LifePort Kidney Perfusion Reference Guide

Step by Step Perfusion Guide
and Alert Guide
## LifePort Kidney Transporter Use Steps

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Prepare the device

- Step 1: Remember to bring necessary supplies
  - One Perfusion Circuit per kidney plus one spare
  - One 1 Liter bag KPS-1, per kidney, cooled ideally to 3°C - 6°C, plus one spare
  - Set of all types/sizes of cannula (at least two/type)
  - One additional drape per kidney (for removing kidney after perfusing)
Prepare the device

Step 2: Prepare Ice Container

A. Load ice

B. Press to compact ice

C. Load more ice

D. Add water

E. Top with ice

F. Add more water

G. Replace Ice Container Lid

- Use crushed ice (3kg) and cold water (between 1.5 - 2 Liters)
- Use small amount of ice at first to be able to push into hollow sides
- Push the ice as far as you can throughout interior. Press to compress.
- Well-packed ice is important for 24-hour autonomy
Prepare the device

Step 3: *Using aseptic technique (not scrubbed)*, open Perfusion Circuit

Step 4: *Using aseptic technique (scrubbed)*, remove Perfusion Circuit from tray and unpack components.

Circulating nurse leaves Perfusion Circuit on sterile table after unpacking it from outer packaging.

Scrubbed nurse (or surgeon) removes Perfusion Circuit from tray and removes white banding.

Scrubbed nurse (or surgeon) removes outer lid from Perfusion Circuit, then inner lid, then takes out the kidney cradle.
Prepare the device

Step 5: *Using aseptic technique (not scrubbed)*, add KPS-1®.

- Circulating nurse connects dispensing line to KPS-1 bag.
- KPS-1 is poured into Perfusion Circuit (Organ Chamber).

Step 6: *Using aseptic technique (scrubbed)*, replace Inner and Outer Perfusion Circuit Lids.

- Surgeon/scrubbed nurse closes both inner and outer lids of the Perfusion Circuit. (Note that the KPS-1 is in the chamber.)
Prepare the device

Step 7: *Using aseptic technique*, hand over Perfusion Circuit. **Note:** Exterior is no longer sterile.
Prepare the device

Step 8: Place the Perfusion Circuit into the Ice Container well. Snap the Tubeframe into place at 90° angle.

Step 9: Install the Tubeframe onto the LifePort Kidney Transporter.

After Tubeframe is securely snapped into place, rotate it downward toward the Pump Deck. Open Pumphead Raceway.

Stretch the pump tube around the Pumphead Raceway.

Close Pumphead Raceway and secure with Spring Latch Arm.
Prepare the device

Step 10: Secure the Tubeframe onto the Pump Deck.

Close Tubeframe Locking Arm, until it ‘clicks’.

Step 11: Connect the Pressure Sensor Cable.

Extend the screw until it can be moved over the connector

Once in place over the connector, rotate screw ¼ turn
Initialize LifePort Kidney Transporter

Step 12: Power on LifePort Kidney Transporter.

**IMPORTANT**: Turn LifePort Kidney Transporter on *only after* installing Perfusion Circuit.
Initialize LifePort Kidney Transporter

Step 13: Delete oldest case from memory if requested. (Press STOP to erase data file.)

Step 14: Check temperature and ready status. Temperature must be below 8°C.
Initialize LifePort Kidney Transporter

Step 15: Press WASH to remove air from Perfusion Circuit.

Step 16: Gently lift LifePort Kidney Transporter and “rock-and roll” to remove all air from filter and Bubble Trap.
Initialize LifePort Kidney Transporter

Step 17: Add donor and kidney data using the 5-way keypad. Keep in WASH mode until kidney is ready for connection to LifePort Kidney Transporter. (Organ ID should be entered before pressing INFUSE.)
Initialize LifePort Kidney Transporter

Step 18: Close LifePort Kidney Transporter Cover and latch to preserve temperature until kidney is ready.
Prepare the kidney: Introduction

- Ideally, leave a sufficient patch

- Use the cannulation decision trees to choose a cannula (following pages)
Cannula Decision Tree

2 arteries

Do you have one artery or two?

See next page

1 artery

Patch

Do you have a patch or no patch?

