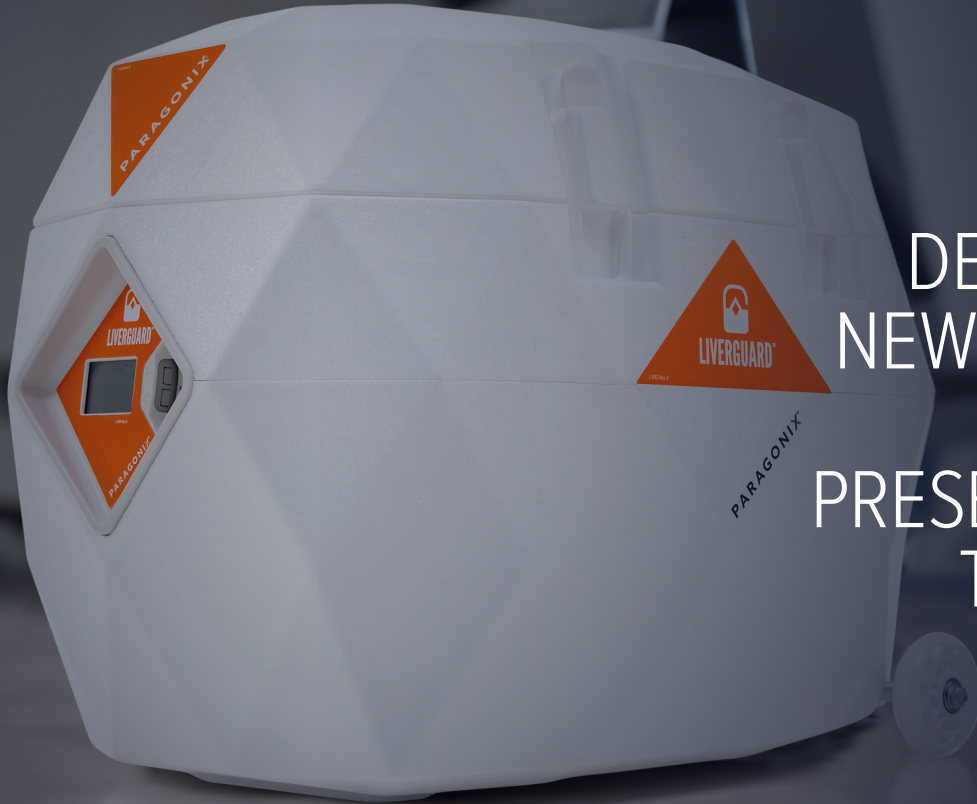
IMPROVE TRANSPLANT LOGISTICS & EXPAND PROGRAM REACH

Communication of advanced preservation, clinical support services, and real-time insights into organ conditions provide peace of mind on long distance procurements



MAXIMIZE POST-TRANSPLANT OUTCOMES

Early indicators of both clinical porcine model and clinical registry data show potential for reduction in post-transplant complications



DELIVERING A
NEW STANDARD
IN LIVER
PRESERVATION &
TRANSPORT

POOR OUTCOMES LINKED WITH COLD ISCHEMIC TIME^{1,2,3}

Multiple studies conducted on organs transported via ice storage (<4°C) have shown a correlation between CIT and worse outcomes:

"CIT over 4 hours was associated with increased risk for graft loss..."

Paterno, et al.
Liver Transplantation. 2019



"Longer post-transplant hospital stay... increases with every additional hour of CIT..."

Pan, et al.
Liver Transplantation. 2018

"Longer CIT was associated with a longer post-transplant hospital stay..."

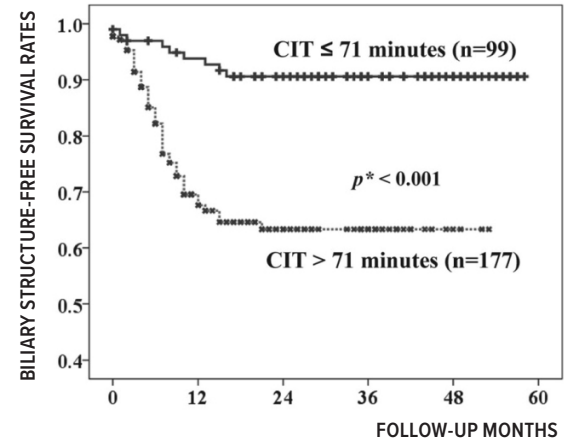
Paterno, et al.
Liver Transplantation. 2019



