



**Organ Recovery**  
systems

## **LifePort® Kidney Transporter Disposable Sterile Drape**

### **Instructions for Use**

LifePort Kidney Transporter Disposable Sterile Drape is for use only with LifePort Kidney Transporter system.



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**LKT300**

## 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 Sterile Drape is used to aid in maintaining aseptic conditions within LifePort Kidney Transporter Disposable Perfusion Circuit.

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 and LifePort Kidney Transporter Disposable Perfusion Circuit as described in their Instructions for Use.



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

1. A person outside the aseptic field, remove the Outer Perfusion Circuit Lid.
2. *Using standard aseptic technique*, carefully place LifePort Kidney Transporter Disposable Sterile Drape onto LifePort Kidney Transporter, lining up the drape gasket with the Organ Chamber.
3. *Using standard aseptic technique*, ensure the arrow on the orientation guide is pointing toward the Pump Deck.
4. *Using standard aseptic technique*, unfold LifePort Kidney Transporter Disposable Sterile Drape in the following order: **right**, **left**, **front**, and **back**. The drape gasket should fit securely around the Organ Chamber with the tabs snapping into place under the lid latches.
5. *Using standard aseptic technique*, unlatch and remove the Inner Perfusion Circuit Lid and place it facedown onto the sterile field.



**CONSULT INSTRUCTIONS FOR USE:** Before continuing to Step 6, follow the procedure outlined in LifePort Kidney Transporter Disposable Perfusion Circuit Instructions for Use.

6. *Using standard aseptic technique*, replace and secure Inner Perfusion Circuit Lid before removing LifePort Kidney Transporter Disposable Sterile Drape.
7. *Using standard aseptic technique*, remove LifePort Kidney Transporter Disposable Sterile Drape carefully to maintain aseptic conditions of the Inner Perfusion Circuit Lid by either lifting LifePort Kidney Transporter Disposable Sterile Drape up and away from the sterile field or by cutting away LifePort Kidney Transporter Disposable Sterile Drape.
8. 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.

**INTENDED USE**

LifePort Kidney Transporter (LKT) system is intended to be used for the continuous hypothermic machine perfusion of kidneys.

**TARGET POPULATION**

The targeted populations are both adults and pediatrics.

The intended patient population for machine preserved kidneys are kidney transplant-eligible patients under the care of a licensed kidney transplant surgeon. The patient, however, does not come in contact with LifePort Kidney Transporter system.

**INTENDED USER**

Primary users of LifePort Kidney Transporter system will be medical professionals who have been trained to operate LifePort Kidney Transporter system. It is expected that users of LifePort Kidney Transporter system will also have a substantive working knowledge and clinical experience with donor organ recovery and transplantation.

**CLINICAL BENEFIT**

Hypothermic machine perfusion of kidneys using LifePort Kidney Transporter system with KPS-1 Kidney Perfusion Solution has been demonstrated through clinical evidence to improve kidney function post transplantation by reducing delayed graft function.

**DEVICE PERFORMANCE/PERFORMANCE CHARACTERISTICS**

The LifePort Kidney Transporter system is intended to be used with KPS-1 Kidney Perfusion Solution to provide continuous hypothermic machine perfusion of kidneys for the preservation, transportation and eventual transplantation into a recipient. The device maintains the organ in a cool, aseptic container during perfusion and transport to achieve this function.

**RESIDUAL RISK**

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended users, there are no known side effects that can occur during or after use and thus no residual risk is associated with use of LifePort Kidney Transporter.

**SERIOUS INCIDENT REPORTING**

User should report the occurrence of any serious incident to Organ Recovery Systems and to the competent authority of the Member state in which the user and / or patient is established.

**CONTRAINDICATIONS**

There are no known contraindications when used as directed.

**DEVICE LIFETIME**

LifePort Kidney Transporter Sterile Drape is a single use, disposable device. The sterile shelf life of the unopened device is 3 years, based on the available test data.

**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.

**TECHNICAL ASSISTANCE**

Please contact Organ Recovery Systems 24/7 Perfusion Helpline at +866.682.4800 (toll free in US), +32.2.715.0005 (Belgium), +1.352.721.5301 (Central and South America), or +33.9.6723.0016 (France).

**WARNINGS AND PRECAUTIONS**

**R<sub>Only</sub>** **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:** 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.

**EXPLANATION OF SYMBOLS**

	Warning/Caution		Use By, YYYY-MM-DD		Temperature Limits
	Lot Number		Date of Manufacture, YYYY-MM-DD		Consult Instructions for Use
	Reference Number		Manufacturer		Keep Away From Sunlight
	Do Not Reuse		Do Not Resterilize		Keep Dry
	Sterile Medical Devices Using Ethylene Oxide		Medical Device		Prescription Medical Device
	Country of Origin		Importer		Single Sterile Barrier System
	Do not use if package is damaged and consult instructions for use.				

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