




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.

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_{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:** 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 +33.9.6723.0016 (France).

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

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