Use the following cannula, based on the diameter of the vessel

- SealRing Cannula, 7x20
- SealRing Cannula, 10x35
- Universal SealRing Cannula, 3mm
- Universal SealRing Cannula, 5mm
- Universal SealRing Cannula, 7mm
- Universal SealRing Cannula, 9mm

No patch or small patch

Use the following cannula, based on the diameter of the vessel

- Straight Cannula, 3mm
- Straight Cannula, 5mm
- Straight Cannula, 8mm
- Universal SealRing Cannula, 3mm
- Universal SealRing Cannula, 5mm
- Universal SealRing Cannula, 7mm
- Universal SealRing Cannula, 9mm
Cannula Decision Tree

If there are two arteries, what is the distance between them?

< 3cm
- Use the following cannula, based on the diameter of the vessel
  - SealRing Cannula, 7x20
  - SealRing Cannula, 10x35
- Treat each artery as a single. Refer to prior page and use the appropriate cannula based on the anatomy and diameter of the vessel/s
  - Straight Cannula, 3mm
  - Straight Cannula, 5mm
  - Straight Cannula, 8mm
  - Universal SealRing Cannula, 3mm
  - Universal SealRing Cannula, 5mm
  - Universal SealRing Cannula, 7mm
  - Universal SealRing Cannula, 9mm
  - SealRing Cannula, 7x20
  - SealRing Cannula, 10x35

> 3cm
- If cut
  - Two options: Cut the patch in two OR keep the patch intact
  - Connect cannula with a coupler before perfusing.
    (Connect one cannula to LifePort Kidney Transporter and the Coupler; connect the other cannula to the Coupler and seal off the other end)
    - Straight Cannula, 3mm
    - Straight Cannula, 5mm
    - Straight Cannula, 8mm
    - Universal SealRing Cannula, 3mm
    - Universal SealRing Cannula, 5mm
    - Universal SealRing Cannula, 7mm
    - Universal SealRing Cannula, 9mm
  - If not cut
    - Use 2 Straight cannula or 2 Universal SealRing cannula or one of each based on anatomy.
    - SealRing Cannula, 7x20
    - SealRing Cannula, 10x35
Prepare the kidney: Option A, SealRing Cannula

Step 19, Option A: If aortic patch is present, cannulate using SealRing cannula (sizes 7x20, 10x35)

Cover plastic opening of cannula leaving no space for leakage.
Prepare the kidney: Option A, SealRing Cannula

Step 19, Option A (continued): Close the cannula without moving the patch – keep close to the kidney. Clamp in place using the flexible straps.

Clamp to ensure that cannula fits snugly and there are no leaks.

Optionally, you may use a syringe to check for leakage if desired after cannula is closed (first remove cap and air from cannula).
Prepare the kidney: Option B, Straight Cannula

Step 19, Option B: If aortic patch is not present, cannulate using the Straight cannula (sizes 3mm, 5mm, 8mm)

Note ridge in cannula
Prepare the kidney: Option B, Straight Cannula

Step 19, Option B (continued): Place cannula in renal artery – be careful of any atherosclerotic plaques at the orifice.

Artery with no aortic patch

Place tie in ridge of cannula.

Alternative option: Attach cannula to renal artery with vessel loop or other atraumatic tie.
Prepare the kidney: Option C, Universal SealRing Cannula

Step 19, Option C: Use Universal SealRing Cannula for either ‘patch’ or ‘no patch’ situations (sizes 3mm, 5mm, 7mm, 9mm)
Step 19, Option C (continued): To use the Universal SealRing Cannula with an aortic patch, thread the artery through the cannula, then fold the cannula gasket gently over the orifice.

View the vessel

Open the SealRing and position the vessel inside the ring

Close the ring around the vessel. Lower the seal, bringing it to rest inside the vessel opening. Secure with straps. Use sight glass to verify vessel is in place and not occluded.
Prepare the kidney: Option C, Universal SealRing Cannula

Step 19, Option C (continued): To use the Universal SealRing Cannula with no patch, thread the artery through the cannula, then close the cannula gasket gently over the orifice.

