PARAGONIX®

# Paragonix LUNGguard®

## INSTRUCTIONS

**Paragonix LUNGguard®**
**Part # 108, L-079 Ver. 11**
**Issue Date: 04APR2025**
For technical assistance:
Paragonix Technologies, Inc.®
950 Winter Street, North
Waltham, MA 02451
USA
support@paragonixtechnologies.com
+1.781.428.4828
www.paragonixtechnologies.com/indications-of-use

Patents: paragonixtechnologies.com/patents/

Caution: Federal (US) law restricts this device to sale by or on the order of a licensed healthcare practitioner

MD

EU REP
CE 2797
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany
+49.511.6262.8630

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# 1 INDICATIONS FOR USE

The Paragonix LUNGguard® (LUNGguard®) is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the lungs.

The intended organ storage time for LUNGguard® is up to 8 hours.

Donor lungs exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.
Note: Partial lungs can be transported via LUNGguard® by packaging lungs per institutional protocol and UNOS guidelines.

## 1.1 WARRANTY STATEMENT

**Paragonix Technologies, Inc. (Paragonix®) warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling and storage of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Paragonix's control directly affect the device and the results obtained from its use. Paragonix's obligation under this warranty is limited to the repair or replacement of this device and Paragonix shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. Paragonix does not authorize any other person to assume for it any other or additional liability or responsibility in connection with this device. Paragonix assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.**

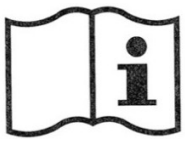
# 2 SAFETY REQUIREMENTS

⚠ **Caution:** Donor lungs exceeding 8 hours static hypothermic preservation time will require transplant surgeon evaluation to determine transplantability.

Should any serious incident occur in relation to the device, please contact Paragonix and the appropriate regulatory authority in the county of use where the incident occurred. Paragonix can be reached via your local sales rep or contacted via:

email: support@paragonixtechnologies.com
telephone: +1.781.428.4828

## 2.1 IMPORTANT INFORMATION



**It is important that all personnel who will operate LUNGguard® read and understand these instructions for use before operating the device**. All personnel should follow all warnings and precautions outlined below, for their safety and the safety of those around them.

LUNGguard® is a device for use by hospitals that perform lung recovery procedures to store and transport donor lungs to the transplant facility. LUNGguard® is for use within acute care facilities that have an existing agreement with an Organ Procurement Organization (OPO) requiring the hospital to notify the OPO or third party designated by the OPO in a timely manner about all deaths and imminent deaths that occur in the hospital. Such hospitals must also have documented protocols and procedures for determining death or imminent death, obtaining family consent, and trained personnel with fully equipped surgical recovery operating rooms to perform the recovery procedure. The facility must also be able to provide Advanced Lung Life Support, should that be required.

## 2.2 SYMBOL DEFINITIONS

**Table 1: Symbols used in the labeling of LUNGguard® and their definitions.**

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
|  | Use by YYYY-MM-DD |  | Fragile, handle with care |
|  | Do not reuse |  | Keep Dry |
|  | Do not use if package is damaged or open |  | Temperature limits |
|  | Indicates the need to consult the instructions for use |  | Pressure limits |
| LOT | Batch code |  | Humidity limits |
|  | Caution, consult accompanying documents | UDI | Unique Device Identifier |
|  | Manufacturer | SN | Serial Number |
| MD | Medical Device | # | Model Number |
| NON STERILE | Device or device component is non-sterile | CC | Country of Manufacture |
| STERILE R | Sterilized using irradiation |  | Date of Manufacture |
| CH REP | Indicates the Swiss authorized representative | EU REP | Indicates the authorized representative in the EU |
|  | Indicates European Importer | | |

## 2.3 WARNINGS ⚠

- **Caution: Federal (US) law restricts this device to sale by or on the order of a physician.**
- **Use aseptic technique as appropriate.**
- **Chilled (4°C) preservation solution, cleared for use with the lungs, must be available**.

