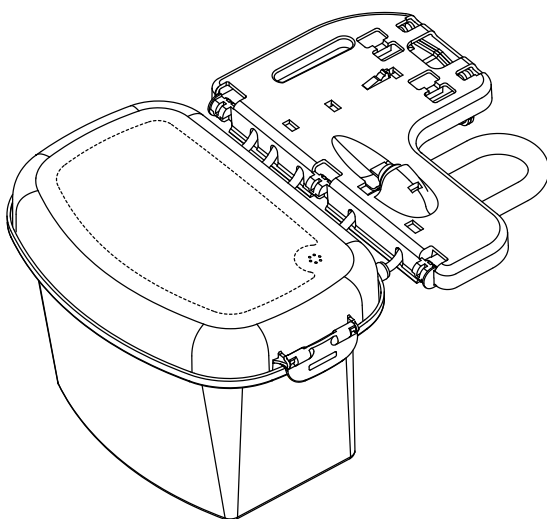




**Organ Recovery**  
systems

## **LifePort® Kidney Transporter Disposable Perfusion Circuit**



### **Instructions for Use**

LifePort Kidney Transporter Disposable Perfusion Circuit is for use only with LifePort Kidney Transporter system.

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**LKT201**

**INDICATIONS FOR USE**

LifePort Kidney Transporter (LKT) system is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, transportation, and eventual transplantation into a recipient.

**DEVICE DESCRIPTION**


LifePort Kidney Transporter Disposable Perfusion Circuit is used to contain the kidney and perfusate under aseptic conditions during transport.

The complete LifePort Kidney Transporter system is comprised of the following components:


- LifePort Kidney Transporter (LKT100P/LKT101P/LKT101PNG)
- LifePort Kidney Transporter Disposable Perfusion Circuit (LKT201/LKT201X)
- LifePort Kidney Transporter Disposable Sterile Drape (LKT300)
- LifePort Kidney Transporter Disposable Cannula (CAN/UCAN)

**INSTRUCTIONS FOR USE**


Prepare LifePort Kidney Transporter as described in the LifePort Kidney Transporter Operator's Manual. Prepare KPS-1®, Kidney Perfusion Solution in accordance to the Instructions for Use. Maintain perfusate at appropriate temperature, approximately 2–8°C.

 **WARNING:** Where noted, perform the following procedure on an aseptic field using aseptic technique.


1. *Using standard aseptic technique*, prepare a sterile field on a work table and introduce all necessary materials.
2. *Using standard aseptic technique*, remove LifePort Kidney Transporter Disposable Perfusion Circuit from the packaging.

 **WARNING:** Visually check LifePort Kidney Transporter Disposable Products before use. Do not use if parts are cracked, broken, or disconnected.


3. *Using standard aseptic technique*, remove Outer Perfusion Circuit Lid and Inner Perfusion Circuit Lid and place onto the sterile field.
4. *Using standard aseptic technique*, remove the Kidney Cradle and set aside within the sterile field.


 **CAUTION:** Verify the Uptake Line is within the Low Fluid Detection Chamber inside the Organ Chamber.

5. *Using standard aseptic technique*, fill LifePort Kidney Transporter Disposable Perfusion Circuit with 1 Liter chilled (2–8°C) perfusate.
6. *Using standard aseptic technique*, replace and secure Inner Perfusion Circuit Lid followed by the Outer Perfusion Circuit Lid.


 **WARNING:** LifePort Kidney Transporter Disposable Perfusion Circuit inner surfaces are considered sterile, while outer surfaces are not considered sterile.

7. Place LifePort Kidney Transporter Disposable Perfusion Circuit into LifePort Kidney Transporter.
8. Position the Tubeframe upright, perpendicular to the Pump Deck. Insert the hinges into the receivers before rotating flat onto the Pump Deck.
9. Open the Pumphead Raceway and stretch the Pump Tubing Loop around the Infusion Pump. Close and latch the Pumphead Raceway.
10. Rotate the Pump Deck Locking Arm 90 degrees until it clicks into place.
11. Connect the Pressure Sensor Cable from the Pump Deck to the Pressure Sensor Connector on the Tubeframe.