REDUCTION IN SURVIVAL RATES³

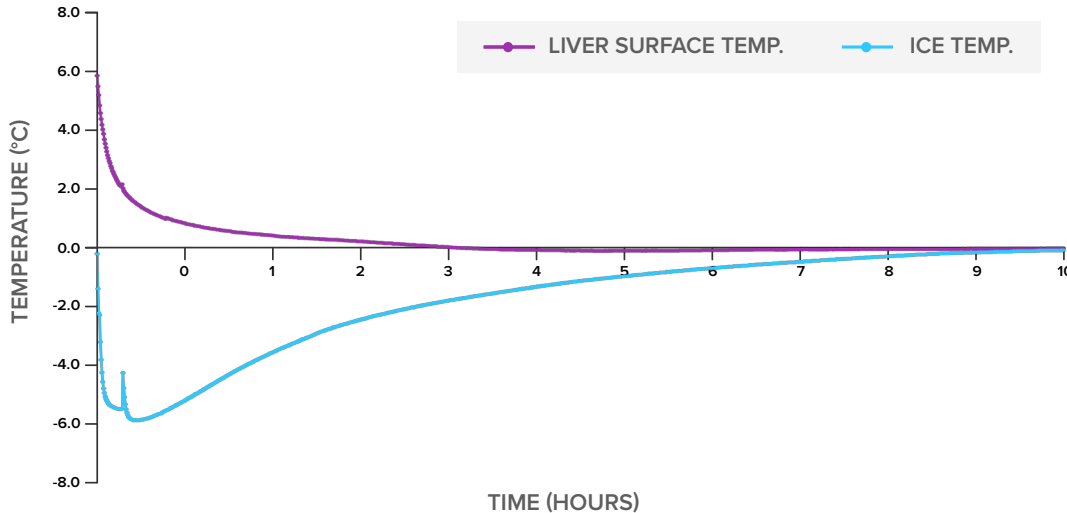
Cold Ischemic Time (CIT) >71 minutes associated with a decrease in biliary stricture-free survival rate ($p < 0.001$) in a univariate analysis

BILIARY STRICTURE-FREE SURVIVAL RATES



ASAIO 2023 PRESENTATION: ICE IS NOT 4°C⁴

THERMODYNAMIC CHARACTERIZATION OF LIVERS PRESERVED ON ICE VS ADVANCED HYPOTHERMIC PRESERVATION TECHNOLOGY EARLY ALLOGRAFT DYSFUNCTION RISK FACTORS



AVERAGE LIVER SURFACE TEMPERATURES DECREASED FROM AN INITIAL 5.9°C TO 0.8°C (1 HR) TO -0.1°C (4 HRS) IN THE ICE GROUP



STUDY CONCLUSIONS

- Donor livers packaged and preserved on ice undergo rapid drop in temperature, approaching freezing in an uncontrolled manner.
- Actual temperatures are lower than the historically assumed 4°C. In contrast, donor livers packaged using LIVERguard[®] remained between 4°C and 8°C.
- Centers may benefit from adopting controlled hypothermic strategies to prevent cold injury to donor livers.

SPECTRUM OF DONOR LIVER ISCHEMIA REPERFUSION INJURY (IRI)

Could Advanced Preservation Reduce the Impact of Cold Ischemic Time?

CLINICAL RISK FACTORS

Recipient factors
Macrosteatosis
ECD & DCD donors

PRESERVATION RISK FACTORS

Cold ischemia time
Warm ischemia time
Preservation temperature excursions <4°C

CELLULAR & MOLECULAR PATHWAYS

Increased vascular resistance
Metabolic/electrolyte disturbances
Microcirculatory dysfunction/
regional hypoperfusion
Immune activation

CLINICAL MANIFESTATIONS

Post-reperfusion syndrome (PRS)
Early allograft dysfunction (EAD)
Primary non-function (PNF)
Biliary strictures

HEPATIC ISCHEMIA REPERFUSION INJURY (IRI)

