PARAGONIX®

KIDNEYVAULT™

PORTABLE RENAL PERFUSION SYSTEM

INSTRUCTIONS

KidneyVault™
Part # 114, L-525, Ver. 7
Issue Date: 28OCT2025
For technical assistance:
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Patents: paragonixtechnologies.com/patents/

⚠Caution: Federal (US) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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1 INDICATIONS FOR USE

The Paragonix KidneyVault Portable Renal Perfusion System is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for the preservation, transportation, and eventual transplantation into a recipient using cold storage solutions indicated for use with this organ.

The Paragonix KidneyVault Portable Renal Perfusion System can maintain the donor organ storage temperature between 4°C and 8°C through 24 hours.

Donor kidneys exceeding clinically accepted 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.

1.1 CONTRAINDICATIONS

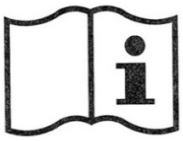
There are no known contraindications when used as directed.

1.2 WARRANTY STATEMENT

Paragonix Technologies, Inc. (Paragonix) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling and storage of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Paragonix's control directly affect the device and the results obtained from its use. Paragonix's obligation under this warranty is limited to the repair or replacement of this device and Paragonix shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Paragonix does not authorize any other person to assume for it, any other or additional liability or responsibility in connection with this device. Paragonix assumes no liability with respect to devices reused, reprocessed, or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

2 SAFETY REQUIREMENTS

2.1 IMPORTANT INFORMATION



It is important that all personnel who set up, package, recover, and transplant donor organs during operation of the device will operate the KidneyVault™ Portable Renal Perfusion System (KidneyVault™) **read and understand these instructions for use before operating the device**. All personnel who set up, package, recover, and transplant donor organs during operation of the device should follow all warnings and precautions outlined below, for their safety and the safety of those around them.

The KidneyVault™ Portable Renal Perfusion System is a device for use by clinical personnel that perform kidney recovery procedures to store and transport donor kidneys to the transplant facility. The KidneyVault™ Portable Renal Perfusion System is for use within acute care facilities that have an existing agreement with an Organ Procurement Organization (OPO) requiring the hospital to notify the OPO or third party designated by the OPO in a timely manner about all deaths and imminent deaths that occur in the hospital. Such hospitals must also have documented protocols and procedures for determining death or imminent death, obtaining family consent, and trained personnel with fully equipped surgical recovery operating rooms to perform the recovery procedure.

2.2 SYMBOL DEFINITIONS

Table 1: Symbols used in the labeling of the KidneyVault™ System and their definitions.

Symbol	Definition	Symbol	Definition
	Use by YYYY-MM-DD		Fragile, handle with care
	Do not reuse		Keep Dry
	Do not use if package is damaged or open		Temperature limits
	Indicates the need to consult the instructions for use		Pressure limits
LOT	Batch code		Humidity limits
	Caution, consult accompanying documents	UDI	Unique Device Identifier
	Manufacturer	SN	Serial Number
MD	Medical Device	#	Model Number
NON STERILE	Device or device component is non-sterile	CC	Country of Manufacture
STERILE R	Sterilized using irradiation		Date of Manufacture
	Fill Port		Vent Port

2.3 WARNINGS ⚠

- **Caution: Federal (US) law restricts this device to sale by or on the order of a physician.**
- **Use aseptic technique as appropriate.**
  Certain components of the KidneyVault™ system are provided sterile. Maintain aseptic technique when handling sterile components of the KidneyVault™ system.
- **Pre-Chilled (4°C) machine perfusion solution, cleared for use with the kidney, must be available.**

	Do NOT reuse any component of the KidneyVault™. The KidneyVault™ is intended for single use only. DO NOT RE-USE. Certain components of the KidneyVault™ are sterile as supplied (sterilization method is gamma irradiation). The KidneyVault™ should be disposed of in accordance with local guidelines for biomedical waste.

- **Use institution-specific precautions with the donor kidney and machine perfusion solution when operating the KidneyVault™.**
  The kidney and machine perfusion solution may carry undetected pathogens from the donor. Use universal precautions for bloodborne pathogens in handling the kidney, and in handling and disposing of the KidneyVault™ and machine perfusion solution to prevent the possible transmission of pathogens to personnel. As appropriate, this may include use of personal protective equipment (e.g., gloves, masks, gowns, goggles, or equivalent eye protection) and disposal of materials as potentially infectious biohazard waste.
- **Prior to use, inspect all components of the KidneyVault™. Do not use if any component is loose, broken, or damaged.**
- **Do not open the KidneyVault™ during organ transport.**
- **No modification of the KidneyVault™ is allowed.**
- **Judgement of organ quality is the responsibility of the surgeon.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the KidneyVault™ device. Otherwise, degradation of the performance of this equipment could result.**
  NOTE: Table 2 contains the standard levels of compliance:

Table 2. EMC/EMI Safety

Test Standard	Test Level
CISPR 11	Group 1 Class B, 30-1000 MHz
IEC61000-4-2	±8kV contact, ±2kV, ±4kV, ±8kV, ±15kV air
IEC61000-4-3	Radiated RF EM fields 3V/m, 80MHz-2.7GHz, 80% AM at 1 kHz
IEC61000-4-8	30 A/m 50Hz & 60 Hz
IEC6100-4-39	134.2 kHz and 13.56 MHz

2.4 DATALOGGER COMMUNICATION AND ACCURACY

- **Wireless Data Standard: Bluetooth Low Energy (Bluetooth Smart)**
  KidneyVault™ datalogger monitors temperature and pressure and can transmit to a mobile device using optional mobile app (section 4.4) using Bluetooth® Low Energy Technology.
- **Datalogger Radio Power: 1 mW (0 dBm)**
- **Datalogger Transmission Range: Approximately 30.5 m (100 ft) line-of-site**
- **Temperature Accuracy**
  KidneyVault™ comes with a pre-installed datalogger capable of reporting the temperature within the Organ Assembly. Temperature Accuracy is ±0.5°C from 0° to 50°C.
- **Pressure Accuracy**
  KidneyVault™ comes with a pre-installed datalogger capable of reporting renal artery pressure of the donor kidney. Pressure accuracy is ±10% at 65mmHg.
- **Time Accuracy**
  The pre-installed datalogger logs temperature and time with an accuracy of ±1 minute per month.

2.5 TRANSPORT AND STORAGE CONDITIONS

- **Transport and Storage Temperature: -20°C to 40°C**
- **Transport and Storage Pressure: 625hPa – 1060hPa**
- **Transport and Storage Humidity: 5 – 80% Relative Humidity**

2.6 OPERATING CONDITIONS

- **Operating Temperature: 20 to 24°C**
  Recommended Operating Room temperature is 22°C. Direct sunlight and outdoor temperature extremes (high and low) can affect KidneyVault™ internal temperature (4°C to 8°C). During exposure to temperature extremes, KidneyVault™ temperature must be frequently monitored.
- **Operating Pressure: Sea Level to 8000ft (1015 to 750hPa)**
  The operating pressure range conforms to commercial airliner transport. Extreme pressure levels can impact performance. During exposure to extreme pressures (altitudes), KidneyVault™ operation must be frequently monitored.
- **Operating Humidity: 40 – 60% Relative Humidity**
  Extreme humidity levels can impact performance. During exposure to extreme humidity levels, KidneyVault™ operation must be frequently monitored.

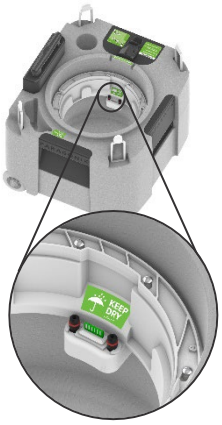
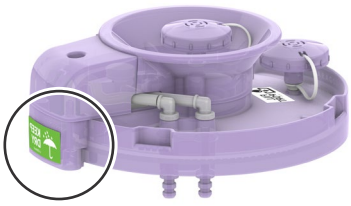
2.7 PRECAUTIONS

- **The KidneyVault™ does not allow pressure adjustments by the perfusionist during preservation and transport.**
- **Exercise Caution when using KidneyVault™ in presence of other electronic devices and electromagnetic emitters.**
- **Do not wet temperature probe connectors on Paragonix KidneyVault™**
  A series of 3 key areas are identified on the Paragonix KidneyVault™ as being regions to “Keep Dry”. These regions are called out by the following label:

Figure 1: Example of “Keep Dry” labels located on KidneyVault™ to designate specific areas to be protected from water.

These labels are affixed in the below-indicated locations, and the warning must be followed in order to ensure proper device function.

Table 3. Identification of temperature probe connector locations on Paragonix KidneyVault™ to be protected from water.

Shipper	Inner Canister Lid (Part #2)	Outer Canister Base (Part #3)
		

- **During Preparation and Access of the Donor Organ**
  Should the user notice that during preparation of the system any of the connectors become wet, the device may not provide or collect accurate temperature or pressure data during device operation. This has no impact on safety or effectiveness, and the device will continue to manage temperature and pressure. If the user prefers to correct the issue and regain temperature and pressure monitoring prior to departure from the donor site, remove the Inner and Outer Canister Assemblies from the Shipper, then replace with a new Inner and Outer Canister Assemblies following aseptic technique.

  NOTE: REPLACEMENT OF THE INNER AND OUTER CANISTER ASSEMBLIES SHOULD BE PERFORMED IN ACCORDANCE WITH SECTION 5.1 BELOW.

- **After Preparation**
  If after complete packaging of the donor kidney into the Shipper and activation of the datalogger, the temperature reading is above 15°C or the pressure reading is above 65mmHg, this indicates that the connectors have likely been wetted during the preparation steps or a datalogger failure. If this occurs, the device may not provide or collect accurate temperature or pressure data for that period of the run. This has no impact on safety or effectiveness, and the device will continue to manage temperature and pressure. If the operator prefers to correct the issue and regain temperature and pressure monitoring, they must do so in a temperature-controlled space at either the donor site while the sterile area is maintained, or after arrival at the OPO where another sterile area is present. Never attempt to do this while in transit. To regain temperature and pressure monitoring, remove the Inner and Outer Canister Assemblies from the Shipper, then replace with a new Inner and Outer Canister Assemblies following aseptic technique.
- **In the unlikely event that perfusion is unrecoverable, turn off the KidneyVault™ device pump and continue preservation using static cold storage**
  This has no impact on safety or effectiveness of thermal maintenance, and the device will continue to manage temperature.

- **The KidneyVault™ device should be attended throughout preservation, users are advised to stay in the vicinity of the device and never leave the device unattended.**
  Regularly check whether perfusion is ongoing as expected and the KidneyVault has not generated an alert.

