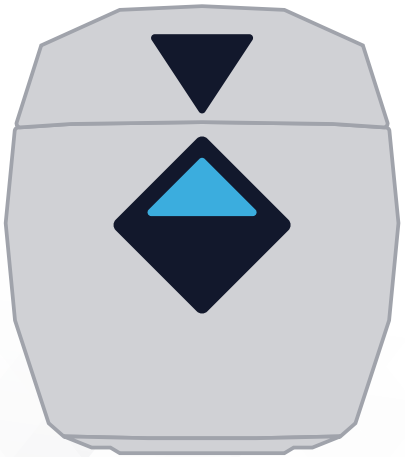
BAROGUARD®

DONOR LUNG PRESERVATION SYSTEM

PARAGONIX

Introduction



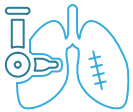
At Paragonix our mission is to create a new standard for organ preservation and transport that improves patient outcomes worldwide. We strive to protect the ultimate donation with the dignity and safety it deserves to give patients every possible advantage to thrive.

The Paragonix BAROguard® System unveils a new degree of standardization in preservation technology with the introduction of an automated pressure regulation system. Building on the legacy of The Paragonix LUNGguard®, the BAROguard® system is the first commercially available hypothermic preservation system that is equipped to automatically calibrate the airway pressure of donor lungs during transportation. The product is designed to be easy-to-use in high-stakes environments where there is no room for mistakes.

Pressures and temperatures are monitored throughout the organ journey via the Bluetooth® connected Paragonix App and Web Portal. The Paragonix BAROguard® provides a secure transport system that provides predictable, repeatable, and measurable preservation environment.

ISHLT 2020 CONSENSUS STATEMENT [1]

Recommends inflation be held at a static pressure of 12-15 cm H_2O



A NEW STANDARD OF CARE

1 in 3 U.S. lungs were transported in the LUNGguard® Donor Lung Preservation System so far in 2024[2]

ISHLT 2024 PRESENTATION ON DONOR LUNG PRESERVATION

Data supports growing evidence that elevated temperature reduces post-transplant complications[4]

DELIVERING A NEW STANDARD IN LUNG PRESERVATION & TRANSPORT

MANAGEMENT OF AIRWAY PRESSURE IN DONOR LUNGS

CURRENT STANDARD OF CARE: IN THE DONOR OPERATING ROOM

Donor lungs inflated to an uncontrolled pressure and volume

Air released to account for preservation and transport

Trachea is cut & stapled

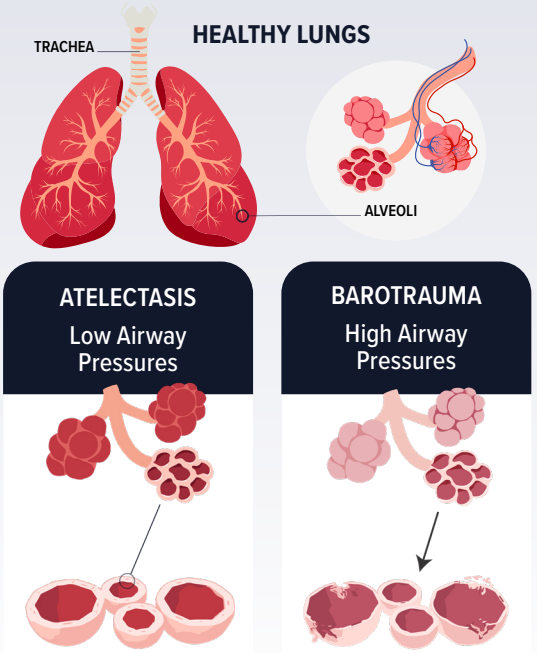
POTENTIAL CAUSES OF PRESSURE CHANGE

Decrease in pressure due to hypothermic conditions

Difference in ambient pressure between recovery & transplant sites

Pressure changes due to potential gas exchange

POTENTIAL COMPLICATIONS DUE TO SUBOPTIMAL PRESSURES[4]



BRIEF HISTORICAL SYNOPSIS ON INFLATION PRESSURE[5-10]

1971 - Faridy et al. *JOURNAL OF APPLIED PHYSIOLOGY*

"Transpulmonary pulmonary pressure gradient of **15 cm H_2O, sufficient oxygen is available from the airways and alveoli to permit ongoing ATP** syntheis in excised canine lung lobes."

