



2022

ADVANCEMENT LEARNING SERIES



INNOVATION FOCUS

THE ALLIANCE
ADVANCEMENT
LEARNING SERIES

2021 Innovation Showcase: Advancing Donation and Transplantation Using Novel Technologies & Solutions

Thursday, January 6, 2021

2:00pm – 3:00pm ET

SPEAKERS:

2021 Alliance Corporate Partners





2022

ADVANCEMENT LEARNING SERIES



INNOVATION FOCUS

THE ALLIANCE
ADVANCEMENT
LEARNING SERIES

Continuing Education Information

Evaluations & Certificates

Certificate of Attendance

Participants desiring CE's that are not being offered, should complete a certificate of attendance.

- Certificates should be claimed within 30 days of this webinar.
- We highly encourage you to provide us with your feedback through completion of the online evaluation tool.
- Detailed instructions will be emailed to you within the next 24 hours.
- You will receive a certificate via email upon completion of a certificate request or an evaluation
- Group leaders, please share the follow-up email with all group participants who attended the webinar.





Deanna Fenton
Program Manager



Need Assistance?

Contact Us via Zoom Chat, or
info@organdonationalliance.org
786-866-8730

Meet Our Moderator



Corey Bryant

Senior Director,
Communications and Strategic
Initiatives



Meet Our Panelists



Gina Dunne Smith

Executive Director



Carie Kadric

Vice President of Clinical
Operations



Eric Brown

National Sales Director



Jenna Woodley

Product Manager, LifePort
Products



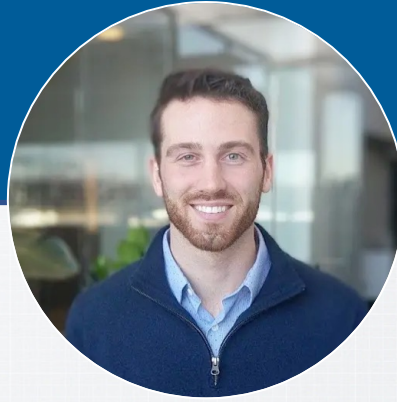
Meet Our Panelists



Meredith Thompson

TBD

PARAGONIX®
Advancing Organ Preservation



Dalton Shaul

Chief Executive Officer &
President



Scott Wunsch

Chief Operating Officer



Koren Axelrod, CPHQ

Associate Director, Digital
Products



Innovation at IIAM

Gina Dunne Smith
Executive Director

Motivation for Innovation

IIAM



DONATION



ALLOCATION



IMPACT



Innovation in Operating System: eReferral and Matching

You can now also send case UPDATES to IIAM using this page instead of calling!

To CREATE or UPDATE an Electronic Referral, please complete the form below. All fields are required.

IMPORTANT: Please only click the SUBMIT button once.

! IIAM is accepting Back Up Offers for organs and tissue for research except for Intestine and Kidney. (please offer these if they become primary).

When submitting the referral, please be aware of the following:

1. IIAM is accepting Back Up Offers for organs and tissue for research except for Intestine and Kidney. (please offer these if they become primary)
2. O.R. time allows IIAM to utilize the researcher's CIT requirements. If O.R. is estimated, please clarify in "case notes" section.
3. Please call IIAM directly with any Neonatal offers.
4. Please only click the SUBMIT button once.

Donation Portal

OPO UNOS Code

Contact Name

www.iiam.org/make-a-referral/

Safe, secure e-referral system

- Designed for busy professionals: mobile friendly, eliminates wait time
- Real time communication: submit e-updates without making a phone call

Electronic screening to efficiently match donors to researcher studies

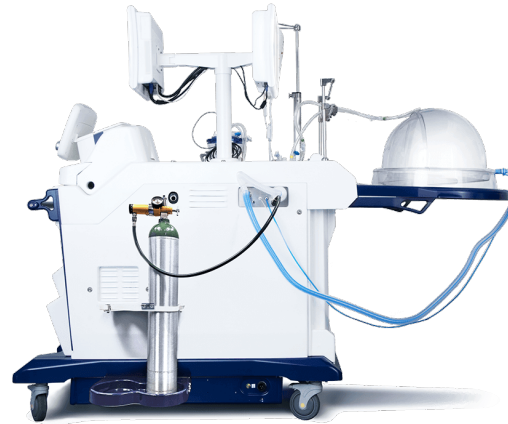
- Unique to IIAM in research community
- Faster response times to OPO recovery partners (43%)
- Reduced allocation time (51%)

A NETWORK OF INNOVATORS:

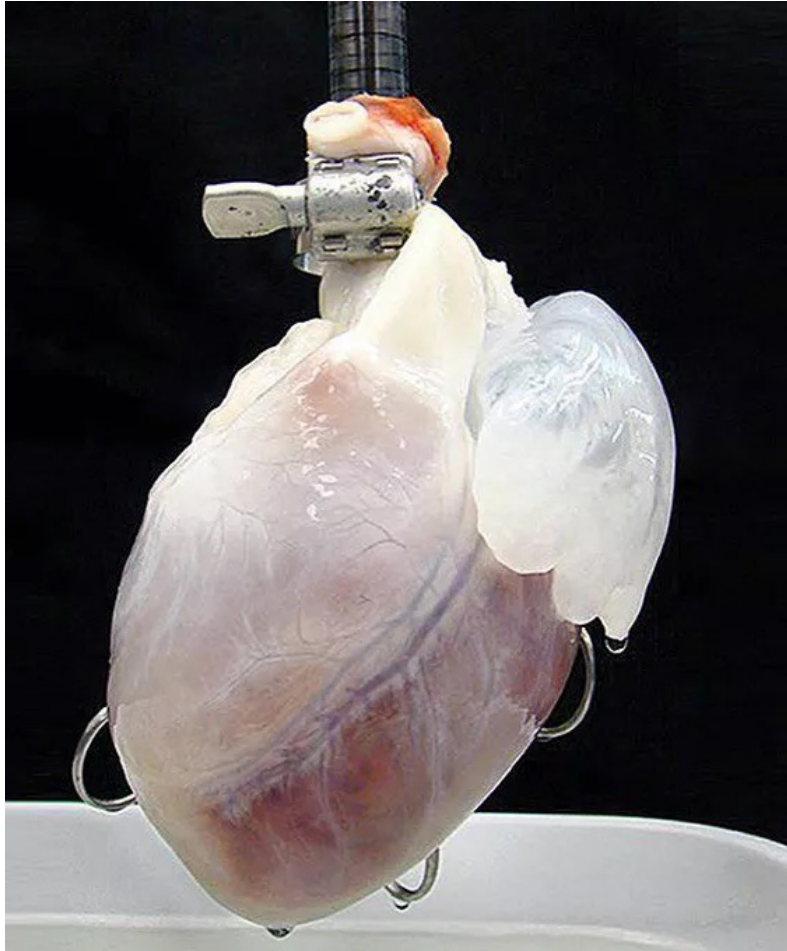
Transplant Technology and Therapeutics

Game Changers

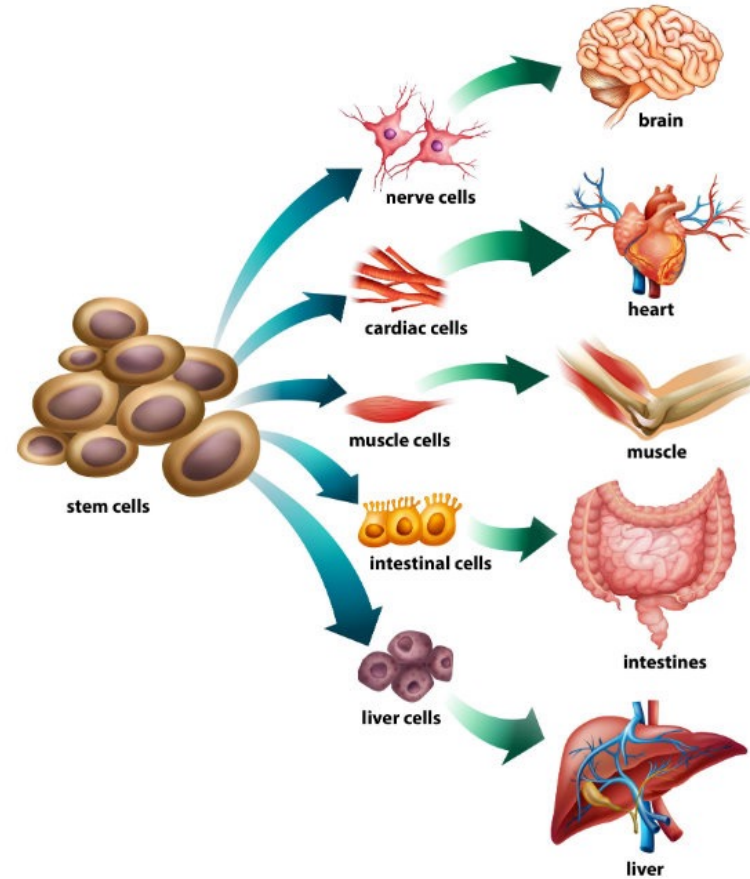
- Ex Vivo, Normothermic, Hypothermic



Game Changers

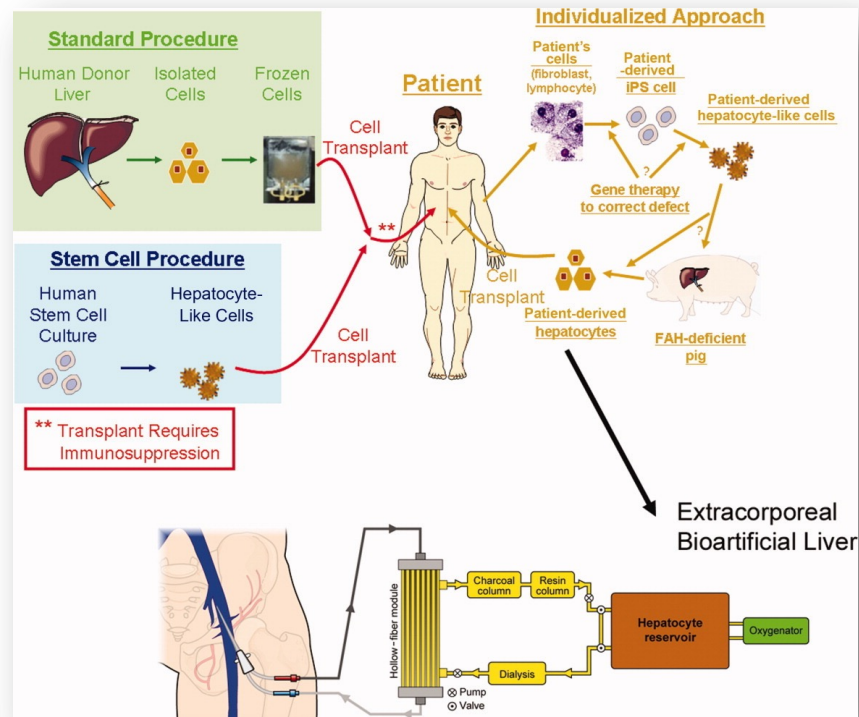


Potential Application of Human Stem Cells



Game Changers

Liver Cell Therapy



Evolution of Applications

- Acute Liver Failure
- Chronic Liver Failure
- Banked vs Fresh Hx
- Bioreactors; cell expansion
- Liver “patch” vs direct Hx infusion

Single liver can treat upwards of 150 patients!

#TheGoodWeDo



Innovation Showcase

Carie Kadric'

January 6, 2022



Leadership & Engaged Learning in Organ Donation & Transplantation

CompuMedTM

The Leaders in Diagnostic Telemedicine.

*Leveraging innovation and technology to
connect donors, doctors & health professionals
in a 'virtual' organ evaluation*

OPO Pathology Challenge

Obtaining Pathology Slides

- Availability, priority
- Hospital pathologist/techs are not always available for slide preparation
- If able to have slide made, inability to get slide read

Pathology Interpretations

- Variations in biopsy interpretation/experience at multiple hospitals

Pathology Information Sharing

- Share report
- Sending a physical slide with organ to the transplant center to view
- Provisional acceptance pending biopsy

CompuMed Telepathology Solution

Technology Advancements

- Cloud-based
- High resolution
- 24/7 availability
- Works with low-speed internet
- Digital scanning



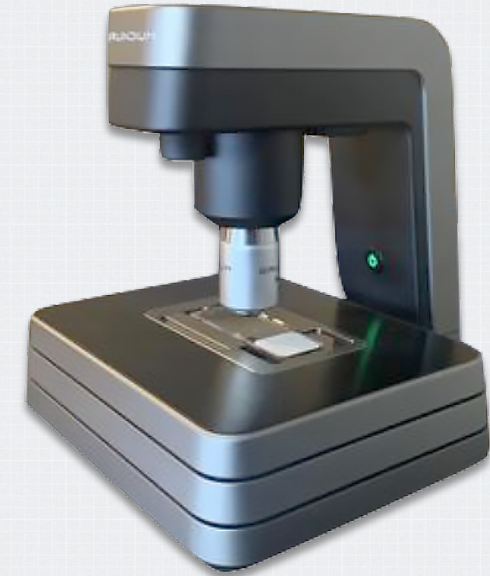
CompuMed Telepathology Solution

Digital Camera / Mobile Microscope



- Compact and Portable
- Optimized for Image Sharing
- Multiple Connectivity Options
- Donor Recovery Centers
- Digital camera on hospital microscope

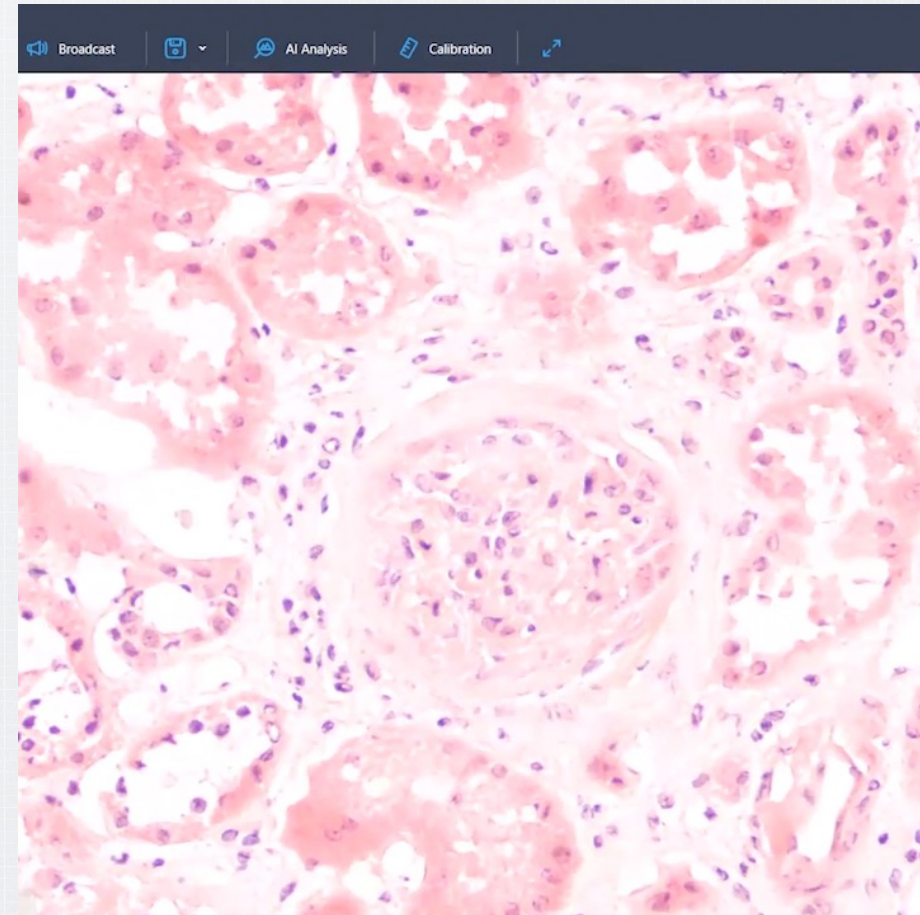
Semi-automated Slide Scanner



CompuMed Telepathology Solution

Live View

- Real-time sharing, annotating, and collaboration
- Shareable link or QR code
- Viewable on any computer or mobile device



CompuMed Telepathology Solution

+ PATIENT: TEST, PATIENT 23Y - M

+ STUDY: PATHOLOGY RIGHT KIDNEY (108213)

+ COORDINATOR: TSHAH, TESTADMIN

GLOMERULI SEEN (MIN 25):

Required

NUMBER SCLEROSED:

Required

% SCLEROSED:

Required

GLOMERULAR THROMBI

Required

ACUTE TUBULAR INJURY/NECROSIS

Required

TUBULAR ATROPHY

Required

INTERSTITIAL FIBROSIS

Required

None

INTERSTITIAL INFLAMMATION

Required

None

ARTERIAL SCLEROSIS (INTIMAL FIBROSIS)