ADVANCING LIVER PRESERVATION

Optimize Preservation and Transplant Logistics with the **LIVERguard®** Donor Liver Preservation System



Predictable, Repeatable, Measurable



Expansive on-demand procurement network



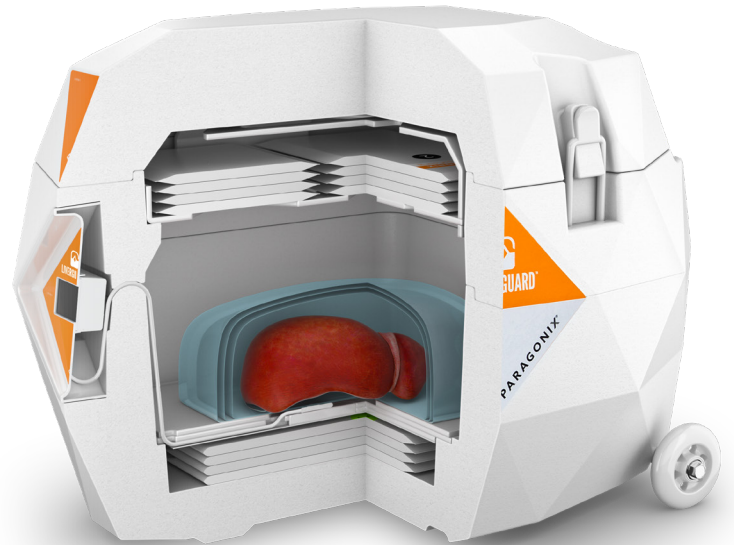
Control over organ preservation environment that is currently unachievable with ice storage



Connectivity, communication, and data reporting for the entire transplant team

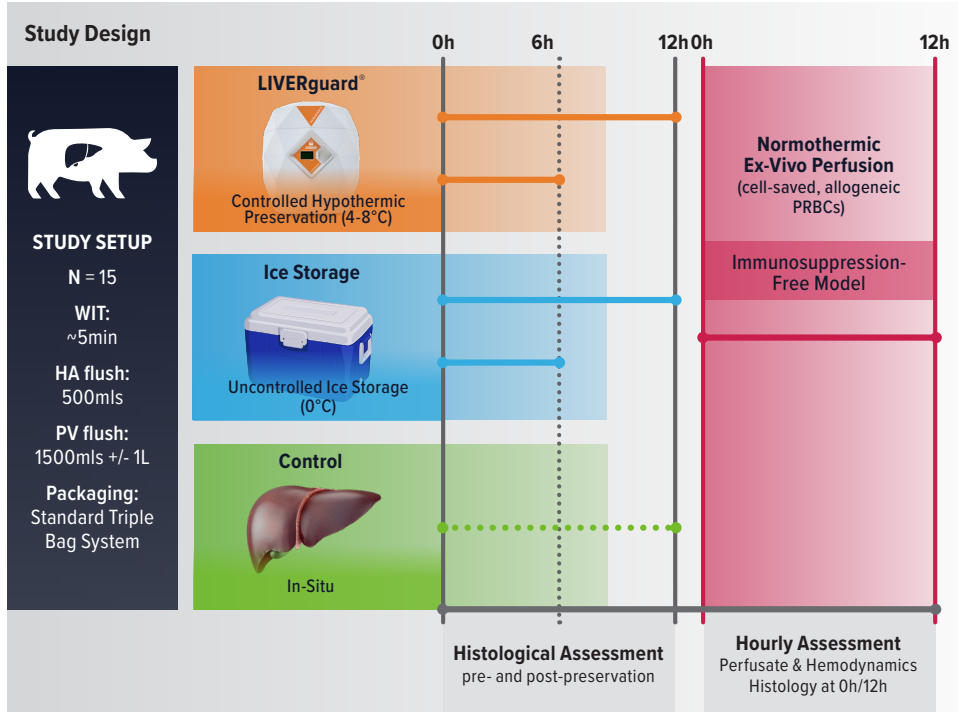


Utilizes SherpaCool® phase-change technology to prevent exposure to excessive temperature reduction