1980 - Eagan et al. *JOURNAL OF PHYSIOLOGY*

"Beyond critical inflation pressure **(≈35 cm H_2O) pulmonary epithelium becomes non selectively permeable to solutes. Presumably, the increased pore radius at intercellular junctions caused by excessive stretch at high lung volumes does not diminish when lung volume is reduced**, causing the pulmonary epithelium to no longer function as an effective barrier between the circulation and the air space."

1985 - Dreyfuss et al. *REVIEW OF RESPIRATORY DIS.*

"Excessive hyperdistention of the donor lung may be harmful in that it may **increase lung solute permeability and produce pulmonary microvascular injury and edema.**"

1998 - Decampos et al. *JOURNAL OF HEART & LUNG TRANS.*

"**Hypoinflation followed by reinflation can also cause persistent atelectasis and barotrauma,** which are associated with poor post transplantation lung function."

1999 - Kayano et al. *CIRCULATION*

"Hypoinflation and hyperinflation of lung allografts influence short term survival and accumulation of neutrophilis in animals."

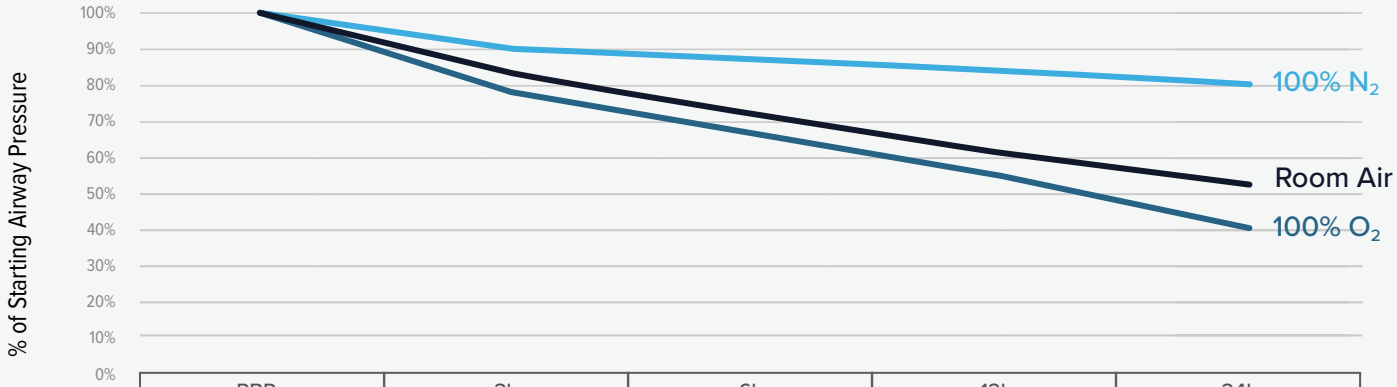
2013 - Munshi et al. *LANCET RESPIRATORY MED.*

"However, the amount of inflation is crucial, since **hyperinflation can also have a detrimental effect on the lungs due to barotrauma and reperfusion oedema. Furthermore, if donor lungs are transported by air, the degree of inlfation must take into account possible additional expansion,** which can occur even in pressurized cabins where barometric pressure might not exactly match ground pressure."

CARDIAC AND PULMONARY REPLACEMENT EFFECTS OF INFLATION VOLUME DURING LUNG PRESERVATION ON PULMONARY CAPILLARY PERMEABILITY[11]

Haniuda, Hasegawa, Shiraishi, Dresler, Cooper & Patterson, J Thorac and Cardiovasc Surg. 1996