Required

None

ARTERIOLAR HYALINOSIS

Required

COMMENTS

Comments

EXAMTAG

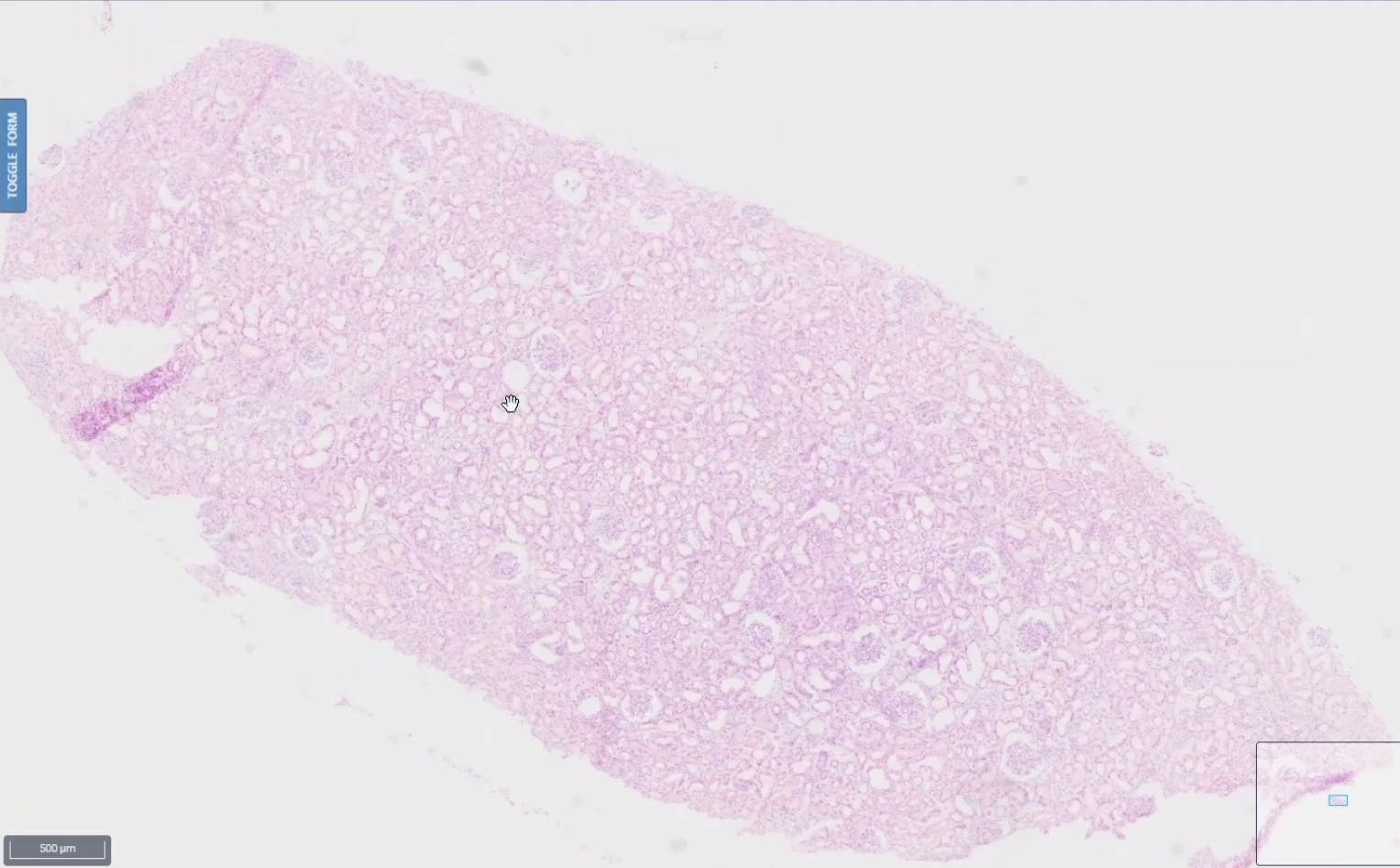
Finalize Report

Save Changes


Close Exam

010-AHEE484-KI-L-10x(0.30)

TOGGLE FORM



500 µm

 **THE Alliance**

Advancing Organ
Donation & Transplantation

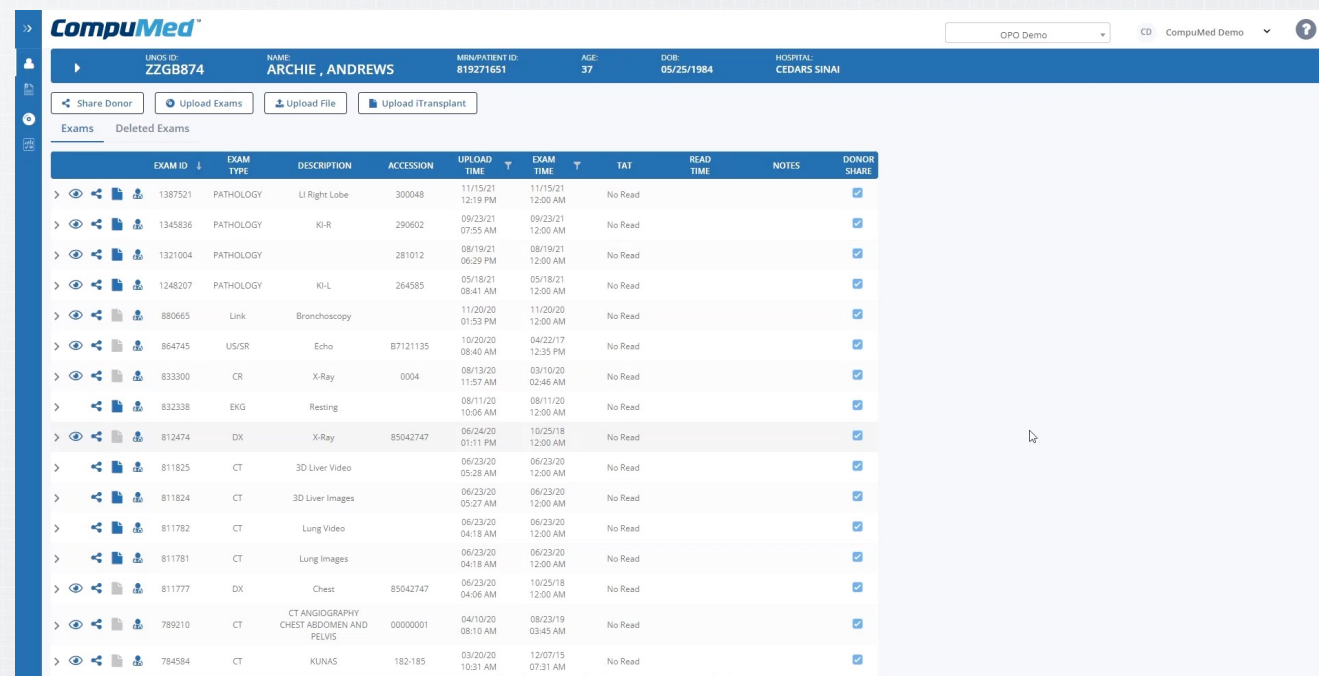
organdonationalliance.org/

1/5/22 | 7

CompuMed Telepathology Solution

Online Portal

- Secure cloud-based portal to upload, review and share
- Request an interpretation directly on the portal
- Final report/standardization
- Share biopsies along with all donor studies



EXAM ID	EXAM TYPE	DESCRIPTION	ACCESSION	UPLOAD TIME	EXAM TIME	TAT	READ TIME	NOTES	DONOR SHARE
1387521	PATHOLOGY	LI Right Lobe	300048	11/15/21 12:19 PM	11/15/21 12:00 AM	No Read			<input checked="" type="checkbox"/>
1345836	PATHOLOGY	KI-R	290602	09/23/21 07:55 AM	09/23/21 12:00 AM	No Read			<input checked="" type="checkbox"/>
1321004	PATHOLOGY		281012	08/19/21 06:29 PM	08/19/21 12:00 AM	No Read			<input checked="" type="checkbox"/>
1248207	PATHOLOGY	KI-L	264585	05/18/21 08:41 AM	05/18/21 12:00 AM	No Read			<input checked="" type="checkbox"/>
880665	Link	Bronchoscopy		11/20/20 01:53 PM	11/20/20 12:00 AM	No Read			<input checked="" type="checkbox"/>
864745	US/SR	Echo	87121135	10/20/20 08:40 AM	04/22/17 12:35 PM	No Read			<input checked="" type="checkbox"/>
833300	CR	X-Ray	0004	08/13/20 11:57 AM	03/10/20 02:46 AM	No Read			<input checked="" type="checkbox"/>
832338	EKG	Resting		08/11/20 10:06 AM	08/11/20 12:00 AM	No Read			<input checked="" type="checkbox"/>
812474	DX	X-Ray	85042747	06/24/20 01:11 PM	10/25/18 12:00 AM	No Read			<input checked="" type="checkbox"/>
811825	CT	3D Liver Video		06/23/20 05:28 AM	06/23/20 12:00 AM	No Read			<input checked="" type="checkbox"/>
811824	CT	3D Liver Images		06/23/20 05:27 AM	06/23/20 12:00 AM	No Read			<input checked="" type="checkbox"/>
811782	CT	Lung Video		06/23/20 04:18 AM	06/23/20 12:00 AM	No Read			<input checked="" type="checkbox"/>
811781	CT	Lung Images		06/23/20 04:18 AM	06/23/20 12:00 AM	No Read			<input checked="" type="checkbox"/>
811777	DX	Chest	85042747	06/23/20 04:06 AM	10/25/18 12:00 AM	No Read			<input checked="" type="checkbox"/>
789210	CT	CT ANGIOGRAPHY CHEST ABDOMEN AND PELVIS	00000001	04/10/20 08:10 AM	08/23/19 03:45 AM	No Read			<input checked="" type="checkbox"/>
784584	CT	KUNAS	182-185	03/20/20 10:31 AM	12/07/15 07:31 AM	No Read			<input checked="" type="checkbox"/>

→ CompuMed Telepathology Solution

Physician Network

Expert Knowledge

- U.S. Board-Certified
- Transplant-focused
- Highly experienced

24/7/365 Availability

- Built for high urgency telemedicine
- STAT diagnostic turn-around times from 30 mins to 2 hours
- Verbal consultations on demand

Consistent Interpretations

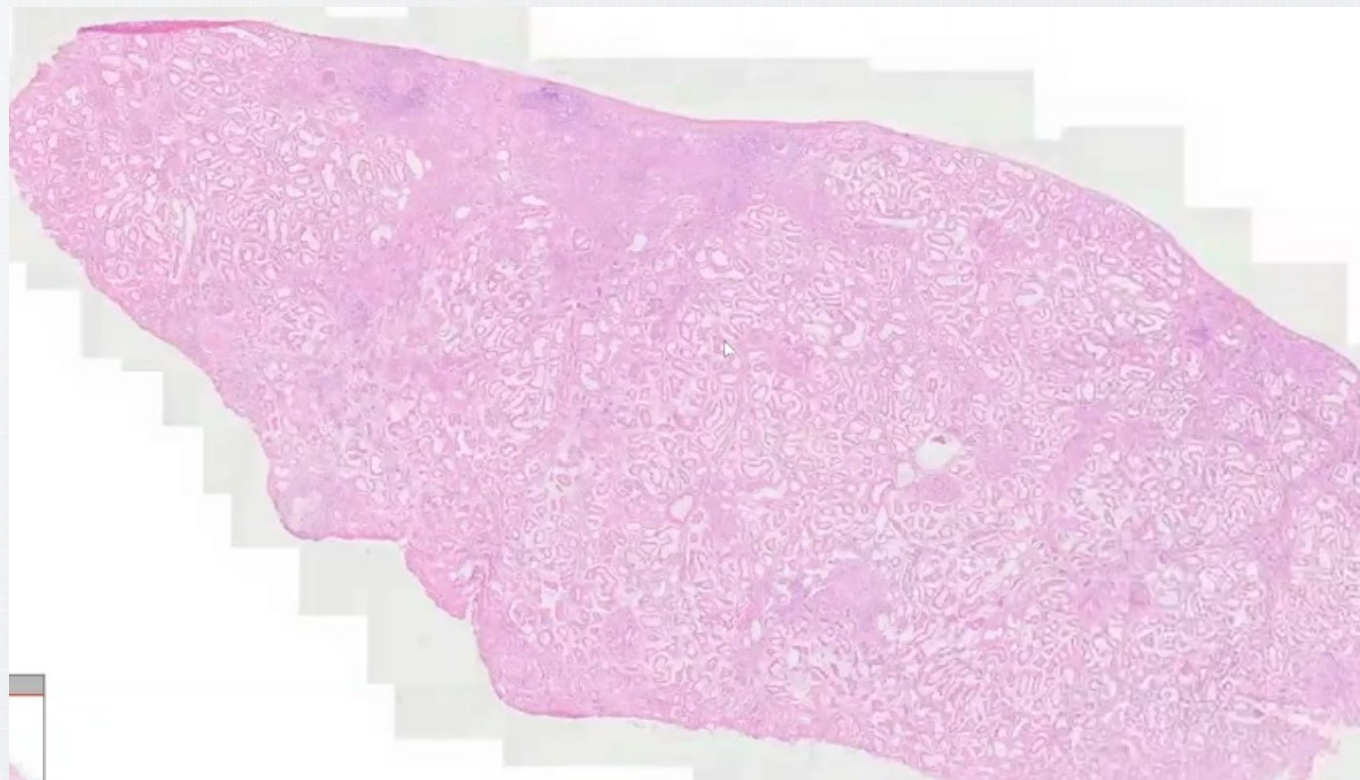
- Dedicated “core” reading groups
- Continuous peer reviews
- Personalized, accountable results



CompuMed Telepathology Solution

AI Automated Analysis

- Learns, detects and quantifies specific features
- Improves efficiency, accuracy & Consistency
- 90% faster than manual image analysis
- Discover novel quantitative data-glomerular density



CompuMed Telepathology

Benefits

Hospital

- Reduce use of On-Call staff
- Reduce Pathology Fatigue
- Ability to use camera to improve workflow within hospital

OPO

- Greatly reduce reliance on Donor Hospitals
- Timely/Consistent interpretations
- Read by Specialist
- Reduce Case Time & Cost
- Improve expedited placement on late declines
- Reduce cold time
- Support OPO Donor Recovery Centers

Transplant Teams

- View full pathology images on computer or mobile device
- Consistent, reliable interpretations
- Timely actionable information

JUST SOME OF OUR SATISFIED CUSTOMERS



CompuMed™

For more information

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Carie Kadric'

VP of Clinical Operations

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Sterile Surgical Slush

Why Quality Matters

CE Credit Information

1.2 Contact hours will be provided by TG&A, an approved provider by the California Board of Registered Nursing, Provider Number CEP 16550. info@terrigoodman.com

The presenter, Amanda Budak, PhD, RN, CBN, is a paid Clinical Consultant for C Change Surgical.

Learning Objectives

Describe the purpose of sterile slush in the surgical setting.

Explore surgical procedures facilitated by sterile slush.

Describe the considerations for ideal sterile slush as defined by clinicians.

Describe the evolution of sterile slush technology.

Discuss the considerations as they apply to each method of producing sterile slush.

What is Sterile Slush?

Sterile isotonic saline-based solution
that is neither a solid nor a liquid

Made from 0.9% sodium chloride,
Normasol, or Lactated Ringers (D5LR)



Thermodynamic Phenomenon

As ice forms in a saline solution, it produces a crystal matrix (think of a snowflake).

Agitation during the freezing process produces small crystal formations, resulting in soft slush ideal for atraumatic tissue management.

Why Sterile Slush?

Preserve the viability of living tissue once it has been disconnected from its blood supply.

Topically cool tissue to provide mild hypothermia.

Reduce the amount of oxygen required to sustain viability.

Slow the rate of cellular damage.

Applications of Sterile Slush

Sterile surgical slush has applications in more than 400,000 procedures annually in the U.S.

More than 1,000,000 liters of sterile slush are used annually in the U.S. in different surgical specialties.

Cardiac and urology procedures typically use 1 to 2 liters of sterile slush. Procurement or transplant procedures typically use 3 to 8 liters.



Dr. Steven Rudich

Liver & Transplant Surgeon
Gift of Life

Dr. Rudich is an organ procurement specialist and surgeon who provides insight on why sterile slush is essential in certain surgical procedures.





“Dr Rudich, why is sterile slush essential to the success of your surgical procedures?”



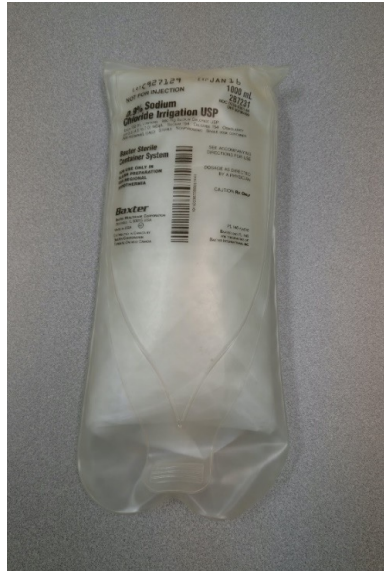
Considerations for ideal Sterile Slush

- Accessibility
- Sterility
- Consistent quality
- Ease of use
- Time
- Affordability

Approaches to providing Sterile Slush



Saline Bottles



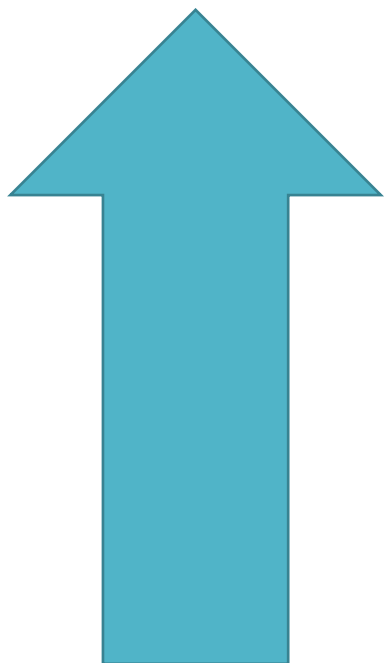
Saline Bags



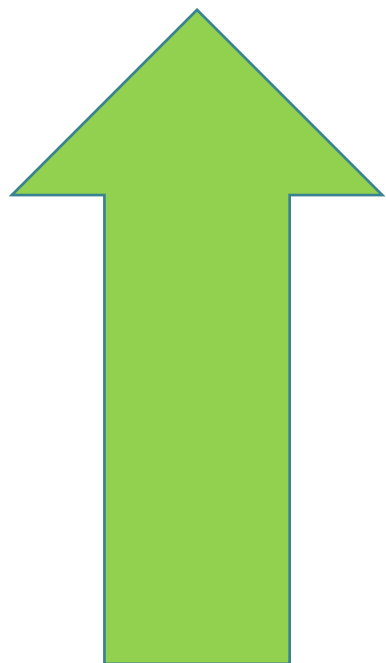
Open Basin System



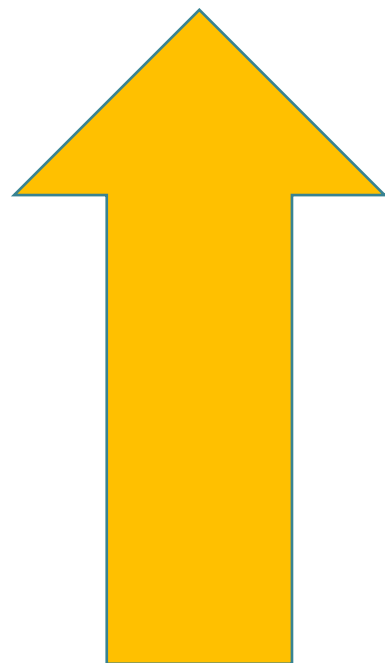
Slush Freezer & Containers



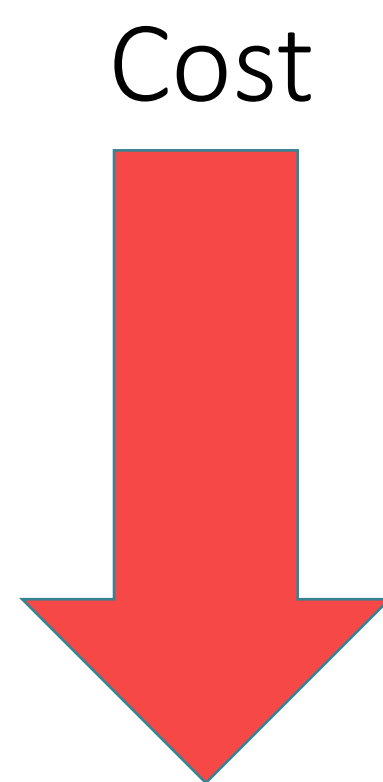
Quality



Efficiency



Sterility



Cost

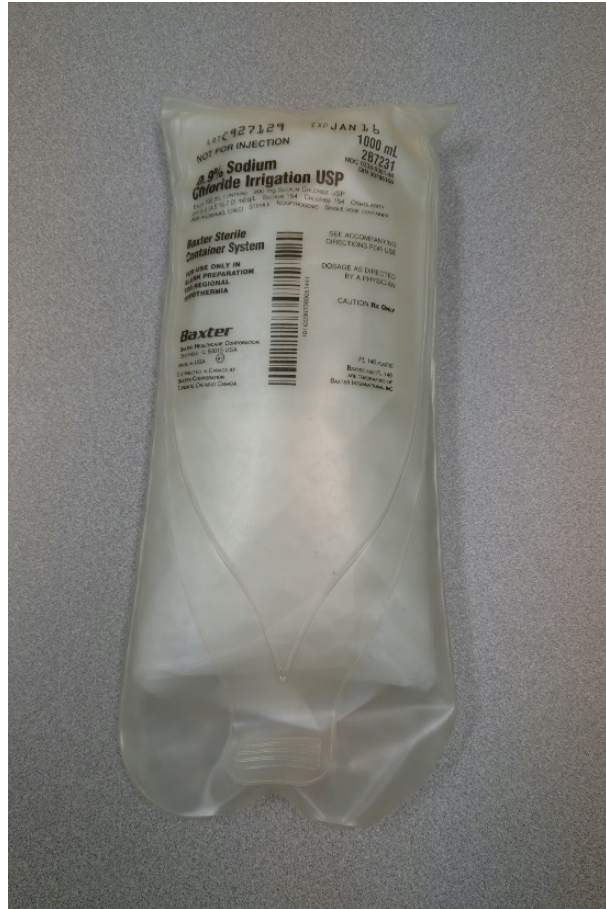
Slushing Saline Bottles



Freezing saline bottles
in a receptacle with
non-sterile ice and
Isopropyl alcohol