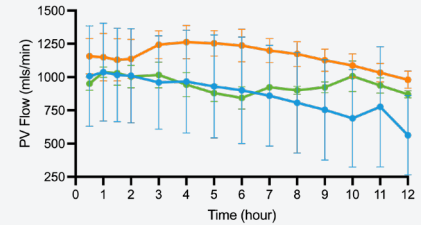
ANALYZING IMPACT OF ADVANCED PRESERVATION

Studying the Circulatory and Metabolic Effects of LIVERguard® Preservation in a Preclinical Porcine Model⁵



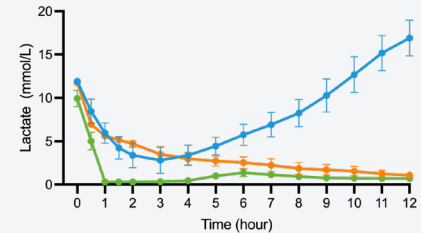
Study Results

— LIVERguard® — Ice Storage — Control



Portal Vein (PV) Metrics

PV Flow (LIVERguard® vs Ice Storage)



Markers of Ischemia Reperfusion Injury

Lactate (LIVERguard® vs Ice Storage)

GUARDIAN CLINICAL REGISTRIES

Observing the impact of preservation on donor livers, lungs, and hearts

The GUARDIAN registries are post-market, observational registries of adult transplant recipient patients whose donor organ was preserved and transported within a Paragonix device. The data is 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.

Design

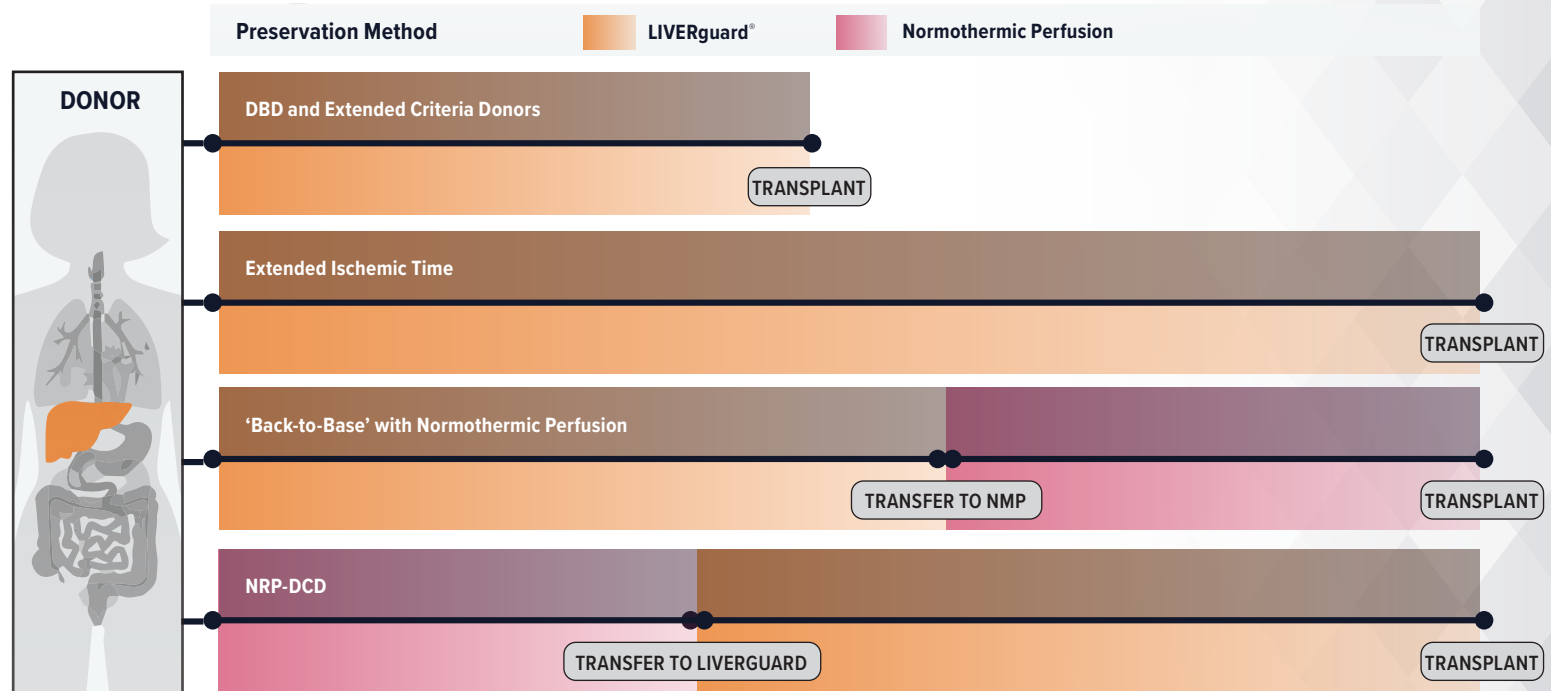
- ClinicalTrials.gov Identifier: NCT04141605, NCT04930289, NCT05082077
- Post-market, observational registry sponsored by Paragonix
- Retrospective chart review
- Broad eligibility criteria to capture real-world experience
- 1:1 match Paragonix to Ice Storage patients