CHANGES IN AIRWAY PRESSURES DURING PRESERVATION

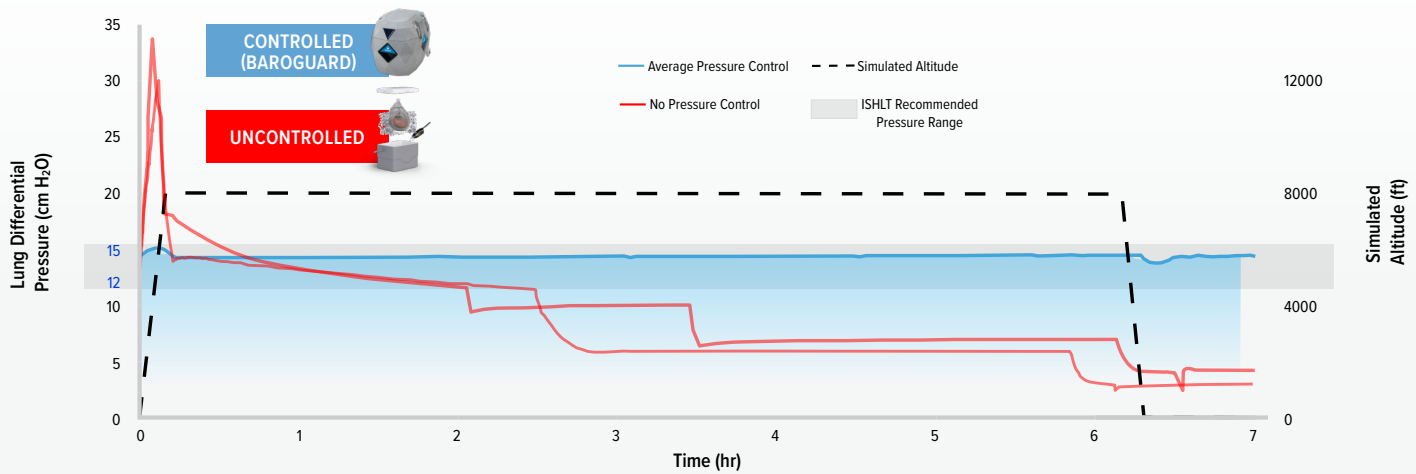


	PBP	3hr	6hr	12hr	24hr
Room Air	100%	82%	71%	60%	52%
100% O_2	100%	78%	65%	54%	39%
100% N_2	100%	89%	86%	83%	79%

*Adapted from study, from table to graphical form

BENCH TOP PRESSURE STUDY[2,12]

UNCONTROLLED VS CONTROLLED AIRWAY PRESSURE



Group	Unit	Max Pressure (cm H_2O)	Min Pressure (cm H_2O)	Max Pressure (cm H_2O, stable)	Min Pressure (cm H_2O, stable)
Pressure Control	1	14.5	13.0	14.5	13.1
Pressure Control	2	16.6	13.7	15.7	14.3
Pressure Control	3	15.1	13.6	14.8	13.9
No Pressure Control	1	33.8	2.3	17.4	2.3
No Pressure Control	2	30.1	2.8	12.1	2.3

KEY TAKEAWAYS

- Airway pressures of lungs without active control approached ~35 cm H_2O
- Airway pressures of lungs with pressure control were maintained between 12 - 15 cm H_2O

PROVIDING CONTROL FOR KEY PRESERVATION WITH BAROGUARD®

Monitor and Data Transmission

- Simple Bluetooth® pairing allows the system to transmit full data reports to users

Active Airway Pressure

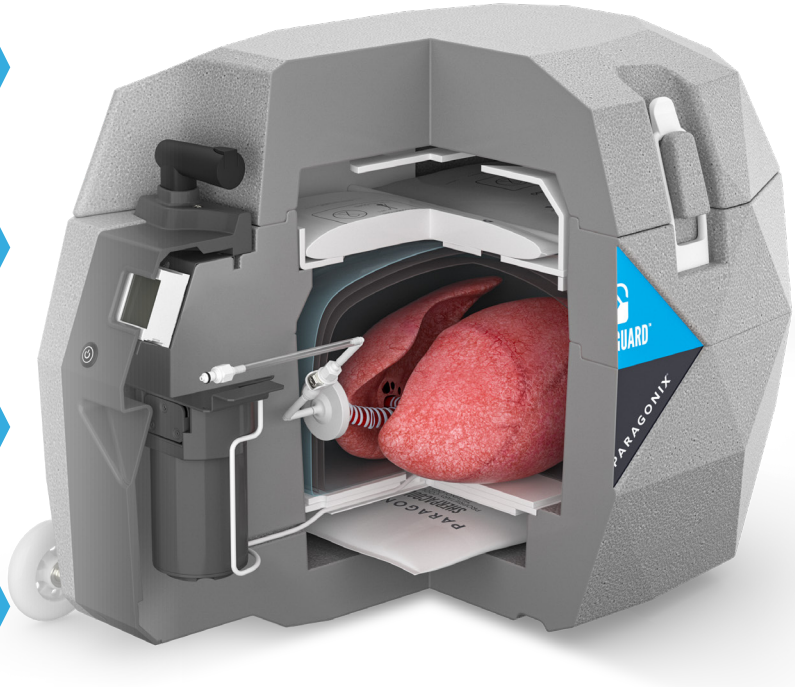
- Automated system actively maintains pressure at a range of 12-15 cm H_2O