| | |
|---|---|
|  | ⚠ Do NOT reuse any component of LUNGguard®. LUNGguard® is intended for single use only. DO NOT RE-USE. Re-use of the device may result in infection and other complications due to the loss of sterility. Certain components of LUNGguard® are sterile as supplied (sterilization method is gamma irradiation). LUNGguard® should be disposed of in accordance with local guidelines for biomedical waste. |

- **Use institution-specific precautions with the donor lungs and preservation solution when operating LUNGguard®.**
  The lungs and preservation solution may carry undetected pathogens from the donor. Use universal precautions for bloodborne pathogens in handling the lungs, and in handling and disposing of LUNGguard® and preservation solution to prevent the possible transmission of pathogens to personnel. As appropriate, this may include use of personal protective equipment (e.g. gloves, masks, gowns, goggles or equivalent eye protection) and disposal of materials as potentially infectious biohazard waste.
- **Prior to use, inspect all components of LUNGguard®. Do not use if any component is loose, broken or damaged.**
- **Do not open LUNGguard® during organ transport.**
- **No modification of LUNGguard® is allowed.**

## 2.4 OPERATING CONDITIONS ⚠

- **Operating Temperature: 22°C**
  Recommended Operating Room temperature is 22°C. Direct sunlight and outdoor temperature extremes (high and low) can affect LUNGguard® internal temperature (4 to 8°C). During exposure to temperature extremes, LUNGguard® temperature must be frequently monitored.

- **Operating Pressure: Sea Level to 8000 ft.**
  The operating pressure range conforms to commercial airliner transport. Extreme pressure levels can impact performance. During exposure to extreme pressures (altitudes), LUNGguard® operation must be frequently monitored.

- **Operating Humidity: 40-60% Relative Humidity**
  Extreme humidity levels can impact performance. During exposure to extreme humidity levels, LUNGguard® operation must be frequently monitored.

## 2.5 ACCURACY ⚠

- **Temperature Accuracy**
  LUNGguard® comes with a pre-installed datalogger capable of reporting both the ambient temperature and the temperature within the Organ Assembly. Temperature Accuracy is ±0.5°C from 0° to 50°C.
- **Time Accuracy**
  The pre-installed datalogger logs temperature against time with an accuracy of ±1 minute per month.

## 2.6 PRECAUTIONS ⚠

- **Keep LUNGguard® primarily upright during transportation.**
  LUNGguard® is designed to be transported upright. Temporary tilting ±45˚ from horizontal in any direction is acceptable.
- **Avoid direct sunlight and hot or cold temperature extremes.**
  LUNGguard® is designed to be transported under the same environmental conditions as is appropriate for people. Avoid extended exposure to outdoor conditions (sunlight, heat or cold).
- **Use caution when lifting LUNGguard®**
  A fully loaded LUNGguard® weighs ~30 lbs. Use proper lifting practices.
- **Exercise Caution when using in presence of other electronic devices.**
  While no significant risk of reciprocal interference has been identified, LUNGguard® should always be closely monitored when in use.

## 2.7 SIDE EFFECTS

All surgical procedures and medical devices have potential risks. The potential surgical risks of a transplant with donor lungs are similar for the Paragonix LUNGguard System and traditional ice storage preservation. There is a risk of receiving lungs that do not function properly after transplant. There is also a risk that the donor lungs may be damaged during preservation.

## 2.8 SIDE EFFECTS ASSOCIATED WITH LUNGGUARD

- It is possible that after preservation using the Paragonix LUNGguard system, the transplant doctor may decide that the donor lungs are not suitable for transplantation.
- The Paragonix LUNGguard system is prepared and operated by trained medical professionals. Like with many medical technologies, there are inherent risks including injury to the donor tissue, air leaks, infection or delayed organ function.

## 2.9 CLINICAL BENEFITS (EU)

The Paragonix LUNGguard System is designed to improve organ preservation during transportation and storage from organ donor to recipient. Improved organ preservation can mitigate the risks of cold ischemic time on reperfusion injury, leading to reduced post-operative complications and improved long-term outcomes.

