



LifePort Kidney Transporter Operator's Manual 1.0

This Operator's Manual references
LifePort Kidney Transporter
Model Number: LKT100P



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LifePort Kidney Transporter manufactured in the USA for Organ Recovery Systems.

Retain the following in your records:

Institution_____

Contact_____

Model Number_____

Serial Number_____

Date of Purchase_____

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How To Use This Manual

Introduction

It is important that all personnel who will operate the LifePort Kidney Transporter (LifePort):

- Read and understand this manual before operating the LifePort.
- Follow all warnings and precautions outlined in the sections **Specifications**, **Precautions and Limitations** on page 55, and **Hazards** on page 62 for their own safety and the safety of those around them.

The LifePort is intended to be used for the hypothermic machine perfusion of kidneys. If more information is needed about installation, organ perfusion, or if you have any questions, please contact Organ Recovery Systems Perfusion Helpline.

Purpose of Manual

The instructions within this manual should be carefully followed for safe, trouble-free, and effective equipment use.

This manual provides the essential information necessary for installation, operation, and routine servicing of the LifePort. It contains important operation and maintenance information for personnel who have been trained in organ perfusion.

This manual is **NOT** to be used as a replacement for training in the art or science of organ perfusion. This manual does **NOT** contain information for servicing internal components of the system.

In this manual, the following definitions apply for all **WARNING** and **CAUTION** statements.



WARNING: A warning statement covers any operation, procedure, practice, etc., which if not strictly observed, might result in injury or long-term health hazards to personnel or patients.



CAUTION: A caution statement covers any operation, procedure, practice, etc., which if not strictly observed, might result in damage or destruction of equipment or loss of treatment effectiveness.

Abbreviations

The abbreviations used in this manual are listed and defined in the following table.

A	Amperes
AC	Alternating current
A-hr	Ampere-hours
°C	Degrees Celsius
cm	Centimeter (1 cm = .01 m)
L	Liter (1L =0.001 m3)
lb(s)	Pound (1 lb = 0.45 kg)
LCD	Liquid Crystal Display
LED	Light Emitting Diode
kg	Kilogram (1 kg = 2.2 lbs)
mL/min	Milliliters per minute (1 mL/min = 0.00006 m3/sec)
mmHg	Millimeters of mercury (1 mmHg = 1 Torr = 133.3 Pa)
V	Volts

System Description

Intended Use

The LifePort is intended for use in continuous hypothermic machine perfusion of kidneys.

Safety

The responsibility for safety when using LifePort resides within the healthcare professionals who use it. The LifePort is safe when used as described in this manual. It is designed to meet recognized U.S. and international standards for medical equipment and systems, as stated by the Underwriters Laboratories and the International Electro-technical Commission.

Electrical and mechanical safety features have been designed into the LifePort to ensure safe operation. These features are as follows:

- The electrical and electronic components are contained within a secure enclosure.
- Perfusate temperature, flow rates, and pressure levels are only adjustable within a set range, which cannot be changed by the operator.
- Perfusate pressure, flow rate, and temperature are continuously monitored.
- A power indicator light is provided to indicate when the unit is powered on. Stop, Wash, Prime and Infuse lights are provided to indicate whether the LifePort is stopped, washing, priming, or infusing.
- Acceptable operating ranges are established within the LifePort for pressure, temperature, flow rate, battery charge state, bubbles in the perfusate, and configuration integrity. Hard-wired and software interlocks are built-in to bring the LifePort to a failsafe condition if an unacceptable operating state is detected.
- An error light, audible alert and descriptive message are given by the LifePort if an unacceptable operating state is detected.

Physical Description

The LifePort is a portable transport device designed to maintain a transplantable kidney under cold and aseptic conditions, while perfusing it at the same time. An insulated, plastic housing encloses the kidney and perfusate within a disposable Perfusion Circuit (Cassette). The LifePort's components also include an Ice Container, Pump Deck, four lithium-ion batteries, electronics, Bubble Detectors, a Control Panel, and an Outer Display.



The LifePort is designed to integrate with the clinical environment by using readily available supplies, requiring minimal user intervention, and by being easy to use.

Once the Ice Container is properly loaded, even when the LifePort is powered off, it preserves kidneys hypothermically to the same degree as conventional static (ice-pack) storage methods.

Main Enclosure

The LifePort is enclosed in a rugged, insulated plastic housing designed for easy carrying. The lower section contains an Ice Container, Perfusion Circuit (Cassette), Pump Deck, batteries, electronics, sensors, Bubble Detectors, Control Panel, Outer Display, and Disposables. Two handles make the unit easy to lift and carry.

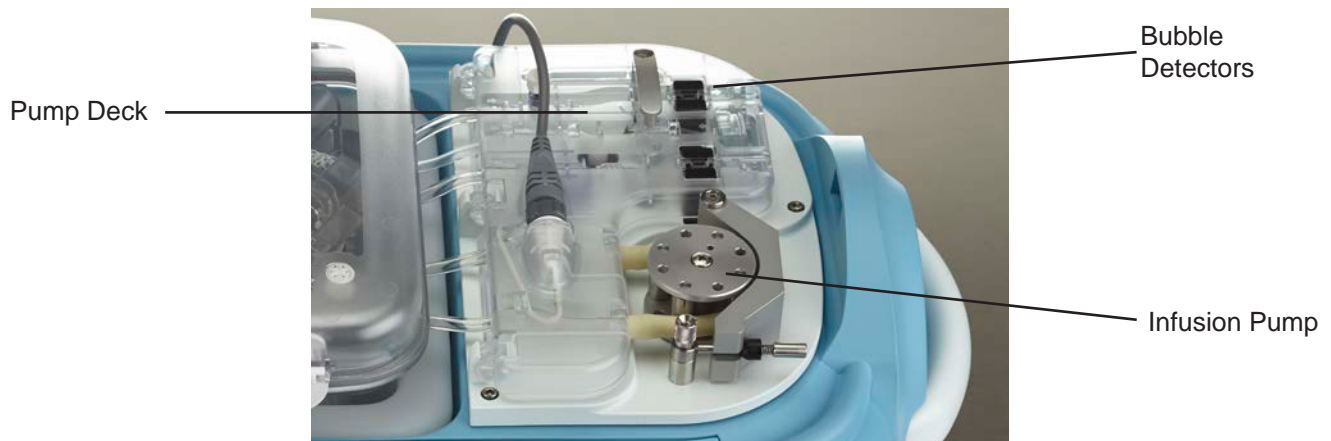
An insulated, removable, latched Cover encloses the lower housing during perfusion to keep the kidney secure and at the proper temperature.

Ice Container

The Ice Container is a sealed enclosure with a removable Lid, which is filled with a mixture of ice and water to provide a stable cold temperature environment for the kidney.

Pump Deck

The Pump Deck is the fluid management area of the LifePort. On the Pump Deck, the Perfusion Circuit (Cassette) tubing traverses a peristaltic pump, valves, and sensors, which control the pressure, speed, and routing of the perfusate.



- **Infusion Pump** — A peristaltic pump that propels perfusate through the kidney. By moving rollers against the pump tubing, the Pump pushes the perfusate through the kidney, while keeping it sealed within the Perfusion Circuit (Cassette). The LifePort electronics regulate pump speed to control perfusion pressure.
- **Bubble Detectors** — Two non-contact Bubble Detectors on the Pump Deck check the perfusate to prevent bubbles from entering the kidney.

The first Bubble Detector is located upstream of the Bubble Trap and Wash Line, and diverts detected bubbles away from the kidney and into the Wash Line, after which the LifePort will resume perfusing.

The second Bubble Detector is located immediately before the kidney, and prevents detected bubbles from entering the kidney by stopping perfusion altogether.

- **Pressure Sensor Cable** — Provides the LifePort computer with information about the perfusion pressure felt by the kidney. If the Pressure Sensor connection is broken, the LifePort stops and displays an error message.
- **The Infuse and Wash Valves** — Determine whether the perfusate enters (Infuse Valve) or bypasses (Wash Valve) the kidney. In **INFUSE** mode, the Infuse Valve is open and the Wash Valve is closed, allowing perfusate to flow into the kidney. In **WASH** mode and during bubble purge, the Wash Valve is open and the Infuse Valve is closed, directing the perfusate through the bypass line, directly back into the perfusate reservoir. The valves are electrically activated.

Electronics

Electronic circuits control LifePort functions and user interactions, manage power, and enable communications over standard computer interfaces. All circuits are contained within the LifePort electronics module, and include:

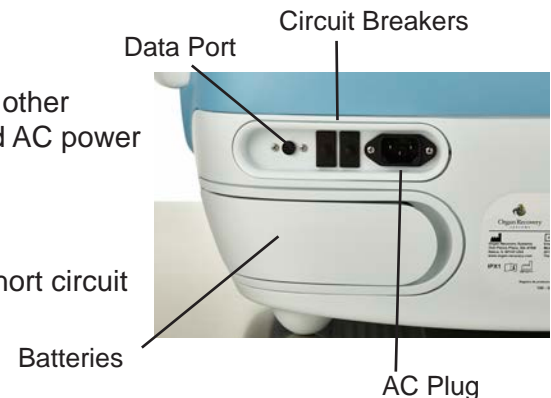
- Computer
- Batteries and battery charger
- Communications interface
- Sensor interface
- Power supply (A hospital-grade power cord is supplied...do not substitute.)
- Pump and valve driver circuits
- Fan

External Connections

The LifePort connects with an external power source and other devices through its back panel, which provides a standard AC power cord connector and a serial interface Data Port.

Circuit Breaker

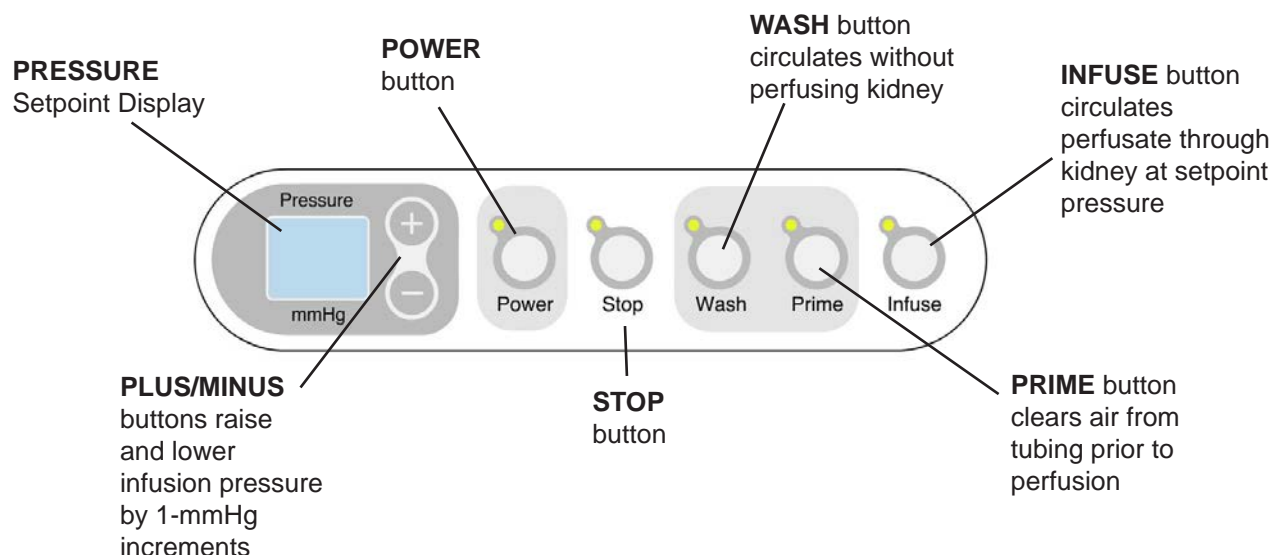
Two circuit breakers, located on the back panel, trip if a short circuit occurs. Depressing the button resets the breaker.



Control Panel

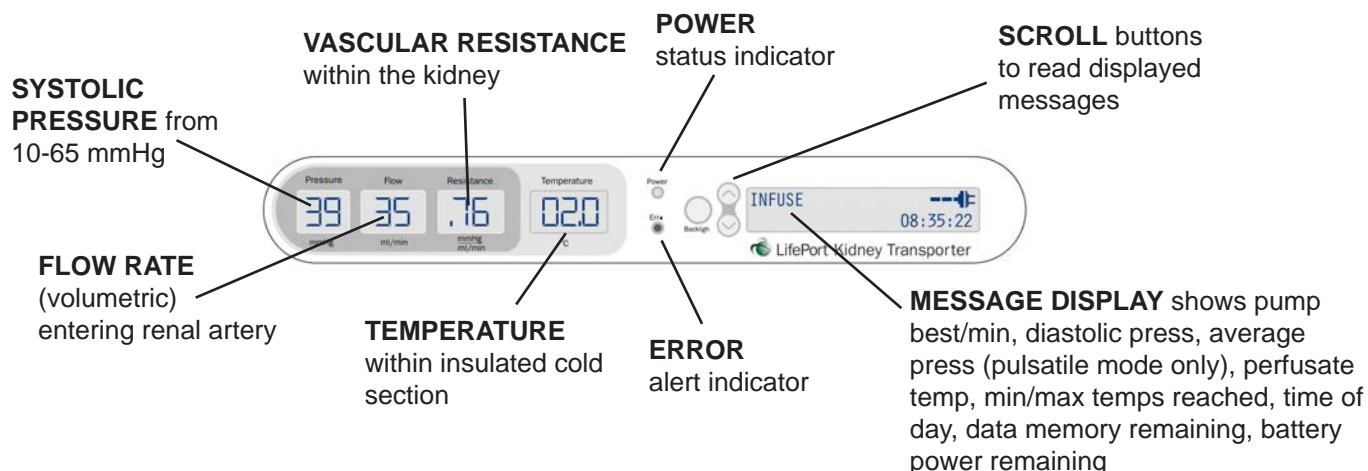
The Control Panel is located next to the Pump Deck. The panel can be accessed only when the Cover is removed, which prevents inadvertent and unauthorized access to the controls.

LEDs indicate when the Power, Stop, Wash, Prime, and Infuse modes have been selected.



Outer Display

The Outer Display — a horizontal panel visible whether the Cover is in place or removed — provides information on operational parameters as well as additional information about the perfusion history.