Temperature Control

- Consistent 4°C - 8°C air temperature and preservation solution environment

Conditioned Room Air

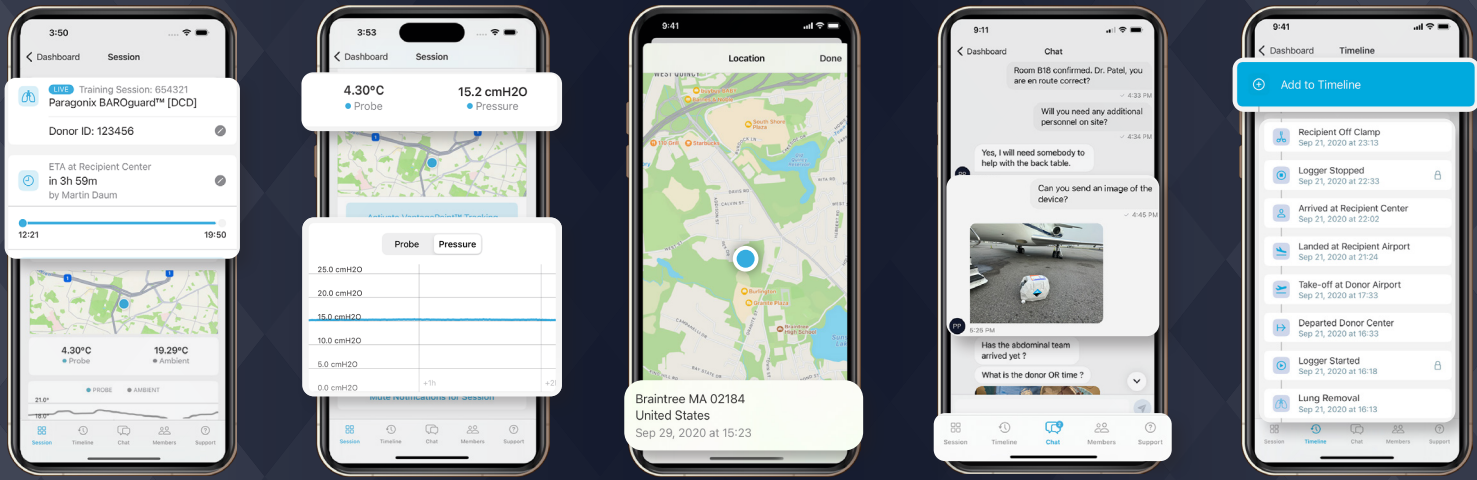
- Maintains room oxygen levels in air



*Variables Established by Peer Reviewed Studies

FOLLOW YOUR CASE'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

AIR PRESSURE STATUS

Live updates

LOCATION

GPS tracking

COMMUNICATION

HIPAA compliant messaging

CASE STATUS

Snapshot summaries

BAROGUARD ADDS CONTROL OF KEY PARAMETERS, BUILDING ON MARKET LEADING LUNGGUARD PLATFORM

LUNGGUARD®
DONOR LUNG PRESERVATION SYSTEM

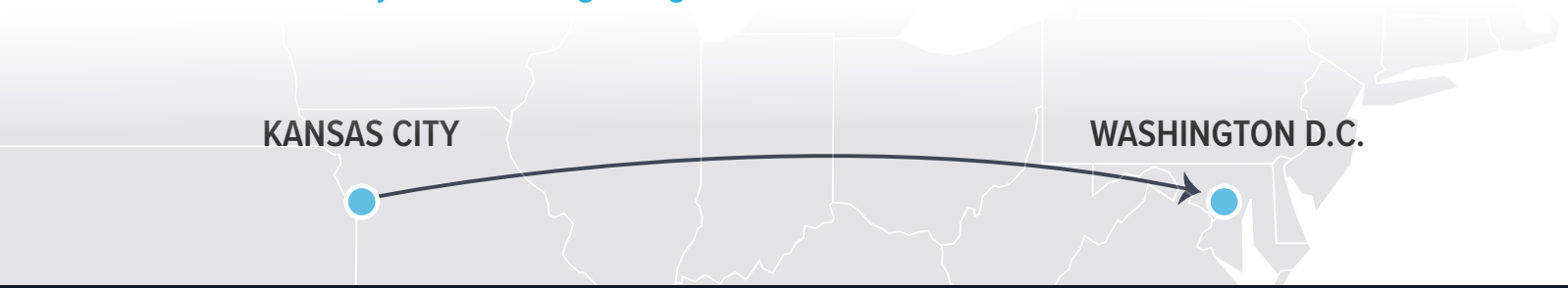
- Controlled Hypothermic Storage
- Improved Clinical Outcomes[2]
- Real-Time Temp Updates and On-Demand Reporting
- Digital Ecosystem