# 3 PRE-ASSEMBLY CHECKLIST

**Table 3: Pre-Assembly Checklist for LUNGguard® identifying component counts, locations, and sterility disposition.**

| Box Location | Item | Supplied Sterile | Supplied Non- Sterile | Quantity | ✓ |
|---|---|---|---|---|---|
| Large Box | Shipper | | x | 1 | |
| Small Box | Paragonix SherpaCool® Materials<br>⚠ **CAUTION: PRECONDITION AT -20°C OR BELOW FOR AT LEAST 48 HOURS PRIOR TO USE.** | | x | 1 | |

LUNGguard® Set-up and Preparation

1. Inspect all parts on arrival for any signs of damage that may have occurred during transport.
2. Report any damage or concerns about the condition of LUNGguard® immediately to Paragonix Technologies Inc.®
3. When in transit, the SherpaCool Pouches may be stored in the shipper for up to 18 hours and with a total maximum of 7 liters of saline and/or preservation solution based on required practice.
    - Note: If SherpaCool is set up in the shipper, place the pouches in the intended locations as shown in section 4.7.
    - SherpaCool pouches should not be placed in direct contact with the temperature probe.
    - Hard plastic should not be placed directly on top of temperature probe

Figure 1: LUNGguard®, and as shipped (in boxes)

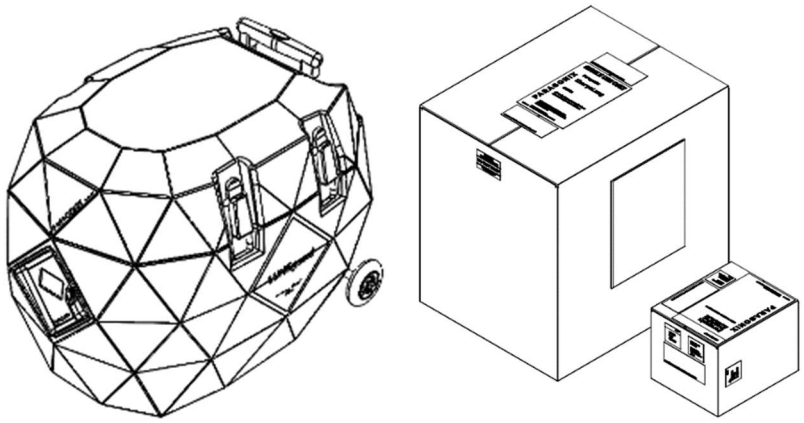


Figure 2: Shipper

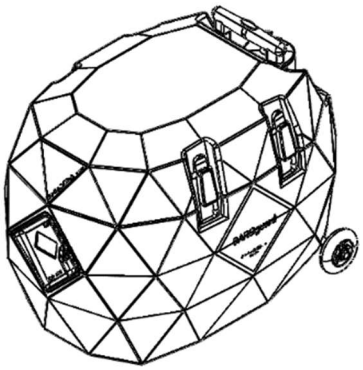


Figure 3: Paragonix SherpaCool® Materials.

CAUTION:

⚠ **PRECONDITION AT -20°C OR BELOW FOR AT LEAST 48 HOURS PRIOR TO USE.**

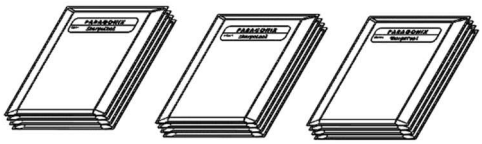


Figure 4: Sterile Isolation Bags

⚠ **CAUTION: FOLLOW DIRECTIONS IN THE ENCLOSED IFU REGARDING STORAGE AND PREPARATION FOR USE**

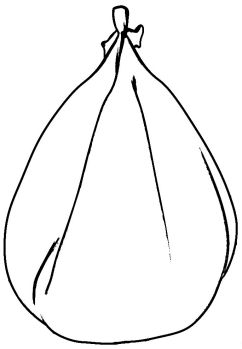


Figure 5: Preservation Solution and/or Saline

⚠ **CAUTION: FOLLOW DIRECTIONS IN THE ENCLOSED IFU REGARDING STORAGE AND PREPARATION FOR USE**

# 4 OPERATING INSTRUCTIONS

## 4.1 GENERAL INFORMATION

- **Before using in a clinical setting, operators must be trained in the use and functional understanding of the LUNGguard® system.**