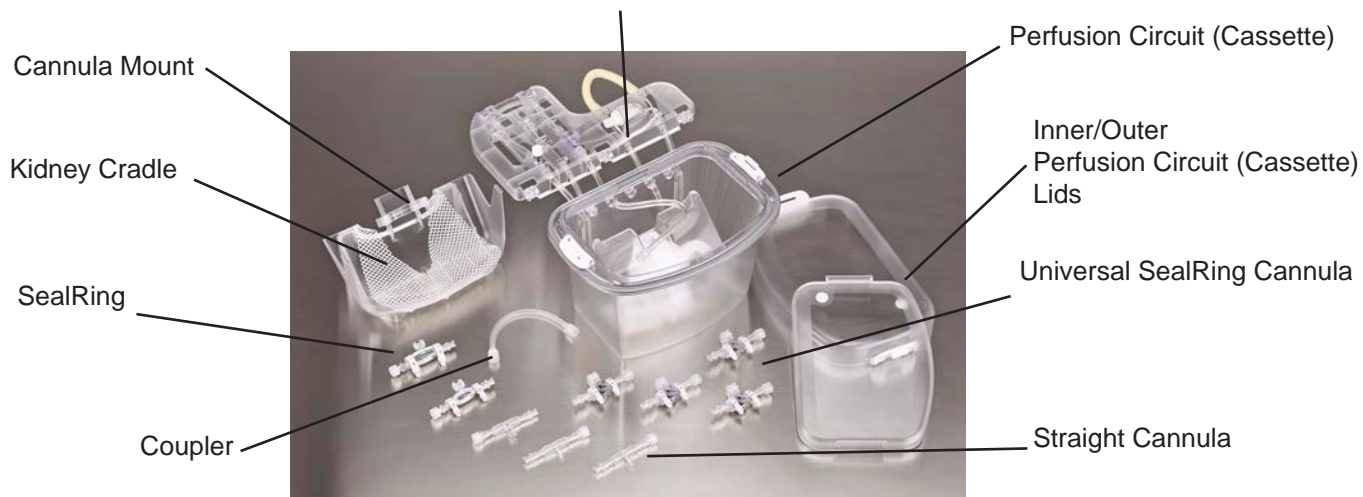
LifePort Disposables

Single-use Disposables, an integral part of the LifePort, are used to contain the kidney and perfusate under aseptic conditions during transport, to connect the kidney to the Perfusion Circuit (Cassette), and to help maintain aseptic conditions while working inside the Perfusion Circuit (Cassette). Each Disposable is factory pre-sterilized and delivered in an easy-to-open sterile pack.

NOTE: To reorder Disposables, please contact Organ Recovery Systems. (See inside front cover for contact details.)

The primary disposables are shown—separated for easier visualization—in the illustration below. A full description follows.

Perfusion Circuit (Cassette) and Tubeframe



LifePort Perfusion Circuit (Cassette)

Contains the fluid management components necessary for perfusing a single kidney. The Perfusion Circuit (Cassette) is comprised of:

- The **PERFUSION CIRCUIT (CASSETTE)** is the housing that contains the kidney. The kidney is supported by the Kidney Cradle, and held in place by the Mesh Organ Restraint.

The watertight Organ Cassette acts as the perfusate reservoir, where the kidney is maintained partially submerged. A transparent sterile Inner Lid and transparent Outer Lid provide a redundant watertight seal.

The Organ Cassette has Infuse, Wash, and Return ports that mate with the Perfusion Circuit (Cassette). Inside the Perfusion Circuit (Cassette), the Infuse Line continues and terminates with a male Luer fitting, which connects to the cannula.

- The **PERFUSION CIRCUIT (Cassette)** is the sealed fluid path that draws from the perfusate bath and delivers perfusate into the kidney. The Perfusion Circuit (Cassette) is comprised of:
 - TubeFrame, which positions the tubing per the pump, valves, and sensors of the Pump Deck, and simplifies attaching the Perfusion Circuit (Cassette) to the Pump Deck.
 - Bubble Trap, located on the TubeFrame to help keep air from entering the Infuse Line.
 - Infuse, Wash, and Return Lines located on the TubeFrame to manage perfusate flow.
 - Pump Tubing Loop, extending from the TubeFrame and stretched around the Infusion Pump Head. Sample Port, protruding from the top of the TubeFrame, provides access to sample perfusate or inject fluids without opening the Perfusion Circuit (Cassette).
 - Pressure Sensor and Connector, a flow-through pressure sensor within the Infuse line that measures perfusate pressure within the Circuit. Connects to the Pump Deck Pressure Sensor Cable and sends pressure data to the internal computer.
 - Filter, located under the Perfusion Circuit (Cassette), collects material that could block kidney vasculature from achieving proper flows.
 - Compliance Chamber, located under the Perfusion Circuit (Cassette), helps maintain steady perfusion pressures.

LifePort Disposable Cannulas

LifePort Disposable Cannulas attach the Perfusion Circuit (Cassette) to the kidney's renal artery. A large range of cannula types and sizes are available, making it possible to choose the cannula most compatible to the anatomy of the kidney: large artery, multiple arteries, or plaque on artery (with or without the aortic cuff).

LifePort Sterile Drape

The Sterile Drape is used to aid in maintaining aseptic conditions while working within the Perfusion Circuit (Cassette).

Operational Accessories

In operation, the LifePort uses special accessories and supplies. To work properly, it is important to use only accessories and supplies provided by Organ Recovery Systems or from vendors identified as compatible with the LifePort.

Power Cord

The LifePort comes equipped with a Power Cord (hospital grade), which can be connected to the LifePort back panel and to a standard grounded power outlet of commercial or hospital quality. Do not substitute an alternate Power Cord.

Batteries

The LifePort uses four specially designed lithium-ion rechargeable batteries as its portable source of power.



CAUTION: Do not substitute batteries. Use only LifePort batteries from Organ Recovery Systems. For information, contact the Organ Recovery Systems Perfusion Helpline.

The LifePort draws power from one at a time, using the batteries in series. Therefore, it is possible to operate with any number from one to four batteries, since each delivers the 11 to 12 volts required. However, it is recommended to use all four batteries, which you should keep as fully charged as possible.

NOTE: There are two ways to verify a battery's charge:

1. By pressing the battery's **ON** button and observing the display located on each battery.
 2. By pressing the **SCROLL** buttons to scroll the Message Display.
-

Access the batteries through the Battery Door on the LifePort rear panel. Each battery can be slid in and out of its slot. When inserted in the proper orientation, the battery should be flush with the slot panel, with the fabric-pull visible and available for removing the battery. If the battery does not push flush, it may be in the wrong orientation. Turn the battery 180 degrees and try again. The following tips will help you obtain maximum life and serviceability from the batteries.

- Always replace the Battery Door. The LifePort should not be operated or shipped without the Battery Door in place.
 - The LifePort's built-in charger will replenish the batteries whenever the LifePort is plugged into an external power supply. It's a good idea to plug in the LifePort whenever not in transit, keeping the batteries at the highest possible charge. Normally, it takes five hours to completely recharge all four batteries.
-

NOTE: Keep spare charged batteries handy for long transportations or successive LifePort uses.

- During storage of the LifePort without connection to an external power supply, the batteries will slowly drain. After 30 days the batteries could have little or no charge and will need a full five-hour recharge.
 - For periods of storage for longer than 30 days, remove the batteries from the LifePort.
-

NOTE: Long periods of storage may damage the batteries.

- Lithium-ion batteries must be disposed of according to local regulations. If in doubt, consult Organ Recovery Systems Perfusion Helpline.
-

Battery Charger (optional)

In addition to charging installed batteries by connecting the LifePort to an external power supply, you can use an optional Battery Charger to charge them separately. This enables you to maintain a supply of spare charged batteries. The Battery Charger is available from Organ Recovery Systems.

1. Plug the Battery Charger into an external power supply.
 2. Insert the batteries into their respective slots and charging begins.
-

NOTE: A charge state indicator displays when the batteries are fully charged.

Data Cable

The Data Cable is a 6-ft (2m) cable used to connect the LifePort to an external computer. The round end connects to the Data Port on the LifePort, and the opposite end connects to a 9-pin serial port of a personal computer. A Serial-to-USB converter (not included) may be necessary for computers without 9-pin serial ports.






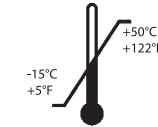


















Perfusion Mode

The LifePort is available in Pulsatile mode. Mode is indicated in the LifePort Model Number found on the label on the back of the device:

- **LKT-100-P** (Pulsatile mode) — A LifePort set to run in Pulsatile mode will pulse the pressure at a fixed pulse repetition rate to a systolic pressure set by the user on the Control Panel. The diastolic pressure is determined in response to the kidney vascular resistance. The diastolic pressure can be found on the Message Display.

Label Graphics Explanations

The following table provides an explanation of the label graphics found on the LifePort.

	Reference Model Number		Circuit breaker, push to reset
	Serial Number		Data Port, RS232 Serial Data
	Lot Number		Storage Condition: Temperature
	Sterile, method is ethylene oxide		EU Authorized Representative
	CAUTION! Consult Accompanying Documents		Battery Slot Graphic showing slot numbering and insertion orientation. Replace batteries only with manufacturer's battery model
	Do not reuse. Risk of contamination, infection or potential serious hazard if single use is not followed		Protected against falling water
	Date of Manufacture		VAC – Voltage AC
	Consult Instructions for Use		Amp
	To assure grounding reliability, equipment should be connected to a power system of commercial or hospital quality.		Do not resterilize
	Manufacturer		Hertz
	WARNING!		European Conformity Mark (CE) Mark
	Power button-standby power. When on mains power, this button turns LifePort on and off, however the battery charging and power supply fan remain on at all times. When on battery power, LifePort is completely powered off.		Interference may occur in the vicinity of equipment

Safe Disposal of LifePort and LifePort Batteries

For safe disposal of your LifePort Kidney Transporter or the LifePort batteries, you may return them to Organ Recovery Systems. You can call the Organ Recovery Systems Perfusion Helpline to arrange for pickup from your facility, or return them directly to Organ Recovery Systems. **See information** on page 2.

Unpacking, Setup, and Preliminary Testing

Overview

This section provides information for use upon receiving, unpacking, setting up, and preliminarily testing the LifePort. The instructions provided in this section are to be performed one-time only. Routine operating instructions are provided in the section titled **Using the LifePort** on page 22.

Introduction

The LifePort is shipped in a special container that is marked for appropriate handling. It should be opened and checked only by a responsible person trained and qualified in working with electronic medical equipment.

Selecting a Home Base Station

A home base station should be designated for each LifePort where it can be set up and recharged between cases. The home base station should be a secure area and provide a clean bench top or tabletop space. The following facilities and utilities are required:

- Climate controlled 24 hours a day to standard office or laboratory conditions (approximately 21°C, 50% humidity).
- No direct sunlight.
- AC electrical outlets (2 to 4 plugs: 120V/15A in the USA).
- Storage for LifePort disposables, batteries, tools, and spares.
- Space to place the LifePort Cover when it is removed.
- Easy access to crushed or cubed ice (hollow cubes not recommended).
- Easy access to a sink for clean-up and to provide water for the ice bath.
- Easy access to medical waste disposal.
- Easy access to refrigerated storage for perfusate and other medications.
- Tabletop space for Battery Charger and computer (recommended).
- Serial (RS232) connection for computer (recommended).
- Storage for transplant coordinator gear: cart, bags, procedure kits, and coolers.
- Proximity to operating rooms and ready access to car, ambulance, or helicopter loading areas.

Unpacking and Inspecting

Carefully remove the LifePort and its accessories from the Shipping Container. Save the packing materials for shipping and storage.

After unpacking, thoroughly inspect the system and all accessories for damage. During this inspection, ensure that:

- The LifePort housing is not bent or distorted.
- There are no dents, chips, or cracks in the housing surface.
- Manual controls and movable parts, such as connectors, operate properly.
- Control Panels are properly aligned.
- All items listed on the shipping documents are present.

Report any damage found from this inspection to the carrier immediately. If you have any concerns about the condition of the LifePort or accessories, contact Organ Recovery Systems Perfusion Helpline.

Running Preliminary Tests

Perform the following trial run with the LifePort to make sure that it is working properly. After each step, observe the system to make sure that it functions as described and that there are no malfunctions, leaks, or irresolvable errors. If difficulties arise during setup and checkout, refer to the section titled **Troubleshooting and Diagnostics** on page 49.

Setting Up the LifePort



CAUTION: The LifePort weighs 45 lbs (20.9 kg) fully loaded. Use proper lifting procedures to avoid injury.

1. Holding the handles, lift the LifePort and place on its home base station table or countertop so that the Outer Display is easily accessible and facing you.
2. Unlatch and remove the LifePort Cover, and store it nearby.
3. Complete your review of the LifePort — making sure that it is complete, secure and intact, and that nothing appears broken — before starting these tests.

Filling the Ice Container

1. Open the Ice Container Lid and fill it with crushed or cubed ice, making sure to push the ice as far as possible into the ice bath.
2. Pour about 1.0 Liter of cold water (less than 10°C) into the Ice Container, which will gradually loosen the ice.
3. Add more ice and another 0.5-1.0 Liter water until the Ice Container is filled with an ice and water mixture, maximizing the amount of ice added.
4. Close and lock the Ice Container Lid.

Loading the Perfusion Circuit (Cassette)

NOTE: For detailed instructions, refer to the document LifePort Kidney Perfusion Circuit (Cassette) Instructions For Use (IFU).

1. Unpack a sterile Perfusion Circuit (Cassette) and assemble the Circuit into the LifePort, positioning and securing the Tubeframe on the Pump Deck so that the tubing mates properly with the Pump, valves, and sensors.
2. Place the sealed Perfusion Circuit (Cassette) in the Ice Container. The Tubeframe must be perpendicular to the Pump Deck, and the hinges must be positioned inside of the receivers on the Pump Deck.
3. Rotate the Tubeframe flat onto the Pump Deck.
4. Open the Pump Head and stretch the tubing over the wheel.

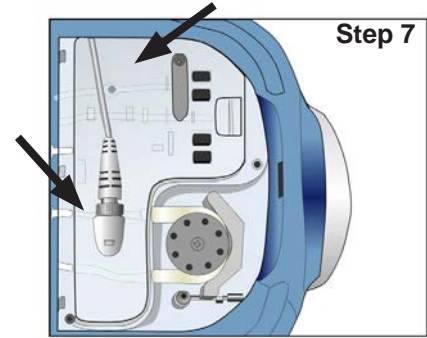
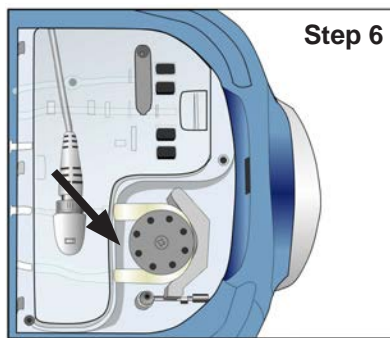
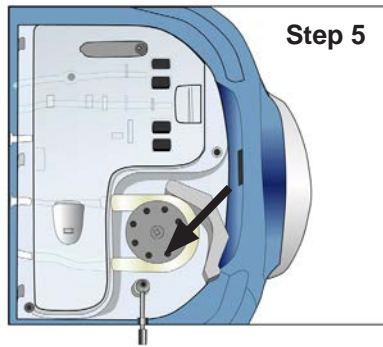
Step 3



Step 4



5. Close and latch the Pump Head Loop to clamp the tubing.
6. Rotate the Pump Deck Locking Arm 90° and snap into place.



7. Connect the Pressure Sensor Cable from the Pump Deck to the connector on the Tubeframe.
8. Remove the Inner and Outer Cassette Lids and pour 1 Liter of cold (less than 10°C) saline into the Cassette housing.
9. Replace the Inner and Outer Cassette Lids.