View the vessel

Open the SealRing and position the vessel inside the ring

Close the ring around the vessel. Lower the seal, bringing it to rest inside the vessel opening. Secure with straps. Use sight glass to verify vessel is in place and not occluded.
Prepare the kidney: Option C, Universal SealRing Cannula

Step 19, Option C (continued): Once the cannula is in place, you may test closure seal with a syringe (optional).
Prepare the kidney: Option D, Coupler

Step 19, Option D: If there are multiple arteries, use a Coupler to join multiple cannula

Note two cannula and a coupler
Prepare the kidney

Step 20: Place cannulated kidney into cradle

- Place kidney into cradle
- Place cannula in Cannula Mount
- Secure Mesh Organ Restraint
- **Note:** Install artery straight and with vein on top so that effluent can be seen after infusion starts. Click in one side of the cannula only, so that air can be removed later. (See Step 24.)
Transfer kidney to LifePort Kidney Transporter

Step 21: *Using aseptic technique (not scrubbed)*, remove non-sterile Outer Perfusion Circuit Lid

Step 22: *Using aseptic technique (scrubbed)*, unfold the Sterile Drape (included in LifePort Perfusion Kit), creating a sterile field.

Unfold drape in step by step fashion as shown or, alternatively unfold drape completely before laying on top of device.
Transfer kidney to LifePort Kidney Transporter


Place cradle inside cassette.
Connect kidney and start perfusion

Step 24: *Using aseptic technique (scrubbed)*, install one side of cannula on cannula support, leaving cannula inclined. Connect Infuse Line to cannula.

NOTE: Leaving cannula on an angle helps to remove air during the PRIME mode.
Connect kidney and start perfusion

Step 25: *Using aseptic technique (scrubbed)*, remove cannula End Cap and press PRIME button to de-air final section of tubing + cannula.

Step 26: *Using aseptic technique (scrubbed)*, replace the End Cap to close the Perfusion Circuit. The LifePort Kidney Transporter should automatically stop and ‘beep’ because it will sense high pressure. Press STOP to clear the message.

NOTE: If pump does not automatically Stop and Beep, it means there is a leak!
Connect kidney and start perfusion

Step 27: *Using aseptic technique (scrubbed)*, start to infuse the kidney.

Press the UP/DOWN arrow button to choose pumping pressure (default is 30mmHg).

Then start to perfuse the kidney by pressing INFUSE. Case recording will begin.
What to do after perfusion begins

Step 28: Check that the artery is straight (no kinks, twists or occlusions) and the vein is positioned on top of the organ.

Adjust the height of the Cannula Mount, if required, and/or rotate the cannula to assure no kinks, twists or occlusions. Liquid must be able to freely pass through the vasculature, but perfusionist should avoid placing too much tension on the artery.

Step 29: Check that pressure is achieved.
What to do after perfusion begins

Step 30: Do a visual inspection.

• Look for leaks around the gasket
• Is the artery filling
• Are the side branches closed
• Are there expected amounts of fluid exiting the kidney
• Is the color of the kidney becoming blanched, as expected
What to do after perfusion begins

Step 31: *Using aseptic technique (scrubbed)*, close the Inner Perfusion Circuit Lid.

Step 32: *Using aseptic technique (scrubbed)*, remove drape *(scrubbed)*; replace Outer Perfusion Circuit Lid *(not scrubbed)*

Remove drape without touching Inner Perfusion Circuit Lid

Replace Outer Perfusion Circuit Lid – non sterile
What to do after perfusion begins

Step 33: *Using aseptic technique (not scrubbed)*, close and latch LifePort Kidney Transporter Cover.

Optionally, attach a tag or easily removable label on the exterior of the pump for identification purposes. **Do not make any marks on the LifePort unit itself.**

LifePort Kidney Transporter is designed for unattended use, with no need for continuous monitoring.
Checklist for Transporting LifePort

- Check ice (replenish if needed)
- Check batteries
- Add extra drape
- Power cord
- Contact details
- Crossmatch samples
- Donor paperwork
- Shipping information
LifePort Kidney Transporter Cover

Retractable handle storage

Storage for power cable & extra battery

Sealable crossmatch specimen compartment

Shipping documents

Access to batteries & power
Removing kidney from LifePort Kidney Transporter

Step 34: *Using aseptic technique (not scrubbed)*, unlatch and remove LifePort Kidney Transporter Cover.