Over 2,500 patients enrolled from over 30 international transplant programs

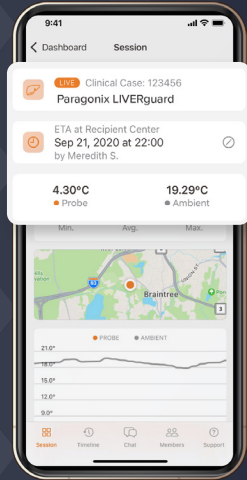
ADVANCED PRESERVATION TO SUPPORT COMPLEX CASES

LIVERguard® is being applied in many case applications to explore the potential benefits



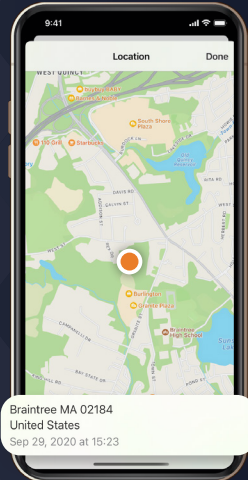
FOLLOW YOUR TRANSPLANT'S JOURNEY FROM BEGINNING TO END

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



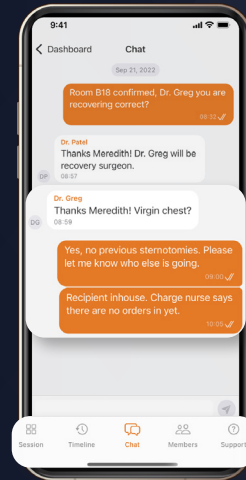
ORGAN STATUS

Bluetooth® pairing



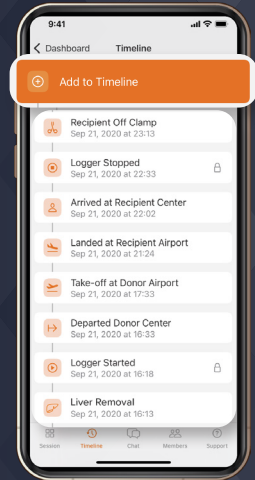
LOCATION

GPS tracking



COMMUNICATION

HIPAA compliant messaging



CASE STATUS

Snapshot summaries

References

1. Paterno, et al. Clinical Implications of Donor Warm and Cold Ischemia Time in Donor After Circulatory Death Liver Transplantation. Liver Transplantation. 2019
2. Pan, et al. Cold Ischemia Time Is an Important Risk Factor for Post–Liver Transplant Prolonged Length of Stay. Liver Transplantation. 2018
3. Park, et al. Prolonged Cold Ischemic Time Is a Risk Factor for Biliary Strictures in Duct-to-Duct Biliary Reconstruction in Living Donor Liver Transplantation. Transplantation. 2008
4. Patel et al. Ice Is Not 4°C: Thermodynamic Characterization of Livers Preserved on Ice Vs Advanced Hypothermic Preservation Technology. ASAIO 2023 Presentation
5. Data on file

Indications for Use: The Paragonix LIVERguard® Donor Liver Transport System is intended to be used for the static hypothermic preservation of livers during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with donor livers. The intended organ storage time for the LIVERguard® system is up to 15 hours.

Donor livers 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: A partial liver can be transported via the LIVERguard® System by packaging liver per institutional protocol and UNOS guidelines.

DOWNLOAD THE PARAGONIX TECHNOLOGIES APP NOW



PARAGONIX

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