Slushing Saline Bags



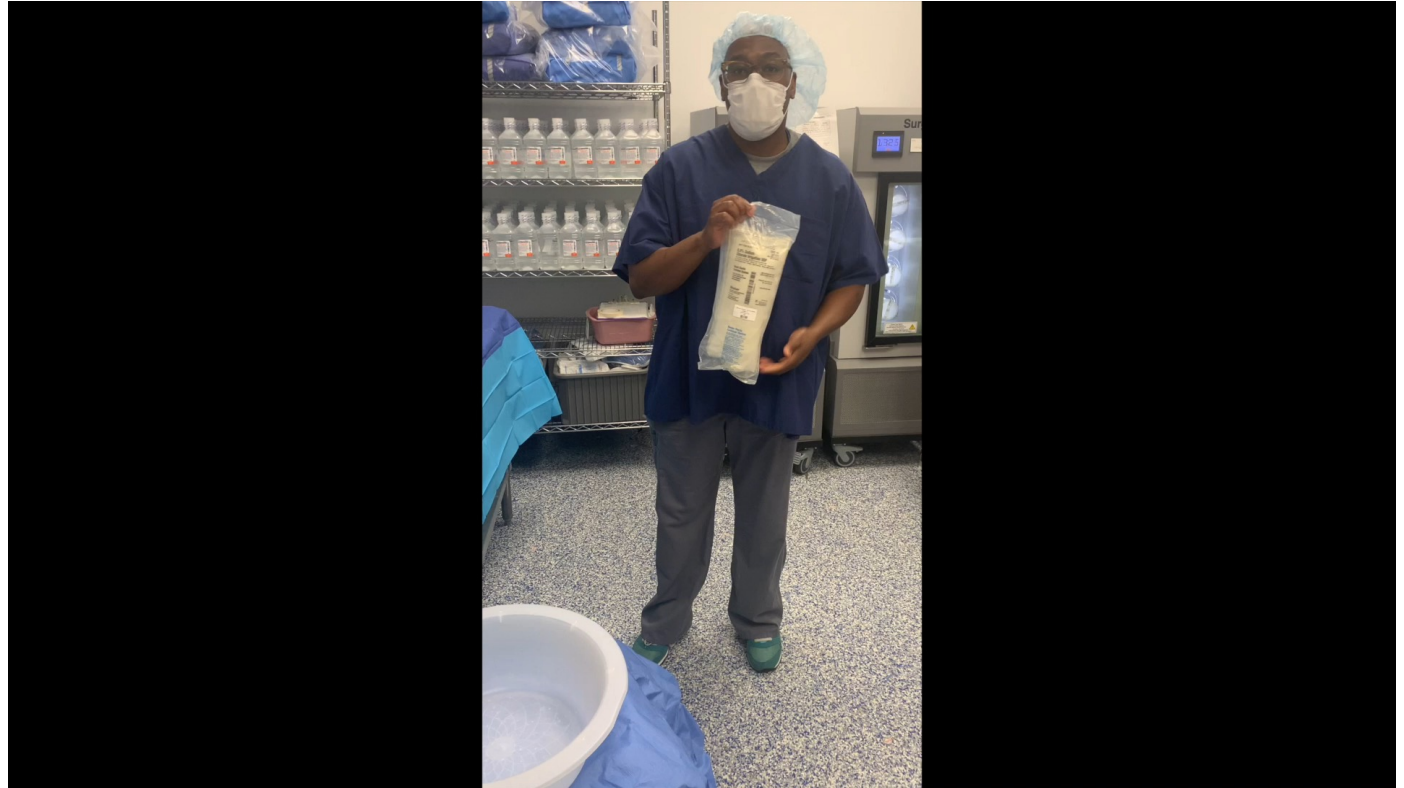
Freezing double
enclosed saline bags
in a chest freezer

Slushing Frozen Saline Bricks



Prepared on the sterile field

Slushing Frozen Saline Bricks



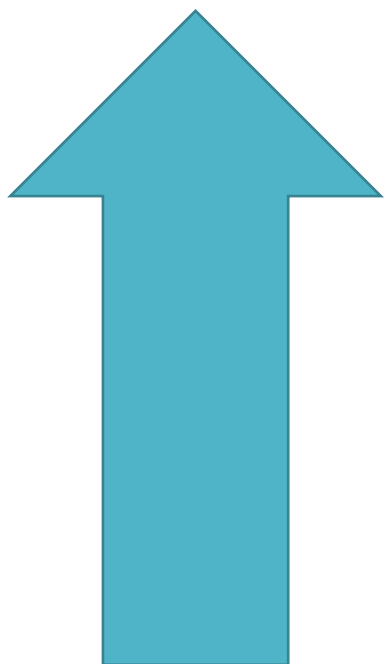
Prepared first, then delivered to the sterile field

Open Basin System

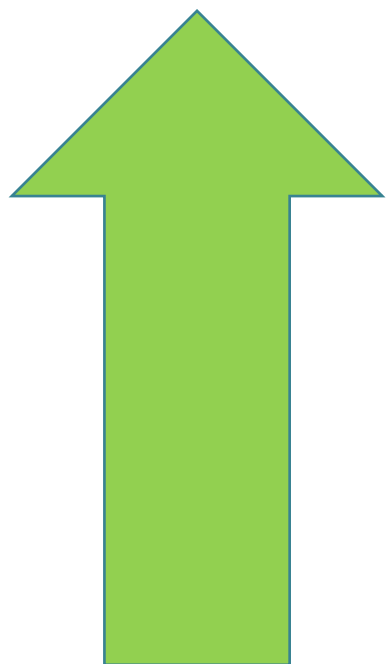


Open Basin System

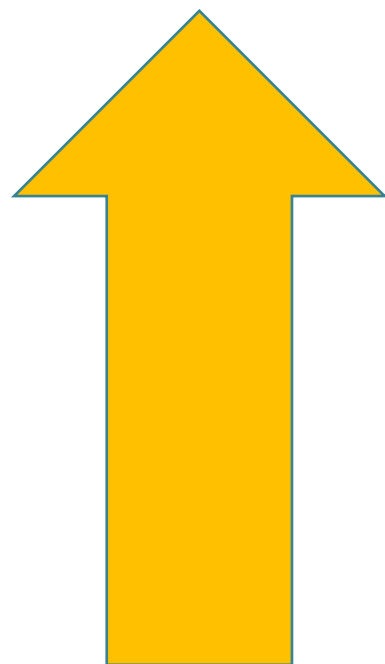




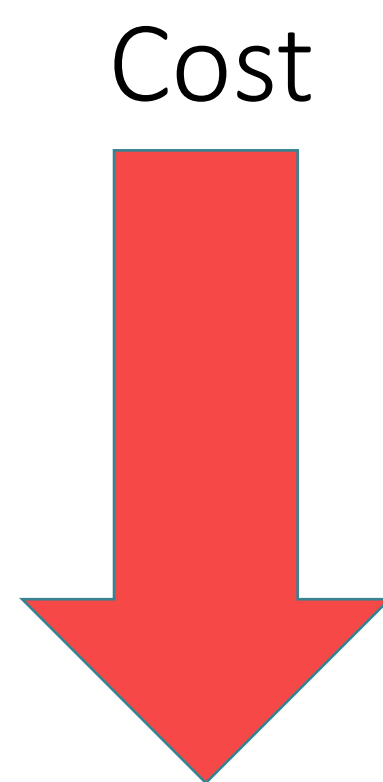
Quality



Efficiency



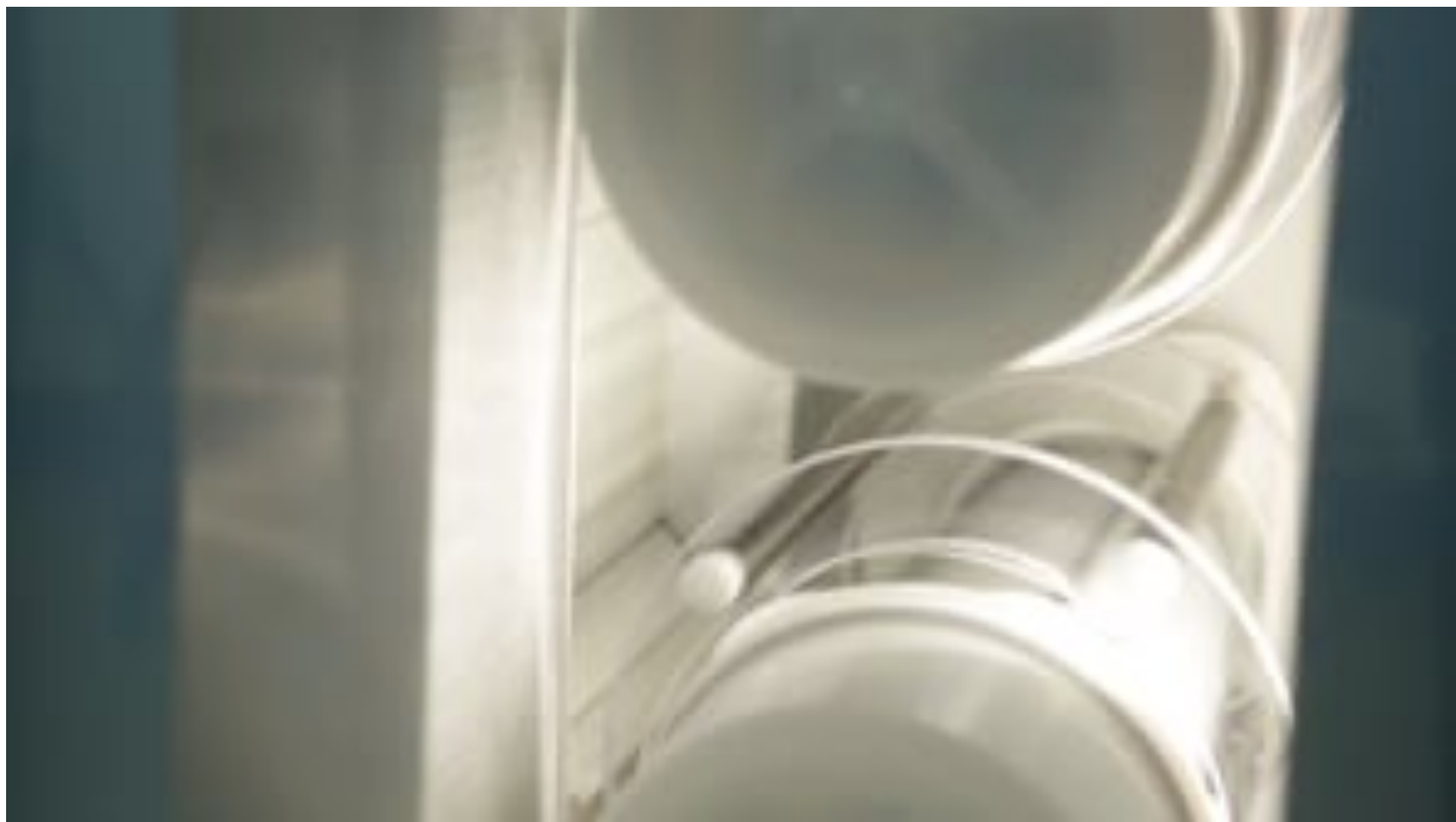
Sterility



Cost

Slush Freezer and Containers







Slush Freezer and Containers

Procurement-Specific

Advantages over other slush methods

- High-volume. Produce & store. Make more
- Soft slush provides better coverage and cooling of the organ
- No loud noise or disruption
- Removes risk of plastic shards inside the slush
- Users gain control of supply
- Automatically makes consistently soft slush



Clinician Feedback - Closed System

“The SurgiSLUSH™ freezer is a major improvement over our old system! ... The OR environment is much quieter, and less crowded ... our surgeons have smoother, high quality slush to work with and our nurses don’t have to attend to making sure the slush is maintained ...”

Clinical Coordinator | CVOR

OR teams value fewer disruptions,
high-quality slush, and greater efficiency.

Clinician Feedback - Closed System

“My team and our surgeons ... big supporters of SurgiSLUSH™!”

Director | Surgical Services

Improved slush production is
important to the entire OR team.

Clinician Feedback - Closed System

“It was a definite upgrade with sterile slush in a tamper-proof container.”

Clinical Director | Perioperative Services

Staff views sterile protection as a key upgrade from other slush methods.

Clinician Feedback - Closed System

*“Should slush in a sterile self-contained package be standard of care?
I believe it should. Great patient-safety centered innovation!”*

Medical Director | Practicing Urologist

Medical professionals value container system
with patient-safety features.

Clinician Feedback - Closed System

“As a CVOR traveler, I get to see how many different ways we do the same thing. I was in place when a facility switched to a closed system ... LOVE IT! One less piece of equipment in the way and making noise. One less cord on the floor to trip over.”

RN | CVOR

Decreased noise and lack of need for additional equipment in the OR can contribute to a safer workspace.

Consistent
Quality

**Consistent
actions
create
consistent
results**

A background image showing a person's hand writing on a notepad with a pen. A cup of coffee is visible in the background, suggesting a workspace or study environment.



Questions?

(877) 989-3737

info@cchangesurgical.com

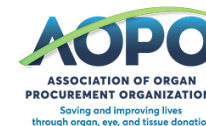


LifePort® Kidney and Liver Transporters: Setting the New Standard

December 2021

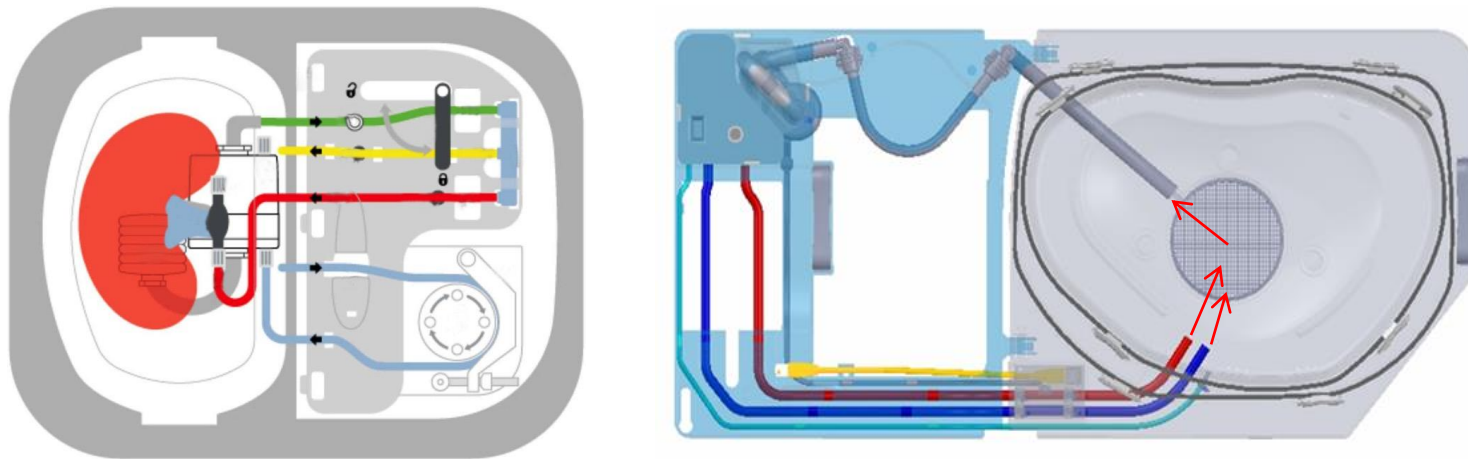
About Organ Recovery Systems

- Founded in 1998
- Mission: extend lives by creating faster, safer, easier ways to transport donated organs
- Vision: deliver exceptional clinical tools and services to help provide more and better-quality organs
- Dedicated to the transplant community through key alliances with partner organizations and clinical advisors with 200+ years of preservation experience
- Reinvest profits into research that improves preservation technology



Key Technology: Hypothermic Machine Perfusion

- Specially formulated acellular solution is pumped through the organ at hypothermic temperatures to minimize tissue damage
- Mimics the flow of blood through the organ vasculature
- Proven advantages over static cold storage



Our Kidney and Liver Transporters

LifePort Kidney Transporter

- Provides a sealed, sterile environment for kidney perfusion in a lightweight, powered and portable device
- Introduced in 2003 and now in wide use with over 150,000 kidneys preserved