- **Perfusion parameters provided by the KidneyVault™ datalogger are for reference only and should not be used as the sole clinical determination to transplant or discard a donor kidney**
  Historic clinical studies on hypothermic machine perfusion systems have not been shown to have high predictive values of clinical outcomes. Multiple studies and guidelines show the low correlation between these values and clinical outcomes. [1, 2, 3]
- **Keep the KidneyVault™ primarily upright during transportation.**
  The KidneyVault™ is designed to be transported upright. Temporary tilting ±45˚ from horizontal in any direction is acceptable.
- **Avoid direct sunlight and hot or cold temperature extremes.**
  The KidneyVault™ is designed to be transported under the same environmental conditions as is appropriate for people. Avoid extended exposure to outdoor conditions (sunlight, heat or cold).
- **Use Caution when lifting the KidneyVault™**
  A fully loaded KidneyVault™ weighs 25 lbs. Use proper lifting practices.
- **Exercise Caution when using KidneyVault™ in presence of other electronic devices and electromagnetic emitters.**
  KidneyVault has been tested for radiated immunity only at selected frequencies listed in Section 2.4 of this manual. While no significant risk of reciprocal interference has been identified, KidneyVault™ should always be closely monitored when in use and reoriented or relocated if abnormal performance is observed. Electromagnetic emitters include radiofrequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment.
- **Do not use KidneyVault™ in oxygen rich environment.**
  KidneyVault™ is not designed or evaluated for use in an oxygen rich environment.
- **Do not use KidneyVault™ with flammable anesthetics.**
  KidneyVault™ is not designed or evaluated for use with flammable anesthetics.

[1] Moers et al., Machine Perfusion or Cold Storage in Deceased-Donor Kidney Transplantation, N Engl J Med, 2009
[2] Breda et al. EAU Guidelines on Renal Transplantation. ISBN 978-94-92671-23-3. EAU Guidelines Office, Arnhem, the Netherlands, 2024
[3] Jochmans et al., Prognostic Value of RR During HMP of Deceased Donor Kidneys, Am J Trans, 2011

3 PRE-ASSEMBLY CHECKLIST

In addition to preferred backtable setup, please ensure the followings items are present:

Table 4.
Pre-Assembly Checklist for KidneyVault™ identifying components and sterility disposition.

Included with KidneyVault System	Item	Sterile	Non-Sterile	✓
Yes	**KidneyVault™** Shipper		X	
Yes	**KidneyVault™** SherpaCool® Materials ⚠**CAUTION: PRECONDITION AT -20°C OR BELOW FOR AT LEAST 48 HOURS PRIOR TO USE.**		X	
Yes	**KidneyVault™** Canister Assembly	X		
Yes	**KidneyVault™** Kidney Cannula Box	X		
No	2 Liters of pre-chilled (4°C) machine preservation solution	X		
No	Cysto Tubing	X		
No	2x Luer-lock Syringe	X		

3.1 KIDNEYVAULT™ SET-UP AND PREPARATION

1. Inspect all parts on arrival for any signs of damage that may have occurred during transport.
2. Report any damage or concerns about the condition of the KidneyVault™ immediately to Paragonix Technologies Inc.

Figure 2. KidneyVault™ Canister, SherpaCool®, and Cannulas, as shipped (in boxes)

(Large) Shipper Box

(Medium) Canister Box

(Smaller) SherpaCool®

Cannulas
(Smallest)

Figure 3.
Shipper Box containing Inner Box and Shipper, nested, in protective bag, grouped together.

Figure 4.
Inner Box

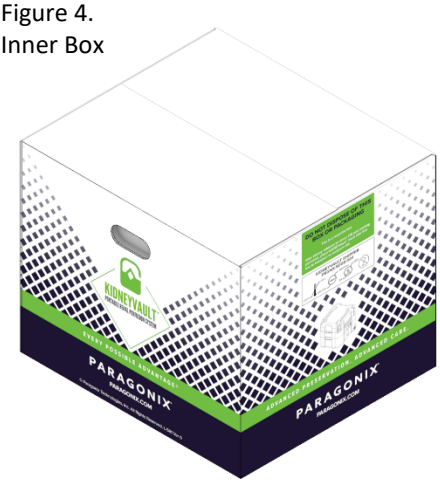


Figure 5.
KidneyVault™ Shipper

Figure 6.
Canister Box containing Inner and Outer Canister Assemblies including Outer Canister Lid (Part #4), Outer Canister Base (Part #3) and Inner Canister Lid (Part #2), Kidney Retainer, and Inner Canister Base (Part #1), assembled and nested, in Sterile Pouch, grouped together.

Figure 7.
Canister Assembly:
Outer Canister Lid (Part #4), Outer Canister Base (Part #3) and Inner Canister Lid (Part #2), Kidney Retainer, and Inner Canister Base (Part #1)

Figure 8.
Outer Canister Base (#3)

Figure 9. Outer Canister Lid (#4)

Figure 10.
Inner Canister Assembly: Inner Canister Base (#1), Kidney Retainer, and Inner Canister Lid (#2)

Figure 11.
Inner Canister Base (#1)

Figure 12.
Inner Canister Lid (#2)

Figure 13.
Kidney Retainer

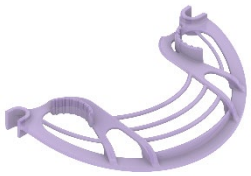


Figure 14.
SherpaCool® Box containing 5 (five) SherpaCool® Ribbons (#5) and 1 (one) SherpaCool® Pouch (#6), nested, grouped together.

Figure 15.
SherpaCool® Ribbons (#5). ⚠CAUTION: PRECONDITION AT -20°C OR BELOW FOR AT LEAST 48 HOURS PRIOR TO USE.

Figure 16.
SherpaCool® Pouch (#6).
⚠CAUTION: PRECONDITION AT -20°C OR BELOW FOR AT LEAST 48 HOURS PRIOR TO USE.

Figure 17.
KidneyVault™ Cannula Box containing Cannulas assembled and nested in Sterile Pouches.

Figure 18.
KidneyVault™ Cannula Varieties

Opening sizes:

Round	***Oval***	***Straight***
3mm, 5mm, 7mm, 9mm	7x20mm, 10x35mm	4mm, 6mm 8mm

4 OPERATING INSTRUCTIONS

4.1 GENERAL INFORMATION

- Before using in a clinical setting, operators must review and understand the Instructions For Use for the use and functional understanding of the KidneyVault™.

4.2 OVERVIEW

Using the KidneyVault™ involves performing the following procedures:

1. Removal of external shipping packaging, preconditioning of inner SherpaCool® Box (Section 4.3) containing SherpaCool® Pouch and SherpaCool® Ribbons at or below -20°C for at least 48 hours
2. Setup of supplemental Datalogging App for use with KidneyVault™ (Section 4.4, optional, recommended)
3. Transport of KidneyVault™ to the recovery site (Section 4.5)
4. Preparing the KidneyVault™ for deployment at recovery site (Section 4.6)
5. Preparing the KidneyVault™ for kidney receipt at recovery site (Section 4.7)
6. Kidney recovery and preservation (Section 4.8)
7. Kidney Perfusion (Section 4.9)
8. Traveling with the KidneyVault™ with donor kidney to secondary site (i.e., Organ Procurement Organization) (Section 4.10, as required)
9. Storage of KidneyVault™ with donor kidney at secondary site (i.e., Organ Procurement Organization) while awaiting allocation (Section 4.11, as required)
10. Traveling with the KidneyVault™ to the transplant site (Section 4.12)
11. Removing the kidney from KidneyVault™ for transplant (Section 4.13)

The instructions below are designed for preparing the KidneyVault™ Portable Renal Perfusion System at the recovery site and the transplant site. It is important that the medical staff responsible for preparation and use of the device have the necessary personnel available and be thoroughly familiar with the information in this user manual prior to attempting preservation and storage of a donor kidney.

4.3 REMOVAL OF PACKAGING AND PRECONDITIONING OF SHERPACOOL® BOX CONTAINING SHERPACOOL® RIBBONS AND SHERPACOOL® POUCHES

KidneyVault™ must be maintained in a ready-to-use condition, so that it can be available to the kidney recovery team at all times.
Make the following preparations:

1. **Do not remove SherpaCool® Ribbons and Pouches from the SherpaCool® Box.**
2. **On the Label affixed to the SherpaCool® Box, write the date and time of when SherpaCool® Box is placed into -20°C storage.**
3. Place the SherpaCool® Box into a -20°C (or colder) freezer for a minimum of 48 hours.
4. Remove SherpaCool® Box after a minimum preconditioning time of 48 hours at -20°C (or colder).
5. Do not remove SherpaCool® Box from freezer until KidneyVault™ deployment is imminent.
6. Do not remove SherpaCool® Box from freezer until all other components of KidneyVault™ and associated equipment and materials have been prepared for transport.
7. SherpaCool® Box must be transported to the donor site on ice OR within the KidneyVault™ Shipper as described in Section 4.5.
8. 2L of pre-Chilled (4°C) machine perfusion solution, cleared for use with the kidney, must be available as described in Section 4.8.

4.4 SETUP OF SUPPLEMENTAL DATALOGGING APP FOR USE WITH KIDNEYVAULT™ (OPTIONAL, RECOMMENDED)

In order to recover logged perfusion data from KidneyVault™ system, the user must first download and install the latest version of the mobile Paragonix App at either the App Store or Google Play store. This requires use of a Bluetooth®-enabled iOS or Android device.

NOTE: KIDNEYVAULT ™ SYSTEM COMES PRE-CONFIGURED WITH APPROPRIATE TEMPERATURE AND PRESSURE MONITORING SETTINGS INSTALLED IN THE ON-BOARD DATALOGGING SYSTEM. THIS CONFIGURATION MUST NEVER BE MODIFIED BY THE USER.

NOTE: THE VALUES DISPLAYED IN THE SUPPLEMENTAL DATALOGGING APP ARE FOR REFERENCE ONLY AND ACTUAL VALUES SHOULD BE CONFIRMED ON THE DATALOGGER SCREEN INTEGRATED INTO THE KIDNEYVAULT ™ SYSTEM.

After setting up an account for use of the Paragonix App:

- After logger is started (Section 4.8 Kidney Recovery and Preservation, Step 23 of this manual) it is possible to visualize the logged data by connecting the KidneyVault**™** device to the Paragonix App.
    - Log in to the Paragonix App on your mobile device.
    - Scan the QR code on the Shipper to the left of the pump to pair the device.
    - If necessary, manually re-enter the Datalogger PassKey provided under the QR code.