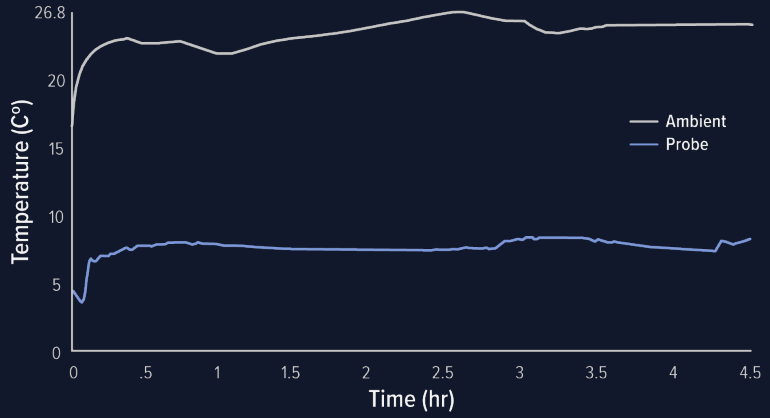
BAROGUARD®
DONOR LUNG PRESERVATION SYSTEM

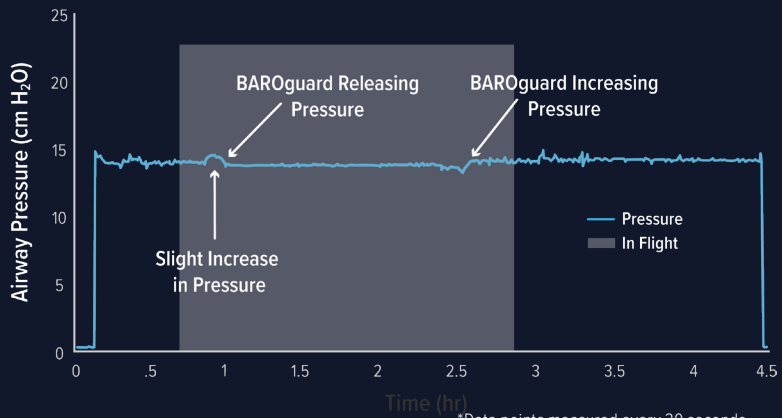
- Controlled Airway Pressure
- Controlled Hypothermic Air
- Room Air Oxygen Levels
- Real-Time Airway Pressure Monitoring

CASE REVIEW: KANSAS CITY TO WASHINGTON D.C. IN BAROGUARD

Consistent Airway Pressure Beginning to End[2,3]







*Data points measured every 30 seconds

References

1. Copeland et al. ISHLT Donor Heart and Lung 2020 Consensus Statement
2. Data on file.
3. Bush, Errol, STS Symposium Presentation 2024
4. Haney et al., ISHLT Presentation 2024
5. Decampos et al. Journal of Heart & Lung Trans. 1998
6. Faridy et al. Journal of Applied Physiology. 1971
7. Eagan et al. Journal of physiology. 1980
8. Dreyfuss et al. Review Of Respiratory Dis. 1985
9. Kayano et al. Circulation. 1999
10. Munshi et al. Lancet Respiratory Med.
11. Haniuda et al. J Thoac and Cardiovasc Surg 1996
12. Bulka et al. ASAIO Presentation 2023

Indications for Use: The Paragonix BAROguard® (BAROguard®) 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 BAROguard® 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 BAROguard® by packaging lungs per institutional protocol and UNOS guidelines.

DOWNLOAD THE PARAGONIX TECHNOLOGIES APP NOW

PARAGONIX

paragonix.com

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