Energizing the LifePort

1. Connect the Power Cord to the LifePort back panel, and plug it into an external power supply.
2. Press the **POWER** button:
 - On the Control Panel, observe the following:
 - The Power LED should illuminate
 - The Pressure Set Point Display on the control panel should show a default value of 30 mmHg
 - On the Outer Display Panel, observe the following:
 - The message display screen should briefly flash *****Power up self test*****

NOTE: If the LifePort detects any errors during its power on self-test, the first line of the message display will say Power up test FAILED and the second line will provide the name of the error.

- The LCDs on the outer display panel should show normal values as follows:
 - The PRESSURE LCD should show double zeros (00)
 - The FLOW and RESISTANCE LCDs should display a double dash (- -)
 - The TEMPERATURE LCD should display the ice bath temperature
-

NOTE: It is common that the temperature of the LifePort will be high when first energized. When the ice bath temperature is above 8°C, the LifePort will beep, the red **ERROR** LED will illuminate, and the second line of the message display will indicate Check Ice. If this happens, push the **STOP** button to temporarily silence the audible alert. Then make sure that the Ice Container is properly filled and in position. After installation of the Ice Container, it may take several minutes before the display reads a temperature below 8°C.

NOTE: It is possible to run the LifePort in **WASH** mode in spite of the Check Ice error. However, **PRIME** and **INFUSE** modes are not functional until the temperature is below 8°C.

- The top line of the message display should indicate **READY**.

Other errors may also occur at power on. If they do, refer to the section titled **Troubleshooting and Diagnostics** on page 49 for information on how to proceed.

Testing Operating Modes

1. Close and latch the Pump Head Loop to clamp the tubing.
2. Rotate the Pump Deck Locking Arm 90° and snap into place.
3. Connect the Pressure Sensor Cable from the Pump Deck to the connector on the TubeFrame.
4. Remove the Inner and Outer Cassette Lids and pour 1 Liter of cold (less than 10°C) saline into the Cassette housing.

Replace the Inner and Outer Cassette Lids.

1. Press the pressure **PLUS/MINUS** buttons and verify that the pressure setpoint changes up or down by 1 mmHg with each press.
2. Using the **PLUS/MINUS** buttons, set the pressure to 40 mmHg.
3. Press the **WASH** button and verify pump rotation.
4. Verify that perfusate is drawn from the Perfusion Circuit (Cassette), into the Pump, and then down into the filter.

NOTE: Within a couple of minutes, perfusate should flow out of the filter, into the Bubble Trap, then into the wash port of the Perfusion Circuit (Cassette).

5. Verify that perfusate is contained within the tubing without leaks, and is not flowing through the Infuse Line into the Perfusion Circuit (Cassette).
6. Press the **STOP** button.
7. Press the **PRIME** button and observe that the flow diverts into the Infuse Line of the Perfusion Circuit (Cassette).
 - a. Verify that perfusate is contained within the tubing without leaks, and is flowing only into the Infuse Line of the Perfusion Circuit (Cassette) (and not into the Wash Port).
 - b. Remove the Perfusion Circuit (Cassette) Lids and squeeze or clamp the Infuse Tubing. The Transporter should beep, the Pump should stop, and the message display should read: **Stopped – Check Tubing**.
 - c. Release the tubing and press the STOP button, which should clear the error message.
8. Attach the Flow Restrictor onto the Luer fitting on the Infuse Tubing (a 20-ga. or smaller syringe needle will also work).
9. Press the **INFUSE** button. The pump should start up and begin regulating pressure toward the setpoint level.
10. Verify that a flow rate and a vascular resistance are displayed on the front panel.
11. Press the **STOP** button to end the infuse test.
12. Turn the LifePort off by pressing the **POWER** button.
13. Verify that the power indicator is flashing green, which indicates the batteries are being charged.

Testing the Batteries

1. Open the LifePort Battery Door by sliding it away from the product label.
2. Insert the batteries.
3. Replace the Battery Door.

NOTE: The Battery Door should be in place whenever the LifePort is operated or transported. Allow the batteries to charge for at least five hours. Fully charged batteries should be ready to run the LifePort for 24 hours.

4. Re-run the **ENERGIZE** and **TEST OPERATING MODES** tests as described above, using battery power.

NOTE: The power indicator will not flash when the LifePort is running only on batteries and the LifePort is switched Off.

Checking Duration of Operation (optional)

1. While unit is connected to an external power supply, press the **SCROLL** buttons on the Outer Display to observe battery data on the Message Display Panel. The batteries should display a range between 95% to 100% capacity.
2. With the batteries fully charged and the Ice Container full, operate the LifePort in **INFUSE** mode for 24 hours. During this test:
 - Keep the Flow Restrictor positioned on the Infuse Line.
 - Keep the Lid closed for the entire 24 hours.
3. Verify that the ice and batteries last throughout the entire 24-hour duration of the test.

Setting up External Communications using Data Station

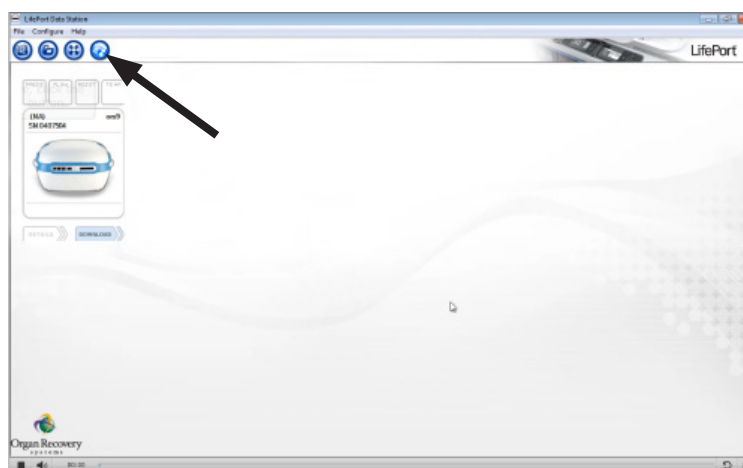
Data Station software allows communication between a LifePort and a computer, making it possible to monitor LifePort operations with the computer, and any other computers networked to it.

Use instructions provided with the Data Station software to install the app on the computer(s) you plan to use for monitoring.

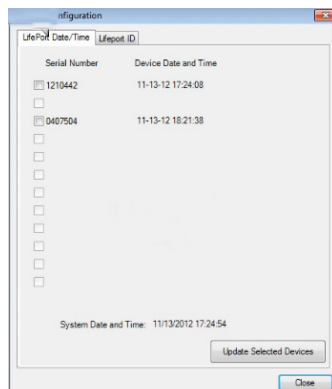
Use these instructions to synchronize the LifePort with the computer's time and date, and to create a Unit ID.

NOTE: This procedure can only be performed with a LifePort that is not currently streaming data to a computer.

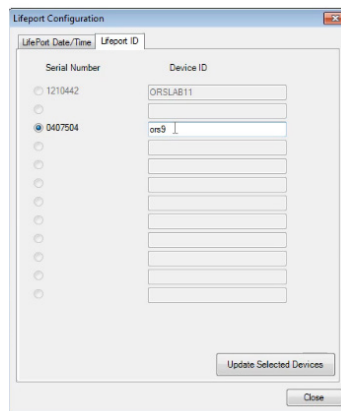
1. Connect the LifePort to the computer using the data cable.



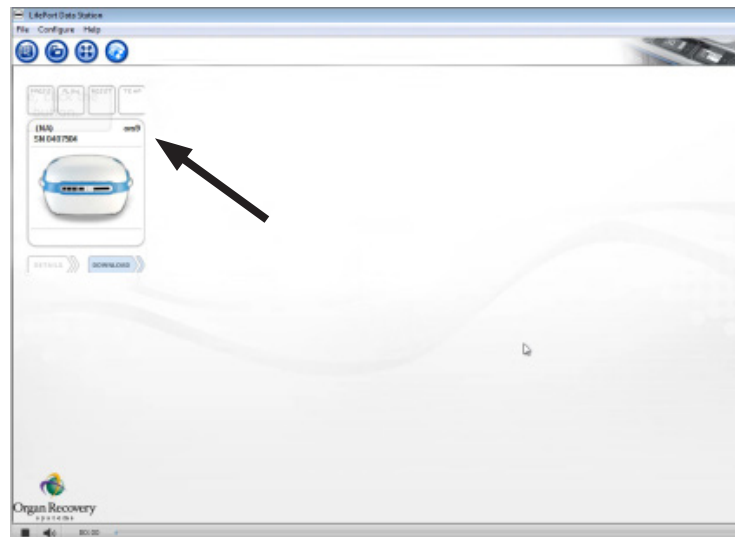
2. Start the Data Station app on the computer.
3. Click the **CONFIGURE LIFEPORT** button as shown. The screen displays the LifePort Configuration window.
4. Click on the LifePort Date/Time tab to synchronize the LifePort's onboard clock with the Data Station



- Click to select the serial number of the LifePort you are synchronizing with.
- Click the **UPDATE SELECTED DEVICES** button to complete the procedure, sending the computer's date and time to the LifePort.
- Click on the LifePort ID tab to enter a name to the unit's serial number.



- Type in a device name to identify this specific unit.
- Click the **UPDATE SELECTED DEVICES** button to complete the procedure, locking in the new device name. This ID is now displayed at the top right of the unit's screen, as shown.



Cleaning Up and Review after Use

- Press the **STOP** button.
- Press the **POWER** button.
- Remove the Perfusion Circuit (Cassette) and properly dispose in accordance with local guidelines for biomedical waste.
- Empty the Ice Container.

Problems uncovered during any of these tests should be investigated and resolved. Be aware to look for leaks, misrouted flow, and extra or missing error messages.

The system should always stay dry and error-free.

If you need assistance, contact Organ Recovery Systems Perfusion Helpline.

Using the LifePort

Introduction

This section provides information on routine use of the LifePort — from preparing to receive a kidney to returning the unit for storage until its next use.

NOTE: Be sure to keep the batteries plugged in and charging when the LifePort is not in use.

Professional Overview

Before using the LifePort in a clinical setting, thoroughly familiarize yourself with the device and kidney perfusion. Consider practicing on discarded or animal kidneys. Various settings should be tried and a sense obtained as to the effects on the kidney.

Be aware of the following important factors:

- **Select an infusion pressure** for use according to good clinical practice to assure sufficient flow, while preventing vascular damage.
- **Secure cannulas to avoid perfusate leaks**, while preventing damage to the transplanted artery.
- **Inspect and position the cannulated artery** to avoid any twists or kinks that would occlude the flow of perfusate.
- **Maintain aseptic conditions** for the kidney and perfusate at all times. Sealing the Perfusion Circuit (Cassette) while following sterile procedures is required.
- **Maintain cold conditions** for the kidney by keeping the LifePort's Ice Container filled. Use only ice and water to prevent freezing.

Maintaining the LifePort for Quick Response Use

Before you receive the call that the LifePort is needed, keep it ready to go at a moment's notice by performing the following procedures.

Preparing the Home Base Station

The LifePort and its supplies and accessories are designed to be an integral part of the recovery team's supply pack, to be seamlessly included in the recovery and transplant process. The following preparations will keep the LifePort in a ready-to-use state.

- Cubed or crushed ice — 10 lbs. (5-6 kg.) or more — readily available in a freezer or icemaker.
- Batteries loaded in the LifePort and kept fully charged. Maintain the batteries' charge by keeping the LifePort plugged into an external power supply.
- Perfusion Circuit (Cassette), Sterile Drapes, and cannula packed and ready.
- Portable wheeled cart available and ready.
- Surgical instruments, suture, solution decanter, and supplies packed and ready.
- Distilled, sterile or regular tap water (about 5 Liters) — chilled in the refrigerator.
- Perfusion solution and organ flush solution — chilled in the refrigerator.



CAUTION: Use only machine perfusion solution. The LifePort is designed to work with machine perfusion solutions only. Check the labeling of the perfusion solution and make sure that it is intended for machine perfusion. If you are uncertain about which solutions are appropriate, contact Organ Recovery Systems Perfusion Helpline for information on recommended perfusates that work best in the LifePort.

- Spare parts at hand, such as additional charged batteries, power cord, spare cannula, etc.

Preparing the LifePort for Recovery

You can modify these instructions according to your institution's procedures.

When you receive the call that the LifePort is needed, perform the following procedures to prep the device before taking it to receive a kidney.

Make Sure You Have Everything You Need

Using a checklist, double check all your equipment and supplies to make sure it is all packed and on the cart.

Recheck the Batteries

Check the batteries to make sure that all are fully charged. Press the **POWER** button and verify that the LifePort powers up. Press the **POWER** button again to turn it off.

Visually Check LifePort and Perfusion Circuit (Cassette)

Visually check the LifePort and Perfusion Circuit (Cassette) for overall integrity and transport-worthiness before each use. Do not use if parts are loose, cracked, or broken, or liquid is leaking.

Turn the LifePort **ON**, check ice and battery levels, and check its operation using the startup methods outlined below.

Cooling Down the LifePort



CAUTION: To avoid inadvertently freezing the kidney, **USE ONLY ICE AND WATER** in the LifePort Ice Container. A mixture of ice and water in the Ice Container will assure that temperatures remain within the appropriate range for kidney preservation.

NOTE: As a safeguard to the kidney, the LifePort Pump will not operate unless the Ice Container temperature is chilled below 8°C. After installation of the Ice Container, it may take several minutes before the display reads a temperature below 8°C.

1. Remove the Cover from the LifePort and remove the Ice Container.
2. Open and fill the Ice Container with crushed or cubed ice, then pour in about 1 Liter of cold water. Add more ice and water until filled, maximizing the amount of ice.
3. Close the Ice Container when filled and make sure it is properly sealed.
4. Place the Ice Container in the LifePort and replace the Cover on the LifePort.



Step 1

Step 2



Step 4



Traveling with the LifePort and Supplies

If you're traveling with the LifePort, be sure to take the following precautions: if you are taking a vehicle, push the cart with LifePort and supplies to the vehicle, and place the LifePort on the seat or in the trunk. Secure the LifePort from sliding or rolling. The cart and supply packs can also be loaded onto the seats or into the trunk.