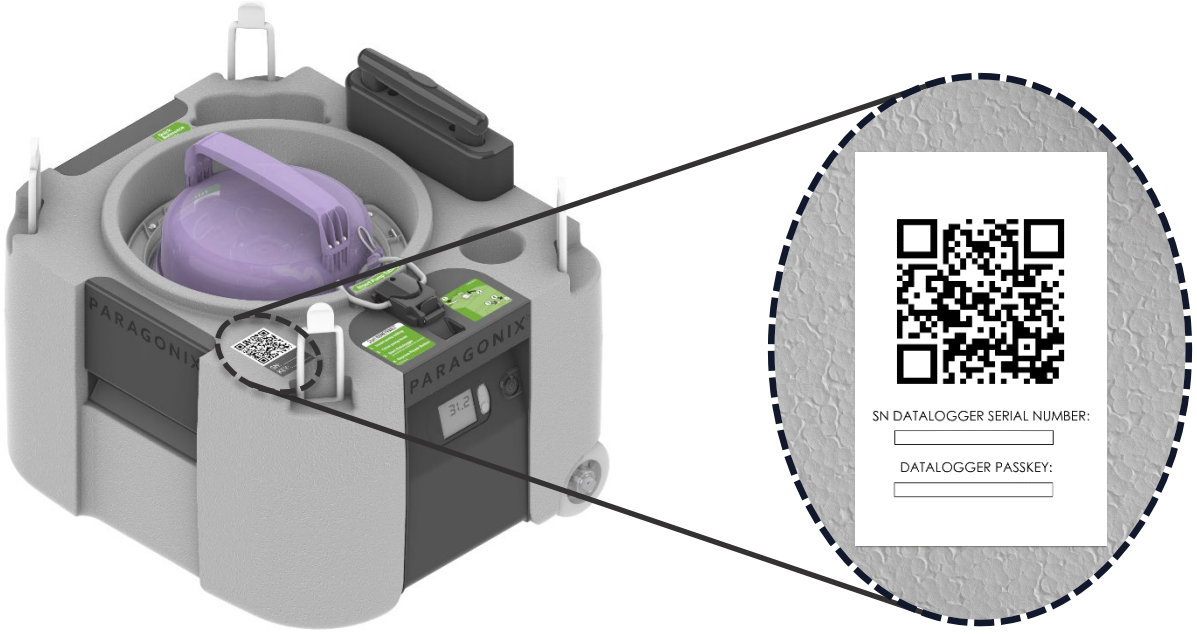


Figure 19: Indication of datalogger Serial Number and PassKey on Shipper

NOTE: IT IS RECOMMENDED TO DOWNLOAD AND ASSESS THE LOGGED DATA AT THE COMPLETION OF PRESERVATION.

- **Once connected to the datalogger, logged data may be viewed locally and/or uploaded to alternative devices via the Paragonix software application.**
- **For additional assistance in data recovery, contact Paragonix® directly via provided telephone number and have available the Shipper Serial Number and Datalogger Serial Number.**
- **Do not dispose of Shipper unit until desired data has been obtained.**

4.5 TRANSPORT OF KIDNEYVAULT™ TO RECOVERY SITE

Transport various supplies of KidneyVault™ to the recovery site:

- Collect common kidney recovery supplies and tools (Luer-lock syringes, forceps, scissors, silk ties, etc.).
- Remove and discard the outer cardboard layer of the Canister Assembly box prior to transportation to the recovery site and leave the inner layer.
- Unbox Shipper prior to transportation to the recovery site and discard packaging.
  - **CONSIDERATION:** If shipping kidney via cargo, refer to Section 4.12 for instructions on packing the loaded shipper into the **Cargo Transport Box**.
- Place SherpaCool® Box into an ice chest OR in the KidneyVault™ Shipper for transportation.
  - SherpaCool® may be transported with its box in the same ice chest as other adjunct supplies (perfusion solution, etc.) OR placed within the KidneyVault™ shipper.
  - Maximum allowable transit time for SherpaCool® Box is 4 hours.
- Place 2L of pre-chilled (4°C) machine perfusion solutions into an ice box for transportation.
- Carry KidneyVault™ Canister Assembly and Kidney Cannula boxes, in a separate bag or, optionally, place on top of Shipper or ice box while still boxed and securely fasten.
- Wheel or carry Shipper to Recovery Site.

4.6 PREPARATION OF KIDNEYVAULT™ FOR DEPLOYMENT AT RECOVERY SITE

Prepare various KidneyVault™ supplies of at the recovery site:

- Place box containing Outer Canister Assembly with nested Inner Canister Assembly onto a nearby non-sterile table in the operating room (OR).
- Follow hospital procedures for moving equipment into the OR.
- Verify presence of SherpaCool® in ice box.
- Using checklist (See Section 3.1), verify presence of all the KidneyVault™ components PRIOR to unpacking the components.

4.7 PREPARING THE KIDNEYVAULT™ FOR KIDNEY RECEIPT AT RECOVERY SITE

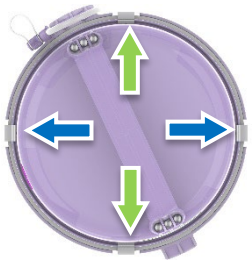
1.	Open the inner Canister Assembly box containing the nested Canister Assembly in a sterilization pouch.		NON-STERILE FIELD
2.	Remove the sterilization pouch containing the nested Canister Assembly and place pouch containing the Canister Assembly onto a non-sterile table in the OR.		NON-STERILE FIELD
3.	Remove the nested Canister Assembly from the sterile pouch and, without compromising sterility, introduce it to the sterile field to unwrap and remove the CSR covering. **NOTE: ALL COMPONENTS OF THE CANISTER ASSEMBLY SHOULD REMAIN STERILE THROUGHOUT THE RECOVERY PROCEDURE.**	 	STERILE FIELD

4.

Unclasp all four (4) latches on the Outer Canister Assembly by opening two (2) sets of opposing latches.

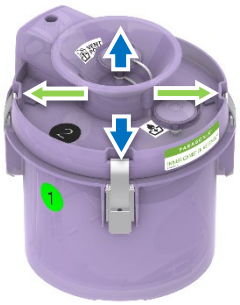
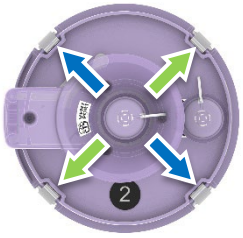
First **Group 1** of opposing latches, then **Group 2** of opposing latches.

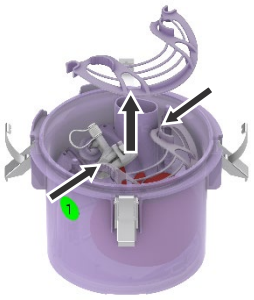
(closed configuration shown at right)



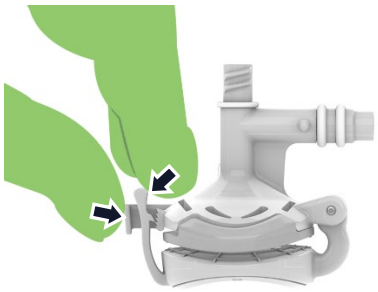
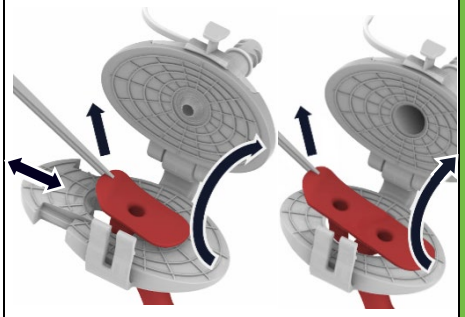
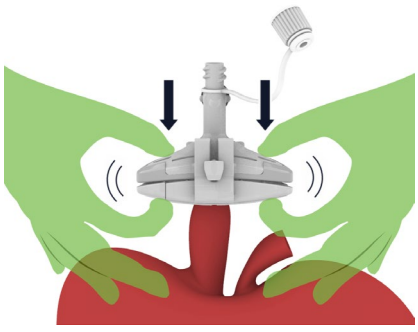
(open configuration shown at right)

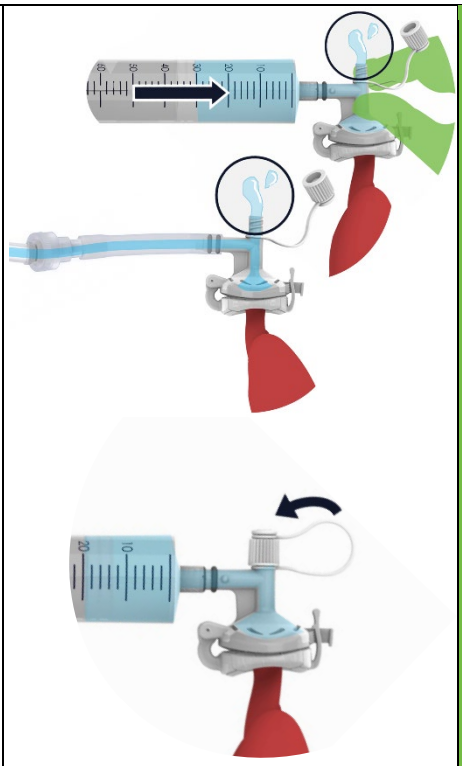
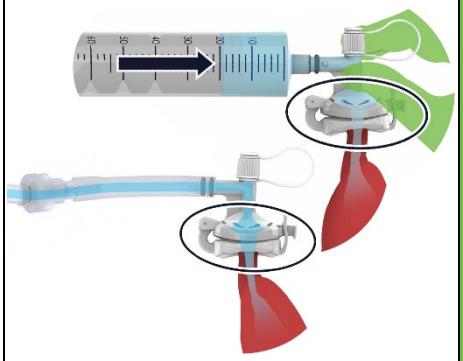
STERILE FIELD

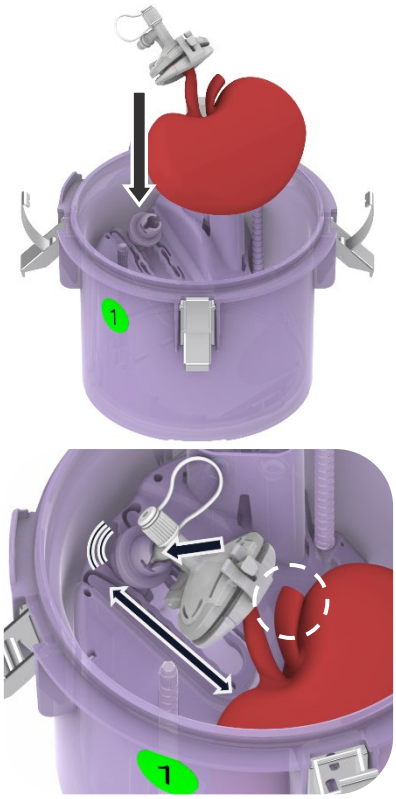
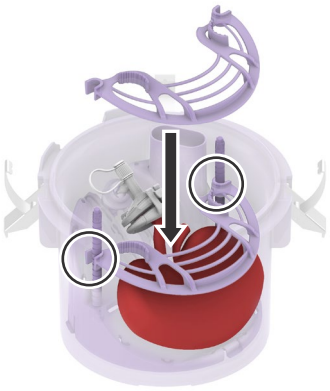
5.	Remove the Outer Canister Lid (part #4) from the Outer Canister Base (part #3).		STERILE FIELD
6.	Remove the Inner Canister Assembly (parts #1 and #2) from the Outer Canister Base (part #3).		STERILE FIELD
7.	Unclasp all four (4) latches on the Inner Canister Assembly by opening two (2) sets of opposing latches. First **Group 1** of opposing latches, then **Group 2** of opposing latches. (closed configuration shown at right)	 	STERILE FIELD