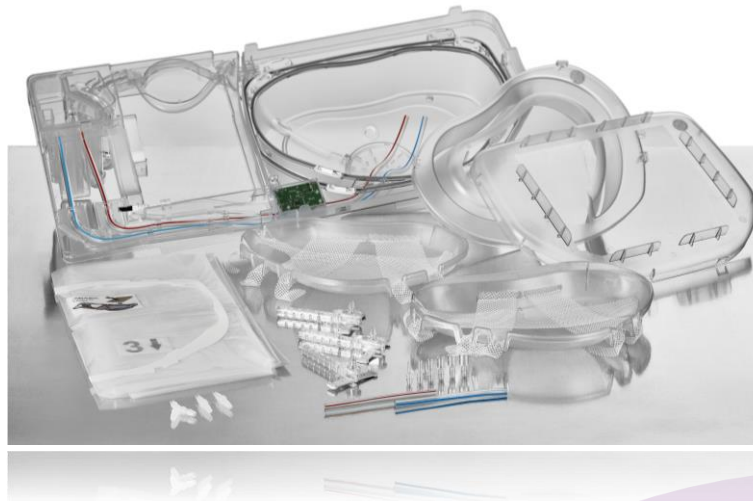
LifePort Liver Transporter

- Delivers precision-controlled perfusion through the liver's hepatic artery and portal vein
- Used in several clinical studies
- Approval and launch expected in early 2022



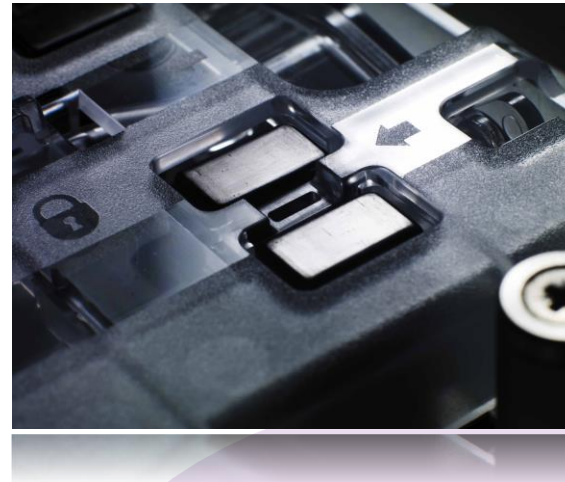
Key LifePort Product Features

- Perfusion Circuit protects the organ and the perfusate under aseptic conditions
- Preservation solutions specially formulated to preserve kidney or liver viability
- Sterile drape maintains aseptic conditions while connecting the organ inside the device
- Custom-made cannulas provide secure connections to the organ vasculatures



LifePort Safety Features

- Ultrasonic bubble detectors designed to prevent air from entering the vasculature
- User-controlled parameters to protect the organ
 - Kidney: pressure-controlled, time limited
 - Liver: flow-controlled, pressure limited
- Gentle flow increase during vasodilation to avoid barotrauma
- Ice and water surround the Perfusion Circuit, serving as backup for ultimate safety



Optimized for Transportability

- Easy to set up, use, and monitor the organ from donor hospital to transplant center
- Battery or AC power so the LifePort can continue perfusion during transportation
- Can perfuse end-ischemically, e.g., after initial cold storage, if transportation isn't immediately available



Shared Form Factor

Innovative design and engineering approaches that we pioneered with the Kidney Transporter have been brought over to the Liver Transporter

- Insulated housing
- Sealed covers
- Ergonomic carry handles
- Easy-to-read data display
- Electric plug and/or battery powered

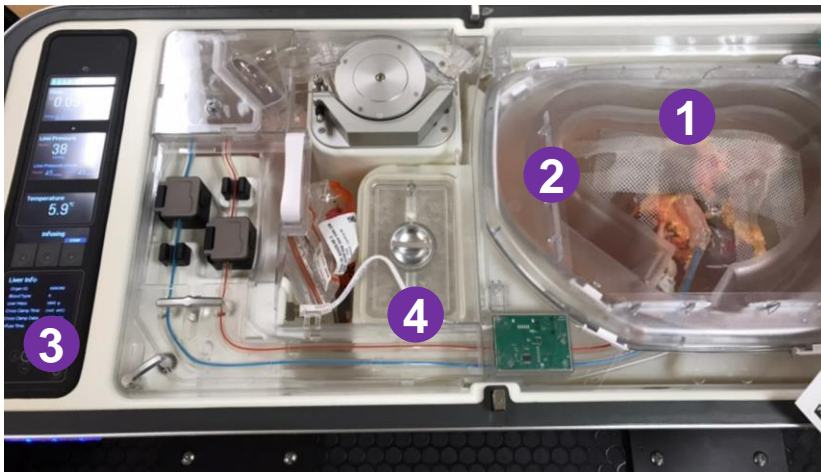


Shared Design Features

LifePort Kidney Transporter



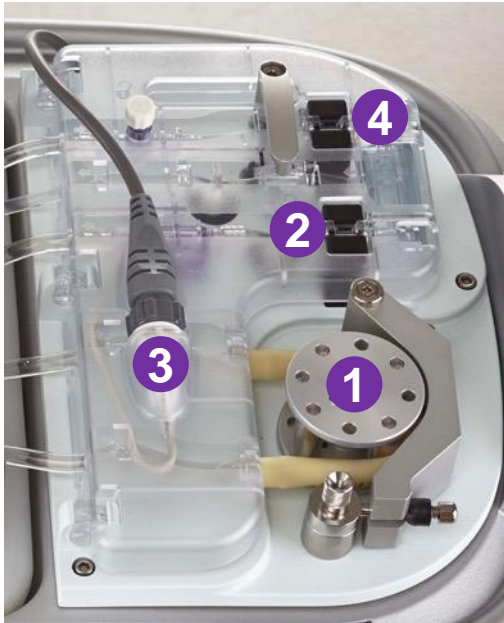
LifePort Liver Transporter



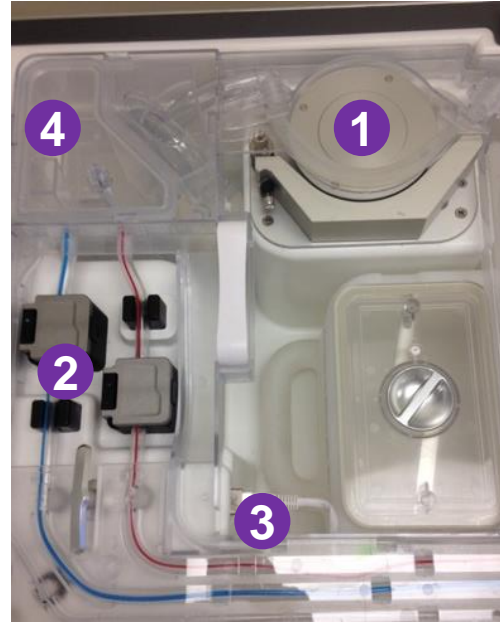
- 1) Organ submerged and secured in cradle within sterile Perfusion Circuit
- 2) Micron filter prevents particles from occluding perfusion
- 3) Display and user interface with temperature monitoring
- 4) Ice Container maintaining hypothermic temperature

Shared Technical Features

LifePort Kidney Transporter



LifePort Liver Transporter



- 1) Same Pump Technology
- 2) Ultrasonic Air Bubble Detector
- 3) Pressure Sensor Cable
- 4) Bubble Trap

The image shows the control panel of the LifePort Kidney Transporter. The panel is silver with a black digital display area. The display is divided into five main sections:

- PRESSURE:** Shows 30/14 mmHg. A small icon of a dial is visible to the left.
- FLOW:** Shows 115 mL/min.
- RESISTANCE:** Shows 0.18 mmHg/mL/min.
- TEMPERATURE:** Shows 2.8 °C and 5 °C Trap.
- Status/Time:** Shows 'Infuse 20h 14m 2s' and '4.6 L (20h)'.

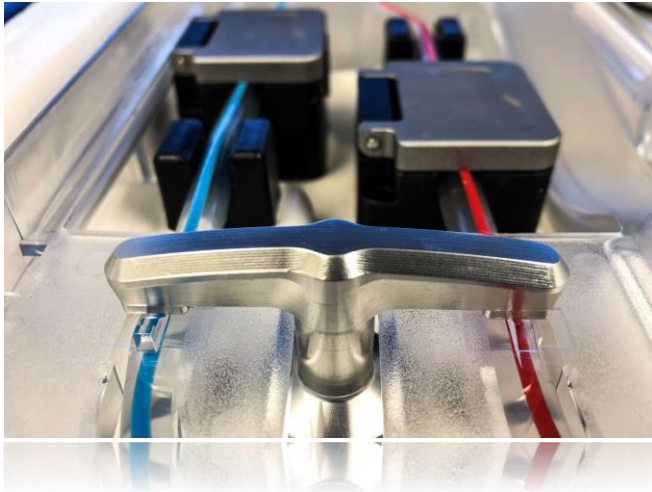
Below the display, the text 'LifePort® Kidney Transporter' is visible. Above the display, there are several physical buttons and a small screen showing '30'.

- Organ ID
- Pressure
- Temperature
- Flow
- Renal resistance



- Workstation to view and save kidney data

Liver Transporter-Specific Features



Precision controlled, dual perfusion of the liver's hepatic artery and portal vein



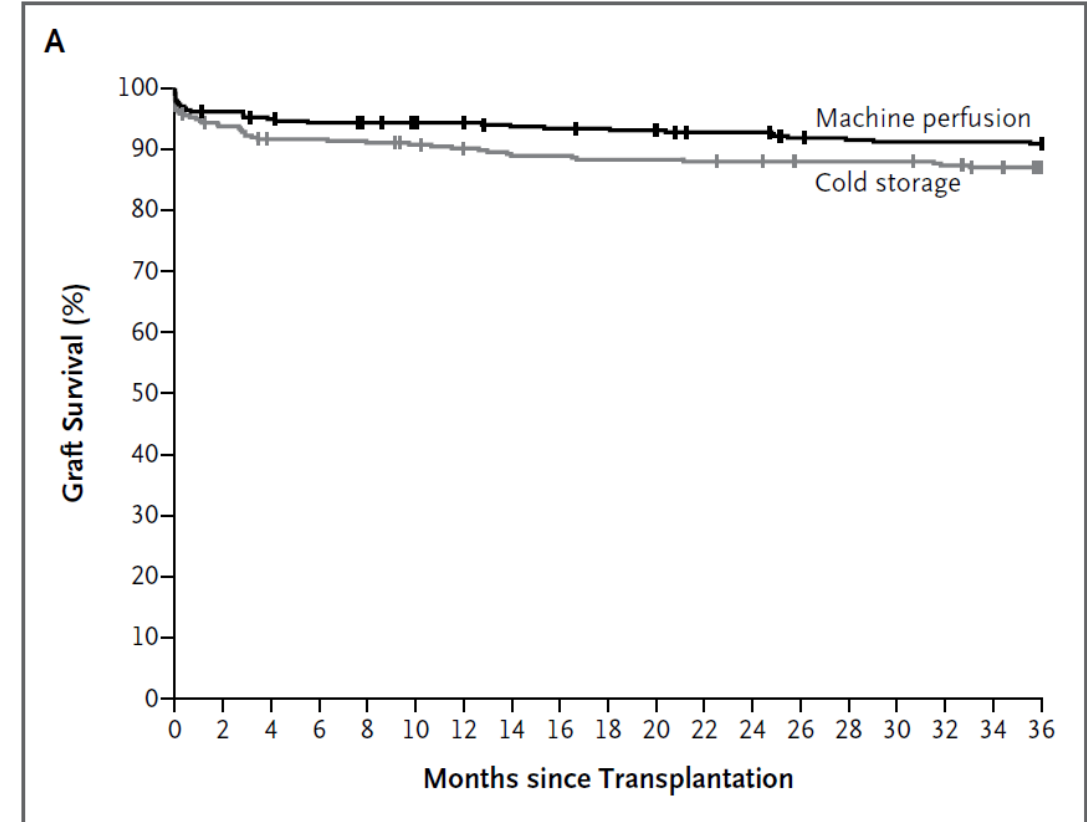
Programmable display for easy viewing and control of:

- Real-time perfusion status
- Organ ID number and blood type
- Cross-clamp and total infusion time
- Perfusate temperature
- Hepatic and portal flow/pressure
- Total flow

How Kidney Transporter Improves Outcomes

Hypothermic machine perfusion of kidneys vs. static cold storage (SCS):

- Reduces delayed graft function (DGF) by 8%, which can reduce length of stay and failure recurrence¹
- Significant increase in graft survival at 1 year and 3 years²
- Significant decrease in discards of higher KDPI kidneys, e.g., kidneys with higher risk of graft failure³



1. Cannon et al. *J Am Coll Surg* 2013; 216:4
2. Moers et al. *N Engl J Med* (2012) 366;8: 770-771
3. Mohan et al. *Kidney International* (2018) 94, 187–198

How HMP and LifePort Liver Transporter Can Improve Outcomes

In two controlled studies comparing liver HMP to SCS:

- Fewer patients had ischemic biliary complications with HMP livers^{1,2}
- HMP liver recipients recovered faster with shorter ICU and shorter hospital stays^{1,2}



Biliary Complications

HMP 13%
CS 43%



4.4 Days

HMP liver recipient
hospital stay

1. Guarrera JV, et al. Am J Transpl 2010;**10**:372–81
2. Guarrera JV, et al. Am J Transpl 2015;**15**(1):161–9

Hypothermic Machine Perfusion: The New Standard

- Our innovative transporter technology helps meet the increasing need for viable kidneys and livers
- We're focused on using technology to increase the safety of kidney and liver preservation
- Clinical data shows that hypothermic machine perfusion leads to better outcomes for recipients



LifePort Kidney Transporter



LifePort Liver Transporter



Thank you!

Chicago

1 Pierce Place Ste 475W
Itasca, IL 60143
USA

T +1.847.824.2600

F +1.847.824.0234

Perfusion Helpline

+1.866.682.4800

Brussels

Culliganlaan 1B
1831 Diegem
Belgium

T +32.2.715.0000

F +32.2.715.0009

Perfusion Helpline

+32.2.715.0005

São Paulo

170 Moema Ave Ste 11&12
São Paulo, SP 04077-020
Brazil

T +55.11.98638.0086

Perfusion Helpline

+55.11.98638.0086

www.organ-recovery.com

PARAGONIX

Paragonix SherpaPak® Cardiac Transport System

Product Introduction



ISHLT 2020 Consensus Statement

Consensus Statement on Donor Heart Procurement

Avoid direct contact with ice because of irreversible cellular damage¹

- Preserve and maintain heart at $> 4^{\circ}\text{C}$
- Avoid freezing any part of the heart
- Freezing may cause irreversible cellular damage
- Freezing injury is an underappreciated cause of graft failure

“This protects against contact mediated hypothermic injury, an often-underappreciated cause of graft failure”¹



“Direct contact of ice with the myocardium may cause freezing. Freezing of any part of the heart is undesirable because freezing and thawing cause irreversible cellular damage”¹



CONSENSUS STATEMENT

Donor heart and lung procurement: A consensus statement



Hannah Copeland, MD,^a J.W. Awori Hayanga, MD, MPH,^b
Arne Neyrinck, MD, PhD,^c Peter MacDonald, MD,^d Goran Dellgren, MD, PhD,^e
Alejandro Bertolotti, MD,^f Tam Khuu, PharmD,^g Fay Burrows, Bpharm,^h
Jack G. Copeland, MD,ⁱ Danyel Gooch, BSN, RN,^j Amy Hackmann, MD,^k
David Hormuth, MD,^l Christa Kirk, MD,^m Virginia Linacre, MD,ⁿ
Haifa Lyster, PharmD,^o Silvana Marasco, MD,^p David McGiffin, MD,^q
Priya Nair, MD,^r Axel Rahmel, MD,^s Michael Sasevich, MD,^t
Martin Schweiger, MD,^u Aleem Siddique, MD,^v
Timothy J. Snyder, C.P.T.C. CCEMT, W, William Stansfield, MD,^x
Steven Tsui, MD,^y Yishay Orr, MD,^z Patricia Uber, PharmD,^A
Rajmyer Venkateswaran, MD,^B Jasleen Kukreja, MD,^C and
Michael Mulligan, MD^D

From the ^aDivision of Cardiac Surgery University of Mississippi Medical Center Jackson, MS; ^bDivision of Thoracic Surgery West Virginia University Morgantown, WV; ^cDepartment of Anesthesiology University Hospital Leuven, Leuven, Belgium; ^dDepartment of Cardiology, St. Vincent's Hospital Sydney, Australia; ^eDepartment of Cardiothoracic Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden; ^fDepartment of Cardiothoracic Surgery, Favaloro Foundation Buenos Aires, Argentina; ^gBioCryst Pharmaceuticals, Durham, North Carolina; ^hDepartment of Pharmacy, St. Vincent's Hospital Sydney, Australia; ⁱDepartment of Surgery University of Arizona Tucson, Arizona; ^jIndiana University Health, Methodist Hospital Indianapolis, Indiana; ^kDepartment of Surgery, University of Texas Southwestern, Dallas Texas; ^lMarian University Indianapolis, IN; ^mDepartment of Pharmacy - Seattle Children's Hospital Seattle, Washington; ⁿInstituto Nacional de Torax, Santiago, Chile; ^oDepartment of Pharmacy Royal Brompton and Harefield NHS Foundation trust London, United Kingdom; ^pDepartment of Cardiothoracic Surgery Alfred Hospital Melbourne, Australia; ^qDepartment of Cardiothoracic Surgery Alfred Hospital, Melbourne, Australia; ^rIntensive Care, St. Vincent's hospital, Sydney, Australia; ^sGerman Organ Procurement Organization; ^tFirst California Physician Partners Cardiothoracic and Cardiovascular Surgery, Modesto, California; ^uUniversity Children's Hospital Zurich Department of Congenital and Cardiovascular Surgery Zurich, Switzerland; ^vDepartment of Surgery, University of Nebraska Medical Center; ^wNorth American Transplant Coordinators Organization (NATCO), Gift of Life Donor Program, Philadelphia, Pennsylvania; ^xAdvocate Christ Medical Center, Oak Lawn, IL; ^yDepartment of Cardiothoracic Surgery Papworth Hospital NHS Foundation Trust, Cambridge, United Kingdom; ^zChildren's Hospital at Westmead and Sydney Children's Hospital in Sydney, Australia; ^ADepartment of Pharmacy, Allegheny Health Network, Pittsburgh, Pennsylvania; ^BDepartment of Cardiothoracic Surgery, University Hospital South Manchester NHS Foundation Trust Manchester, United Kingdom; ^CDepartment of Surgery, Division of Thoracic Surgery University of California San Francisco, San Francisco, California; and the ^DDepartment of Surgery, Division of Thoracic Surgery, University of Washington, Seattle, Washington.