The LifePort can withstand the normal handling involved in traveling between hospitals; however, it should be kept in an upright orientation to minimize the potential for leaks, spills, or air bubbles. If the LifePort is transported in a car seat, the normal seatbelt can be used to restrain the LifePort while driving.

At a remote recovery site, the LifePort and supply packs can be reloaded onto the cart, which can be pushed to the donor operating room.

Setting Up the Kidney Perfusion Circuit (Cassette)

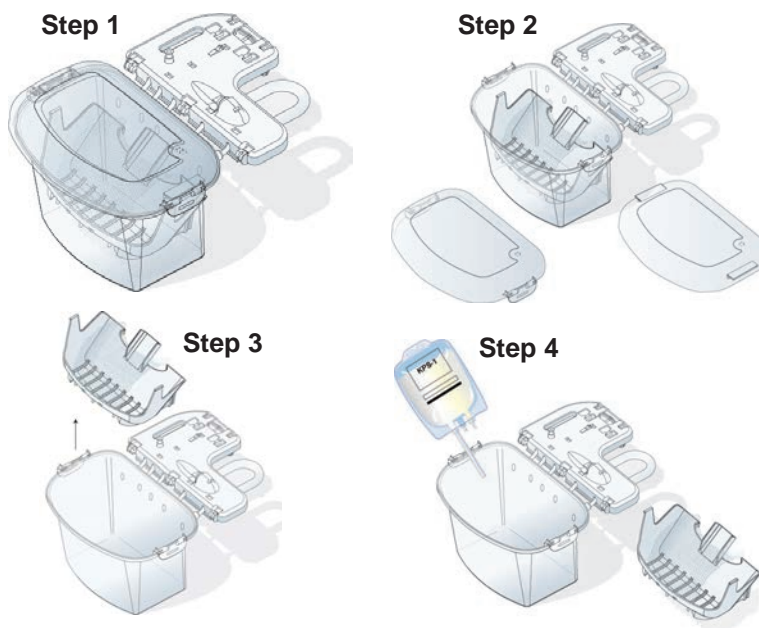
Once you have verified the kidney and checked for any contra-indications against proceeding, use these instructions to set up the Perfusion Circuit (Cassette).

NOTE: The following instructions are designed for two operators, one being gowned and gloved. In the case of a single operator, pay special attention to procedures performed inside an aseptic field.

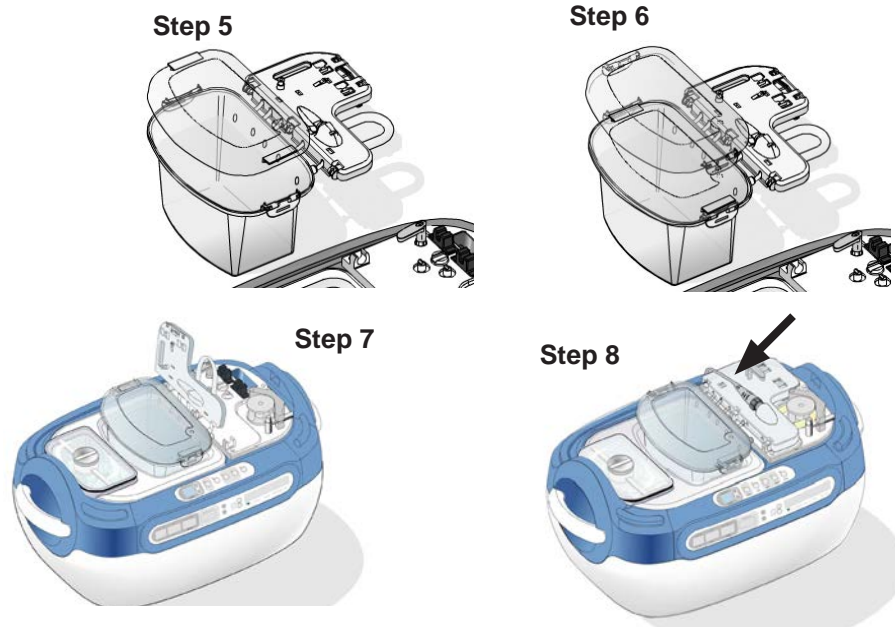


CAUTION: Use Aseptic Technique With The LifePort Perfusion Circuit (Cassette). The Perfusion Circuit (Cassette) is provided pre-sterilized. To minimize the potential for infection of the kidney (and its eventual recipient), aseptic procedures must be used whenever handling the kidney and perfusate, or whenever opening the Perfusion Circuit (Cassette). Aseptic procedures include the use of sterile field, gown, gloves, and instruments and aseptic management of IV tubing, as would be typical in surgical and nursing practice.

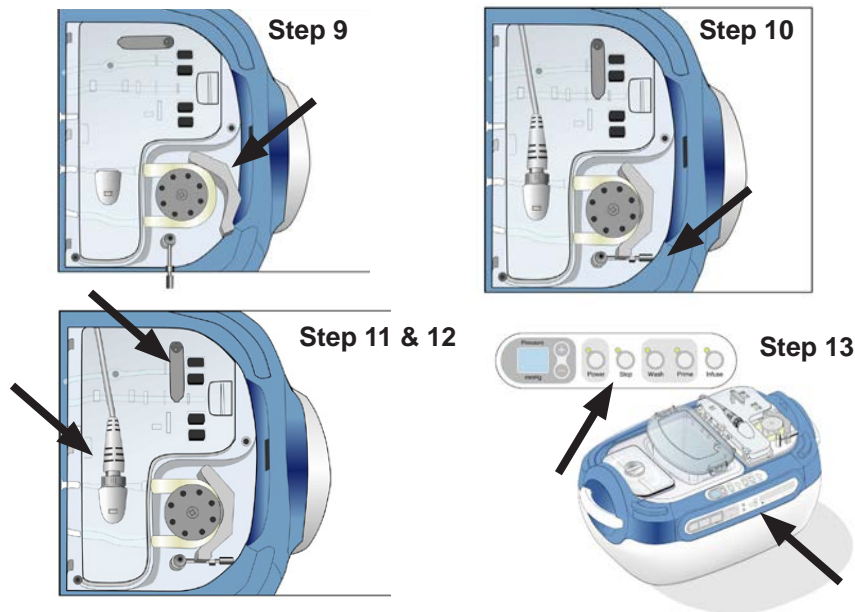
1. *Using aseptic technique*, open a LifePort Kidney Perfusion Circuit (Cassette) and bring it into your sterile field.
2. *Using aseptic technique*, open both Lids.
3. *Using aseptic technique*, remove the Kidney Cradle.
4. *Using aseptic technique*, decant 1 Liter of chilled perfusate into the Perfusion Circuit (Cassette).



5. *Using aseptic technique*, cover the Perfusion Circuit (Cassette) with the Inner Lid.
6. *Using aseptic technique*, cover the Perfusion Circuit (Cassette) with the Outer Lid.
7. Place the sealed Perfusion Circuit (Cassette) in the Ice Container. The Tubeframe must be perpendicular to the Pump Deck, and the hinges must be positioned inside of the receivers on the Pump Deck.
8. Rotate the Tubeframe flat onto the Pump Deck.



9. Open the Pump Head and stretch the tubing over the wheel.
10. Close and latch the Pump Head Loop to clamp the tubing.
11. Rotate the Pump Deck Locking Arm and snap into place.
12. Connect the Pressure Sensor Cable from the Pump Deck to the connector on the Tubeframe.
13. Press the **POWER** button on the Control Panel to energize the unit.

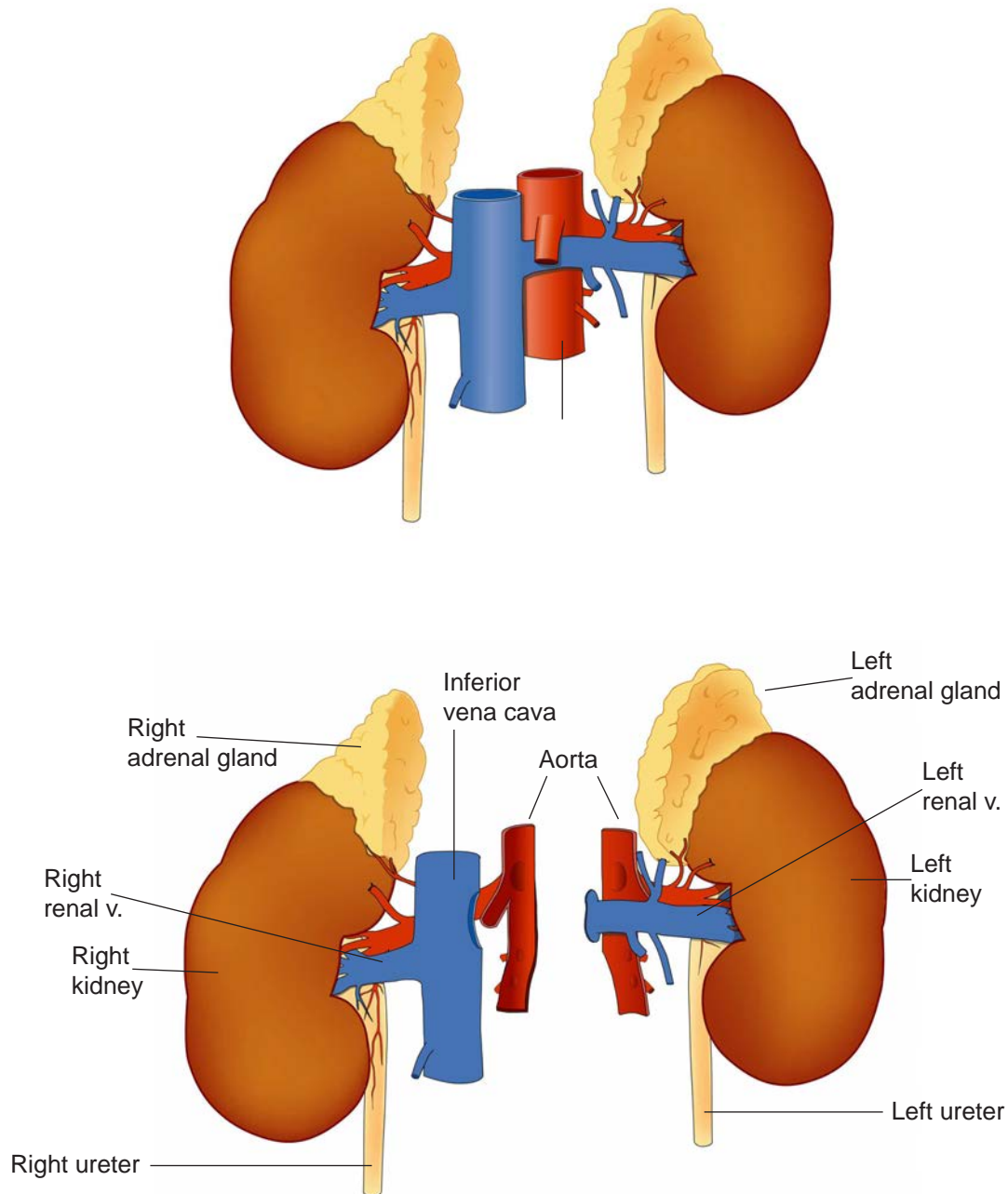


14. Check the external display and verify that the top line reads **READY**.
15. Press the **WASH** button to circulate perfusate until ready to receive the kidney.
16. Close and latch the Cover.

NOTE: If the Outer Display reads: **Power up test FAILED**, reference the error number shown following in **Troubleshooting and Diagnostics** on page 49.

Isolating the Kidney Vascular Structure

Use the procedures specified by your institution for isolating the kidney vascular structure. The following suggestions will facilitate the preparation of kidneys for placement in LifePort disposable cannulas.



1. Visually inspect the kidneys from a gross anatomy standpoint, paying close attention to the aorta, artery(s), vein(s), and ureter.
2. Direct a non-sterile assistant to note any anomalies into the perfusion record.

NOTE: If a non-sterile assistant is not available, write the anomalies initially on the sterile table covers. Transfer the information to the perfusion record as soon as the procedure is finished.

3. Isolate the renal artery(s) and vein, making sure that no small polar arteries are transected.
4. Feel the renal artery(s) for plaque inside the lumen of the artery.
5. Inspect the orifice of the artery to see if there is a partial or completely occluded artery. Make a decision according to the following decision tree:
 - If the artery is not occluded, proceed to cannulation.
 - If the artery has any type of occlusion, determine whether the plaque will break off and block the artery or if cannulation will cause damage to the artery.
 - If you determine that cannulation will be safe, proceed to cannulation.

Cannulating the Kidney

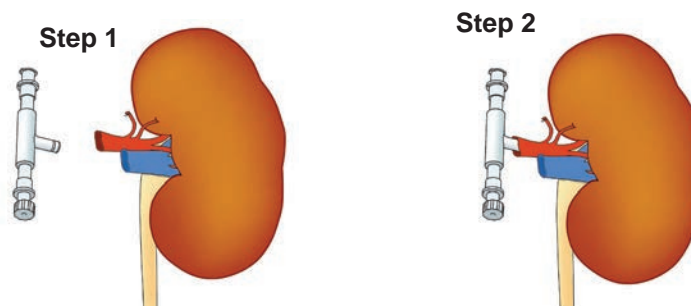
Using the Straight Cannula

INDICATION: The Straight cannula is used when the vessel to be perfused terminates without a patch or when intimal damage to the lining is not a concern. The example shown in the illustration is a kidney with isolated anatomical structures and without an aortic patch.

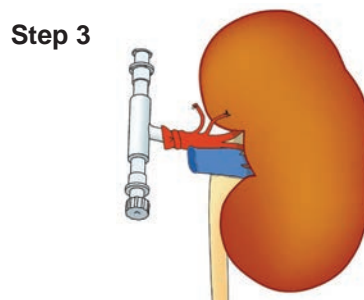
Choose the size appropriate to the diameter of the vessel orifice.

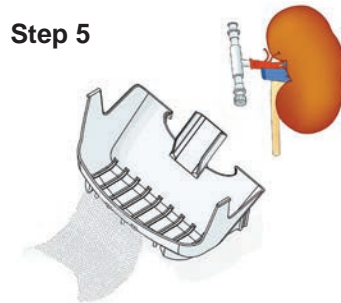
NOTE: Perform the following procedure on an aseptic field using aseptic technique.

1. *Using standard aseptic technique*, to introduce the Straight cannula onto the sterile field.
2. Insert the Straight cannula tip no further than necessary into the vessel.

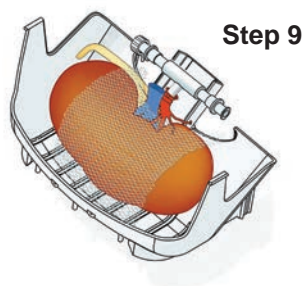


3. Secure the vessel in place using silk ties, vessel loops, or another appropriate material. A groove in the tip is provided for positioning and securing.
4. Gravity-flow small amounts of flush solution into the cannula, then check for and repair any leaks that occurred in the surgical process or with the cannula.
5. Place the kidney in the Kidney Cradle and snap the Straight cannula into the Cannula Mount.