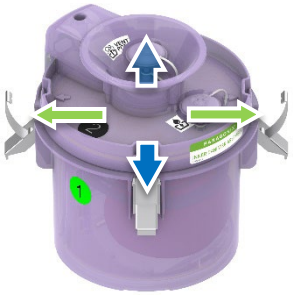
	(open configuration shown at right)		STERILE FIELD
8.	Remove the Inner Canister Lid (part #2) from the Inner Canister Base (part #1).		STERILE FIELD
9.	Remove the Kidney Retainer by pinching it inward and pulling it up and over the retaining posts. For larger kidneys that do not require the Kidney Retainer, discard the Kidney Retainer		STERILE FIELD
10.	Visually inspect all material for damage and discard if necessary.		STERILE FIELD

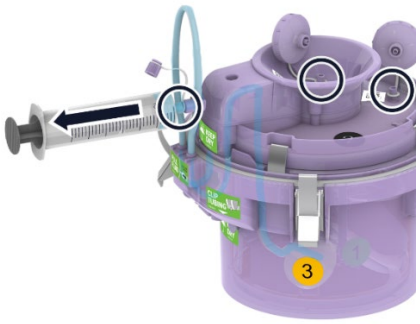
4.8 KIDNEY RECOVERY AND PRESERVATION

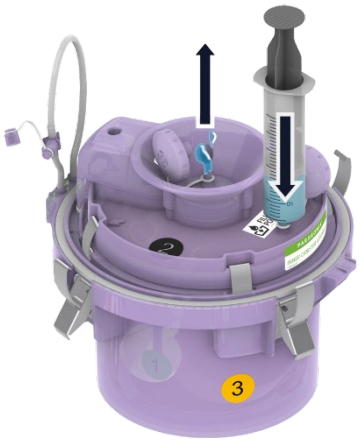
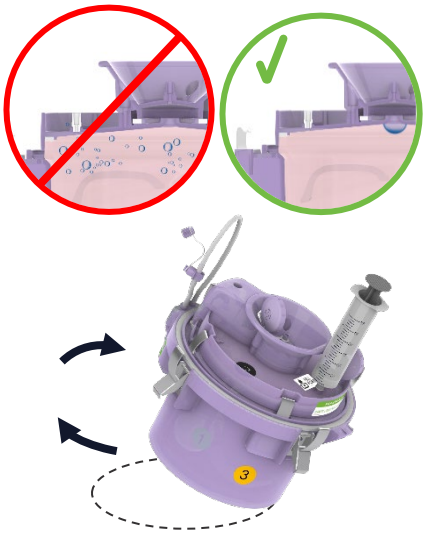
1.	Prepare the kidney for Cannulation.		STERILE FIELD
2.	Identify appropriate Kidney Cannula size. **For Straight Cannulas, follow procedure in L-839 KidneyVault™ Straight Cannula Instructions, packaged with KidneyVault™ Straight Cannula box. This document reviews how to transport, prepare, attach, de-air, and leak test KidneyVault™ Straight Cannulas.** Remove the selected sterile Kidney Cannula from its sterilization pouch and introduce into sterile field.		STERILE FIELD
3.	**Cannulate the Kidney** Unclasp cannula and pull upwards to open. Ensure renal vein is facing upward (towards the clasp) and that the clasp and slider at the bottom portion of the Cannula is open (Slider only present on 3mm, 5mm, 7mm, and 9mm Cannulas). Carefully pull the arterial patch and artery(s) through the opening at the bottom portion of the Cannula. Gently and without pinching, close the slider at the bottom portion of the Cannula around artery(s) to cradle it in place (Slider only present on 3mm, 5mm, 7mm, and 9mm Cannulas). **NOTE: TACTILE FEEDBACK INDICATES THAT THE SLIDER IS FULLY ENGAGED (ONLY FOR 3MM, 5MM, 7MM, AND 9MM CANNULAS)** Firmly close the top portion of the Cannula and engage the bottom of the Cannula to create a seal on the arterial patch. Ensure the arterial patch is secured by pressing down on sides of the cannula. **NOTE: A TACTILE CLICK INDICATES THAT THE LATCH IS FULLY ENGAGED.** Visually inspect that the renal artery(s) is in its proper position (i.e., not twisted, appropriate tension as determined by the user, etc.) and that the Cannula has sealed around the artery patch.	  	STERILE FIELD

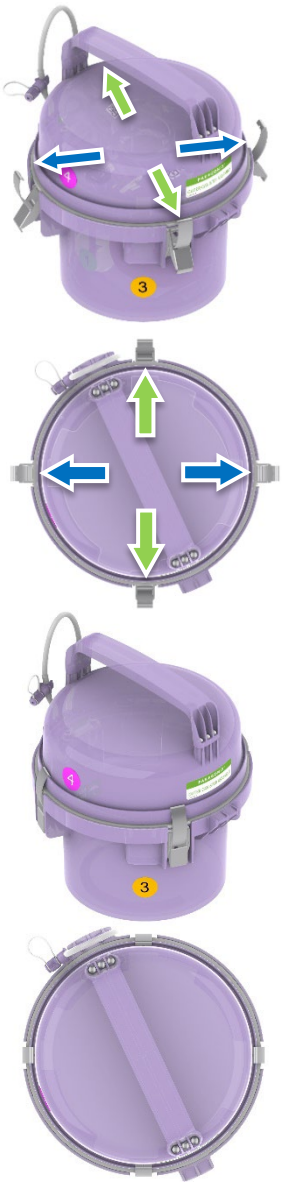
4.	**Air Removal from Cannula:** Unscrew the RELEASE PORT cap on the Cannula. Connect a syringe filled with, or a line in connected to a bag of, machine perfusion solution to the end of the Cannula at the PERFUSION PORT. **NOTE: This is a slip fit connection, press and support cannula to ensure connection.** Inject machine perfusion solution through the Cannula until fluid flows through the release port and all air is visually confirmed as removed from the cannula. Secure the release port cap on the Cannula.		STERILE FIELD
5.	**Check Cannula Connection for Leaks:** Connect a syringe filled with machine perfusion solution to the end of the Cannula, at the PERFUSION PORT. **NOTE: BE CAREFUL TO AVOID INJECTING AIR INTO CANNULA** Gently inject machine perfusion solution through the Cannula until fluid flows **through the renal vein.** Visually check for leaks to ensure a watertight Cannula connection on the artery.		STERILE FIELD

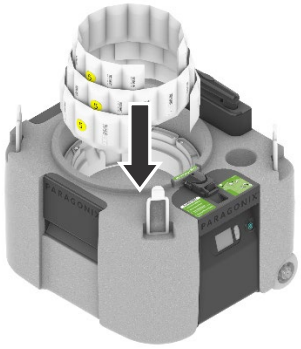
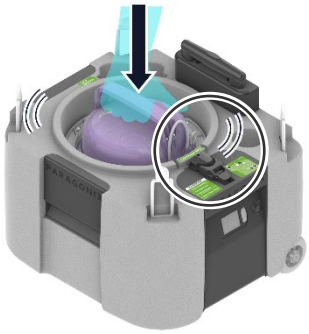
6.	Insert the kidney into the Inner Canister Base (part #1), then connect the Cannula to the Kidney Rest by firmly pressing it into the opening on the Kidney Rest CANNULA PORT. Slide as necessary to adjust tension on renal artery. Visually inspect Cannula connection to Kidney Rest to ensure Cannula is connected. **Optional:** Visually confirm that renal vein is facing upward and that the renal artery is not twisted.		STERILE FIELD
7.	If Kidney Retainer is required, reconnect it to the two retainer posts and press on top to slide it down until it cradles the kidney to prevent it from twisting in transit. **NOTE: KIDNEY WILL EXPAND DURING PUMPING. KEEP THIS IN MIND WHEN SETTING KIDNEY RETAINER HEIGHT TO AVOID RESTRICTING RENAL FLOW.** Visually confirm Inner Canister Lid is clear of fatty tissue.		STERILE FIELD
8.	Fill the Inner Canister Base (part #1) with pre-chilled (4°C) machine perfusion solution per institution recommendation without over-filling (solution level will be topped up prior to final disposition).		STERILE FIELD

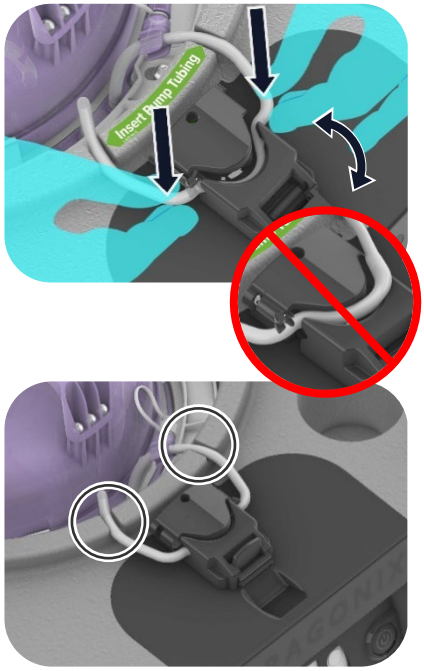
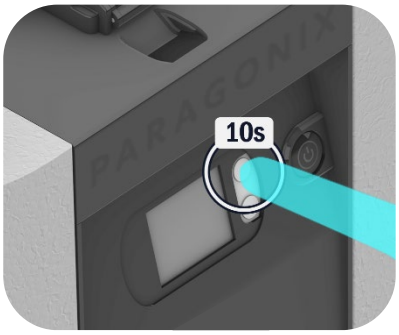
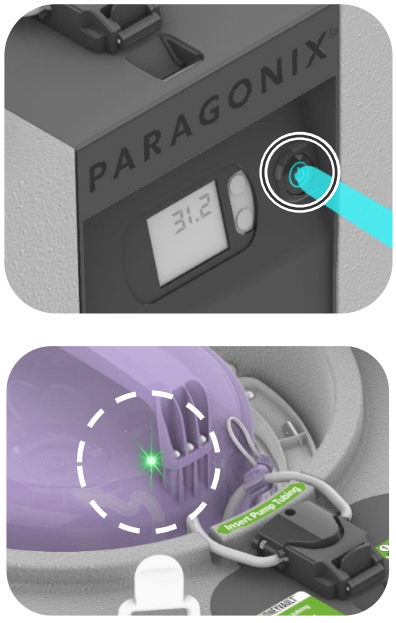
9.	Seat the Inner Canister Lid (part #2) onto the lip of the Inner Canister Base (part # 1). Ensure fittings connect to the Kidney Rest; and that the renal artery, ureter, and excess fat are not caught. **NOTE: ENSURE ELECTRICAL CONNECTORS ARE NOT WETTED DURING HANDLING (REFERENCE TABLE 3).**		STERILE FIELD
10.	Lock the Inner Canister Lid (part #2) to the Inner Canister Base (part #1) by closing two (2) groups of opposing latches. First **Group 1** of opposing latches, then **Group 2** of opposing latches. **NOTE: ENSURE ELECTRICAL CONNECTORS ARE NOT WETTED DURING HANDLING (REFERENCE TABLE 3).**	  	STERILE FIELD