Step 35: *Using aseptic technique (not scrubbed)*, power off and begin removing kidney.

Power off LifePort Kidney Transporter. Remove Outer Perfusion Circuit Lid.
Removing kidney from LifePort Kidney Transporter

Step 36: *Using aseptic technique (scrubbed)*, place sterile drape over LifePort Kidney Transporter, creating a sterile field.

Step 37: *Using aseptic technique (scrubbed)*, continue to remove kidney from cassette.

- Open Inner Perfusion Circuit Lid.
- Disengage Pump Tubing from cannula.
Removing kidney from LifePort Kidney Transporter

Step 38: *Using aseptic technique (scrubbed)*, finish removing kidney from cassette.

Lift Organ Cradle from Perfusion Circuit, draining excess fluid.

Place on sterile field. Unhook Mesh Organ Restraint.

Detach and remove cannula.
Removing Perfusion Circuit from LifePort Kidney Transporter after a case

Step 39: *Using aseptic technique (scrubbed)*, remove drape and discard appropriately.

NOTE: One may take a perfusate sample for culturing before disposing the Perfusion Circuit if desired.

Step 40: *Using aseptic technique (not scrubbed)*, begin removing Perfusion Circuit.

Unscrew the Pressure Sensor Cable.

Unlatch the Pumphead Raceway using the Spring Latch Arm.
Removing Perfusion Circuit from LifePort Kidney Transporter after a case

Step 41: *Using aseptic technique (not scrubbed)*, disconnect Pump Tube.

- Open Pumphead Raceway.
- Remove the Pump Tube from around the Pumphead Raceway.

Step 42: Unlatch the Tubeframe Locking Arm by turning it 90°.

- Turn the locking arm 90 degrees to unlock - until it can slide though the opening in the Perfusion Circuit.
Removing Perfusion Circuit from LifePort Kidney Transporter after a case

Step 43: Rotate the Tubeframe to 90° and lift the Tubeframe off the Pump Deck. Discard appropriately.

Note that locking arm slides through cut-out in perfusion circuit.
After a case

Step 44: Discard all disposable materials and biohazard waste in an appropriate manner. The perfusate, Perfusion Circuit and cannula are single use devices and should go into medical waste disposal. Clean LifePort Kidney Transporter between cases according to LifePort Kidney Transporter 1.1 Operator’s Manual.

Step 45: Clean LifePort Kidney Transporter between cases according to LifePort Kidney Transporter 1.1 Operator’s Manual.

NOTE: User may choose to leave lid and ice container slightly open between cases to ventilate.
LifePort Kidney Transporter Alerts
## Types of Alerts

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**NOTE:**

- Alerts are often solved with common sense. Most often related to
- Detailed overviews, probable causes, corrective actions listed in LifePort Kidney Transporter 1.1 Operator’s Manual
- Do not hesitate to call the Helpline if questions: _______________
Temperature related alerts

- TEMPERATURE related alerts are the most important to address in a timely fashion
- “Check Ice” alert will appear when temperature is between 5°C and 8°C
  - YELLOW ALERT
- To correct, replenish the ice
  - Press screen toggle button to clear

Do not hesitate to call the Helpline if questions.
Temperature related alerts

- “Too Warm Add Ice” alert will appear when temperature is >8°C
  - RED ALERT - requires immediate intervention
  - LifePort stops completely
- To correct, CHANGE ICE ASAP
  - Press Stop to clear after temperature has dropped < 8°C
  - Press Infuse

Do not hesitate to call the Helpline if questions.
Temperature related alerts

- “Too Cold” indicates a temperature < 0.5°C
  - YELLOW ALERT
- To correct, move device to a warmer environment

Note: Never put Ice Container in freezer. Only use ice and water mixture.