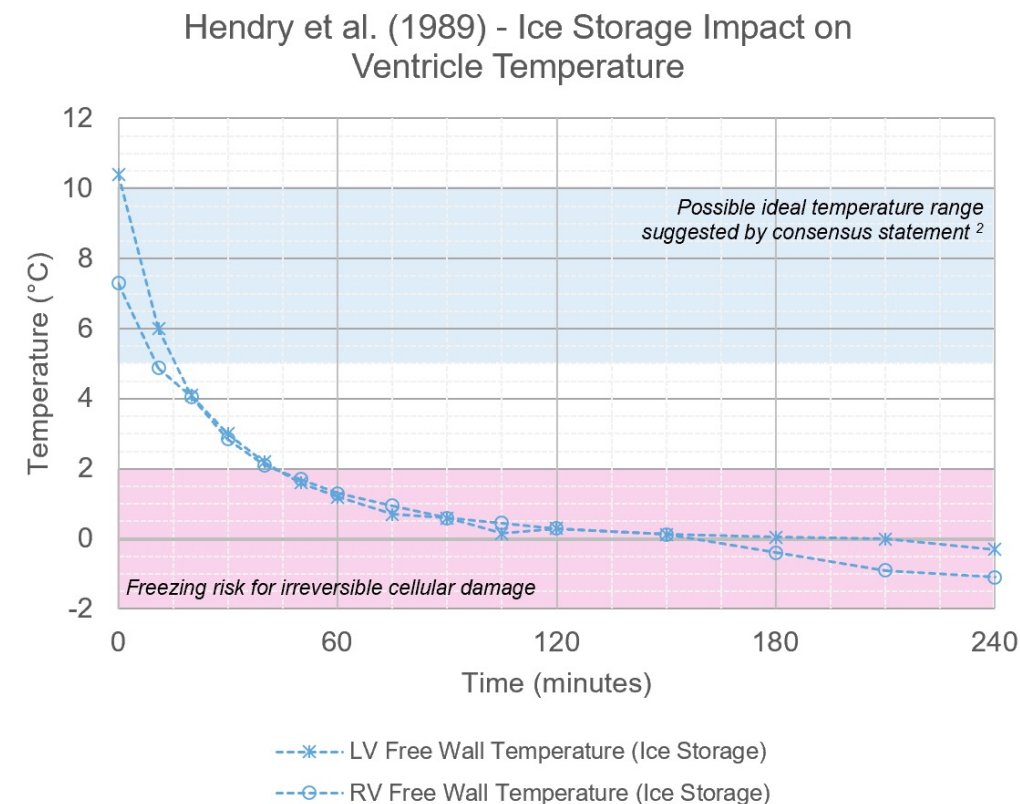
Reprint requests: Hannah Copeland, MD, Division of Cardiothoracic Surgery, University of Mississippi Medical Center, 2500 North State Street, Jackson, MS 39216. Telephone: +1-601-984-5170. Fax: +1-601-984-5918.
E-mail address: hannacopeland41@gmail.com

1053-2498/\$ - see front matter Crown Copyright © 2020. Published by Elsevier Inc. on behalf of International Society for Heart and Lung Transplantation. All rights reserved.
<https://doi.org/10.1016/j.healun.2020.03.020>

A known issue in heart transplantation

Cited in the ISHLT consensus statement¹:

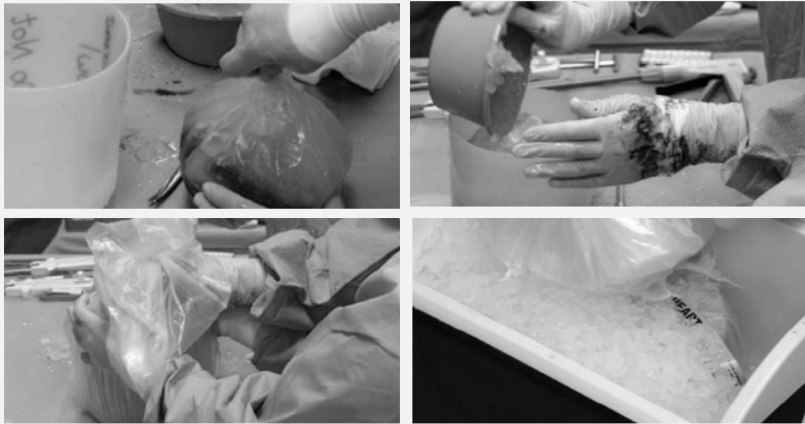
- Hendry *et al.* (1989) paper entitled **“Are temperatures attained by donor hearts during transport too cold?”**
- Found that donor hearts could reach near freezing temperatures within 2 hours



Paragonix Preservation Systems – Overview

Ice Storage

- > Historic method of preserving and transporting organs
- > Uses plastic bags, ice, and consumer ice coolers
- > Non-FDA regulated devices
- > Un-controlled, un-monitored cooling
- > Risks cellular injury to transported organ

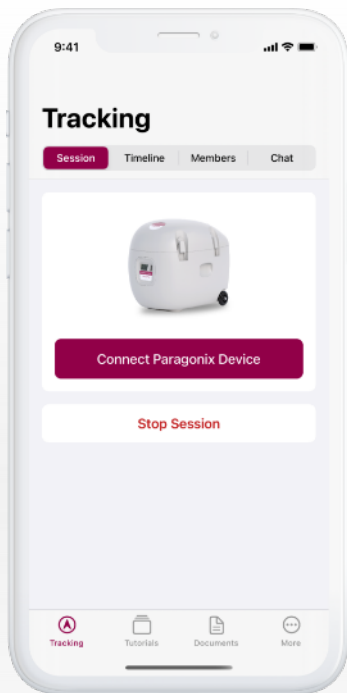


Paragonix SherpaPak® CTS & LUNGguard™ DLPS

- > FDA cleared and CE marked devices for preservation and transportation of donor organs
- > Validated to maintain a consistent 4-8°C temperature for over 40 hours
- > Real-time monitoring, tracking, and communication

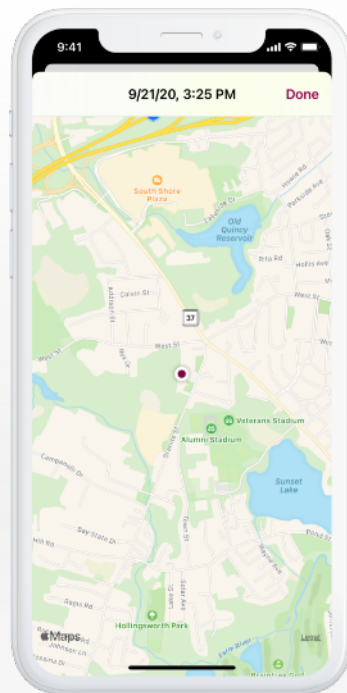


Paragonix Connecting Teams From Start To Finish



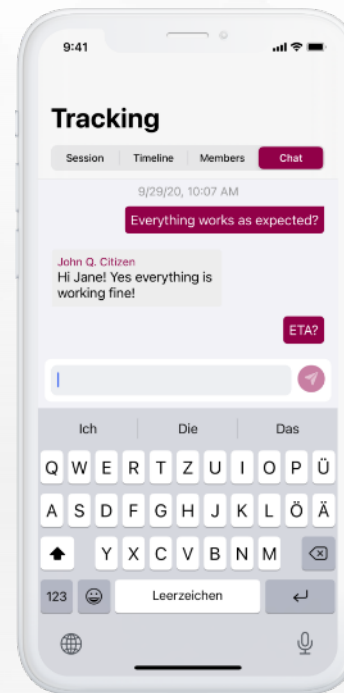
ORGAN STATUS

Bluetooth pairing with all the Paragonix organ preservation systems enables all team members to track the organ conditions including both organ temperature and ambient temperature.



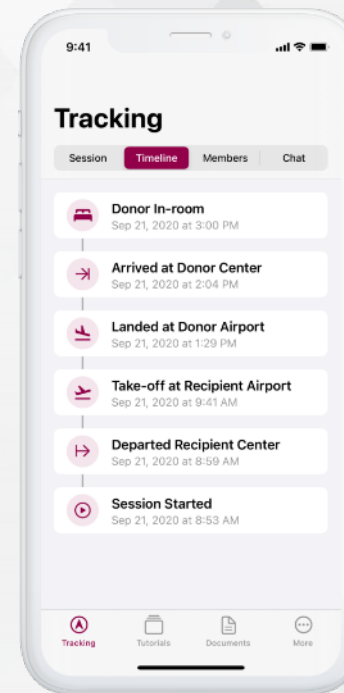
LOCATION

GPS tracking of procurement team en route to and from the donor center.



COMMUNICATION

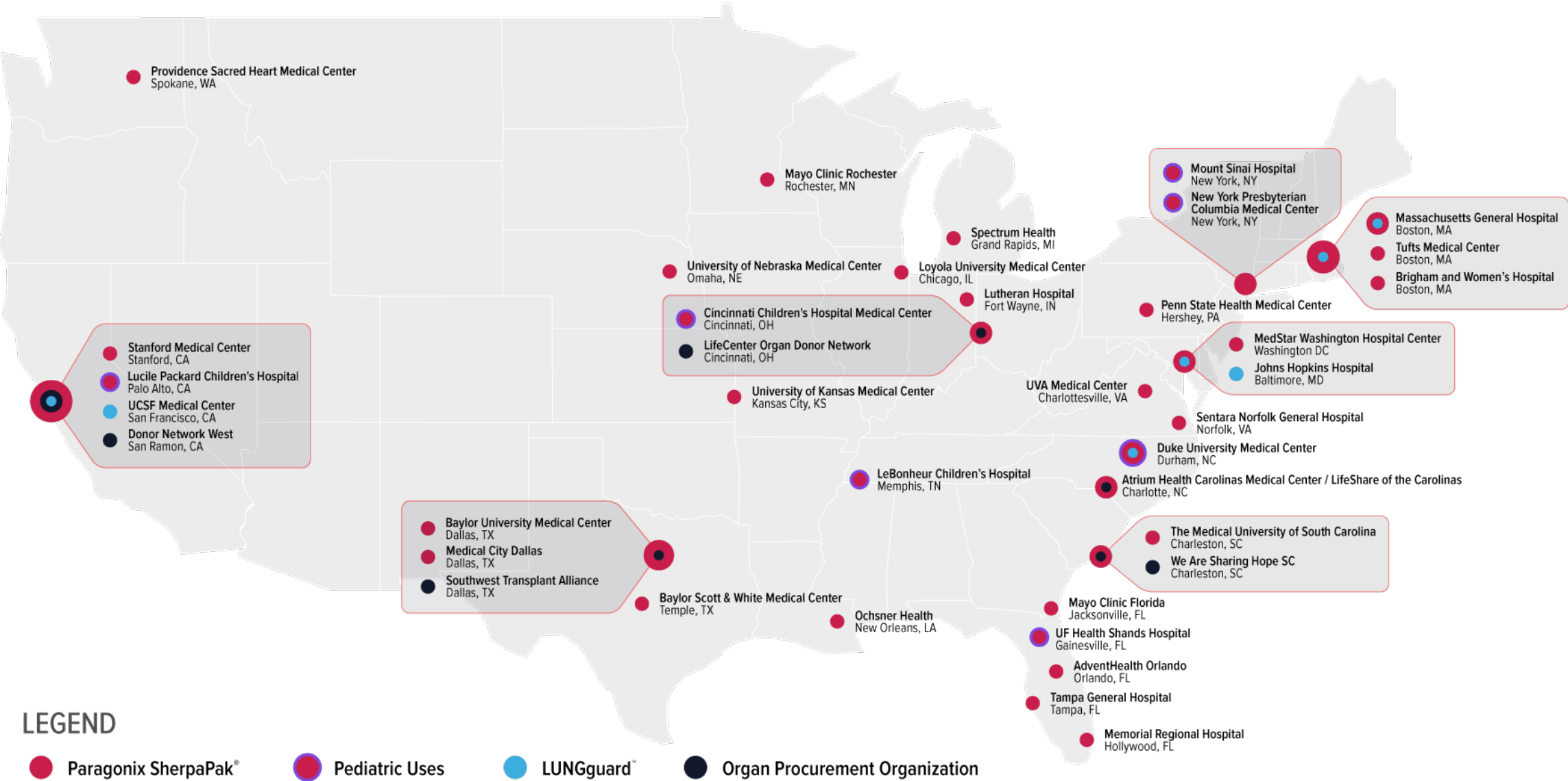
HIPAA compliant messaging and communications to keep the procurement team, OPO, donor hospital, and recipient team informed. Flexibility to invite members from different hospital systems and organizations in a secure manner.



CASE STATUS

At-a-glance graphic status trackers provide a snapshot summary of timing of key events in the transplant.

Current U.S. Paragonix Clinical Users

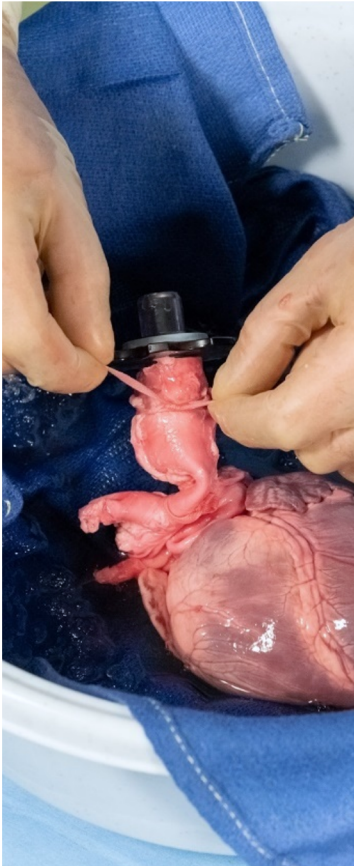


The SherpaPak CTS is employed in six easy to follow steps

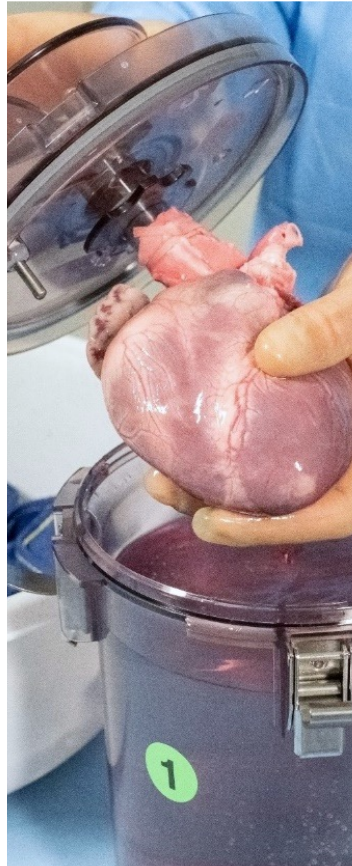
1. FILL ORGAN
CANISTER



2. ATTACH AORTIC
CONNECTOR



3. INSERT HEART
INTO ORGAN
CANISTER



4. NEST CANISTER
ASSEMBLY



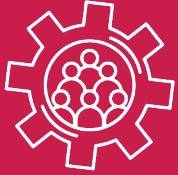
5. LOAD CANISTER
ASSEMBLY



6. LOAD POUCH &
CLOSE FOR
TRANSPORT



Paragonix Product Considerations



STAFFING

- No additional staffing required
- Remote monitoring and communications technologies included for recovery and implant teams



TRANSPORTATION

- Compact size designed for transportation by standard ambulance, helicopter, and fixed-wing aircraft



PROGRAM WORKFLOW

- Considered simpler and easier than conventional storage
- Ongoing proficiency is easily maintained and taught to new staff



CLINICAL SUPPORT

- 1-hour onsite training at hospital to prepare team for clinical usage
- Ongoing 24-hour cases support

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PROGRAM WORKFLOW

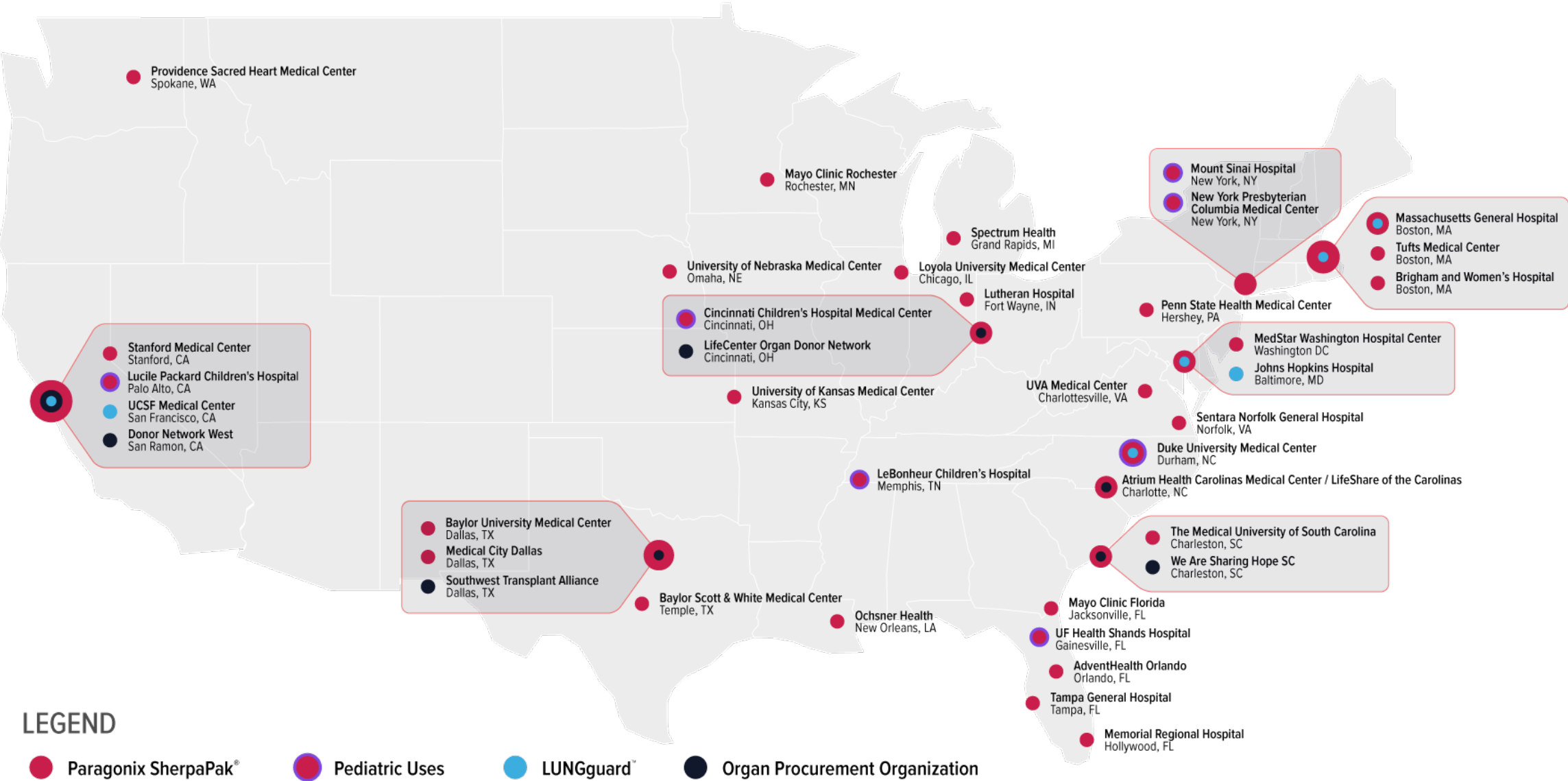
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- 1-hour onsite training at hospital to prepare team for clinical usage
- Ongoing 24-hour cases support