## 4.2 OVERVIEW USING LUNGGUARD®

**Using LUNGguard® involves performing the following procedures:**

1. Removal of packaging, preconditioning of Paragonix SherpaCool® Box (Section 4.3) containing Paragonix SherpaCool® Pouches at or below -20°C for at least 48 hours.
2. Setup of datalogging software for use with LUNGguard® (Section 4.4, optional, recommended)
3. Transport of LUNGguard® to the recovery site (Section 4.5)
4. Preparing LUNGguard® and Shipper for deployment at recovery site (Section 4.6)
5. Lungs recovery, packaging, and preservation (Section 4.7)
6. Traveling with LUNGguard® to the transplant site (Section 4.8)
7. Removing the lungs from LUNGguard® for transplant (Section 4.9)

These instructions may be modified based on actual use. The instructions are designed for implementation by two operators. These instructions may be modified for a single operator, provided that proper aseptic technique is used in conjunction with procedures to be performed on the sterile field with sterile components.

## 4.3 REMOVAL OF PACKAGING AND PRECONDITIONING OF PARAGONIX SHERPACOOL® BOX CONTAINING PARAGONIX SHERPACOOL® POUCHES

**LUNGguard® must be maintained in a ready-to-use condition, so that it can be available to the lung recovery team at all times.**

**Make the following preparations:**

- Do not remove Paragonix SherpaCool® Pouches from the Paragonix SherpaCool® Box.
- Write the date and time of Paragonix SherpaCool® Box transition to -20°C storage on the label affixed to the Paragonix SherpaCool® Box.
- Place the Paragonix SherpaCool® Box into a -20°C (or colder) freezer for a minimum of 48 hours.
- Remove Paragonix SherpaCool® Box after a minimum preconditioning time of 48 hours at -20°C (or colder).
- Do not remove Paragonix SherpaCool® Box until recovery team departs to donor hospital.
- Do not remove Paragonix SherpaCool® Box until all other components of LUNGguard® and associated equipment and materials have been prepared for transport.
- Paragonix SherpaCool® Box must be transported to the donor site on ice.
- Chilled preservation solution according to solution Instructions for Use (preferentially 4°C as appropriate), cleared for use with the lungs, must be available.

## 4.4 SETUP OF DATALOGGING SOFTWARE FOR USE WITH LUNGGUARD® (OPTIONAL, RECOMMENDED)

In order to recover logged temperature data from LUNGguard® system, the user must first download and install the latest version of the mobile Paragonix App at either the App Store or Google Play store. This requires use of a Bluetooth®-enabled iOS or Android device.



⚠ **NOTE: LUNGguard® system comes pre-configured with appropriate temperature monitoring settings installed in the on-board temperature monitoring system. This configuration must NEVER be modified by the user.**

**After setting up an account for use of the Paragonix App:**

- After logger is started (Section 4.7, Step 9 of this manual) it is possible to visualize the logged data by connecting the LUNGguard® system to the Paragonix App.
    - Log in to the Paragonix App on your mobile device.
    - Select the DataLogger matching the serial number shown at the back of the Shipper from the Paragonix software application.
    - When prompted enter the DataLogger PassKey provided on the back of the Shipper

adjacent to the datalogger serial number.