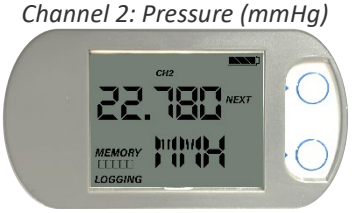
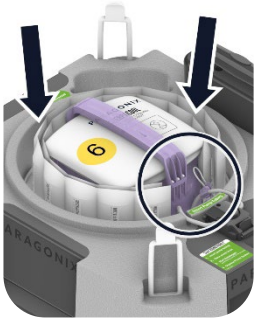
11.	Insert the assembled and filled Inner Canister Assembly into the Outer Canister Base (part #3). The Inner Canister Assembly seats into position when the latches align with the associated notches on the Outer Canister Base (part #3). **NOTE: ENSURE ELECTRICAL CONNECTORS ARE NOT WETTED DURING HANDLING (REFERENCE TABLE 3)**		STERILE FIELD
12.	Open the VENT PORT and the FILL PORT on the Inner Canister Lid (part #2) (so labeled) and the PULL PORT on Outer Canister Base (part #3) pump tubing.		STERILE FIELD
13.	**Removal of Air from Pump Tubing:** Connect a depressed syringe to the PULL PORT (syringe connector) on pump tubing. Pull back on the plunger of the syringe until only machine perfusion solution is filling the syringe and air is no longer being pulled through the Pump Tubing. **NOTE: THIS STEP MAY NEED TO BE REPEATED TO EFFECTIVELY REMOVE AIR.**		STERILE FIELD

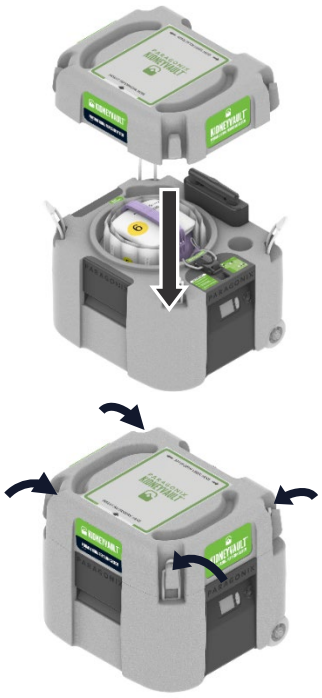
14.	Continue to fill the Inner Canister Assembly with pre-chilled (4°C) machine perfusion solution through the FILL PORT (so labeled) located on the top surface of the Inner Canister Lid (part #2). Filling may be performed directly from a line attached to the bag of machine perfusion solution or syringe. Continue filling until fluid appears at the VENT PORT (so labeled). **NOTE: THIS STEP MAY NEED TO BE REPEATED TO EFFECTIVELY REMOVE AIR.** **NOTE: ENSURE ELECTRICAL CONNECTORS ARE NOT WETTED DURING HANDLING (REFERENCE TABLE 3)**		STERILE FIELD
15.	Visually inspect the Canister Assembly for trapped air under the Inner Canister Lid (part #2) (shown at right) and under the Kidney Rest. **Optional:** If air is observed, cap FILL PORT or leave line/syringe attached and tilt the Canister no more than 45 degrees in each direction from Horizontal while visually checking that trapped air gets dislodged and escapes toward the VENT PORT. When satisfied, repeat filling the canister with machine perfusion solution.		STERILE FIELD
16.	Securely close the VENT PORT and FILL PORT on the Inner Canister Lid (part #2) using the attached Port Caps. Securely close the PULL PORT (syringe connector) on the Pump Tubing using the attached Luer Cap.		STERILE FIELD

17.	Place the Outer Canister Lid (part #4) onto the upper lip of the Outer Canister Base (part #3).		STERILE FIELD
18.	Close the four (4) latches of Outer Canister Assembly by closing two (2) sets of opposing latches. First **Group 1** of opposing latches, then **Group 2** of opposing latches. (open configuration at right) (closed configuration at right)		STERILE FIELD

19.	Remove the Shipper Lid from the Shipper by unlatching it.		NON-STERILE FIELD
20.	Open the SherpaCool® Box (refer to Figure 14), and individually place three (**3)** SherpaCool® Ribbons (part #5) into the cavity of the Shipper and press them out against the walls of the cavity to form a ring. Make sure to alternate orientations of the SherpaCool® to ensure consistent temperatures.		NON-STERILE FIELD
21.	Transfer the fully loaded Canister Assembly into the pre-assembled Shipper. Orient so that the pump tubing on the Canister Assembly faces pump on the Shipper, and press into shipper ring.		NON-STERILE FIELD

22.	**Route Pump Tubing** Unclamp the pump by fully lowering the pump lever. Route the Pump Tubing into the pump by pressing and routing it through the opening. Ensure the Pump Tubing is located between the rollers and clamp of the pump. When the clamp is engaged, the Pump Tubing should not be protruding. Clamp the pump onto the Pump Tubing by fully raising the pump lever. Visually check that the Pump Tubing is routed through grooves in Shipper and is not kinked nor twisted.		NON-STERILE FIELD
23.	With the tip of a finger, press and hold for 10 seconds Button 1 (the top button) on the DataLogger to power on the unit and initiate temperature, pressure, and time logging. **NOTE: THE PRESSURE DISPLAY HAS BEEN CALIBRATED FOR ACCURACY ONLY WHEN THE UNIT IS PERFUSING WITH THE TUBING SECURED (SYSTEM PUMPING).**		NON-STERILE FIELD
24.	Depress the power button to begin pumping. Look for green LED to light at top of Canister Assembly to confirm connection.		NON-STERILE FIELD

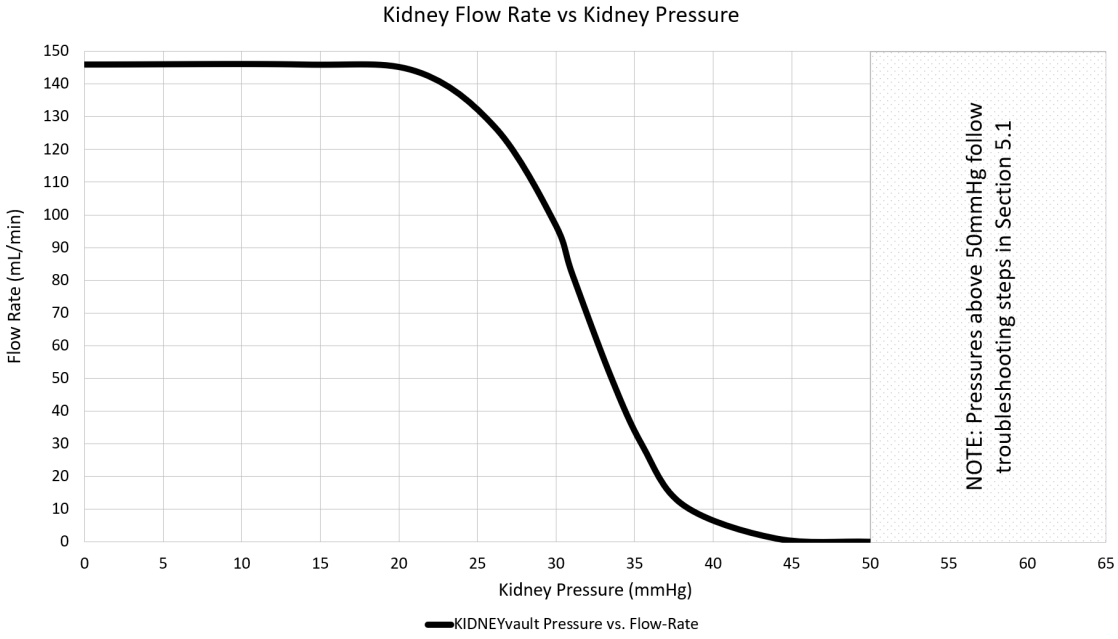
25.	Verify that interior temperature (Channel 1) and pressure (Channel 2) are displayed on the DataLogger display by pressing Button 1 (the top button) to toggle between Channels. **NOTE: FOR THE FIRST HOUR FOLLOWING ASSEMBLY OF KIDNEYVAULT™ YOU MAY EXPERIENCE TRANSIENT TEMPERTAURES. THIS IS DUE TO SYSTEM STABILIZATION IMMEDIATELY FOLLOWING FINAL ASSEMBLY.** **NOTE: CONFIRM PERFUSION PRESSURE IS AS EXPECTED FOR DONOR KIDNEY.**	*Channel 1: Interior Temperature (°C)*  *Channel 2: Pressure (mmHg)*  *Channel 3: Battery Life (Volts)*  *Channel 4: Ambient Temperature (°C)*  	NON-STERILE FIELD
26.	Insert one SherpaCool® Pouch (part #6) beneath the handle of the Outer Canister Lid. Place the two (2) SherpaCool® Ribbons (part #5) around the Outer Canister Lid, with an opening for the Pump Tubing. (Final configuration shown at right) **NOTE: ENSURE SHERPACOOL RIBBONS DO NOT INTERFERE WITH PUMP TUBING, THIS MAY CAUSE DAMAGE OR SLOW PERFUSION.**	  	NON-STERILE FIELD

27.	**Optional:** Place appropriate Kidney identification and labeling on the inside of the Shipper.		NON-STERILE FIELD
28.	Close the Shipper Lid, seat, and lock each of the four Shipper latches securely. **NOTE: DO NOT TRANSPORT ADDITIONAL SUPPLIES, SUCH AS PERFUSION AND PRESERVATION SOLUTIONS, BLOOD SAMPLES, DOCUMENTATION, ETC. WITHIN THE KIDNEYVAULT™ SHIPPER CAVITY.**		NON-STERILE FIELD
29.	Place appropriate Kidney identification and labeling on the outside of the Shipper. **Optional:** Use the clear envelope on Shipper Lid to store appropriate paperwork. The KidneyVault™ is now ready for transport.		NON-STERILE FIELD