6. Adjust the height and rotation of the cannula.
7. Mount the cannula to comfortably position the vessel.
8. Visually inspect the vessel, ensuring there are no twists or occlusions.
9. Drape the Mesh Organ Restraint over the kidney and secure the organ in the Kidney Cradle.



Using the SealRing Cannula

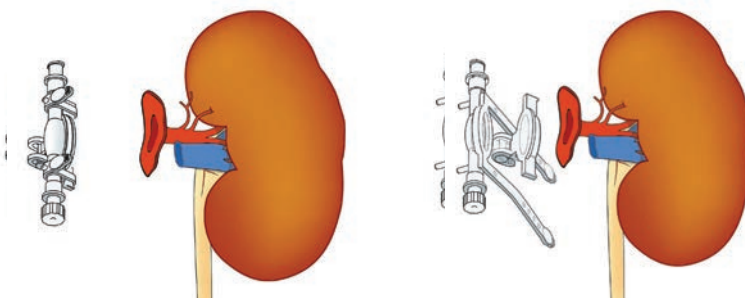
INDICATION: The SealRing cannula is used when the vessel to be perfused terminates with an aortic patch or similar. The example shown in the illustration is a kidney with isolated anatomical structures and aortic patch.

Choose the size appropriate to the aortic patch.

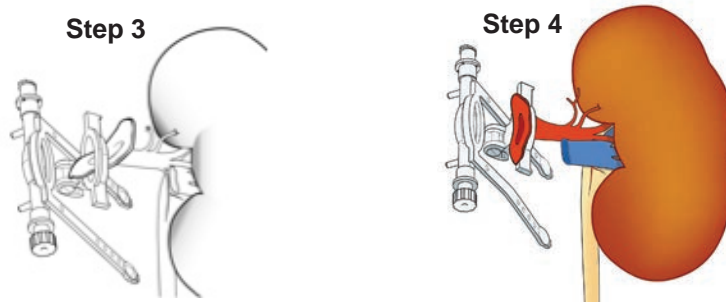
NOTE: Patches that contain multiple arteries may be able to be placed into one SealRing cannula.

NOTE: Perform the following procedure on an aseptic field using aseptic technique.

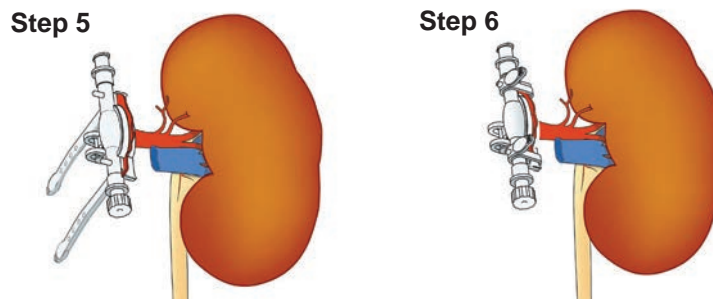
1. *Using standard aseptic technique*, to introduce the cannula onto the sterile field.
2. Open the SealRing cannula.



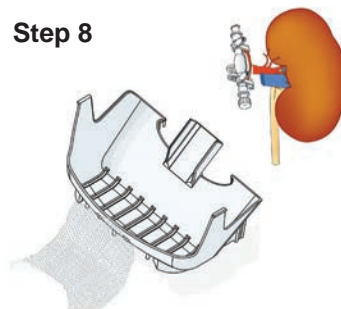
3. Slide the aortic patch through the center of the cannula ring.
4. Lay the patch flat, making sure the tissue covers the entire sealing ring. If necessary, instruments may be used to temporarily hold the tissue in place until the cannula is secure.



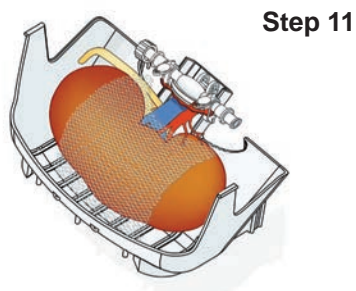
5. Hinge the cannula closed, securing the tissue between the two halves.
6. Wrap each strap — straight and securely — around both cannula halves and fix the straps to their posts.



7. Gravity-flow small amounts of flush solution into the cannula, then check for and repair any leaks that occurred in the surgical process or with the cannula.
8. Place the kidney in the Kidney Cradle and snap the cannula into the Cannula Mount.



9. Adjust the height and rotation of the Cannula Mount to comfortably position the vessel.
10. Visually inspect the vessel, ensuring there are no twists or occlusions.
11. Drape the Mesh Organ Restraint over the kidney and secure the organ in the Kidney Cradle.



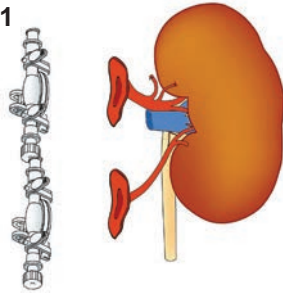
Using the Coupler

INDICATION: The Coupler is used to connect two or more SealRing or Straight cannulas when multiple vessels must be perfused. The example shown in the illustration is a kidney with isolated anatomical structures and aortic patch, but may also apply to any combination of vessel and cannula types.

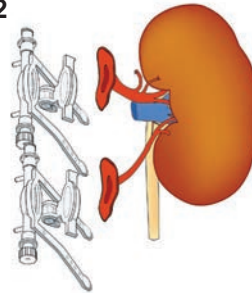
NOTE: Perform the following procedure on an aseptic field using aseptic technique.

1. Use *standard aseptic technique*, to introduce the cannulas onto the sterile field.
2. Open the SealRing cannulas.

Step 1

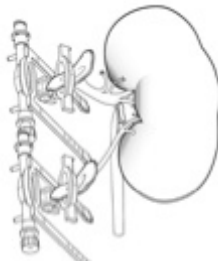


Step 2

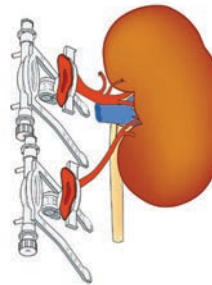


3. Slide aortic patches through the center of each cannula ring.
4. Lay each patch flat, making sure the tissue covers the entire sealing ring. If necessary, instruments may be used to temporarily hold the tissue in place until the cannula is secure.

Step 3

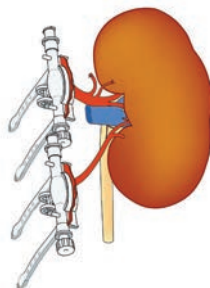


Step 4

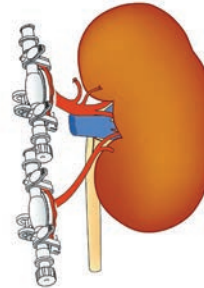


5. Hinge the cannulas closed securing the tissue between the two halves.
6. Wrap each strap — straight and securely — around both cannula halves and fix the straps to their posts.

Step 5

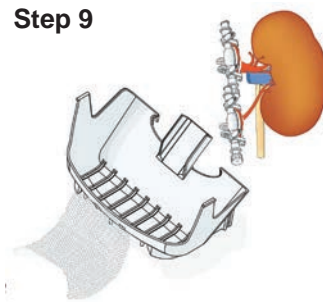


Step 6

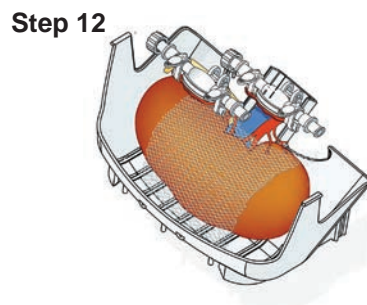


7. Gravity-flow small amounts of flush solution into the cannula, then check for and repair any leaks that occurred in the surgical process or with the cannula.

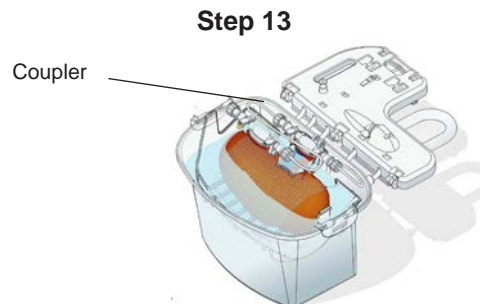
8. Identify a main vessel.
9. Place the organ in the Kidney Cradle and snap the cannula connected to the main vessel into the Cannula Mount.



10. Adjust the height and rotation of the Cannula Mount to position the vessel.
11. Visually inspect the vessel, ensuring there are no twists or occlusions.
12. Drape the Mesh Organ Restraint over the kidney to secure the organ in the Kidney Cradle.



13. Replace the End Cap of the main cannula with one end of the Coupler.



14. Attach the second end of the Coupler to the Infuse Port of the next cannula.

Using the Universal SealRing

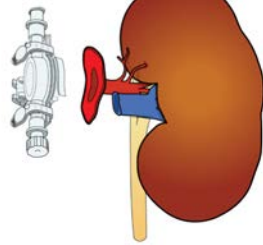
INDICATION: The Universal SealRing is designed for use when the vessel to be perfused terminates with or without an aortic patch or similar condition. The example shown in the illustration is a kidney with isolated anatomical structures and an irregular/incomplete aortic patch.

Choose the size appropriate to the diameter of the vessel orifice.

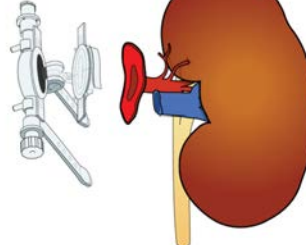
NOTE: Perform the following procedure on an aseptic field using aseptic technique.

1. Using standard aseptic technique, introduce the cannula onto the sterile field.
2. Open the Universal SealRing cannula by unhooking the straps, unsnapping and opening the right anvil.

Step 1

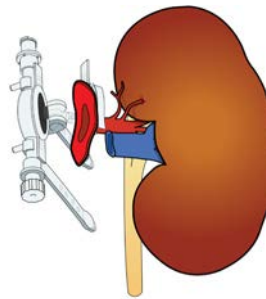


Step 2



3. Position the vessel in the center of the anvils so the terminated end of the vessel is approximately 1.5-2.0mm above the top surface of the anvils.

Step 3



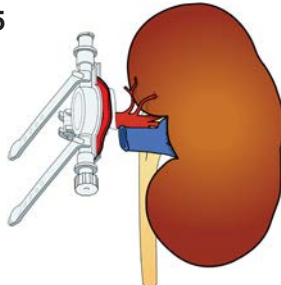
4. Close the right anvil capturing the vessel with an audible click.

NOTE: If necessary, retention stays can be added to the vessel using suture or other appropriate material. Suture Tie Down Cleats and slots have been provided to facilitate positioning.

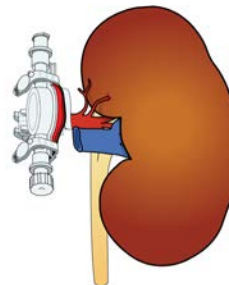
5. Lower the upper portion of the cannula carefully bringing the conical seal into the interior of the vessel. Viewing through the magnified sight-glass, verify that the vessel orifice is centered, circular in shape and not occluded.

6. Wrap each strap, straight and securely, around both cannula halves and fix the straps to their posts.

Step 5

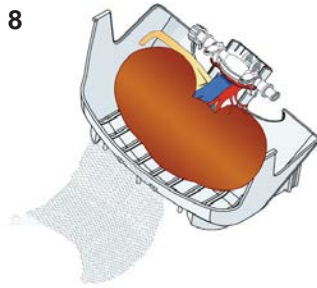


Step 6



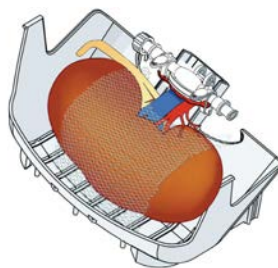
7. Gravity-flow small amounts of flush solution into the cannula, then check for and repair any leaks that occurred in the surgical process or with the cannula.
8. Place the kidney in the Kidney Cradle and snap the cannula into the Cannula Mount.

Step 8



9. Adjust the height and rotation of the Cannula Mount to comfortably position the vessel.
10. Visually inspect the vessel, ensuring there are no twists or occlusions.
11. Drape the Mesh Organ Restraint over the kidney and secure the organ to the Kidney Cradle.

Step 11



Placing the Kidney in the LifePort

BEFORE YOU BEGIN: Make sure you have prepared the LifePort following instructions provided in the *Professional Overview* section on page 22.

NOTE: Perform the following procedure using aseptic technique — ideally the same surgical field used when placing the kidney in the cradle.

1. A person outside the aseptic field, remove the Cover of the LifePort.
2. A person outside the aseptic field, press the **STOP** button to halt the wash cycle circulating perfusate in preparation for use.

Step 1



Step 2



3. A person outside the aseptic field, remove the Outer Lid from the Perfusion Circuit (Cassette).
4. *Using aseptic technique*, position the folded LifePort Sterile Drape (supplied) over the Perfusion Circuit (Cassette) as shown.

Step 3



Step 4



5. *Using aseptic technique*, unfold the Sterile Drape along the length of the LifePort.
6. *Using aseptic technique*, fully unfold the Sterile Drape, side-to-side.

Step 5



Step 6

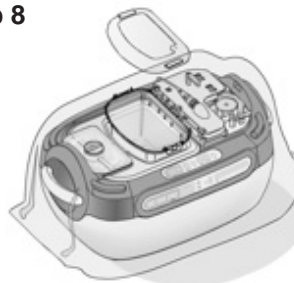


7. *Using aseptic technique*, position the Sterile Drape opening down around the covered Perfusion Circuit (Cassette).
8. *Using aseptic technique*, remove the Inner Lid from the Perfusion Circuit (Cassette).

Step 7



Step 8



9. *Using aseptic technique*, place the Kidney Cradle in the LifePort Perfusion Circuit (Cassette).

Step 9



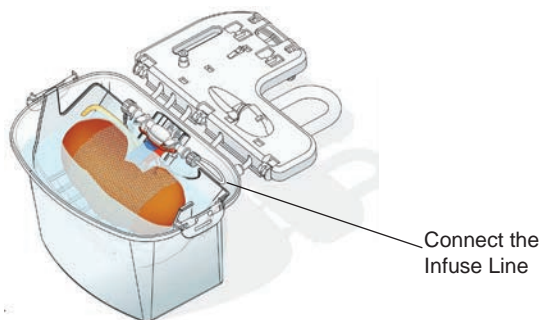
Priming the Infuse Line

When the Kidney Cradle containing the kidney has been placed in the Perfusion Circuit (Cassette), use the following procedure to prime the Infuse Line, removing bubbles from the line and renal artery. This procedure is performed using aseptic technique.