 **CONSULT INSTRUCTIONS FOR USE:** Follow the procedure outlined in LifePort Kidney Transporter Disposable Sterile Drape Instructions for Use to maintain aseptic conditions.

 **CONSULT INSTRUCTIONS FOR USE:** Follow the procedure outlined in LifePort Kidney Transporter Disposable Cannula Instructions for Use to cannulate and secure the kidney.


12. *Using standard aseptic technique*, transfer the cannulated kidney in the Kidney Cradle to LifePort Kidney Transporter, being careful to avoid catching the Infuse Line.

 **CONSULT INSTRUCTIONS FOR USE:** Follow the procedure in LifePort Kidney Transporter Operator's Manual to start the perfusion process and check for leaks.

13. *Using standard aseptic technique*, replace and secure Inner Perfusion Circuit Lid.

 **CONSULT INSTRUCTIONS FOR USE:** Follow the procedure in LifePort Kidney Transporter Disposable Sterile Drape Instructions for Use for removal from LifePort Kidney Transporter.

14. Replace and secure Outer Perfusion Circuit Lid.

 **CONSULT INSTRUCTIONS FOR USE:** Follow the procedure in LifePort Kidney Transporter Operator's Manual to continue the perfusion process.

### STORAGE CONDITIONS


Store between 2°C and 40°C. Avoid excessive heat and humidity. Keep dry and keep away from direct sunlight. Sterile unless package is damaged or open.


### CONTRAINDICATIONS


There are no known contraindications when used as directed.


### WARNINGS AND PRECAUTIONS


**R<sub>x</sub> Only** **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

 **CAUTION:** LifePort Kidney Transporter Disposable Products should be stored indoors in a dry location out of direct sunlight.

 **WARNING:** Visually check LifePort Kidney Transporter Disposable Products. Do not use if parts are cracked, broken, or disconnected.

 **WARNING:** For single use only. Do not reuse, reprocess, or resterilize. Reusing, reprocessing, or resterilization of single-use devices creates a potential risk of patient or user infections due to contamination. This contamination may lead to injury, illness, or other serious patient complications.












 **WARNING:** Use standard aseptic technique and universal precautions (e.g., gloves, masks, gowns, goggles or equivalent eye protection, biohazard bags) when handling the kidney, and when handling and disposing of LifePort Kidney Transporter Disposable Products and perfusate to prevent the possible transmission of pathogens to medical personnel and patients. The single practitioner, working alone must pay special attention to maintain these conditions.

 **WARNING:** Before the operator begins to apply the LifePort Kidney Transporter Disposable Sterile Drape, the Outer Perfusion Circuit Lid should be removed. The exterior surfaces of the Outer Perfusion Circuit Lid are not considered part of a sterile field. Use standard aseptic technique when handling the interior surface.

### TECHNICAL ASSISTANCE

Please contact Organ Recovery Systems 24/7 Perfusion Helpline at +1.866.682.4800 (toll free in US), +32.2.715.0005 (Belgium), +55.11.98638.0086 (Brazil), or +33.967.23.00.16 (France).

### EXPLANATION OF SYMBOLS

	Warning/Caution		Use By, YYYY-MM-DD		Temperature Limits
<b>LOT</b>	Lot Number		Date of Manufacture, YYYY-MM-DD		Consult Instructions for Use
<b>REF</b>	Reference Number		Manufacturer		Keep Away From Sunlight
	Do Not Reuse		Do Not Resterilize		Keep Dry
	Sterile Medical Devices Using Ethylene Oxide	<b>MD</b>	Medical Device	<b>R<sub>x</sub> Only</b>	Prescription Medical Device

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