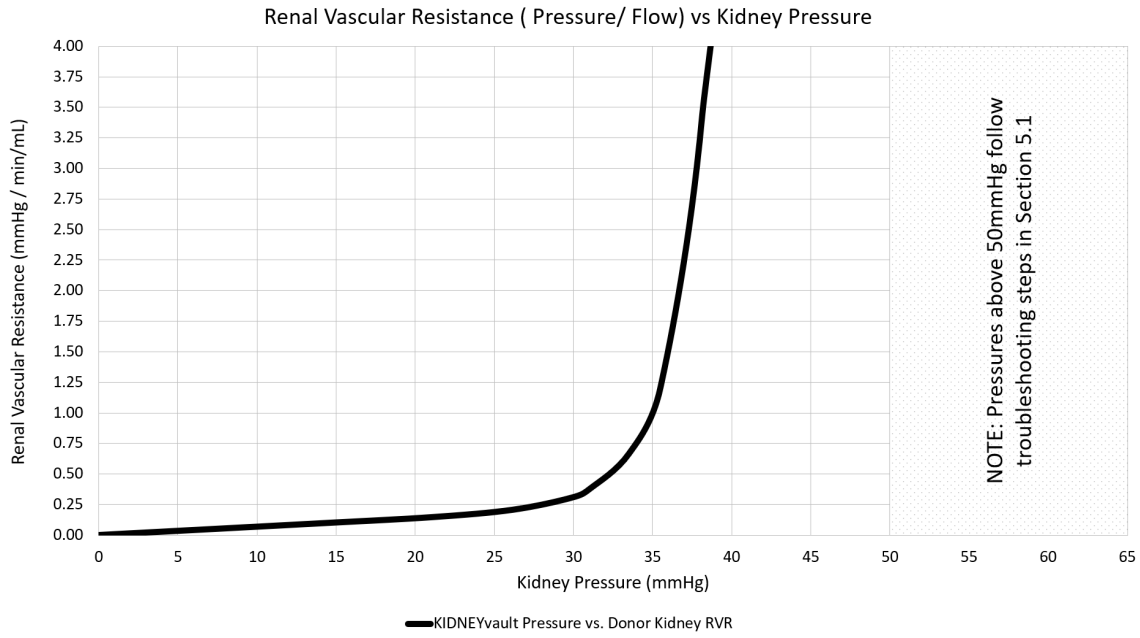
4.9 KIDNEY PERFUSION

The KidneyVault device is now perfusing. The images below show the mean renal flow rate and renal vascular resistance based on the displayed kidney pressure.

NOTE: THERE ARE NO USER SETTABLE VALUES FOR PERFUSION. KIDNEYVAULT PERFUSION OPERATES WITH A DYNAMIC PRESSURE-FLOW RELATIONSHIP THAT RESPONDS TO THE PHYSIOLOGICAL VASCULAR RESISTANCE OF THE DONOR ORGAN RATHER THAN A CONSTANT PRESSURE.



NOTE: PERFUSION PRESSURE AND FLOW ARE DEPENDENT ON DONOR KIDNEY RENAL VASCULAR RESISTANCE. AS THE DONOR KIDNEY VASODILATES, THE PERFUSION PRESSURE SHOULD DECREASE, INDICATING INCREASED FLOW. JUDGEMENT OF ORGAN QUALITY IS THE RESPONSIBILITY OF THE SURGEON.



NOTE: KIDNEYVAULT OPERATES PRESSURE BETWEEN 0-50MMHG AND FLOW BETWEEN 0-150ML/MIN BASED ON DONOR KIDNEY RENAL VASCULAR RESISTANCE WITHOUT USER ADJUSTABLE PRESSURE.

4.10 TRAVELING WITH THE KIDNEYVAULT™ TO THE ORGAN PROCUREMENT ORGANIZATION (AS REQUIRED)

If the Kidney is being transported directly from the donor operating room to the transplant center (not going to the OPO), skip to section 4.12. Otherwise:

Confirm that the Shipper is securely closed with all 4 latches in place.

In the event of transport by vehicle, roll the KidneyVault™ to the vehicle and place the KidneyVault™ in a flat location secured against shifting or tipping during transit.

Upon arrival at the Organ Procurement Organization (OPO), follow institute procedures for moving equipment into the OPO.

4.11 ACTIVE STORAGE OF THE KIDNEYVAULT™ AT THE ORGAN PROCUREMENT ORGANIZATION (AS APPROPRIATE)

If the Kidney is being transported directly from the donor operating room to the transplant center (not going to the OPO), skip to section 4.12. Otherwise:

Confirm that the Shipper is securely closed with all four (4) latches in place.

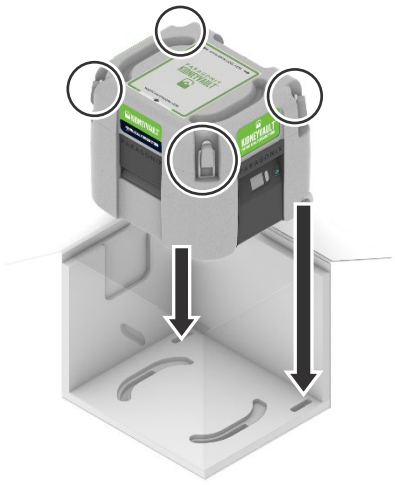
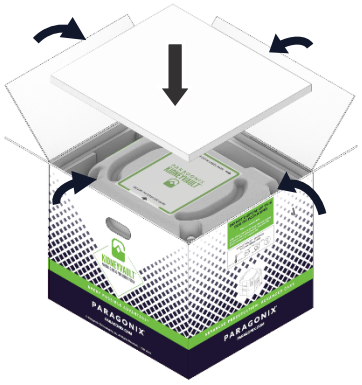
Place the KidneyVault™ in a flat location secured against shifting or tipping.

Note: The KidneyVault™ may be stacked with other units. Do not stack more than two (2) units together.

Figure 20. KidneyVault™ Portable Renal Perfusion System stacked with another KidneyVault™.

4.12 TRAVELING WITH THE KIDNEYVAULT™ TO THE TRANSPLANT SITE

1.	Locate a KidneyVault™ Cargo Transport box. **NOTE: IF TRAVELLING BY GROUND VEHICLE, PLACING KIDNEYVAULT™ IN BOX IS OPTIONAL.**		NON-STERILE FIELD

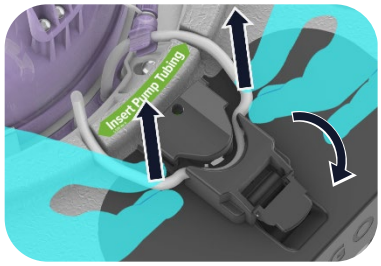
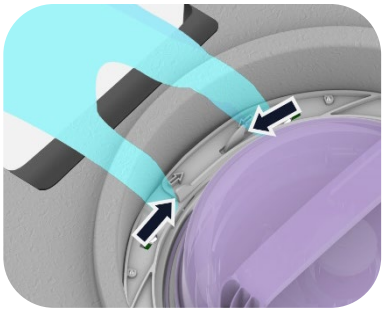
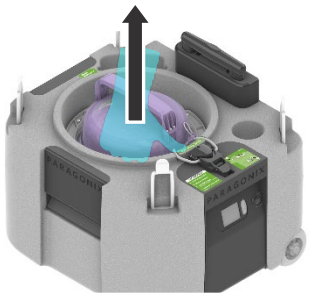
2.	Confirm that the Shipper is securely closed with all four (4) latches in place. Then, place the KidneyVault™ System into the Cargo Transport box, aligning wheels to wheel openings.		NON-STERILE FIELD
3.	Close the shipping box with the KidneyVault™ System and place appropriate labels on the box. **NOTE: IF TRAVELLING BY GROUND VEHICLE, PLACING KIDNEYVAULT™ IN BOX IS OPTIONAL.**		NON-STERILE FIELD
4.	Secure the KidneyVault™ System against shifting or tipping during transit. In the event of transport by vehicle, roll the KidneyVault™ to the vehicle and place the KidneyVault™ in a flat location secured against shifting or tipping during transit. Secure the KidneyVault™ as necessary to accomplish this. If transported by air, either on a helicopter or airplane, follow the instructions of the flight crew and secure the KidneyVault™ to prevent shifting or tipping during transit.		NON-STERILE FIELD

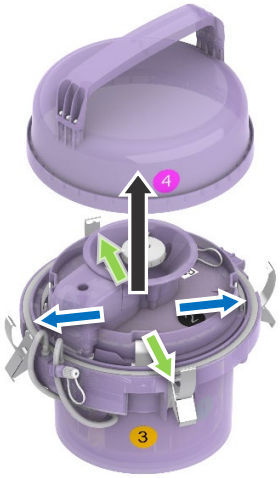
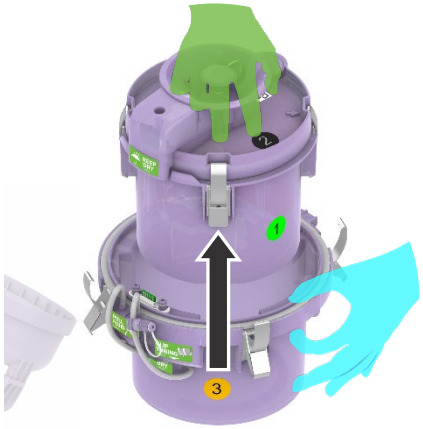
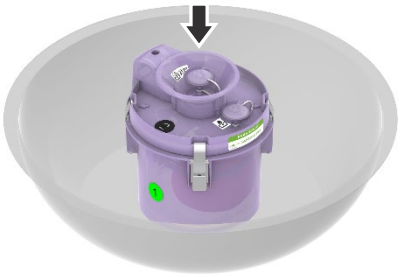
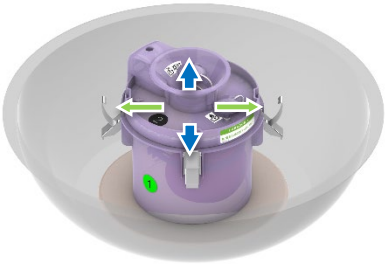
Upon arrival at the transplant site, follow hospital procedures for moving equipment into the transplant OR. Identify a non-sterile table in the OR for the KidneyVault™.