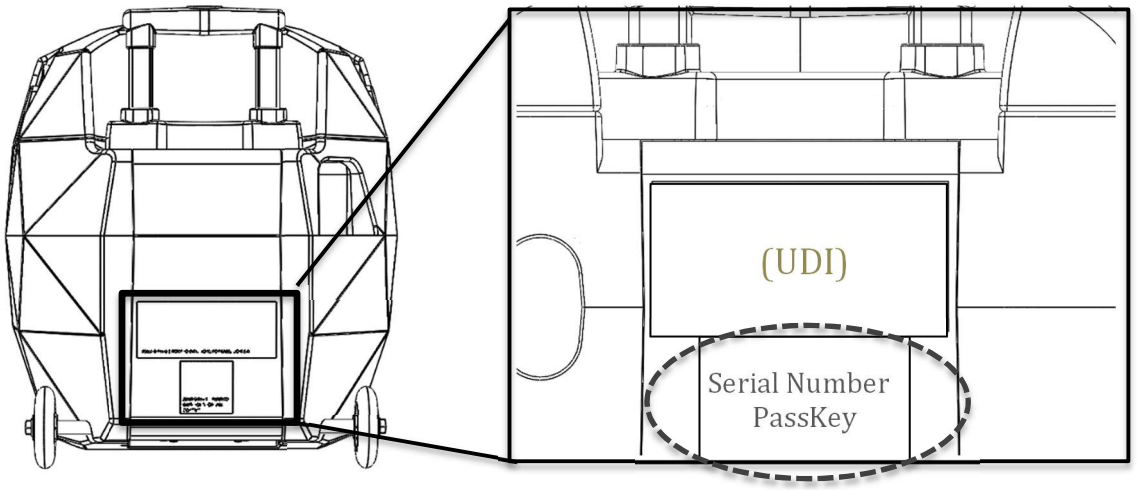



Figure 6: Indication of datalogger Serial Number and PassKey on Shipper

- Once connected to the CX402-TxM, logged data may be viewed locally and/or uploaded to alternative devices via the Paragonix software application by following instructions.
- **For additional assistance in data recovery, contact Paragonix® directly via provided telephone number and have available the Shipper Serial Number and DataLogger Serial Number.**
- **Do not dispose of Shipper unit until desired data has been obtained.**

## 4.5 TRANSPORT OF LUNGGUARD® TO THE RECOVERY SITE

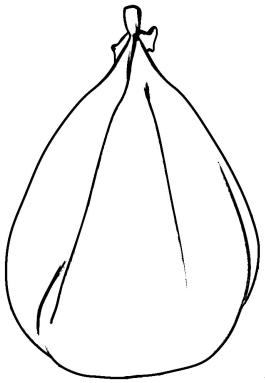
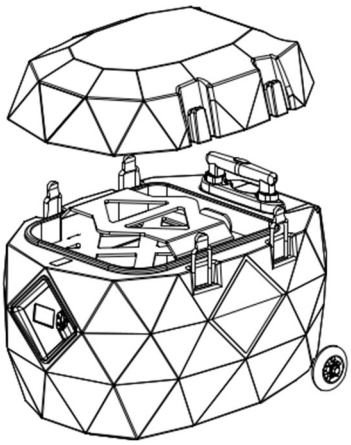
**Transport various supplies of LUNGguard® to the recovery site by:**

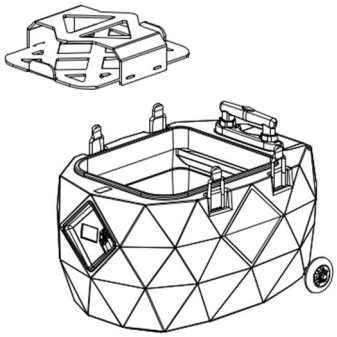
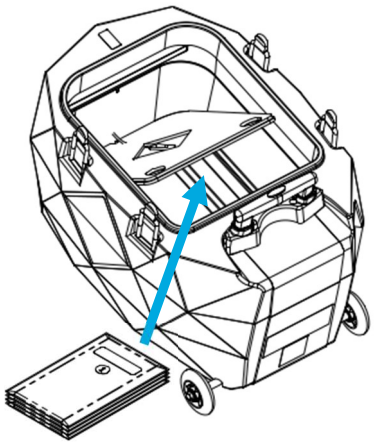
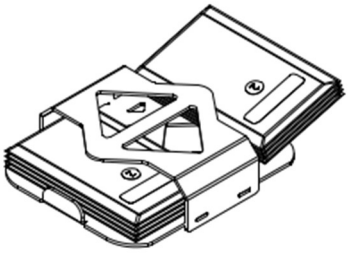
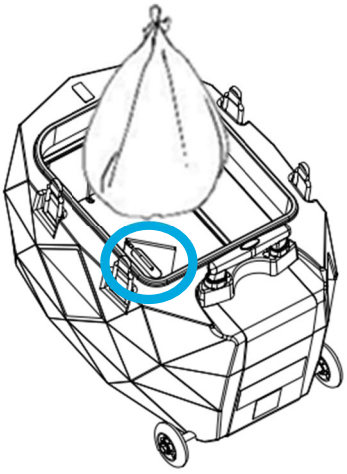
- Place Paragonix SherpaCool® Box onto wet ice in an ice chest for transportation OR in the shipper as described in section 3.3.
  - Paragonix SherpaCool® Box may be transported in the same ice chest as other adjunct supplies (preservation solutions, etc.)
  - Maximum allowable transit time for Paragonix SherpaCool® is 4 hours for wet ice transport, 18 hours within the shipper.
- Unbox Shipper prior to transportation to the recovery site.
- Wheel or carry Shipper to recovery site.