Do not hesitate to call the Helpline if questions.
Temperature related alerts

- “Near Freezing” alert indicates a temperature $< 0.1^\circ \text{C}$
  - RED ALERT - requires immediate intervention
- To correct, pour a little room-temperature water into the ice container and move device to a warmer environment

Do not hesitate to call the Helpline if questions.
Installation related alerts

- “Load Perfusion Circuit” alert will appear if the Tubeframe has not been installed correctly
- To correct, make sure Tubeframe fits nicely into hinges and Tubeframe Locking Arm has been rotated 90°

Do not hesitate to call the Helpline if questions.
Installation related alerts

- “Connect Pressure Sensor” or “Pressure Sensor Failure” alerts appear when the device is not able to detect the pressure sensor.
- To correct, switch off LifePort Kidney Transporter, re-install Perfusion Circuit and connect pressure sensor cable before powering the LifePort Kidney Transporter again.

Note: Make sure the Perfusion Circuit is installed and the pressure sensor is connected before powering on LifePort Kidney Transporter.

Do not hesitate to call the Helpline if questions.
Low resistance alerts

• “Kidney Not Connected” may appear when the device detects low resistance/high flow

• To correct, check for
  • Tubeframe not installed properly
  • Small leakages at cannula, artery or Perfusion Circuit
    • Cannula - recannulate
    • Lateral branch - close
    • Biopsy site - close
    • Wash line - reinstall Perfusion Circuit

Do not hesitate to call the Helpline if questions.
Low resistance alerts

- Alert may read “Cannot Reach Pressure” when the device detects low resistance/high flow
- To correct, check for
  - small leakages at cannula, artery or Perfusion Circuit
    - Cannula - recannulate
    - Lateral branch - close
    - Biopsy site - close
    - Wash line - reinstall Perfusion Circuit
  - If no leak
    - Artery filled during perfusion?
    - Liquid coming out of vein?
- If none of the above work, lower the set pressure
  - Press STOP and reduce pressure by 5mmHG using the arrow keys; press INFUSE to re-start perfusion.

Do not hesitate to call the Helpline if questions.
High resistance alerts

- Alert may read “High Resistance”
- To correct, check for
  - Perfusion Circuit properly installed?
  - Twists/kinks in artery?
  - Vein on top?
  - Intake line is not occluded?
  - Early in perfusion process (kidney is “tight”)?
- If still high after 1 hour, check other donor data

Do not hesitate to call the Helpline if questions.
High resistance alerts

• “Kidney High Resistance” alert may appear if high resistance is detected.
• To correct
  • Loosen Mesh Organ Restraint
  • Check for kinks or twists, adjust Cannula Mount
  • Check for possibility of clots
  • Position vein on top
  • Make sure Intake line is not occluded
  • Make sure Perfusion Circuit is installed correctly
  • Restart perfusion once or twice to see if kidney opens up
• Report parameters to supervising physician

Note: If early in the perfusion process, kidney may be “tight” until vasculature opens up a bit. User might wait to see if kidney opens up and may want to check donor history.
High resistance alerts

• “Too Much Pressure” alert may appear if high resistance is detected.
• To correct
  • Check for venous, arterial occlusions
  • Check for proper valve function in wash and Infuse Lines

NOTE: “Too Much Pressure” usually happens when the system is sensing a sudden pressure peak - to be expected when replacing cap during Prime Mode.

Do not hesitate to call the Helpline if questions.
Bubble alerts

• “Purging Bubbles” alert will appear if LifePort Kidney Transporter has detected air in first Bubble Detector and begins to purge bubbles automatically through the Wash Line. (There is no risk that air will enter renal artery.)
• To correct
  • Let LifePort Kidney Transporter complete the cycle. Every 10 minutes, LifePort Kidney Transporter performs a hygienic Wash cycle for 10 seconds
  • Tilting LifePort Kidney Transporter toward you during WASH Mode to guide air out of filter will limit air being released from filter later on
  • If cycle continues much beyond 15 seconds, press STOP, repeat rock-’n’-roll movement, press INFUSE

Do not hesitate to call the Helpline if questions.
Bubble alerts

- “Bubbles in Infuse Line” alert will appear if LifePort Kidney Transporter has detected air in second Bubble Detector. “Bubbles in Infuse Line” will stop the device.
  - RED ALERT - requires immediate intervention
- To correct
  - Check Perfusion circuit for leaks and/or loose fittings
  - Open Perfusion Circuit (STERILE)
  - Open cannula (STERILE)
  - Press PRIME – wait until bubbles are gone
  - Press INFUSE
  - Infuse Line has to be de-aired via PRIME mode after cannula cap has been removed under sterile conditions
  - DO NOT USE PRIME MODE without removing cannula cap first