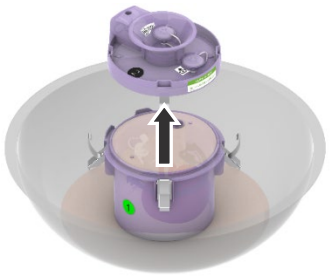
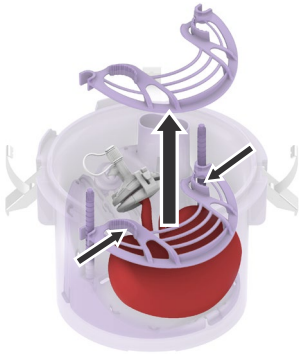
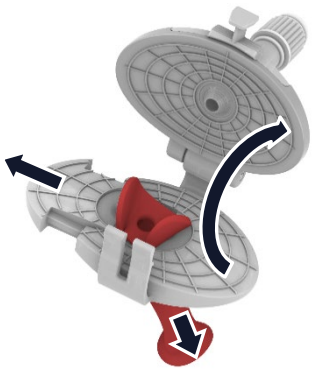
Upon arrival to the recipient site, continue use of the KidneyVault™, with the Shipper securely closed with all four (4) latches in place, until the recipient has been prepared to accept the donor kidney.

4.13 REMOVING THE KIDNEY FROM THE KIDNEYVAULT™ FOR TRANSPLANT

1.	Unbox the KidneyVault™ if boxed and discard packaging.		NON-STERILE FIELD
2.	Depress the power button to turn off pumping.		NON-STERILE FIELD
3.	Remove the Shipper Lid from the Shipper by unlatching it.		NON-STERILE FIELD
4.	Remove the remove the two (2) SherpaCool® Ribbons (part #5) and SherpaCool® Pouch (part #6).		NON-STERILE FIELD

5.	Unclamp the pump by lowering pump lever, then remove the Pump Tubing from the pump.		NON-STERILE FIELD
6.	Pinch the lock arm tabs releasing the Canister Assembly.		NON-STERILE FIELD
7.	Using the handle, lift the Canister Assembly out of the Shipper and place onto a non-sterile table in the OR.		NON-STERILE FIELD
8.	Press Pump Tubing to Clip underneath rim of Outer Canister Base (part #3). **NOTE: THE PUMP TUBING AND OUTER CANISTER EXTERIOR IS CONSIDERED NON-STERILE.**		NON-STERILE FIELD

9.	Remove the Outer Canister Lid (part #4) from the Outer Canister Base (part #3) by unclasping two sets of opposing latches as done previously. **NOTE: THE EXTERIOR OF THE OUTER CANISTER LID AND BASE ARE CONSIDERED NON-STERILE.**		NON-STERILE FIELD
10.	Remove the Inner Canister Assembly from the Outer Canister Base (part #3) using aseptic technique and place on a sterile surface in the sterile field. **NOTE: THE OUTER CANISTER EXTERIOR IS CONSIDERED NON-STERILE.**		STERILE FIELD NON-STERILE FIELD
11.	**Optional:** Place the Inner Canister Assembly in a sterile basin in anticipation of machine perfusion spilling over the edges of the Inner Canister Base (part #1) when the assembly is opened in the following steps.		STERILE FIELD
12.	Unlatch the four (4) latches on the Canister Assembly by opening two opposing sets of latches. **NOTE: FLUID OVERFLOW FROM INNER CANISTER BASE (PART #1) IS EXPECTED.**		STERILE FIELD

13.	Lift the Inner Canister Lid (part #2) and remove from the Inner Canister Base (part #1). **Optional:** Pour excess fluid into sterile basin. **NOTE: FLUID OVERFLOW FROM INNER CANISTER BASE (PART #1) IS EXPECTED.**		STERILE FIELD
14.	Remove the Kidney Retainer, if present, by pinching it inward and pulling it up and over retaining posts.		STERILE FIELD
15.	Remove the Cannula from the Kidney Rest CANNULA PORT and remove the kidney from the Inner Canister Base (part #1).		STERILE FIELD
16.	**Remove Straight Cannula from the Kidney:** Remove silk tie and detach kidney per institutional standards. **Remove Round or Oval Cannulas from the Kidney:** Pull back the clasp at the bottom of the Cannula to release the arterial patch. Pull open the slider at the bottom portion of the Cannula, if present, to release pressure on arteries. Carefully pull arterial patch and arteries through the opening at the bottom portion of the Cannula.		STERILE FIELD
17.	Allow for Kidney preparation for transplantation as per transplant facility protocol. Following use, dispose of Kidney preservation solution, and discard the entire KidneyVault™ per facility protocol.		

5 TROUBLESHOOTING

5.1 PROBABLE CAUSES AND ACTIONS

Table 5. KidneyVault™ Troubleshooting

Trouble	Probable Cause	Action
No Power	Dead Batteries Device not powered on	1. Depress power button per step 4.8.24. If problem is not resolved, call Paragonix 24/7 Helpline.
Visible bubbles or air pockets in Inner Canister	Insufficient priming	1. Under aseptic conditions (re-prime the device following steps 4.8.12 through 4.16). 2. If needed, tip Canister Assembly slightly to the side to dislodge trapped bubbles per step 4.8.15. Repeat fill and purge process. If problem is not resolved, call Paragonix 24/7 Helpline.
Leaking Perfusate	Loose fitting between Inner Canister Base and Inner Canister Lid Vent and fill caps not tightened	1. Reposition Inner Canister Lid on Inner Canister and ensure latches are closed. 2. Ensure vent and fill caps are securely in place. If problem is not resolved, call Paragonix 24/7 Helpline.
Blank Display	Datalogger not activated and collecting data Datalogger failure	1. First attempt to start datalogger by pressing Button 1 and holding for 10 seconds (repeat step 4.8.23). If problem is not resolved, call Paragonix 24/7 Helpline.
Missing or Incorrect Display on Datalogger LCD Screen	Canister Assembly not fully seated in Shipper Wet Chip Device failure	1. Ensure Canister Assembly is correctly placed in the Shipper (step 4.8.21) Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations). If problem is not resolved, call Paragonix 24/7 Helpline.

Table 5. KidneyVault™ Troubleshooting		
Trouble	**Probable Cause**	**Action**
Irregular Datalogger sampling interval	Canister Assembly not fully seated in Shipper Wet Chip Device failure	1. Ensure Canister Assembly is correctly placed in the Shipper (step 4.8.21). 2. Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations). If problem is not resolved, call Paragonix 24/7 Helpline.
Unresponsive Datalogger Buttons	Datalogger not activated and collecting data Datalogger failure	1. First attempt to start Datalogger by pressing Button 1 and holding for 10 seconds (repeat step 4.8.23). If problem is not resolved, call Paragonix 24/7 Helpline.
High Pressure - Pressure Reading Above 50mmHg	Pump tubing kinked or twisted Wet Chip Device failure	1. Ensure Canister Assembly is correctly placed in the Shipper (step 4.8.21) . 2. Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations). 3. Confirm pump tubing is routed per step 4.8.26 and tubing is not kinked or twisted. If problem is not resolved, call Paragonix 24/7 Helpline.
High Pressure Alert - Pressure Above 65mmHg	Pump tubing kinked or twisted Wet Chip Device failure	1. Turn off KidneyVault™ device pump 2. Ensure Canister Assembly is correctly placed in the Shipper (step 4.8.21) . 3. Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations). 4. Confirm pump tubing is routed per step 4.8.26 and tubing is not kinked or twisted. If problem is not resolved, turn off the KidneyVault device pump and continue preservation using static cold storage and call Paragonix 24/7 Helpline.

Table 5. KidneyVault™ Troubleshooting		
Trouble	**Probable Cause**	**Action**
Unexpected Pressure Reading	Renal artery kinked, twisted, or has too much tension/ compression on it	5. Under aseptic conditions, adjust position of kidney and/or renal artery. If problem is not resolved, call Paragonix 24/7 Helpline.
	Cannula not properly seated within kidney rest	1. Under aseptic conditions, reseat the cannula with the kidney rest. If problem is not resolved, call Paragonix 24/7 Helpline.
	Air in Canister	1. Under aseptic conditions, remove air from pump tubing and inner canister (repeat steps 4.8.12 through 4.8.16). If problem is not resolved, call Paragonix 24/7 Helpline.
	Outer Canister Assembly not electrically docked to Shipper	1. Open Shipper Lid and press down on Canister handle until “click” is heard (repeat step 4.8.21). 2. Confirm that green LED under Canister Lid is on (repeat step 4.8.21). If problem is not resolved, call Paragonix 24/7 Helpline.
	Pump tubing not connected to pump	1. Open Shipper Lid and visually inspect pump tubing, reseat as necessary. If problem is not resolved, call Paragonix 24/7 Helpline.
	Pump tubing kinked or twisted	
	Pump not turned on	1. Depress power button.
	Wetted Electrical Connected	1. Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations).
	Canister assembly is leaking	1. Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations).

Table 5. KidneyVault™ Troubleshooting		
Trouble	**Probable Cause**	**Action**
	Improper Cannulation	1. Under aseptic conditions, check cannulation and recannulate if necessary.
Unable to connect to optional datalogger app	Incorrect Passkey	1. Confirm passkey under the Shipper lid and re-enter in app. 2. Continue to use physical datalogger display for readings. If problem is not resolved, call Paragonix 24/7 Helpline.
	Incorrect/no app installed on mobile device	1. Install app following section 4.4. 2. Continue to use physical datalogger display for readings. If problem is not resolved, call Paragonix 24/7 Helpline.
	Out of Bluetooth transmission range	1. Ensure mobile device is within Bluetooth transmission range (Section 2.4). If problem is not resolved, call Paragonix 24/7 Helpline.
	Bluetooth not activated on mobile device	1. Enable Bluetooth on mobile device. 2. Continue to use physical datalogger display for readings. If problem is not resolved, call Paragonix 24/7 Helpline.
Loss of connection to optional Datalogger app	Datalogger failure	1. Continue to use physical datalogger display for readings. If problem is not resolved, call Paragonix 24/7 Helpline.
	Bluetooth deactivated on mobile device	1. Reenable Bluetooth on mobile device. 2. Continue to use physical datalogger display for readings. If problem is not resolved, call Paragonix 24/7 Helpline.

Table 5. KidneyVault™ Troubleshooting		
Trouble	**Probable Cause**	**Action**
	Out of Bluetooth transmission range	1. Ensure mobile device is within Bluetooth transmission range (Section 2.4). If problem is not resolved, call Paragonix 24/7 Helpline.
	Datalogger failure	1. Continue to use physical datalogger display for readings. If problem is not resolved, call Paragonix 24/7 Helpline.
Unexpected Temperature	Wetted Electrical Connected	1. Under aseptic conditions confirm electrical connections are dry (reference Table 3 for connections locations). If problem is not resolved, call Paragonix 24/7 Helpline.
	Canister assembly is leaking	1. Under aseptic conditions, reposition organ lid on organ canister and ensure latches are closed. If problem is not resolved, call Paragonix 24/7 Helpline.
	SherpaCool® not properly placed	2. Open Shipper Lid and adjust top SherpaCool® location.
Probe Temperature Above 8°C	Machine preservation solution not properly pre-chilled SherpaCool® not properly placed Datalogger failure	1. Open Shipper Lid and adjust top SherpaCool® location. 2. Allow time for the temperature to stabilize per 4.8.25. If problem is not resolved, call Paragonix 24/7 Helpline.
Probe Temperature Below 4°C	Machine preservation solution not properly pre-chilled SherpaCool® not properly placed Datalogger failure	1. Open Shipper Lid and adjust top SherpaCool® location. 2. Allow time for the temperature to stabilize per 4.8.25. If problem is not resolved, call Paragonix 24/7 Helpline.