Current U.S. Paragonix Clinical Users



Current U.S. Paragonix Clinical Users



LEGEND

● Organ Procurement Organization

LIVERguard™ System – Overview

Donor Liver Preservation System

- FDA cleared and CE marked device for hypothermic preservation and transportation of donor livers
- Validated to maintain a consistent 4-8°C temperature for over 40 hours
- Bluetooth® connected real-time monitoring, tracking, and communication
- Clinical application: any DBD or DCD liver

“Temperatures below 1°C are reached only 40 minutes after insertion of graft in the cold transport cool [ice] box.”¹



Clinical evidence has shown sub-zero temperatures can generate “Indissoluble particles in preservation solutions [that] may potentially cause thrombosis and occlusion of vessels, in addition to injury to endothelial cells.”²

GUARDIAN-HEART Post-Market Registry

Paragonix supports the largest registry studying clinical outcomes in heart transplantation based on advanced heart preservation

Follow-up Period - 24 hours, 30 days, 1-year post-implant. Retrospective for both ice storage and advanced organ preservation technologies. NCT04141605

15 CENTERS CURRENTLY ENROLLING



Massachusetts General Hospital
Massachusetts, USA



Universitätsklinikum AKH Wien
Vienna, Austria



Sentara Norfolk General Hospital
Virginia, USA



Mayo Clinic Florida
Florida, USA



Spectrum Health
Michigan, USA



Stanford Medical Center
California, USA



Hospital Clinico Universitario Valladolid
Valladolid, Spain



MedStar Washington Hospital Center
Virginia, USA



AdventHealth Orlando
Florida, USA



Baylor Scott & White Health
Texas, USA



University of Florida Health Shands
Florida, USA



Hospital Universitario 12 de Octubre
Madrid, Spain



Tufts Medical Center
Massachusetts, USA



Duke University Medical Center
North Carolina, USA



Lutheran Hospital
Indiana, USA

CENTERS IN PIPELINE



Le Bonheur Children's Hospital
Tennessee, USA



Wythenshawe Hospital UK
Manchester, UK



NewYork-Presbyterian Hospital
New York, USA

GUARDIANHEART



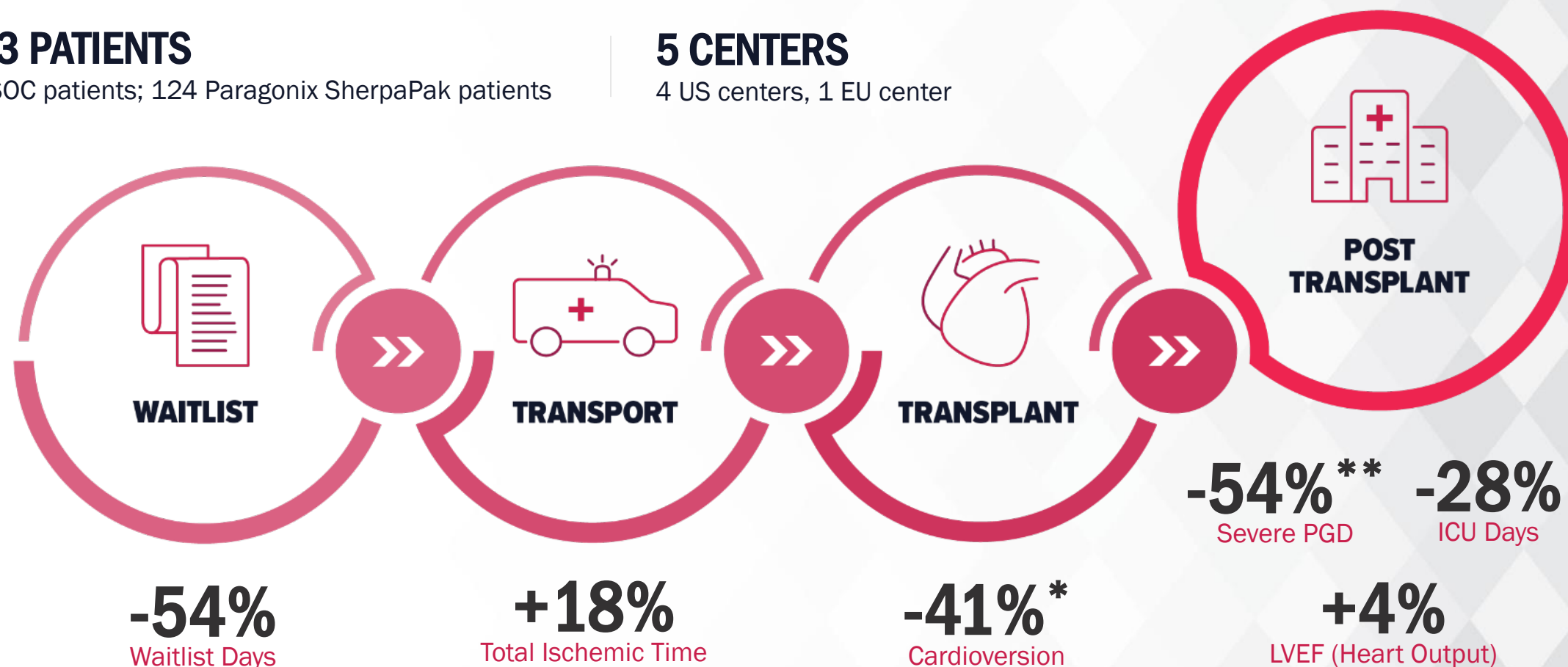
Interim Results of Guardian Registry¹

223 PATIENTS

99 SOC patients; 124 Paragonix SherpaPak patients

5 CENTERS

4 US centers, 1 EU center

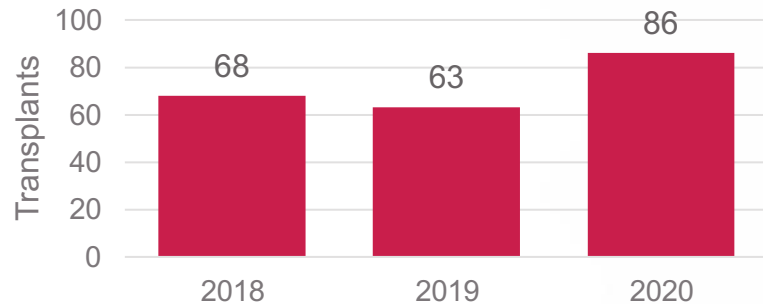


DATA PRESENTED AT ISHLT 2021 26 April 2021

Transport Range

Case Study: Stanford Health Care

Stanford's heart transplant program had a record year last year of 86 and became the 4th largest transplant program in 2020¹



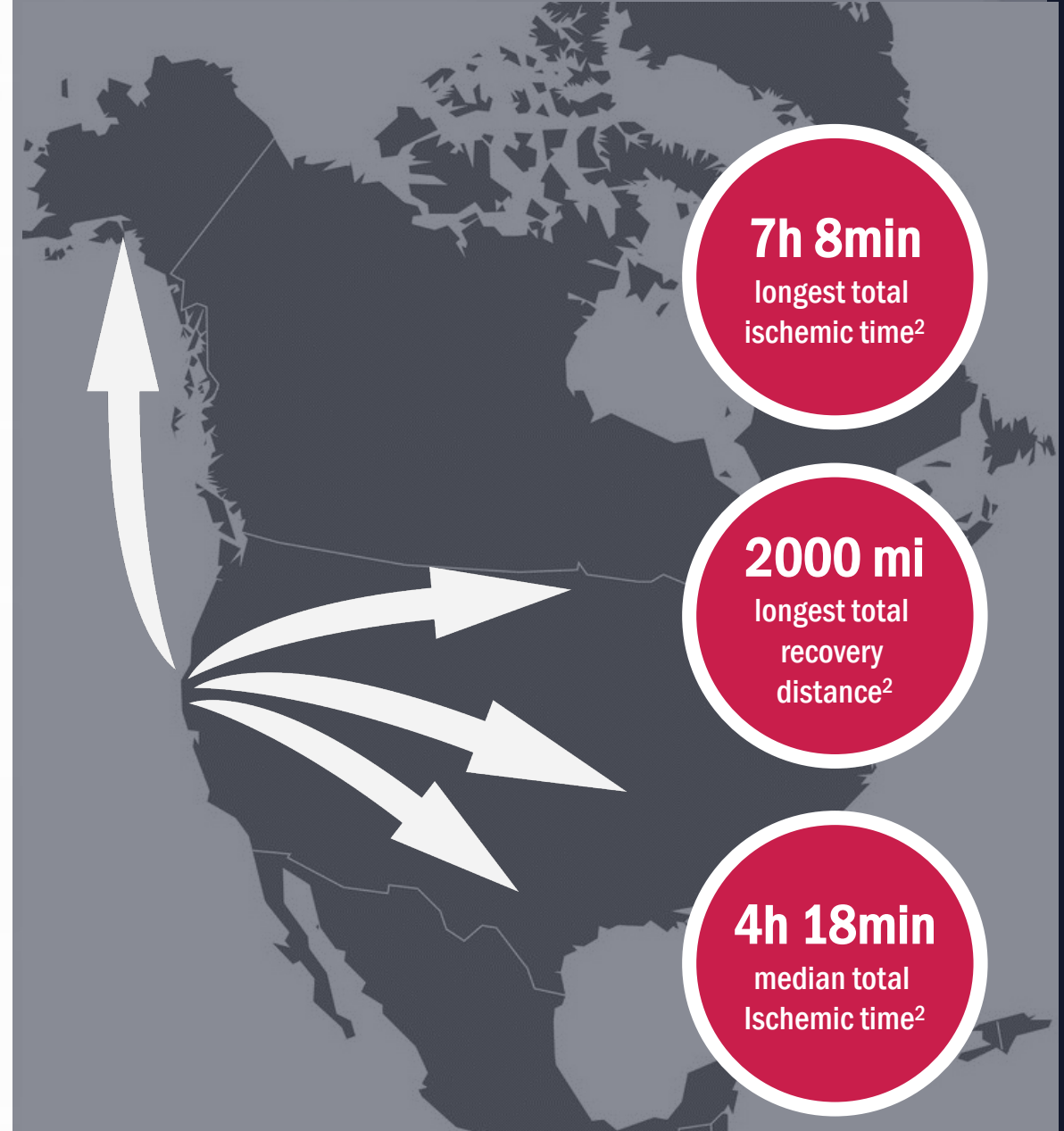
Stanford adopted Paragonix SherpaPak CTS starting in August and by Q4 2020 the CTS has become standard of care and used in over 80% of Stanford heart transplants. Today, their utilization is approximately 100%²



“He said recent improvements in organ preservation also have enabled Stanford to venture farther to obtain donor hearts...The technique has allowed Stanford to collect organs from distant parts of the country — as far away as Alaska, Missouri, the Dakotas and Texas, Teuteberg said.”³

PARAGONIX

1. Data on file, source UNOS data request 2. JTeuteberg, CareDX Heart Innovation Day Webinar 2021 3. <http://med.stanford.edu/news/all-news/2021/02/standout-year-for-stanford-health-care-heart-transplant-program.html>



*The Paragonix SherpaPak™ Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart. The intended organ storage time for the Paragonix SherpaPak™ Cardiac Transport System is up to 4 hours. Donor hearts 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.

PARAGONIX®

Every Possible Advantage™



WHY

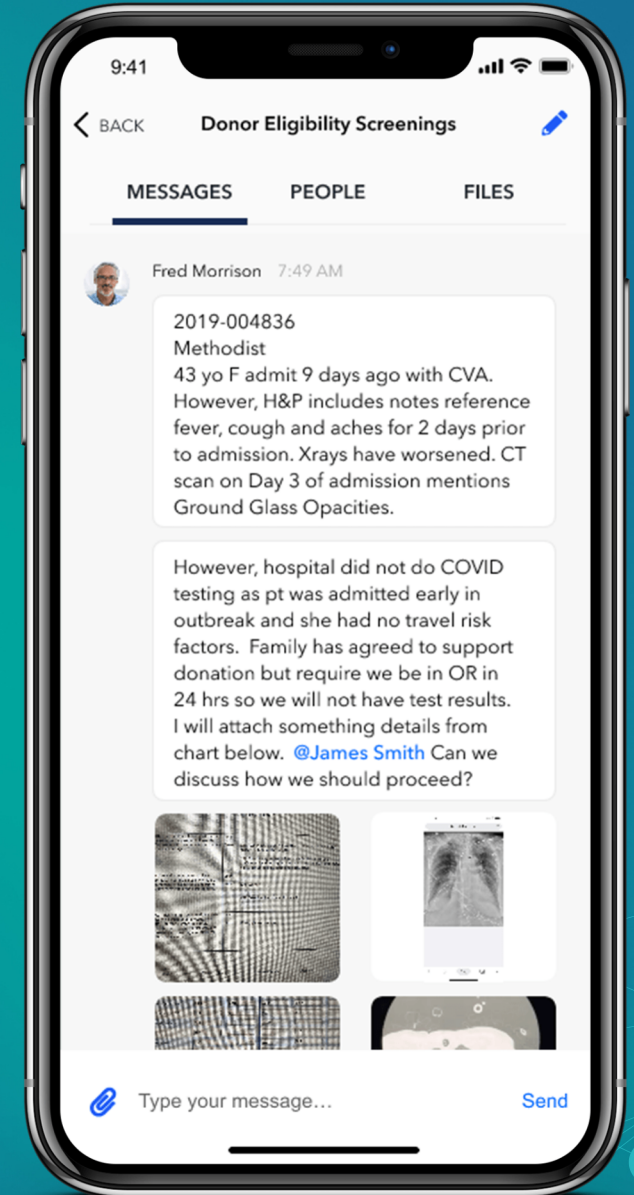
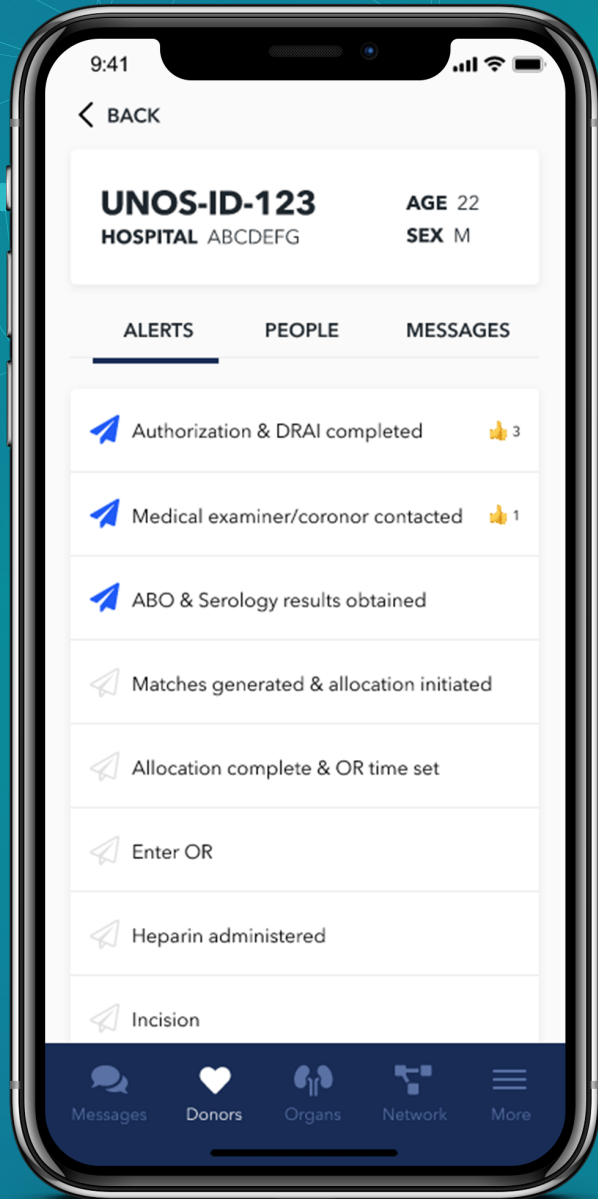
Our goal is to save more patient lives by empowering providers & front-line staff

HOW

We do this by streamlining collaboration and communication between providers/teams

WHAT

One scalable and integrated communication platform that better connects your people, partners, and tools.