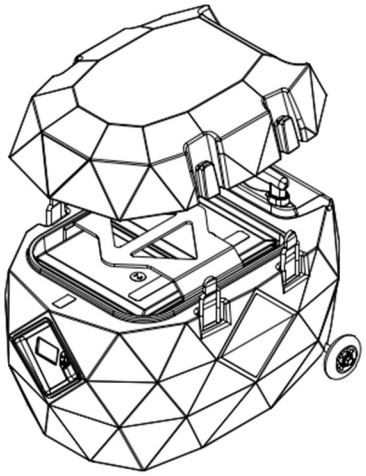
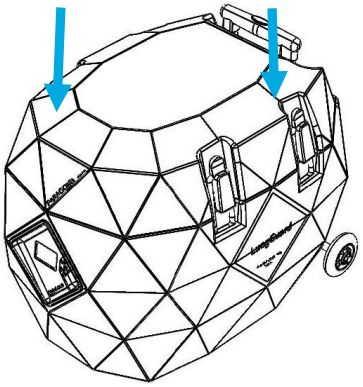
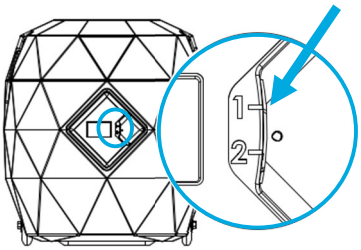
## 4.6 PREPARATION OF LUNGGUARD® FOR DEPLOYMENT AT RECOVERY SITE

| | | |
|---|---|---|
| 1. Using checklist (See Section 3.1), double-check for presence of all LUNGguard® components PRIOR to unpacking the components. | | NON-STERILE FIELD |
| 2. Visually inspect all material for damage and discard if necessary. | | NON-STERILE FIELD |
| 3. Open Paragonix SherpaCool® Box, leaving Paragonix SherpaCool® Pouches on ice until installation in the Shipper. | | NON-STERILE FIELD |

## 4.7 LUNGS RECOVERY, PACKAGING, AND PRESERVATION

| | | |
|---|---|---|
| 1. Package lung using Sterile Isolation Bags with 4L of cold (4°C) lung preservation solution and/or sterile saline and package lung per institution recommendation.<br><br>⚠ **NOTE: LUNG PACKAGING MUST NOT INCLUDE ICE OR SLUSH. LUNGGUARD® IS DESIGNED TO BE OPERATED WITHOUT ICE. EXCESS AIR SHOULD BE REMOVED DURING PACKAGING.** |  | STERILE FIELD |
| 2. Remove Shipper Lid from Shipper |  | NON-STERILE FIELD |

| | | |
|---|---|---|
| 3. Remove upper Paragonix SherpaCool® Tray from Shipper |  | NON-STERILE FIELD |
| 4. Lift up bottom tray from Shipper and place Paragonix SherpaCool® Pouch 1 underneath.<br><br>⚠ **NOTE: TEMP PROBE AFFIXED TO BOTTOM TRAY, DO NOT ATTEMPT TO REMOVE TRAY FROM SHIPPER.** |  | NON-STERILE FIELD |
| 5. Load the 2 Paragonix SherpaCool® Pouch 2 materials into the upper Paragonix SherpaCool® Tray |  | NON-STERILE FIELD |
| 6. Transfer the packaged lung into the Shipper being sure to place directly on the Temperature Probe |  | NON-STERILE FIELD |