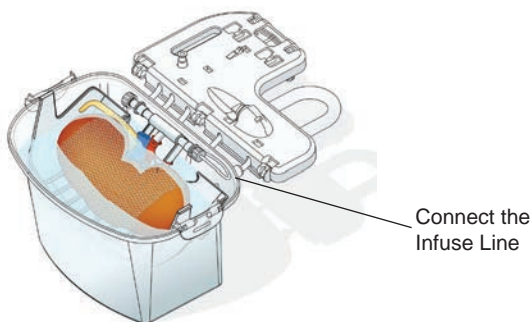
NOTE: For better clarity, the following illustrations of the Perfusion Circuit (Cassette) and Kidney Cradle with kidney will be shown outside the LifePort.

1. Connect the Infuse Line as shown then tighten the Luer Lock fitting.

With the SealRing cannula:



With the Straight cannula:



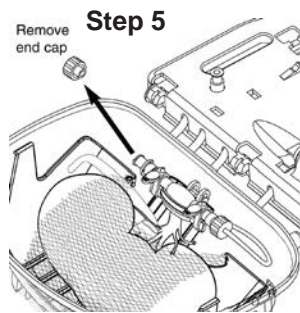
With the Coupler:



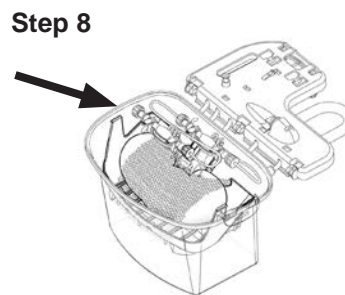
2. Replace the End Cap of the main cannula with one end of the Coupler.
3. Attach the second end of the Coupler to the Infuse Port of the next cannula.
4. Connect the Infuse Line to the main cannula.

NOTE: For simplicity, illustrations from this point forward will show the SealRing cannula as the example.

5. Remove the End Cap from the cannula to provide a path for bubbles to escape.
6. Viewing through the Sterile Drape, press the **PRIME** button to start the Pump.



7. Check for bubbles in the perfusate flowing from the disconnected end of the cannula and through the clear cannula material.
8. Replace the End Cap to close the Perfusion Circuit (Cassette). The pump should automatically stop and “beep.” If the Pump does **NOT** stop and beep, it means there is a leak.



Preliminary Testing for Leaks

Once the LifePort begins pumping, you have your first opportunity to check for leaks. There are two kinds of leaks to look for:

- Leaks in the Perfusion Circuit (Cassette)
- Leaks from the cannulation site or arteries.

If a leak is suspected:

1. Press the **STOP** button to stop the Pump.
2. Check the Perfusion Circuit (Cassette) and address the leak. Frequently, leaks at this point are at the SealRing cannula, where the kidney attaches.
3. Check whether the perfusion fluid is leaking out of the Perfusion Circuit (Cassette). If so:
 - Contact Organ Recovery Systems Perfusion Helpline. We want the Perfusion Circuit (Cassette) returned so we can address the problem.
 - Replace the Perfusion Circuit (Cassette).
4. Repeat the **Priming the Infuse Line** procedure from **Step #2** on page 35.

Initiating Perfusion

1. Viewing through the Sterile Drape, press the **UP/DOWN** arrow button to choose the pumping pressure.

NOTE: The default setting is 30 mmHg.

2. Having resolved any preliminary issues with leaks, press the INFUSE button to start the infusion process. This will begin the recording of perfusion data and other parameters.



3. Viewing through the Sterile Drape, check the operating parameters on the Outer Display, including:
 - Pressure
 - Flow
 - Vascular Resistance
 - Temperature



4. Visually check the kidney as described in the following section.

Checking the Kidney After Placement

Once you have the kidney in the LifePort, there are several simple checks to verify that cannulation and placement are optimal during perfusion.

Visual Inspection

There are several visual inspections to make that will maximize pumping effectiveness.

Cannula Leakage?

Look for visible leaks around the gasket, where it attaches to the artery of the kidney. Depending on the kidney, a small amount of leakage may be acceptable, though it is usually best if there are no leaks at all.

Artery Filled?

Once the Pump is applying pressure to the artery, the artery should expand. If it is not filled, this is evidence that fluid is not being pumped into the artery. Make sure the artery is patent.

Side Branches Closed?

There may be small branches coming off of the main renal artery that go to other arteries that have been snipped off during the recovery process. If these have not been effectively tied off, perfusate can leak from them during perfusion.

Most of these will already be tied off but others may reveal themselves once perfusion begins. Tie them off or clamp them as best you can. We are aware there can be problems. Depending on conditions:

- You may not be physically able to identify the leaking vessels.
- You may not be physically capable of tying off or clamping these vessels.

Do whatever is possible to prevent these leaks.

Vein Positioned on Top?

Having the vein positioned on top of the kidney makes it easy to verify that perfusate is effectively entering the kidney through the artery and exiting from the vein.

You may encounter situations where flow is seen entering the kidney but is not exiting through the vein. In this case, the kidney is likely not being effectively perfused—a situation that should be addressed. Just because perfusate is entering the artery does not automatically mean it is actually moving through the organ as desired.

Conversely, if you detect a slow leak somewhere but a large volume is coming from the vein, there may be no reason to be concerned.

Presence of Blood or Perfusate?

Observe the progress and efficacy of the pumping process by observing the nature of the fluid exiting the kidney. Ideally, as pumping begins, after a short while blood will be flushed from the kidney and will be seen exiting from the vein. Once the blood has been flushed from the kidney, the exiting fluid should clear as it becomes mostly perfusate.

This is a subjective observation, depending on how much blood was flushed from the kidney during removal.

Color of Kidney?

The color of the kidney is another indicator of whether the kidney is being effectively perfused. Typically, the color of the cortex will initially be darker. As perfusion takes place and begins to flush out the blood, the kidney will become blanched and more pale. This is an indication that the pumping procedure is effective. In case some area stays dark, this might be an indication one has missed a (polar) artery. Look for this extra artery, cannulate this extra artery, and use a coupler to connect it to the circuit. Use prime mode to remove air from the coupler and extra cannula before starting to perfuse again.

NOTE: If some part of the kidney is not being perfused, this might have an effect on the recorded flow and resistance.

Closing the LifePort

Having completed the visual inspection, close the LifePort.

NOTE: The LifePort is designed for unattended use, with no need for continuous monitoring of the kidney.

1. Replace the Inner Lid over the Perfusion Circuit (Cassette).

Step 1



2. Remove the Sterile Drape.
3. According to hospital protocol, mark identification information on the Perfusion Circuit (Cassette) as indicated.



CAUTION: Avoid marking identification on the Outer Lid. Identification on the TubeFrame is preferred.

4. A person outside the aseptic field, carefully place the Outer Lid on the Perfusion Circuit (Cassette).
5. A person outside the aseptic field, close and latch the outer Cover.
6. Recheck operating parameters on the Outer Display and record on the chart, per hospital procedure.

Step 5



Step 6



7. Verify that the LifePort is in **INFUSE** mode.
8. Attach a handle tag (or similar approved label), to place identification information on the outside of the LifePort. Do not make permanent markings on the LifePort unit itself.



NOTE: You can also connect the LifePort data port to a computer and download operating parameters. For more information, refer to **Downloading Operational Data** on page 48.

Monitoring Options for a Kidney on the LifePort

Once the LifePort has been closed, there are several options for continuous monitoring of the kidney until removal and transplantation into the recipient.

Monitoring Via LifePort Outer Display

The LifePort Outer Display provides comprehensive information on the status of the pumping procedure during perfusion.

The left side of the Display Panel, shown below, provides the following diagnostic information:



- **Pressure** — this is the actual systolic pressure of the perfusion process, as the LifePort attempts to achieve the pressure you have set. This value is often lower but should never be higher than the selected pressure.
- **Flow** — the flow changes, depending on how the kidney is responding to the pumping. This value is expected to increase over time, as the kidney vasodilates, thus allowing the set pressure to deliver a growing flow rate.
- **Resistance** — this value is expected to decrease, as the kidney “loosening” provides less and less resistance to the pumping over time. Resistance and flow are inversely proportional.
- **Temperature** — this is the temperature of the ice bath. The value will increase as the ice melts, prompting when to add more ice. An alert will be triggered and perfusion will stop when temperatures reaches 8°C.
- **Power LED** — glows steady green when the LifePort is powered ON, whether under battery power or an external power supply. The Power LED flashes green when the unit is powered **OFF**, but is connected to an external power supply.
- **Error LED** — flashes red, accompanied by an audible tone, when the LifePort encounters an error. Reference the error number shown on the Message Display in **Diagnostics and Troubleshooting** on page 49 of this Operator’s Manual.

The right side of the Display Panel, shown below in its default screen, provides a range of functional information. All other screens automatically return to this screen after 5 seconds.



The upper left corner tells the LifePort’s current mode of operation, corresponding to the controls on the top of the unit:

- **INFUSE**
- **STOPPED**
- **PRIME**
- **WASH**

The icon in the upper right corner tells whether the LifePort is operating on AC or battery power.

NOTE: If the unit is connected to a power source but is not operating, the panel says **CHARGING**.

The number below the battery icon provides “stopwatch” time, telling how long the LifePort has been pumping the kidney. The timer will start as soon as Infuse Mode has been pressed for the first time, and will continue until the unit is powered off.

Press the **UP/DOWN Arrow** buttons to rotate between other types of information available on this screen that are useful to monitor as you travel. After 5 seconds, these displays automatically return to the default screen:

- **Beats per minute** — fixed at 30 bpm.
- **Diastolic pressure**
- **Average pressure** — a real-time calculation based on systolic and diastolic values.
- **Perfusate temperature** — measured inside the bubble trap.
- **Minimum and maximum temperatures reached** —these values can be useful after the fact to check whether there were any temperature spikes or drops in temperature during perfusion.

NOTE: If the LifePort is connected to a PC, you can check these values as streamed data.

- **Time of day** — 24-hour format.
-

- **Data memory remaining** — from the point when the INFUSE button was pressed, the LifePort creates and stores a data file of 48 hours in length, useful in creating a record of the case. This clock counts down from 48 hours, telling how much memory time remains.

NOTE: The unit can create five of these files, covering five procedures. When five files are in memory, the unit will prompt you to delete the oldest file(s) before it will allow a new procedure to begin. Therefore, it is advisable to download the data from a procedure when it is completed, and then to delete the file from the LifePort.

- **Battery life remaining** — the LifePort has four batteries, which are used in series. Scroll to review the percentage of remaining power and battery mode (whether Standby or On Line) for each battery. When a battery is charged and waiting, the value for that battery reads **STANDBY**. If the battery has been discharged, the field is blank. View each with a separate press of the Arrow button.
- **Backlight** — this button toggles **OFF** and **ON** to light up the display for easier viewing in low light conditions.

Data Station Monitoring

The Data Station is a software application to be installed on a computer. By connecting the LifePort to the Data Station computer, you can monitor all LifePort functions, in real time, on the Data Station dashboard, as shown at the right.

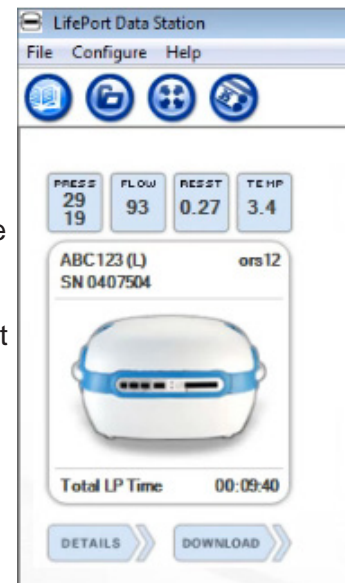
Up to eight LifePorts can be connected to the Data Station computer. A cable is provided that connects to the LifePort. Adapters may be necessary between the unit and the Data Station computer.

The Data Station displays the same perfusion information shown on the Lifeport Display Panel, though it displays the information simultaneously and does not require you to scroll through the menus. It does not show BPM, mean press, Min/Max temperature, battery, etc.

The Data Station software also stores this data, making it easy to generate and print out a case report on the kidney's perfusion experience. You can print a report from the beginning to the current moment, or print a report of the entire case after the perfusion.

In addition, the Data Station stores a permanent record in this database, including all parameters in minute-by-minute format.

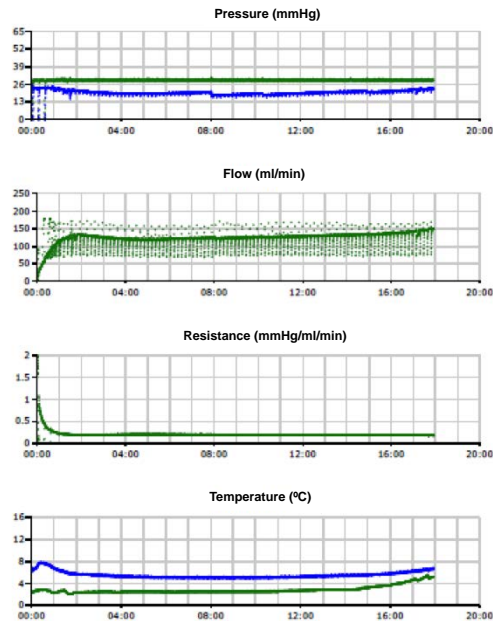
If the Data Station computer is networked or accessible via the Internet, you can access the LifePort data from any computer able to connect to it.



Typical Behavior of a Kidney on LifePort

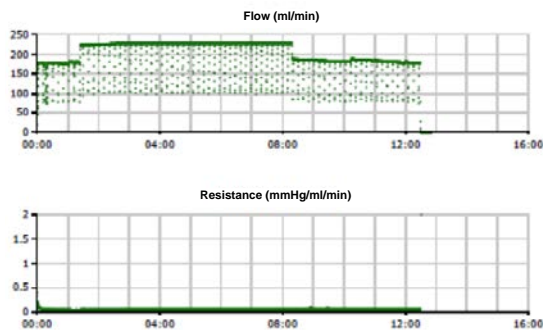
The graphs below — excerpted from the 2nd page of a Data Station case report — show four parameters of the typical behavior of a kidney on the LifePort: Pressure, Flow, Resistance, and Temperature.

It is normal to see flow increase while resistance decreases. This indicates that the kidney is opening (vasodilating). The Pump automatically adjusts the flow rate to achieve the indicated pressure, and will never exceed this setting to avoid barotraumas, or specifically, endothelial injury.