![Bubbles in Infuse Line alert on LifePort device](image-url)
Battery related alerts

• “Low Battery” alert will appear if the batteries are running low. “Low Battery” indicates that only 4 hours of battery life are remaining: two for infusion and two for temperature recording

• To Correct
  • Charge the Lifeport, plug in the device into external power supply, or change batteries

Do not hesitate to call the Helpline if questions.
Battery related alerts

• “Shutdown Low Battery” alert will appear before LifePort shuts down completely
• To correct
  • Plug LifePort Kidney Transporter into external power supply or exchange batteries

  **Note:** Might take up to 5 hours to fully recharge batteries

Do not hesitate to call the Helpline if questions.
Memory related alerts

- Alert may read “Ready to erase file” if there is no room to store a new file.
- To correct
  - Press STOP. Oldest case will be deleted from LifePort Kidney Transporter’s internal memory.

NOTE: LifePort Kidney Transporter can save up to 5 cases in its internal memory. If 5 cases are stored in the device, you must remove one to free up memory space to start another.
Perfusion Helpline service

- Call if in doubt or have any clinical or technical question
- Call handled by experienced perfusionists
- Multiple languages: English, Spanish, Portuguese, French, and Dutch

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<thead>
<tr>
<th>Geography</th>
<th>Telephone</th>
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<tbody>
<tr>
<td>North America</td>
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<tr>
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<tr>
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<td>+33 9 67 23 00 16</td>
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<tr>
<td>Spain</td>
<td>+34 910 911 616</td>
</tr>
</tbody>
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LifePort Kidney Transporter Maintenance, Service and Support
LifePort Kidney Transporter maintenance

- Remember to use sterile drape to both place the kidney in the LifePort Kidney Transporter and remove kidney from Perfusion Circuit.
  - This maintains aseptic conditions as well as avoids any spilling of perfusion fluids on Pump Deck.
- Be sure to discard used KPS-1® solution and disposable Perfusion Circuit in the appropriate manner after every use.
- LifePort Kidney Transporter can be cleaned with a 70% isopropanol solution after each case.
- LifePort Kidney Transporter requires no preventive maintenance.
- Keep LifePort Kidney Transporter plugged in when stored to prevent batteries from draining.
- Annual LifePort Kidney Transporter inspection available upon request.
LifePort Kidney Transporter warranty

- Warranty covers manufacturers defects for two years
  - Covers any malfunction which would be observed during correct use of the device for the first two years after installation
- Warranty does not cover any malfunction as result of malpractice
- Warranty does not cover any accidental damage
What to do if LifePort does not seem to be functioning as it should

- CALL THE HELPLINE. Help is available 24/7.

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<thead>
<tr>
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<tr>
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</table>
Service and support for repairs

• In order to be eligible for product replacement, ALWAYS contact Organ Recovery Systems Perfusion Helpline DURING the case. Our experienced perfusionists will be able to discriminate product defects from user errors.

• Customers must keep any defective pieces and return to ORS for a replacement.

• If you have a LifePort Kidney Transporter or disposable that needs repair, follow the Organ Recovery Systems Product Return Process
  • To start the process, fill out a Product Return Report form and send it to Organ Recovery Systems
Service and support for repairs

- LifePort Kidney Transporter Loaner units are available and shipped from the closest Organ Recovery Systems company office
- Next day delivery for customers with Protection Plan
- Without Protection Plan, fees for repair and use of loaner are charged per incident
LifePort Kidney Transporter Protection Plan

- Recommended insurance plan for entire LifePort Kidney Transporter fleet covering up to a fixed number of incidents during a 12 month timeframe
- Covers costs for spare parts and labor after accidental damage
- Includes free use of loaner device until center’s unit has been repaired
- Excludes theft or loss; excludes damage resulting from deliberate malpractice (e.g. not using drapes)
Person who assembles the reference notebooks should insert here the 1-page guides:
1- Perfusion on LifePort
2- How to fill the ice container
3- How to add ice
4- How to remove a kidney