| | | |
|---|---|---|
| 7. Replace the Paragonix SherpaCool® Tray in the Shipper |  | NON-STERILE FIELD |
| 8. Close the lid of the Shipper. |  | NON-STERILE FIELD |
| 9. With the tip of a finger, press and hold Button 1 on the datalogger for 10 seconds to power on the unit and initiate temperature and time logging.<br><br>Alternatively, the datalogger may be started directly from the Paragonix software application using a Bluetooth-enabled device.<br><br>⚠ **NOTE: FOR THE FIRST HOUR FOLLOWING ASSEMBLY OF LUNGGUARD® YOU MAY EXPERIENCE TRANSIENT TEMPERATURE BELOW 4°C OR ABOVE 8°C. THIS IS DUE TO SYSTEM STABILIZATION IMMEDIATELY FOLLOWING FINAL ASSEMBLY.** |  | NON-STERILE FIELD |

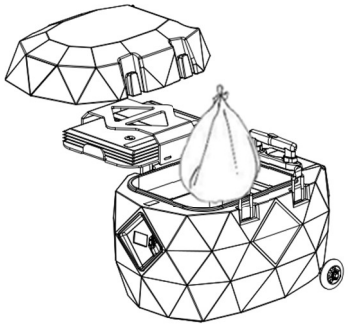
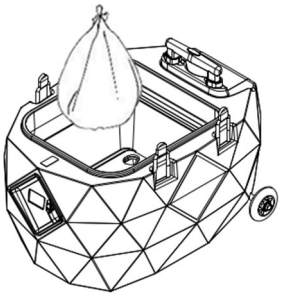
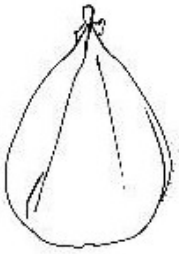
## 4.8 TRAVELING WITH LUNGGUARD® TO THE TRANSPLANT SITE

Confirm that the Shipper is securely closed with all 4 latches in place.

In the event of transport by vehicle, roll LUNGguard® to the vehicle and place LUNGguard® in a flat location secured against shifting or tipping during transit. Secure LUNGguard® as necessary to accomplish this. If transported by air, either on a helicopter or airplane, follow the crew's instructions and secure LUNGguard® to prevent shifting or tipping during transit.
Upon arrival at the transplant site, follow hospital procedures for moving equipment into the transplant OR. Identify a non-sterile table in the OR for LUNGguard®.

Upon arrival to the recipient site, continue use of LUNGguard® until the recipient has been prepared to accept the donor lungs and ensure that the Shipper is securely closed with all 4 latches in place.

## 4.9 REMOVING THE LUNGS FROM LUNGGUARD® FOR TRANSPLANT

| | | |
|---|---|---|
| 1. Remove the Shipper lid and the Paragonix SherpaCool® Tray containing Paragonix SherpaCool® materials from the Shipper. |  | NON-STERILE FIELD |
| 2. Remove bagged lung from the Shipper. |  | NON-STERILE FIELD |
| 3. Introduce the packaged lung into the sterile field per institutional protocol. |  | NON-STERILE FIELD |
| Allow for lungs preparation for transplantation as per transplant facility protocol.<br>Following use, dispose of preservation solution, and discard the entire LUNGguard® per facility protocol. | | |

# 5 TROUBLESHOOTING

| Trouble | Probable Cause | Action |
|---|---|---|
| Isolation bags leaking preservation solution | Insufficient bag seal | 1. Check/re-check bag seal for integrity. Re-seal to ensure integrity |
| No temperature displayed on datalogger LCD screen | Datalogger not activated and collecting data | 1. First attempt to start datalogger by pressing Button 1 and holding for 10 seconds (repeat step 4.8.18).<br>2. Second, attempt to link to datalogger via Paragonix software application and start via Bluetooth-enabled device.<br>3. If the datalogger does not activate and display temperature, contact Paragonix immediately via the phone for further assistance. |

# 6 STORAGE

Unopened LUNGguard® Shippers should be stored indoors in a dry location out of direct sunlight under normal temperature and humidity conditions. Unopened Paragonix SherpaCool® Pouches should be stored at -20°C in preparation for use.

## NOTES

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