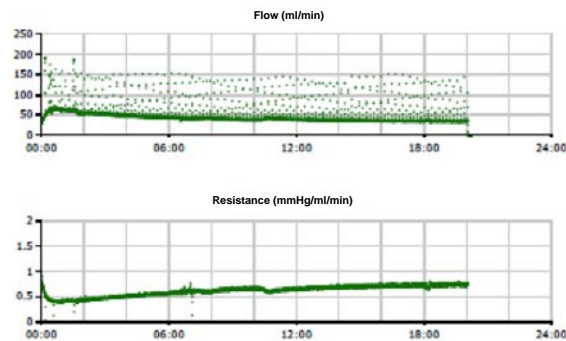
Leakage at Cannula or Open Side Branch

This graph shows immediate flow but no build-up of resistance. This can indicate leakage at the cannula site or an open lateral branch of the renal artery.



Nonresponding Kidney

A nonresponding kidney — not responding to mechanical perfusion — typically shows some degree of flow, however no concurrent decrease in resistance. In this case, it may be appropriate to review available donor, kidney, procurement, and recipient data before making any decision.



Remote Monitoring

The LifePort has the capability of detecting certain situations with the kidney and providing a physical and audible alert on such events.

When the LifePort is connected to a network computer, the Data Station software can be set up to send these alerts via email or text message to any smartphone.

Preparing to Travel to the Transplant Site

These instructions may be modified according to your institutions procedures.

Transport from the Recovery Site

After the recovery, secure the LifePort and supplies for travel. Recheck the LifePort Cover to make sure it is closed and latched. Place the other supply packs containing the disposables, instruments, and supplies on the cart as well. Reviewing your checklist, double check all your equipment and supplies to make sure that nothing is being left behind.

Transport the LifePort and Supplies

If you are transporting the LifePort in a vehicle, push the cart with LifePort and supplies to the vehicle, and place the LifePort on the seat or in the trunk. Secure the LifePort from sliding or rolling. The cart and supply packs can also be loaded onto the seats or into the trunk. If transported in a vehicle seat, the normal seatbelt can be used to restrain the LifePort while driving.



CAUTION: Keep the LifePort upright during transportation. avoid direct sunlight and hot or cold temperature extremes. Extended exposure to outdoor conditions (sunlight, heat or cold), can affect the time that the LifePort can maintain proper temperatures. If the LifePort must be operated under these conditions, frequently monitor the temperature and maintain proper ice levels.

Delivering to the Transplant OR

When the transplant team is ready, the LifePort and supplies can be transported to the transplant team via a combination of the wheeled cart and vehicles, as required.

Checking Battery Power and Ice

The LifePort is designed so the batteries and ice will last for 24 hours of operation with the Cover in place and latched. Monitor battery and ice levels during kidney preservation on the LifePort.

NOTE: The LifePort will alert when the batteries have two hours remaining or when the temperature in the Ice Container reaches 8°C. However, make a habit of checking temperature and battery level.

Adding More Ice

Check the temperature on the Outer Display to make sure that it is steady and below 8°C.

- If the temperature is climbing towards 5.5° to 6.5°C, open the LifePort Cover and visually check the ice level.
- If the ice is mostly melted, remove some water from the Ice Container (using a cup, scoop, hand pump, or electrical pump) and refill with ice. This is part of the non-sterile section of the unit and can be performed while the LifePort stays in perfusion mode.

Replacing Batteries

Check the battery level on the Message Display. Whenever the LifePort is not in transit, plug the LifePort into an external power supply so the batteries are maintained in a charged condition.

- If the batteries are running low, plug the LifePort into an external power supply if possible.
- If an external power supply is not available, the depleted LifePort batteries may be replaced with fully charged LifePort batteries. Batteries may be replaced one at a time without disrupting LifePort function.



CAUTION: Be sure to replace the batteries only one at a time, to ensure that the LifePort will continue to operate during battery replacement.

At the Transplant OR

Observe the following when arriving in the OR.

1. Follow hospital procedures for moving equipment into the OR.
2. Find a non-sterile table in the OR for the LifePort, or park the wheeled cart in the OR, where the cart can act as a table. The table or parking place should be near the sterile back table to ease the process of transferring the kidney from the LifePort to the back table.
3. If a power outlet is nearby, plug in the LifePort to power, charge and preserve the batteries.
4. Monitor perfusion parameters to make sure that the LifePort is working properly at all times.

Waiting until Recipient Surgery Is Ready

If there is a waiting period before the recipient surgery is ready, the kidney is perfused and monitored inside the LifePort to maintain its transplantable condition. During such a period of perfusion, the following activities may take place:

- **Monitoring the kidney**—Pressure, flow, vascular resistance, and temperature can be regularly recorded to observe the vascular trends in the kidney during perfusion.
- **Monitoring the perfusate**—Perfusate samples may be taken aseptically, via the needleless port, to watch for pH, osmolality, electrolytes, biomarkers, etc., according to hospital protocol.
- **Recharging the supplies**—The LifePort may be plugged into an external power supply to enable continued operation while recharging the batteries. The Ice Container should be checked occasionally and replenished when the ice is running low and temperature is beginning to rise.
- **Sterility and hypothermia maintenance**—The kidney is maintained under cold and aseptic conditions, while it is sealed in the Perfusion Circuit (Cassette) and surrounded by ice in the LifePort ice bath.

Removing the Kidney from the LifePort for Transplant

There are several procedures for removing the kidney from the LifePort when the transplant surgeon is ready for the kidney. Two are detailed below.

NOTE: These procedures can be modified as necessary.

1. Unlatch and remove the LifePort Cover.
2. Remove the Outer Cassette Lid and place it upside-down on a table where it will be undisturbed.
3. *Using aseptic technique*, position a folded Sterile Drape over the Perfusion Circuit (Cassette) as shown.
4. *Using aseptic technique*, unfold the Sterile Drape along the length of the LifePort.

Step 3



Step 4



5. *Using aseptic technique*, fully unfold the Sterile Drape, side-to-side.
6. *Using aseptic technique*, position the Sterile Drape opening down around the covered Perfusion Circuit (Cassette).

Step 5

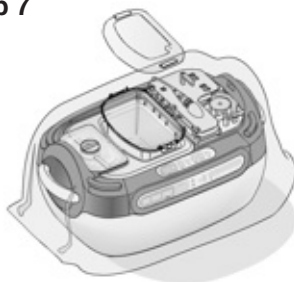


Step 6

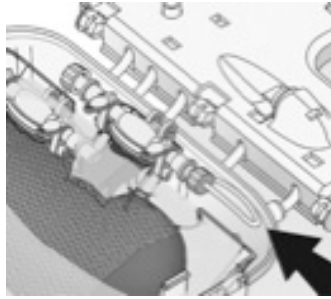


7. *Using aseptic technique*, remove the Inner Lid from the Perfusion Circuit (Cassette).

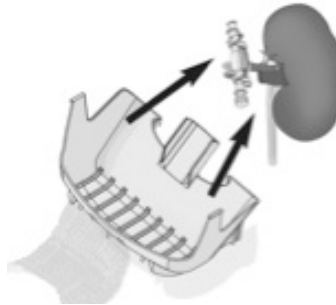
Step 7



Option A:

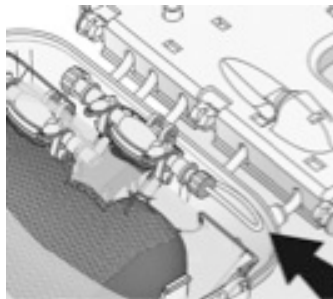


1. Press the **STOP** button to stop the infusion Pump.
2. *Using aseptic technique*, unscrew or cut the Pump Hose.



3. *Using aseptic technique*, carry the Kidney Cradle to the sterile field.
4. *Using aseptic technique*, unhook the Mesh Organ Restraint.
5. *Using aseptic technique*, detach the clamp/ cannula from mount.

Option B:



1. *Using aseptic technique*, unscrew or cut the Pump Hose.
2. Press the **PRIME** button to flow cold perfusate into the bowl.
3. When enough perfusate has been transferred, press the **STOP** button to stop the flow.



4. *Using aseptic technique*, lift the Kidney Cradle containing the kidney from the Perfusion Circuit (Cassette), and place in the bowl/basin for transfer to back table.
5. Carry the bowl/basin to back table or to recipient table to remove Mesh Organ Restraint and cannula

Continue for both Option A and Option B:



6. *Using aseptic technique*, unstrap, open and remove the clamp/cannula.
7. *Using aseptic technique*, perform the pre-transplant preparation on the kidney.
8. Once the kidney has been removed from the Transporter, remove the drape, replace the Cover on the LifePort, power off the device, and prepare it for return to the home base station. The Kidney Cradle and disposable cannula should be disposed of in accordance with local guidelines for biomedical waste.

Downloading Operational Data (optional)

Introduction

The LifePort Data Cable (supplied) can be used to link a personal computer to the LifePort to capture data being generated and stored on board. Data from previous procedures can also be downloaded from stored files.

NOTE: The LifePort is designed to transmit historical data excluding perfusion commands.

The Data Cable plugs into the Data Port, a serial interface connector on the external-connections panel on the back of the unit. Whenever the LifePort is in Infuse Mode, its internal computer is capturing perfusion and status data once every 10 seconds.

Data recording begins when the LifePort enters the Infuse Mode for the first time once powered up. Data recording continues until the LifePort is powered down.

To start a new data file, cycle the power (power off then power on). To start a new data file, cycle the power (power off then power on). The LifePort can store a maximum of five perfusion cases at a time. Files should be downloaded to a computer after each case is finished. After downloading, the cases can be deleted from the LifePort.

Each of the LifePort's five data files can hold up to 48 hours of perfusion data. If a single perfusion case runs longer than 48 hours, a new file can be created only by turning the LifePort off, then on and resuming the perfusion. The stored data includes:

- Sequential record number
- Infuse time
- Pressure set point
- Measured systolic pressure
- Average pressure
- Measured diastolic pressure
- Flow rate
- Organ resistance
- Ice Container temperature
- Bubble Trap temperature
- Error condition status (presence or absence of each error condition)
- Perfusion system state and sub state
- LifePort Cover status (open/closed)



CAUTION: Accessory equipment connected to the Data Port must be certified IEC950 for data processing equipment. Furthermore all configurations shall comply with the systems standard IEC60601-1. Any person who connects additional equipment to the Data Port configures a medical system, and is therefore responsible for ensuring that the system complies with the system standard IEC60601-1. If in doubt, consult Organ Recovery Systems Perfusion Helpline.

Troubleshooting and Diagnostics

Most problems that you encounter in operating the LifePort will be easily solved. The first thing to check when troubleshooting the system is to make sure that power is available from either the batteries or through the Power Cord plugged into a standard electrical outlet. If the power light comes on but the LifePort still does not work, check the following guide.

Troubleshooting Procedures

Trouble	Probable Cause	Action
No power	Dead batteries, batteries not charged, and disconnected from an external power supply.	<ol style="list-style-type: none"> 1. Replace with fresh batteries or plug into an external power supply. 2. Make sure batteries are fully charged before using.
	No power at outlet.	Make sure outlet has power.
	Tripped Circuit Breaker.	<ol style="list-style-type: none"> 1. Reset breaker by pressing in the button on the external connections panel located on the back of the unit. 2. If problem is not resolved, call the Organ Recovery Systems Perfusion Helpline.
Beeping or flashing LEDs	Errors detected internally by the LifePort.	Follow the instructions in the Error Messages Explanation section on page 50.
Missing or incorrect display elements at power-on	Failure of displays or internal computer	Call the Organ Recovery Systems Perfusion Helpline.
Leaking perfusate	Loose fitting or defective Perfusion Circuit (Cassette).	<ol style="list-style-type: none"> 1. Retighten all fittings. 2. Replace Perfusion Circuit (Cassette) if defective.
Leaking coolant	<ul style="list-style-type: none"> • Broken container or seal. • Perfusion Circuit (Cassette) Lids not tightened 	<ol style="list-style-type: none"> 1. Latch Lids and look for leaks. 2. If problem is not resolved, call the Organ Recovery Systems Perfusion Helpline.
Powers on, but buttons are unresponsive	<ul style="list-style-type: none"> • LifePort is internally locked-up. 	<ol style="list-style-type: none"> 1. Power OFF. 2. Disconnect external power supply. 3. Remove all batteries. 4. Wait 30 seconds. 5. Return batteries to the unit. 6. Power back ON. 7. If problem is not resolved, call the Organ Recovery Systems Perfusion Helpline.
Message Display is blank. (Unit functioning properly)	Electronic shock reset display	<ol style="list-style-type: none"> 1. Power OFF then back ON. 2. If problem is not resolved, call the Organ Recovery Systems Perfusion Helpline.

Error Message Explanations

The LifePort sounds audible alerts when it encounters out-of-range conditions for bubbles, pressure, flow, and temperature. The LifePort can recover from many of these errors and perfusion will automatically resume.

The LifePort enters a fail-safe mode if any unrecoverable fault condition is encountered. Scroll the message display to view all of the fault conditions. The error indicators will remain viewable until you clear them.

- To clear the indicators for errors, which are no longer valid, press the **MODE** button with the blinking LED.

Check the following list of error messages, observed problems, probable causes, and recommended actions. In most cases the audible alert can be cancelled or temporarily muted by pressing the **STOP** button.

Error Message	Observed Problem	Probable Cause	Actions
???? in battery status	Computer has lost communication with batteries		<ol style="list-style-type: none"> Operate LifePort connected to an external power supply. Call the Organ Recovery Systems Perfusion Helpline.
Bubbles	System becomes unable to remove air without user intervention.	Air is persisting in the upstream Bubble Detector	Check Perfusion Circuit (Cassette) for leaks and loose fittings.
Can't Reach Pressure	Pump cannot achieve the set arterial pressure	Leaking Cannula or artery	Visually inspect and correct all leaks under aseptic conditions.
		Leak in Perfusion Circuit (Cassette)	<ol style="list-style-type: none"> Tighten loose fittings. Replace circuit if leaking.
		Low resistance kidney	No action for maximum flow or reduce the set pressure.
		Clogged filter	Replace Perfusion Circuit (Cassette) or (if available) replace filter.
Check Filter	Filter may be clogged.		<ol style="list-style-type: none"> Filter is restricting flow. Call the Organ Recovery Systems Perfusion Helpline.
Check Ice	The Ice Container Temperature Sensor is reading above 8°C.		<ol style="list-style-type: none"> Replenish ice. Allow up to 15 minutes for the sensor to drop to the proper temperature if the system was warm prior to installing a filled Ice Container. If problem is not resolved, a sensor failure may exist. Call the Organ Recovery Systems Perfusion Helpline.