Table 5. KidneyVault™ Troubleshooting		
Trouble	**Probable Cause**	**Action**
Unable/incomplete data recovery	Bluetooth deactivated on mobile device Out of Bluetooth transmission range Datalogger failure	1. Ensure mobile device is within Bluetooth transmission range (Section 2.4) and Bluetooth is activated on mobile device. If problem is not resolved, call Paragonix 24/7 Helpline. Do not dispose of Shipper unit until desired data has been obtained.
Perfusion Pump Not Operating	Dead Batteries Device not powered on	1. Depress power button per step 4.8.25. If problem is not resolved, call Paragonix 24/7 Helpline.

6 STORAGE

Unopened KidneyVault™ and Shippers should be stored indoors in a dry location out of direct sunlight under normal temperature and humidity conditions. Unopened SherpaCool® Ribbons and Pouches should be stored at -20°C in preparation for use.

7 CYBERSECURITY

7.1 OVERVIEW

At the time of publication, the following information and recommendations provide measures for helping secure the operating environment of the KidneyVault device and prevent unauthorized access to the device datalogger through Bluetooth (BLE).

The KidneyVault device excludes physical ports and other means of electronic data transfer other than the Passkey-protected BLE mode.

NOTE: THE KIDNEYVAULT DEVICE IS DESIGNED TO MAINTAIN SAFE OPERATING PARAMETERS FOR HYPOTHERMIC MACHINE PERFUSION WITHOUT RELIANCE ON SOFTWARE OR THE DEVICE DATALOGGER. THE PERFUSION PARAMETERS PROVIDED BY THE DATALOGGER ARE FOR REFERENCE ONLY AND SHOULD NOT BE USED AS THE SOLE CLINICAL DETERMINATION TO TRANSPLANT OR DISCARD A DONOR KIDNEY. IF SUSPICIOUS ACTIVITY OR BEHAVIOR IS SUSPECTED, THE PERFUSION VALUES REPORTED ON THE DATALOGGER SHOULD NOT BE USED AND ADDITIONAL CLINICAL ASSESSMENT OF DONOR KIDNEY SHOULD BE PERFORMED PRIOR TO IMPLANTATION.

7.2 PATIENT HEALTH INFORMATION (PHI)

The KidneyVault device does not capture or store any PHI. The only information captured by the device are the perfusion parameters.

7.3 BLUETOOTH CONNECTION

The KidneyVault device provides a Bluetooth Low Energy connection for optional remote monitoring of datalogger values and downloading of data from the datalogger at the completion of the case. There are no other ports or network connections present on the KidneyVault device. The Bluetooth connection utilizes the following protections to prevent unauthorized access to the device datalogger through BLE:

- **Wireless Data Standard: Bluetooth Low Energy (Bluetooth Smart)**
  KidneyVault™ datalogger utilizes Bluetooth® Low Energy Technology
- **Datalogger Transmission Range: Approximately 30.5 m (100 ft) line-of-sight**
  Transmission of the data is limited to devices within this transmission range
- **Unique Datalogger Serial Number and Passkey**
  To connect to the datalogger through BLE, the device requires a unique datalogger serial number and randomly generated 10-digit passkey for connection. The serial number and passkey are located underneath the lid of the KidneyVault Shipper to minimize potential for unauthorized access to the device datalogger during transportation

- **Connection to Datalogger Limited to Single Mobile Device at a Time**
  Only one mobile device may be connected to the KidneyVault device to further prevent unauthorized access.

NOTE: THE PASSKEY IS ONLY LOCATED UNDER THE LID OF THE KIDNEYVAULT SHIPPER AND IS NOT VISIBLE WHEN DEVICE IS WITHIN PACKAGING OR WHILE IT IS LATCHED CLOSED AND IN USE.

NOTE: ONLY SHARE THE PASSKEY WITH AUTHORIZED MEMBERS OF THE TRANSPLANT TEAM.

7.4 CONFIGURATION AND UPDATES

The KidneyVault is a single use disposable device that is configured during manufacturing by Paragonix. It may not be configured or updated by users.

The optional mobile app can be updated at either the iOS App Store or Google Play store.

NOTE: THE KIDNEYVAULT CONFIGURATION CANNOT BE UPDATED OR RESTORED FOLLOWING PARAGONIX MANUFACTURING, AND THE DEVICE SHOULD NOT BE USED IF SUSPICIOUS ACTIVITY OR BEHAVIOR IS SUSPECTED TO HAVE ALTERED THE CONFIGURATION.

7.5 REVIEW OF LOGGED DATA

KidneyVault device logs perfusion parameters every 5 seconds. The logged data can be downloaded to a connected mobile device through the mobile application.

NOTE: IF THE LOGGED DATA IS INCOMPLETE OR CONTAINS SUSPICIOUS DATA, THE LOGGED DATA SHOULD NOT BE USED AND ADDITIONAL CLINICAL ASSESSMENT OF DONOR KIDNEY SHOULD BE PERFORMED PRIOR TO IMPLANTATION.

NOTE: IF SUSPICIOUS ACTIVITY IS SUSPECTED, CONFIRM THE "CONFIGURATION DATE" MATCHES THE MANUFACTURING DATE OF THE KIDNEYVAULT DEVICE. IF THE CONFIGURATION DATE DOES NOT MATCH THE LOGGED DATA SHOULD NOT BE USED AND ADDITIONAL CLINICAL ASSESSMENT OF DONOR KIDNEY SHOULD BE PERFORMED PRIOR TO IMPLANTATION.

7.6 SOFTWARE BILL OF MATERIALS (SBOM)

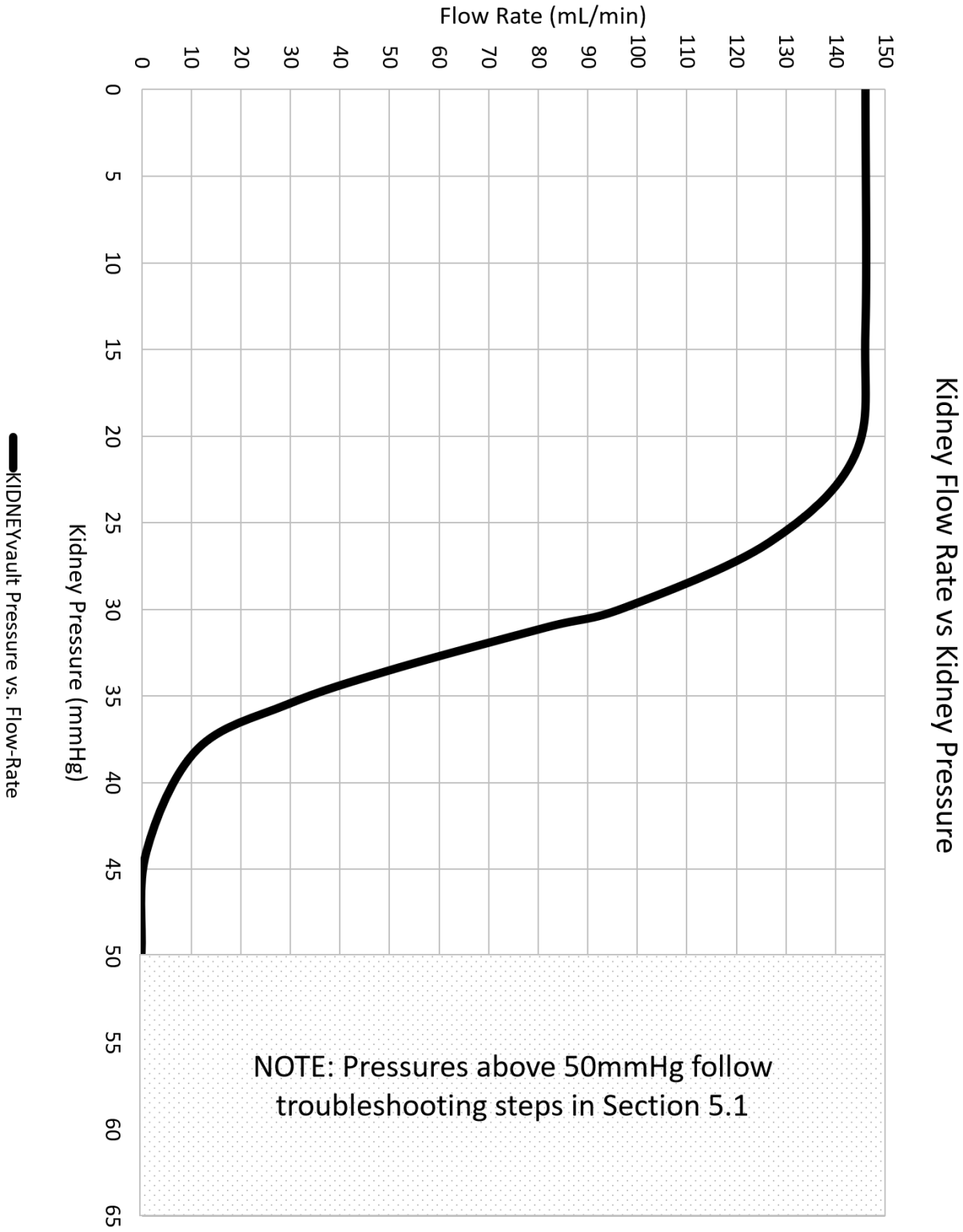
The KidneyVault device SBOM can be provided upon customer request.

7.7 DEVICE DISPOSAL

The KidneyVault device should be disposed of per facility protocol.

NOTE: THE KIDNEYVAULT DEVICE STORES THE PERFUSION PARAMETERS IN MEMORY AND TO PREVENT ACCIDENTAL LOSS OF DATA, THE MEMORY CANNOT BE CLEARED DURING OR FOLLOWING DEVICE USE. THE KIDNEYVAULT DEVICE DOES NOT CAPTURE OR STORE ANY PHI. THE ONLY INFORMATION CAPTURED BY THE DEVICE ARE THE PERFUSION PARAMETERS.

Display Pressure and Mean Flow Chart (*Repeated*)



Display Pressure and Mean Renal Vascular Resistance Chart (*Repeated*)