New Centers/Partners in 2021



MAYO CLINIC



Banner Health®



Cedars
Sinai



LOMA LINDA UNIVERSITY
HEALTH



Stanford
Hospital & Clinics



NATIONWIDE
CHILDREN'S



INOVA®

UPMC
LIFE
CHANGING
MEDICINE



Partnerships Driving Network Growth



12 of the Leading OPOs

12 of the Top Research Organizations



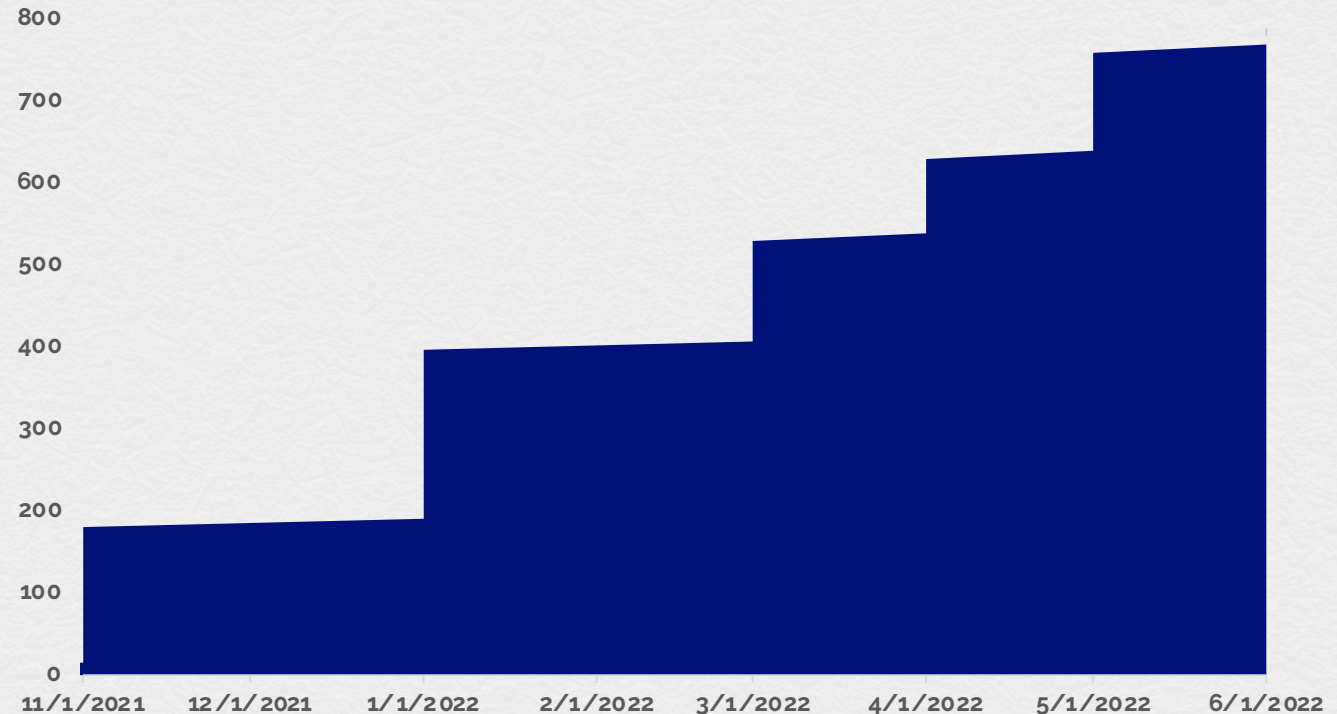
10 of the Best Transplant Centers for Children



55 Thoracic Programs in US

7 International Thoracic Programs

Platform Users Added From Partnerships Since Nov 1



- **Novabiosis** - Nov 1st: joins the platform and brings 12 OPOs and 12 Researchers
- **Stazl Network** – As of Nov 1st, 32 users are from the Starzl Network, 78 more users expected to join the platform through June 1st
- **ACTION Network** – Nov 1st joins the platform with CCHMC, more joining on Jan 1st, Mar 1st, Apr 1st, May 1st, and June 1st



OmniLife Overview

AREAS OF FOCUS



Communications



Coordination



Decision-Making

PRODUCT OFFERINGS

Secure
Messaging

Workflows &
Alerts

Clinical Decision
Support



Published NIH SBIR Study

In 2018, OmniLife conducted a **one-year 3-site NIH SBIR study** which focused on streamlining communication with a secure mobile app designed specifically for donation and transplant. The purpose of the study was to look at the affects of bringing your teams and partners onto a one dedicated communication platform.

RESULTS

- **50% decrease in redundant communication** for front-line staff
- **30% reduction in missed opportunities**
- **Improved front-line staff experience and productivity** as defined by Relational Coordination (RC)
- **Enhanced relationships** with external partners & customers



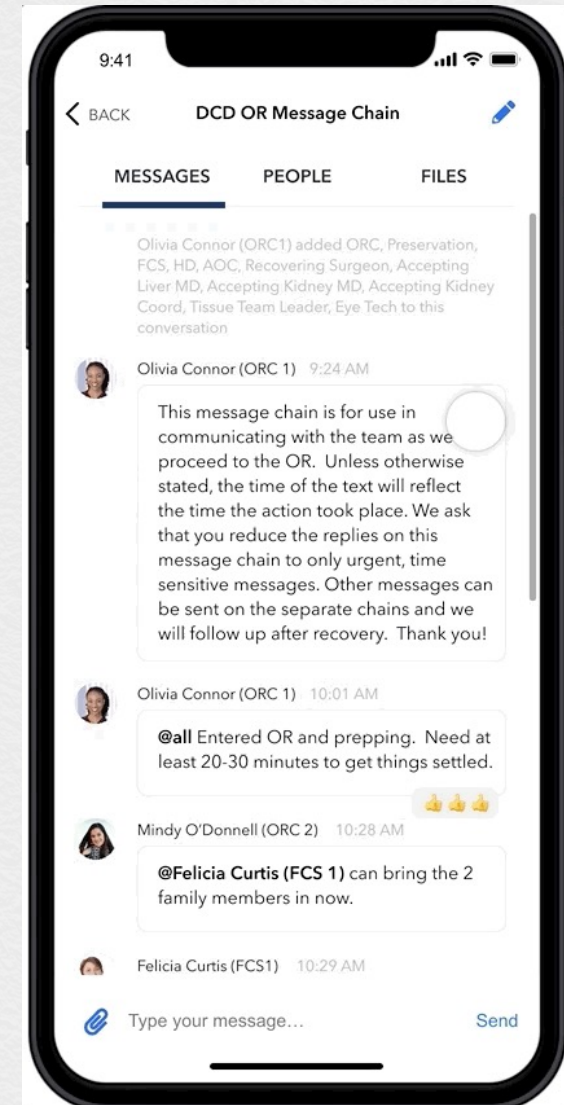
UnityPoint Health

UPMC

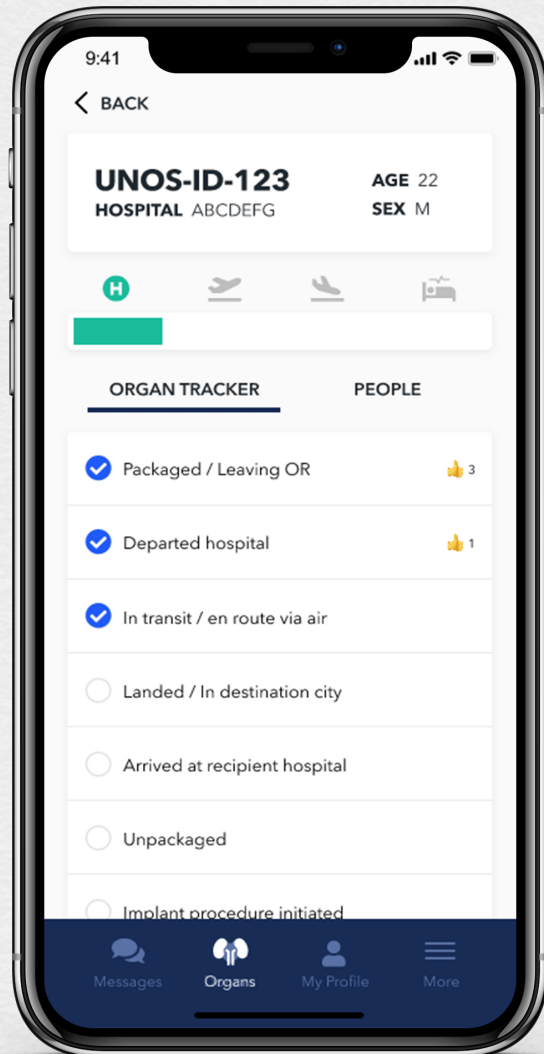


1/ Secure Messaging

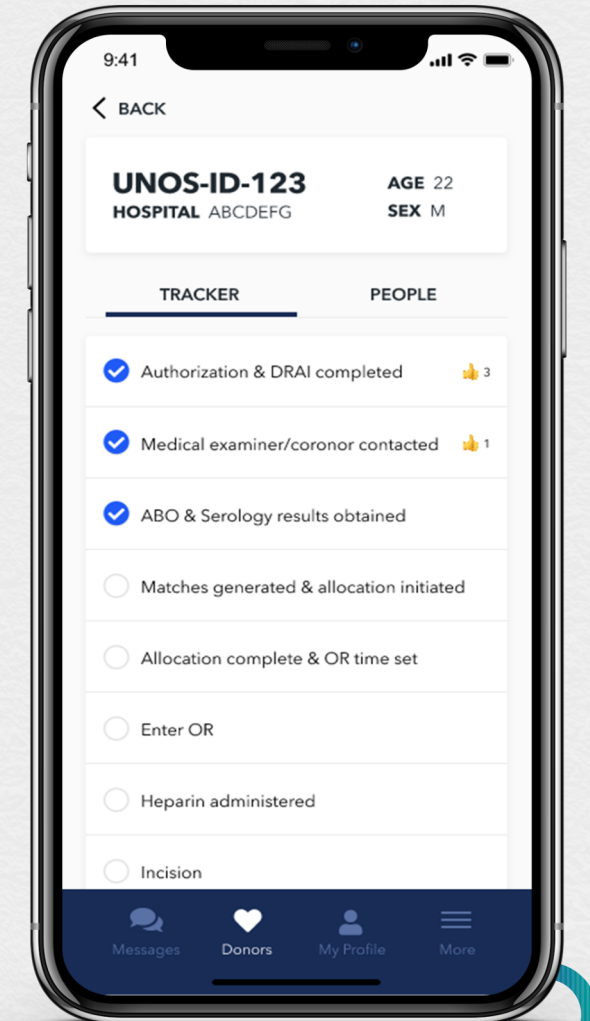
- ✓ ONE secure HIPAA compliant platform for everyone (internal & external)
- ✓ Organized by UNOS # & Patient ID
- ✓ Conversations are logged & timestamped
- ✓ Send and receive photos, PDFs, videos.
- ✓ All from the palm of your hand on any device (iOS, Android, tablets, and web)



2/ Custom Workflows & SmartAlerts™



- ✓ Integrates with your existing process, tools, and workflows
- ✓ One click smart alerts
- ✓ Closed-loop notifications
- ✓ SMS/Email text notifications for invited users outside of app
- ✓ Notification control

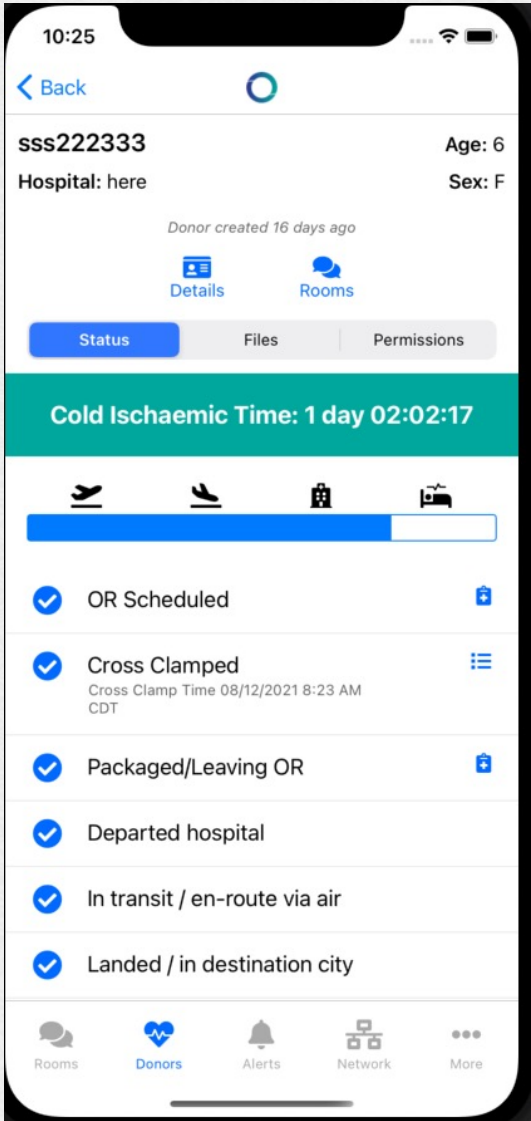


2/ Custom Workflows: Example Use Cases

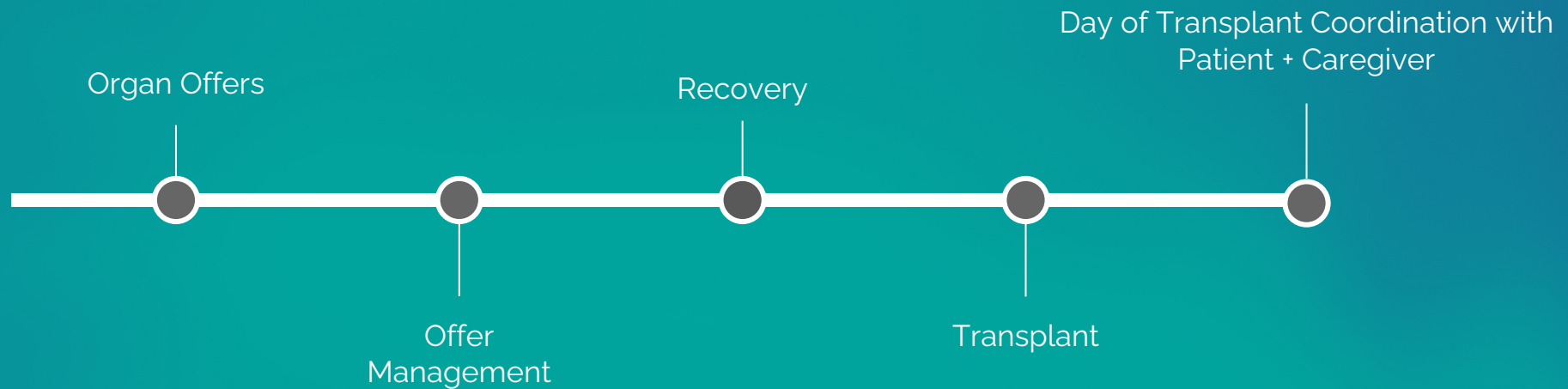
Mayo Clinic: Flight Tracker



Cedars Sinai: Cold Ischemic Time



Mayo Clinic Use Case



Product Package:

OmniLife Premium

- Messaging Module
- Workflows Module

Key Invited Partners/Users:

- **Mayo OR**
- **Logistics (NORA)**
- **Mayo HLA**
- **Blood Bank**

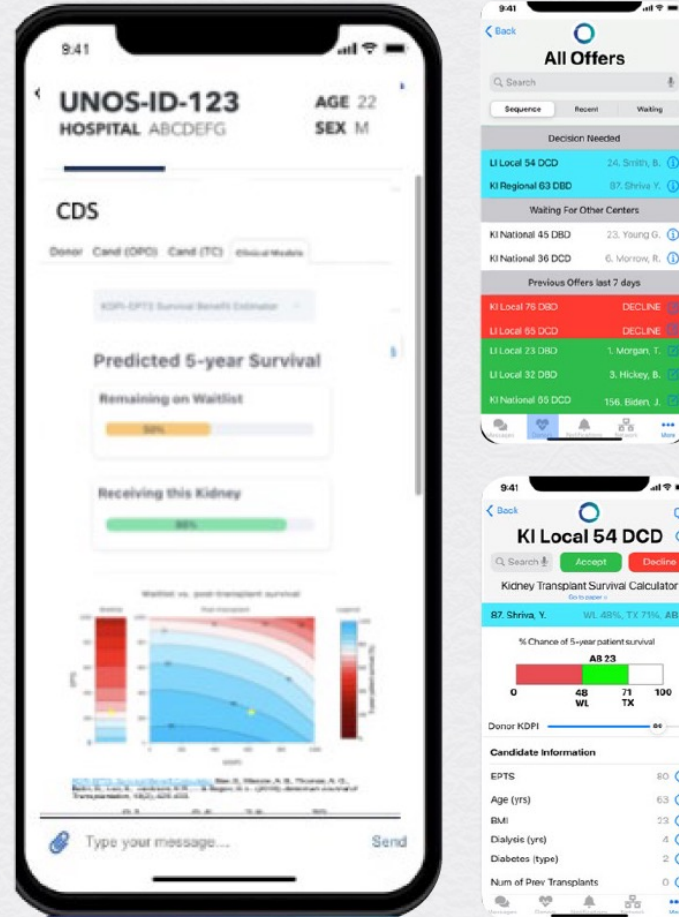
Key Integrations/APIs

- **EPIC Phoenix***

3/ Custom Clinical Decision Support

- ✓ AI/ML algorithm custom to your decision criteria
- ✓ See Donor-to-specific-Patient Graft Survival Scores
- ✓ See how your peers would make decisions on similar offers

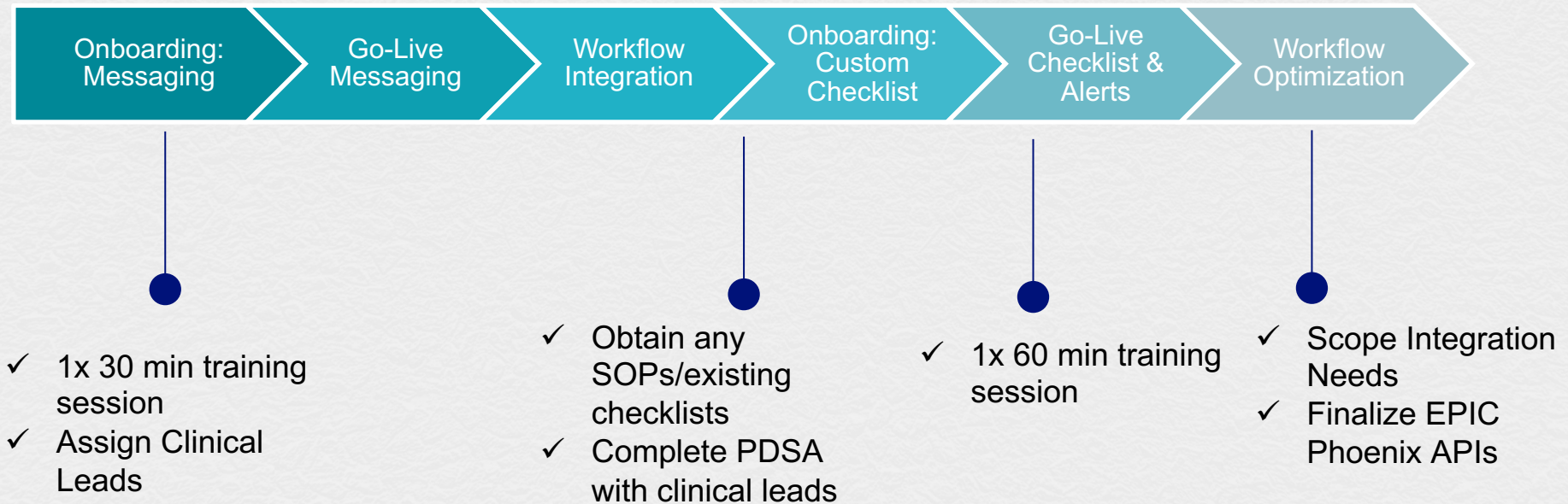
AI/ML Matching Algorithm



Analytics



Implementation



The Future of eVTOL Supporting the Transplant Community

The Alliance Innovation Showcase

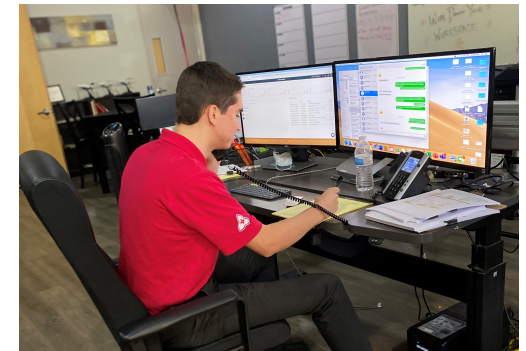


WILL HEYBURN, CFO
SCOTT WUNSCH, COO

Who is Trinity?