Error Message	Observed Problem	Probable Cause	Actions
Check Tubing	System is sensing unexpected conditions in the Perfusion Circuit (Cassette).	Tube frame not positioned properly	Check Tube frame and Locking Arm position.
		Kidney not connected	Visually inspect kidney and cannula, and correct all leaks under aseptic conditions.
		A pressure greater than 120% of the set pressure is persisting	Inspect pressure sensor and call the Organ Recovery Systems Helpline.
		Fluid pressure is not equalizing during non-infuse modes	Check for arterial and venous occlusions, check valves and call the Organ Recovery Systems Helpline.
High Resistance	System is measuring resistance above 3.00		Consult supervising physician.
Load Perfusion Circuit (Cassette)	The Tube frame is not properly installed		<ol style="list-style-type: none"> 1. Make sure that the Tube frame is properly installed and the Tube frame Locking Arm is in the correct position. 2. If problem is not resolved, a sensor failure may exist. Call the Organ Recovery Systems Perfusion Helpline
Low Battery	Only 4 hours of battery life remaining: 2 hours of infusion plus 2 hours of temperature monitoring.		Plug into external power supply or exchange for charged batteries.
Occlusion	System is sensing unexpected pressures during Infuse.	Blocked Infuse Line tubing or twisted or occluded artery	Find and remove blockage or untwist.
POST failure	An error occurred during the Power On Self Test (POST)		<ol style="list-style-type: none"> 1. Remove all power to the LifePort: <ol style="list-style-type: none"> a. Remove all four (4) LifePort batteries. b. Unplug the LifePort from mains power 2. Restore power to the LifePort <ol style="list-style-type: none"> a. Reinstall batteries b. Plug into mains power 3. If problem persists, note the message in the Display Screen and call the Organ Recovery Systems Perfusion Helpline. See list of POST test errors at the end of this section.
Pump Error	Pump is not responding normally.		Call the Organ Recovery Systems Perfusion Helpline.

Error Message	Observed Problem	Probable Cause	Actions
Sensor Error Connect Sensor Push STOP	System becomes unable to interact with pressure sensor properly.	The pressure sensor has become disconnected.	Reconnect pressure sensor.
		The LifePort is unable to set the overpressure alert setpoint	Call the Organ Recovery Systems Perfusion Helpline.
Setpoint Error	LifePort unable to set pressure alert levels.		<ol style="list-style-type: none"> 1. Press STOP to clear alert and enter Stop Mode. 2. Press INFUSE to re-enter Infuse Mode. 3. If problem is not resolved, call the Organ Recovery Systems Perfusion Helpline.
Near Freezing	The Ice Container Temperature Sensor is reading below 0.5 °C.	Incorrect coolant	Use ice slush made from ice and water.
		Environmental conditions too cold	<ol style="list-style-type: none"> 1. Move LifePort into a warmer environment. 2. If problem is not resolved, a sensor failure may exist. Call the Organ Recovery Systems Perfusion Helpline.
Too Much Pressure	Pressure Sensor is seeing higher than expected values.	High G forces are being created during transit.	<ol style="list-style-type: none"> 1. Cushion or reduce impact. 2. If problem is not resolved, a pump, valve, or sensor failure may exist. Call the Organ Recovery Systems Perfusion Helpline.

Power On Self Test (POST)

On Each power up, the LifePort performs a Power On Self Test or “POST”. The CPU within the LifePort checks its memory functions, temperature sensors, air Bubble Detectors and its internal failure routines. In the unlikely event that one of these tests fail, the LifePort will display **POST failure** and it will list the POST error message as shown in the table below. Should one of these errors occur, remove all power to the LifePort by reinstalling the batteries and the mains Power Cord. If the POST message continues to display, call the Organ Recovery Systems Perfusion Helpline.

POST Error Message	Indication
POST AT error	Ice Bucket temperature error
POST failure	Power On self test failed
POST Flash error	Integrity check of Flash memory
POST HPS error	High pressure shutdown error
POST IB error	Infusion Bubble Detector error
POST MD error	Motor drive error
POST MOC error	Motor overcurrent shutdown error
POST PS error	Pressure Sensor error
POST PT error	Perfusion temperature sensor error
POST RAM error	Integrity check of Read Only Memory
POST ROM error	Integrity check of Read Only Memory
POST UB error	Upstream Bubble Detector error
POST WD error	Watchdog error

Maintenance

Overview

The LifePort has no user serviceable parts.

Maintain, clean, and keep the LifePort ready to use according to directions in this manual. If the LifePort is not functioning properly refer to ***Troubleshooting and Diagnostics*** on page 49 or contact Organ Recovery Systems Perfusion Helpline.

Cleaning Up after a Case

The perfusate, Perfusion Circuit (Cassette), and cannula are single use devices and should be disposed of in accordance with local guidelines for biomedical waste.

The LifePort and Power Cord should return to home station where the LifePort can be cleaned with a 70% Isopropanol solution to remove perfusate residue.

Use Universal precautions when performing perfusate cleanup to prevent possible contact with bloodborne pathogens. Once home, the batteries should be recharged and the supply kits should be repacked in preparation for the next transplant.



CAUTION: Do not clean the LifePort with the external power supply connected.



CAUTION: Do not immerse the LifePort.



CAUTION: Do not allow cleaning solutions to enter the rear panel electrical connectors, the ventilation holes, or the battery area.



CAUTION: Ice Container and Lid is a re-usable part of the LifePort, which needs to be cleaned and dried after each case. This is not a single use item.

Storage

If the LifePort will not be used for several days or weeks, clean the device according to instructions provided in ***Cleaning Up After a Case*** on page 54 before storing. The LifePort should be stored indoors in a dry location out of direct sunlight.

For periods of storage for longer than 30 days, remove the batteries from the LifePort. Long periods of storage could damage the batteries.

Store the LifePort in a temperature-controlled space. The LifePort will operate normally after storage in conditions ranging from -15°C to 50°C, 0 to 90% humidity, and at a pressure of 700 to 1060 hecto-Pascal (hPa) (equivalent to an elevation of -380m to 3,000m or -1,250ft to 10,000ft).

Shipping by Common Carrier

If the LifePort requires shipping by common carrier, be sure to use the corrugated carton, with foam inserts — either the original carton or the carton containing the loaner — as provided by Organ Recovery Systems.

Follow instructions for packing that were provided with the loaner, or contact Organ Recovery Systems Perfusion Helpline for instructions.

Make sure the Ice Container is empty, with the Lid removed for shipment.

Specifications, Precautions, Limitations

Product Specifications

Description	Portable, self-contained renal preservation system, which utilizes hypothermic perfusion
Indications for Use	The LifePort is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, optional transportation, and eventual transplantation into a recipient.
Capacity	Single Kidney
Power Source	AC or battery Voltage – 110 to 240 VAC, Frequency – 50 to 60 Hz, current – 1 Amp
Coolant Source	Ice/water bath, 5-1/2 Liters
Perfusate Pump	Peristaltic pump
Pressure Control	Closed loop pressure regulation, 10 to 65 mmHg
Perfusion Modes	Pulsatile
Flow Rates	0 to 240 mL/min (maximum rates decrease by 25% when powered by batteries)
Dimensions	24" x 14.5" x 14.25" (61.0cm x 36.8cm x 36.2cm)
Approximate Weight	45 lbs (20.4 kg) fully loaded
Transport Duration	Up to 24 hours between ice replenishment and battery replacement (or recharge)
Batteries	Four x 11.1 V lithium-ion batteries
Battery Life	24 hours (fully charged)
Perfusate Used	Hypothermic machine perfusate
Data Download	Serial interface (RS 232) data download of all perfusion and status data collected since the point when the INFUSE state was begun following power on.
Storage Conditions	Temperature: -15°C to 50°C Humidity: 0 to 90% Pressure: 700 to 1060 hPa (equivalent to an elevation of -380 m to 3,000 m or 1250 ft to 10,000 ft)
Operating Conditions	Not to exceed 35°C on Mains Not to exceed 40°C on battery

Device Classifications

Medical Device	Class II	FDA listed device
	Class IIa	MEDDEV EU Directive 93/42 EEC
Type of protection from electric shock	Class I / Internally Powered	
Protection from water ingress	IPX1	The LifePort is protected from vertical water droplets
Cleaning recommendations	The LifePort can be cleaned with a 70% Isopropanol solution to remove perfusate residue and other detritus.	

Equipment is suitable for Continuous Operation



CAUTION: Equipment not suitable for use in presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Electromagnetic Compatibility



The LifePort needs special precautions regarding electromagnetic compatibility (EMC) and should be used in accordance with the EMC information provided in this manual.

This LifePort can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio or television reception. However, there is no guarantee that the interference will not occur in a particular installation. If the LifePort does cause interference, which can be determined by turning the LifePort on and off, try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna
- Increase the distance between LifePort and receiver
- Connect the LifePort to an outlet on a separate circuit from that to which the receiver is connected

Portable and mobile RF communications equipment can affect the LifePort.



WARNING: To assure compliance with EMC requirements, use only manufacturer-supplied cables:

Data Cable	Part # 20680
Power Cord	Part # 17664 (US only, contact Organ Recovery Systems for international power cord part numbers)



WARNING: Use of power cords or communications cables, other than those specified, may result in increased emissions or decreased immunity of the LifePort.



WARNING: The LifePort should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the LifePort should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC EMISSIONS

The LifePort is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePort should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment: Guidance
RF emissions CISPR11	Group 1	The LifePort uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class A	The LifePort is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC IMMUNITY


The LifePort is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePort should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LifePort requires continued operation during power mains interruptions, the LifePort can be powered from the internal battery.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

UT is the ac. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration — ELECTROMAGNETIC IMMUNITY

The LifePort is intended for use in the electromagnetic environment specified below. The customer or the user of the LifePort should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the LifePort, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $D = \left[\frac{3.5}{3} \right] \sqrt{P}$ $D = \left[\frac{3.5}{10} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $D = \left[\frac{7}{10} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>...where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifePort is used exceeds the applicable RF compliance level above, the LifePort should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LifePort.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the LifePort

The LifePort is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifePort can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifePort as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power or transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $D = \left[\frac{3.5}{3} \right] \sqrt{P}$	80 MHz to 800 MHz $D = \left[\frac{3.5}{10} \right] \sqrt{P}$	808 MHz to 2.5 GHz $D = \left[\frac{7}{10} \right] \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.69	1.11	2.21
100	11.67	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.


NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Operational Precautions and Limitations


The following information will affect the success in using the LifePort.

Should Be Used Only By Trained Professionals — Federal law restricts the sale of this device to physicians and medical professionals only. Use of the device in procedures other than those described in this manual may result in injury.

 **Do Not Reuse Perfusion Circuits (Cassettes) or Cannulas** — The Perfusion Circuits (Cassettes), tube-sets, and cannula are sterile as supplied, method of sterilization is ethylene oxide gas, and are intended for single-use. After use, they should be disposed of in accordance with local guidelines for biomedical waste.

Use Only Manufacturer-Approved Accessories — Only manufacturer-approved accessories (e.g., batteries, Perfusion Circuits (Cassettes), Power Cable, data cable) are designed to work properly with the LifePort. Do not substitute other batteries, Perfusion Circuits (Cassettes), cables, or accessories.

Use Only Ice and Water in the LifePort Ice Container — A mixture of ice and water in the Ice Container will assure that temperatures remain within the appropriate range for kidney preservation in the LifePort. To avoid inadvertently freezing the kidney, **ONLY USE ICE AND WATER** in the LifePort Ice Container.

 **Single Use Only Disposables** — All LifePort Disposable Accessories are intended for single use only.

 **Disposables Already Sterile** — All LifePort Disposable Accessories are sterile as supplied. Do not re-sterilize any LifePort Disposable Accessory.

Connect the System to an External Power Supply According to Labeling — The LifePort uses externally supplied electricity to operate. Check the voltage and amperage ratings of the external supplies and make sure they match the labeled ratings for electricity inputs shown on the rear of the LifePort.

Assure Adequate Ventilation — Do not block the ventilation areas on the side and bottom of the LifePort, especially when external power is connected.

Electromagnetic Compliance — The LifePort has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 18 of the FCC rules and to the Medical Device Directive 93/42/EEC, and to the Electromagnetic Compliance (EMC) Directive 89/336/EEC. These limits are designed to provide a reasonable protection against normal interference in a commercial or hospital setting.

The LifePort needs special precautions regarding EMC and should be used in accordance with the EMC information provided in this manual. Please refer to Electromagnetic Compatibility on page 84 for details.

Air Transport — Prior to beginning air transport, make sure that ice and battery levels are sufficient for entire transport duration. Do not connect the LifePort to an external electrical power source on a commercial aircraft. Do not connect the Data Cable to the LifePort during flight on a commercial aircraft.



CAUTION: All LifePort users should be familiar with Organ Recovery Systems kidney perfusion solution (KPS-1®). instructions for use (IFU).

Hazards

Overview

This section contains information on hazards involved in using the LifePort that can pose risk to the operator as well as to the environment — information that will affect clinician and staff safety when using the LifePort.



WARNING: Possible Explosion Hazard. Do not use the LifePort in the presence of flammable anesthetics. The LifePort is not designed for use in the presence of explosive mixtures of anesthetic gases with air, oxygen, or nitrous oxide. **USE ONLY IN SAFE ENVIRONMENTS.**



WARNING: Do not open the LifePort to service it. Shock hazard exists if Pump Deck is removed. All aspects of the LifePort that are meant to be attended by the operator are accessible without opening the device. If there is a service problem, please call the Organ Recovery Systems Perfusion Helpline.



WARNING: Beware of rotating parts. Keep hands, clothing, jewelry, ID lanyards, etc. away from the vicinity of the Infusion Pump when the LifePort is turned on.



WARNING: Unauthorized modifications to the LifePort Kidney Transporter will void the warranty and may damage the device and/or organ. This may also result in user being harmed.



CAUTION: Use Universal Precautions with the kidney and perfusate. The kidney and perfusate may carry undetected pathogens from the donor. Use proper precautions (e.g. gloves, masks, gowns, goggles or equivalent eye protection, biohazard bags) in handling the kidney, and in handling and disposing of the Perfusion Circuit (Cassettes) and perfusate to prevent the possible transmission of pathogens to medical personnel.



CAUTION: Do not clean the LifePort while connected to an external power supply.



CAUTION: Do not immerse the LifePort.



CAUTION: Do not allow cleaning solutions to enter the rear panel electrical connectors, the ventilation holes, or the battery area.



CAUTION: Use precautions when lifting. A fully loaded LifePort weighs 45 lbs (20.4 kg). Use proper lifting practices to avoid injury.



CAUTION: Local regulations must be followed for the disposal of the LifePort and lithium batteries. If in doubt, consult the Organ Recovery Systems Perfusion Helpline.



CAUTION: Use only grounded electrical connections. Connect the LifePort to a grounded electrical outlet rated for voltage and amperage according to the labeled ratings on the product back panel. If there is any question about the ground integrity, operate the LifePort from internal power.



CAUTION: You may remove mains power by unplugging the Power Cord from the back of the unit. Exercise care when choosing the location of your LifePort such that removal of Power Cord is not difficult.

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