Trinity Medical Solutions, a BLADE Urban Air Mobility Company, is a dedicated air and ground transportation organization with a singular focus of providing exceptional logistics and transportation services to Transplant Programs and Organ Procurement Organizations around the country. Our 24/7 specialized operations center, dedicated aircraft and Trinity owned vehicles make our team your one call solution to maximize your mission on time, every time.

- Providing contracted services to 11 OPOs and over 30 Transplant centers.
- Close partnerships with other transplant industry leaders such as TransMedics, OrganOx, Paragonix, MediGo, and Lung Bioengineering.
- Detailed weekly, monthly, and annual reporting based on customer needs and meeting CMS quality requirements.



What is eVTOL?

An **electric vertical take-off and landing (eVTOL)** aircraft uses electric power to hover, take off, and land vertically. This technology came about thanks to major advances in electric propulsion (motors, batteries, electronic controllers) and the growing need for new vehicles for urban air mobility (air taxi). Examples are being developed by aircraft companies such as Boeing,^[1] Airbus, Embraer, Honda, Toyota, Hyundai and NASA.

<https://en.wikipedia.org/wiki/EVTOL>
<https://cleantechnica.com/2019/10/18/porsche-boeing-sign-an-agreement-to-work-on-premium-evtol-aircraft/>

eVTOL — BLADE'S CATALYST FOR GROWTH IN URBAN AIR MOBILITY

- Electric Vertical Take-Off and Landing aircraft
- Piloted
- Quiet
- Safe (Engine Redundancy, Fly-by-Wire, limited moving parts)
- Zero Emissions (Full Electric Operation)
- Lower Cost of Manufacture and Operation
- 180mph+ cruising speed vs. ~150mph for rotorcraft
- Certification by FAA in 2023 (BLADE model reflects 2025)



Given low costs, low noise footprints, and zero emissions, eVTOL are poised to supercharge BLADE's business while leveraging the air mobility platform we have been building for 6 years

OVER \$5 BILLION INVESTED IN eVTOL AIRCRAFT OVER 5 YEARS

Tens of thousands of successful flights across the universe of eVTOL platforms

Boeing



- Major investments across the UAM landscape including Aurora Flight Sciences, SkyGrid, and Kitty Hawk/Wisk

Lilium



- \$375 million raised
- Developed and flown two variations of eVTOL prototypes

Bell



- UAM alliance with BLADE

Airbus

BLADE Investor/Partner



- Lead investor in BLADE's Series B round
- Developing airspace management system for eVTOL service
- Performing trial flights for last mile cargo delivery

Joby Aviation



- \$721 million raised, including \$590 million from Toyota
- Began type certification program with FAA in 2018
- Received airworthiness approval by the U.S. Air Force for military use

Volocopter



- \$140 million raised
- Currently testing cargo-only eVTOL prototypes with lead customers
- Passenger flights in Singapore and Dubai

REGULATORY OFFICIALS ARE FOCUSED ON eVTOL CERTIFICATION



Jay Merkle
FAA UAS Executive Director

"We really cracked the code on how to take decades-old aviation [rules] and get to the essence of each of those requirements and say 'What was the safety goal here?'...**It is absolutely not true that there need to be all new regulations governing Urban Air Mobility.**"



Earl Lawrence
FAA Aircraft Certification Service Executive Director

"I have four active formal applications for electric vertical-lift aircraft right now that are going to be the urban air mobility aircraft of the future. These aren't concepts; these are full-up active type certification projects. **And I expect to be issuing a type certificate to one of these aircraft prior to 2022.**"



Steve Dickson
FAA Administrator

"We are **currently engaged with the builders of more than 15 electric vertical takeoff and landing** Urban Air Mobility aircraft projects. In January, we saw North America's first public demonstration of an autonomous two-seat flying taxi..."

Once approved by regulators, eVTOL adoption will rely on existing infrastructure, FAA rules and air traffic control systems – BLADE's existing platform provides the expertise, scale and consumer trust to transition to eVTOL

How will eVTOL impact the Transplant Community?

Reduce Travel Times:

- Teams time away from transplant center (direct point to point flight)
- Fewer transportation legs (eliminates ground transportation)
- In some cases, surgeons/teams don't need to fly
- Lowers opportunity for transportation errors (Reduced transportation legs)

Financial Savings

- Direct hospital to hospital transportation (shorter flights)
- Lower overall flight costs

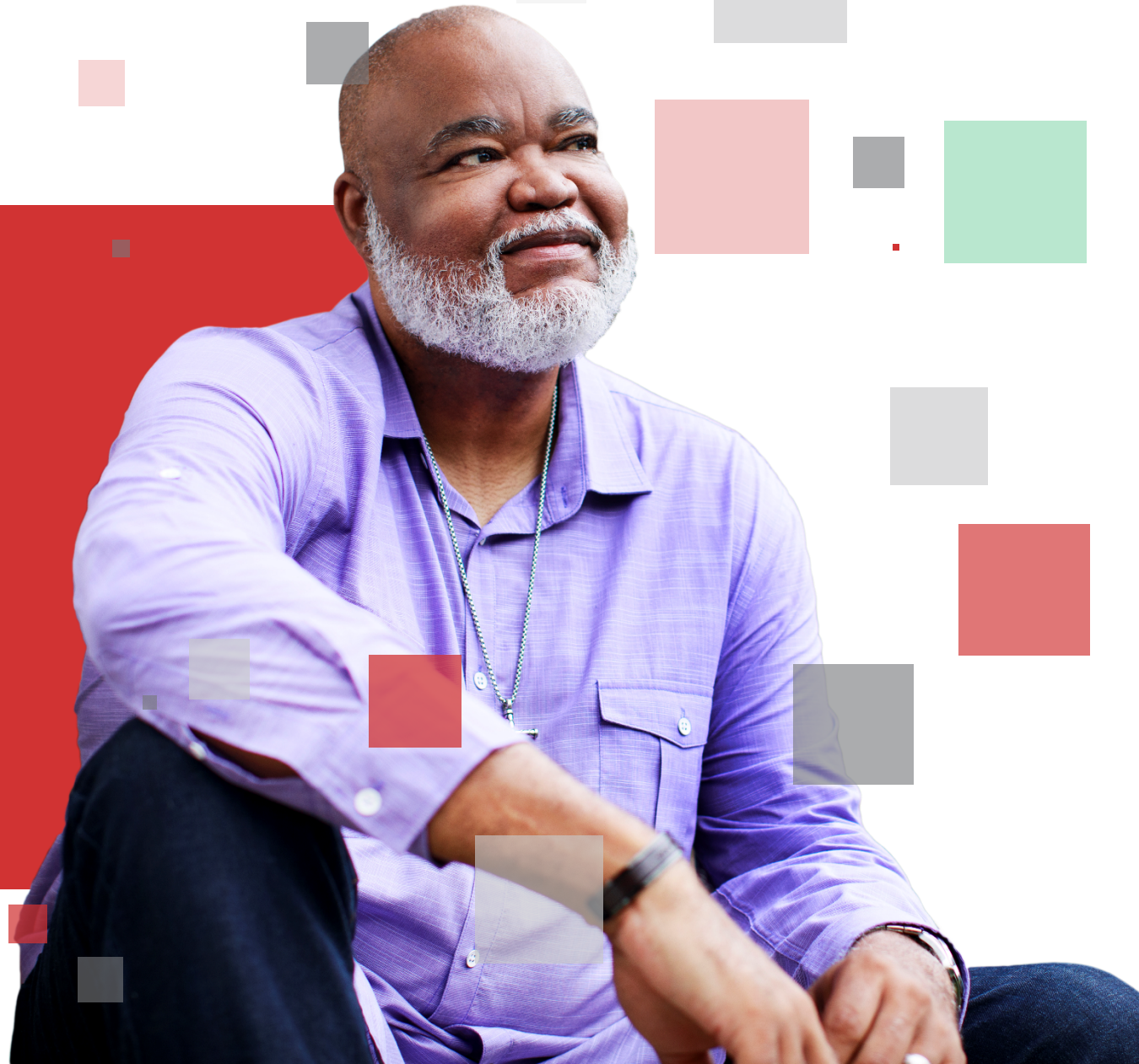
Environmental Savings – reducing carbon footprint

Safety - Remains at a high level for travel

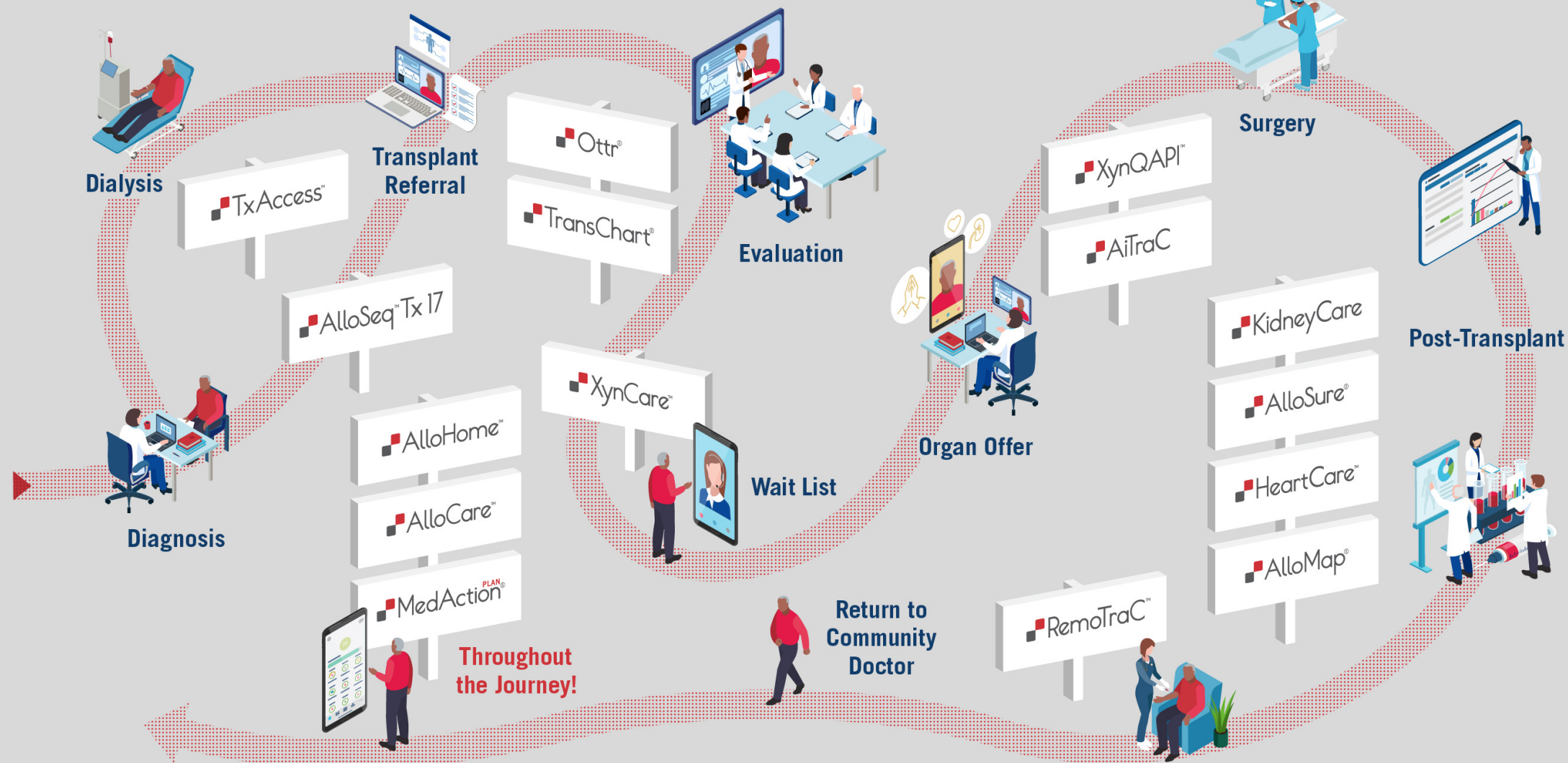


Innovations 2021

Derrick C, Kidney Transplant Recipient



CareDx is With You at Every Step of the Transplant Journey



Digital *Transplant Management Solutions*

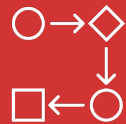
Referral &
Provider
Communication



Waitlist &
Patient Support
Services



Workflow
Management &
Reporting



Quality
Improvement &
Analytics



EMR Integration
Services



Patient
Monitoring &
Engagement





Referral & Provider Communication



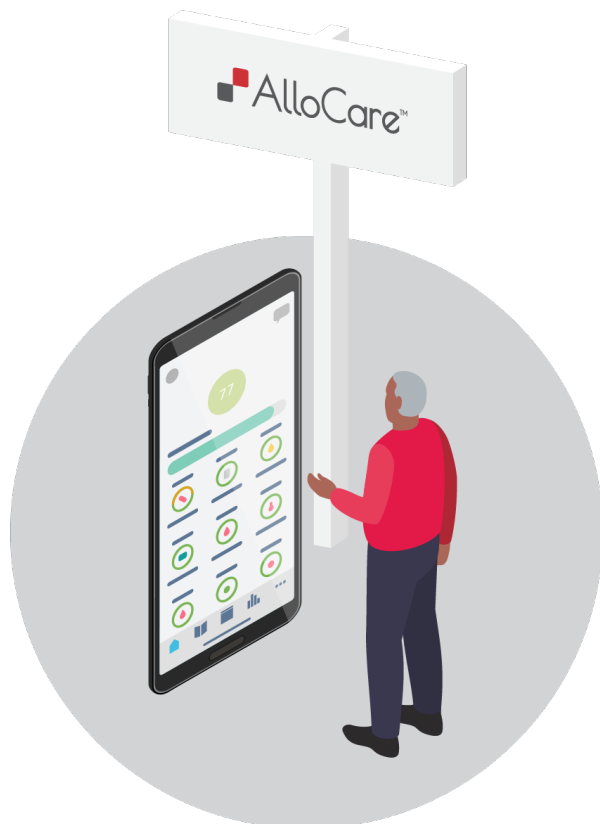
TX Connect 
is now

 TxAccess™

TxAccess (Formerly TX Connect) is a platform that improves continuity of care for transplant patients by facilitating referrals and ongoing communication between transplant programs, nephrology practices, and dialysis centers.

TxAccess

- Provides regular status updates about patients referred to a center regardless of whether initial referral & documentation were submitted via TxAccess
- Promotes better care coordination because providers can see & engage patients about incomplete steps
- Eliminates the need for double documentation because data is integrated with the transplant center's EMR
- Requires minimal transplant center IT involvement because it's a cloud-based solution



AlloCare is a free mobile app that helps transplant patients get ready for and stay on track after organ transplant.

AlloCare

- Provides patients the ability to manage their medication schedule and monitor important health metrics
- Reminds patients to reach daily goals like medication adherence, water intake, and daily steps
- Displays health metrics in an easy-to-read format so patients can track their own progress
- Enables patients to share medication adherence and important health metrics with their care team
- Features educational materials and a monitored community chat board to help patients stay connected and stay informed
- Available in English and Spanish; Android + iOS; all organ types



***XynQAPI** is a new comprehensive quality management solution for OPOs. Start with great reports and analytics to help you identify your quality improvement initiatives, tap into expertise, and get the quality management tools you need to effectively manage your OPO.*

XynQAPI

Predictive Analytics

- Future Tier prediction & improvement planning
- Real-time prediction of organ placement based on donor characteristics

Occurrence Reporting

- Easy analysis
- Facility level reporting

Data Consolidation

- Death review data
- Donor data
- Integrated; limited manual entry

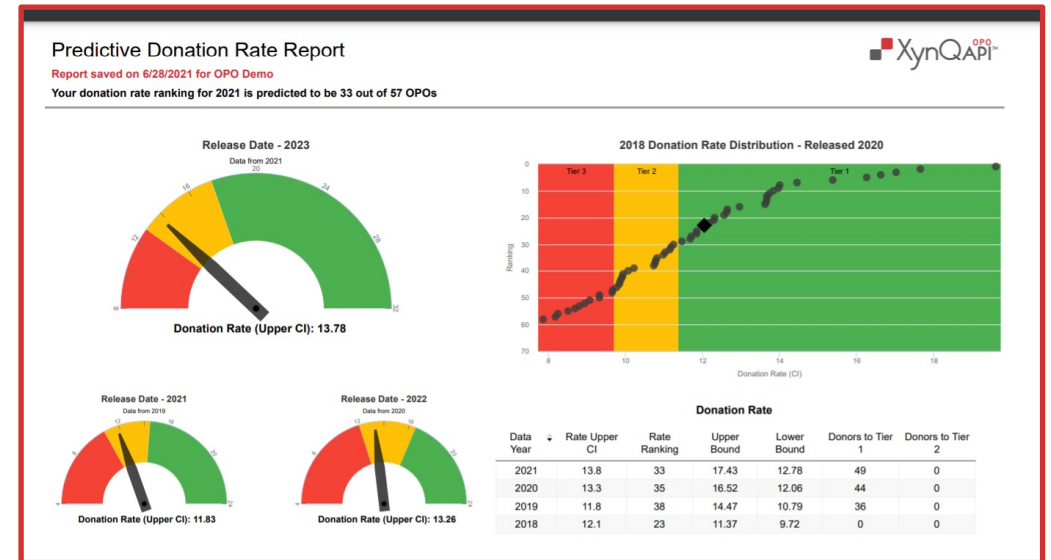
Documentation

- PI projects
- Event reviews
- Meetings
- Staff education

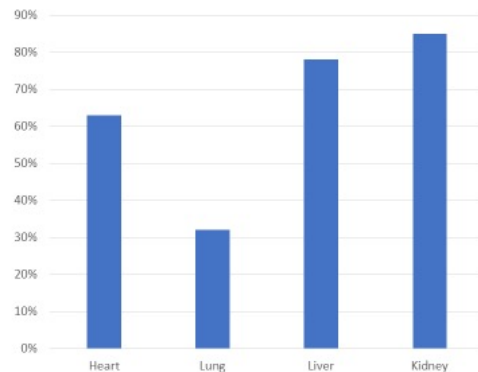
Two key tools of XynQAPI OPO

Prediction of CMS Tier Ranking

- Up to 2 years in advance
- Including how many donors/organs are needed to improve



Probability of organ yield



Donor information

- Donor age
- Donor gender
- Donor BMI
- PHS risk status
- DBD/DCD
- Donor blood type
- Facility
- Coordinator

Risk to placement

- Cold time
- Creatinine
- Biopsy

Likely to accept in region

- 1) Center 1
- 2) Center 2
- 3) Center 3

Likely to accept out of region

- 1) Center 1
- 2) Center 2
- 3) Center 3

Prediction of donor/organ yield

- At the time of referral
- Including identification of risks to placement



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