Paragonix BAROguard®

INSTRUCTIONS

BAROguard®
L-439 ver. 7
Issue Date: 08MAY2026

For technical assistance:
Paragonix Technologies, Inc.®
950 Winter Street, North
Waltham, MA 02451
USA
support@paragonixtechnologies.com
+1.781.428.4828
www.paragonixtechnologies.com/instructions-for-use

EU REP
CE 0123

Maquet Critical Care AB
Röntgenvägen 2
SE-171 54, Solna
Sweden

Patents: paragonixtechnologies.com/patents/

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

MD

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1 INDICATIONS FOR USE

BAROguard® 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 BAROguard® 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 BAROguard® 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 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.

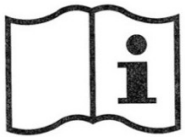
Should any serious incident occur in relation to the device, please contact Paragonix and the appropriate regulatory authority in the county of use where the incident occurred. Paragonix can be reached via your local sales rep or contacted via:

email: support@paragonixtechnologies.com
telephone: +1.781.428.4828

2.1 TRAINING

- **Schedule training prior to first use of the device. To schedule, contact Paragonix by email (support@paragonixtechnologies.com) or by phone at +1.781.428.4828. This training is for intended users to review the steps recommended by the Instructions for Use in concert with appropriate Paragonix Technologies staff.**

2.2 IMPORTANT INFORMATION



It is important that all personnel who will operate the BAROguard® 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.

BAROguard® is a device for use by hospitals that perform lung recovery procedures to store and transport donor lungs to the transplant facility. BAROguard® 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.

2.3 SYMBOL DEFINITIONS

Table 1: Symbols used in the labeling of BAROguard® 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		

2.4 WARNINGS ⚠

- **Caution: Federal (US) law restricts this device to sale by or on the order of a physician.**

Use aseptic technique as appropriate.

Certain components of BAROguard® are provided sterile. Maintain aseptic technique when handling sterile components of BAROguard®.

- **Chilled (4°C), sterile preservation solution, cleared for use with the lungs, must be available**.

	⚠ Do NOT reuse any component of BAROguard®. BAROguard® 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 BAROguard® are sterile as supplied (sterilization method is gamma irradiation). BAROguard® 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 BAROguard®.**
  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 BAROguard® 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 BAROguard®. Do not use if any component is loose, broken or damaged.**
- **Do not open BAROguard® during organ transport.**
- **No modification of BAROguard® is allowed.**
- **WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BAROguard® device. Otherwise, degradation of the performance of this equipment could result.**
- **NOTE: BAROguard® is compliant with IEC 61000-4-2: 8KV contact, 15KV air, IEC 61000-4-3: 3V 80-2700MHz, Table 9 per the standard, IEC 61000-4-8 30A/M and additionally the following:**

Table 2. EMC/EMI Safety

Test Standard	Test Level
TCISPR 11	Group 1 Class B, 30-1000 MHz
IEC61000-4-2	± 8kV contact, ± 2kV, ±4kV, ±8kV, ±15kV air
IEC61000-4-3	Radiated RF EM fields 3V/m, 80MHz-2.7GHz, 80% AM at 1 kHz
IEC61000-4-8	30 A/m, 50Hz or 60 Hz
IEC6100-4-39	9 kHz to 13.56 MHz

2.5 TRANSPORT AND STORAGE CONDITIONS ⚠

- **Transport and Storage Temperature: -20°C to 40°C**
- **Transport and Storage Pressure: 625hPa – 1060hPa**
- **Transport and Storage Humidity: 5-80% Relative Humidity**

2.6 OPERATING CONDITIONS ⚠

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

- **Operating Pressure: Sea Level to 8000 ft (1015 to 750 hPa)**
  The operating pressure range conforms to commercial airliner transport. Extreme pressure levels can impact performance. During exposure to extreme pressures (altitudes), BAROguard® operation must be frequently monitored.

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

2.7 DATALOGGER COMMUNICATION AND ACCURACY

- **Wireless Data Standard: Bluetooth Low Energy (Bluetooth Smart)**
  BAROguard® datalogger monitors temperature and pressure and can transmit to a mobile device using optional mobile app (section 4.4) using Bluetooth® Low Energy Technology.
- **Datalogger Radio Power: 1 mW (0 dBm)**
- **Datalogger Transmission Range: Approximately 30.5 m (100 ft) line-of-site**
- **Temperature Accuracy**
  BAROguard® comes with a pre-installed datalogger capable of reporting the temperature within the Organ Assembly. Temperature Accuracy is ±0.5°C from 0° to 50°C.
- **Pressure Accuracy**
  BAROguard® comes with a pre-installed datalogger capable of reporting airway pressure of the donor lung. Pressure accuracy is ±1.0 cmH_2O.
- **Time Accuracy**
  The pre-installed datalogger logs temperature against time with an accuracy of ±1 minute per month.

2.8 PRECAUTIONS ⚠

- **Keep BAROguard® primarily upright during transportation.**
  BAROguard® is designed to be transported upright. Temporary tilting ±45˚ from horizontal in any direction is acceptable.
- **Do not place BAROguard® in the cargo hold of an airplane.**
  BAROguard® is designed to be transported in pressurized cabin during aircraft transportation.
- **Avoid direct sunlight and hot or cold temperature extremes.**
  BAROguard® 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 BAROguard®**
  A fully loaded BAROguard® weighs ~30 lbs. Use proper lifting practices.
- **Exercise Caution when using BAROguard® in presence of other electronic devices and electromagnetic emitters.**
  BAROguard® has been tested for radiated immunity only at selected frequencies listed in Section 2.4 of this manual. While no significant risk of reciprocal interference has been identified,

BAROguard® should always be closely monitored when in use and reoriented or relocated if abnormal performance is observed. Electromagnetic emitters include radiofrequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment.

- **Do not use BAROguard® in oxygen rich environment.**
  BAROguard® is not designed or evaluated for use in an oxygen rich environment.
- **Do not use BAROguard® with flammable anesthetics.**
  BAROguard® is not designed or evaluated for use with flammable anesthetics.

2.9 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 BAROguard 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.

2.10 SIDE EFFECTS ASSOCIATED WITH BAROGUARD

- It is possible that after preservation using the Paragonix BAROguard system, the transplant doctor may decide that the donor lungs are not suitable for transplantation.
- The Paragonix BAROguard 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.

2.11 CLINICAL BENEFITS (EU)

The Paragonix BAROguard 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 BAROguard® identifying component counts, locations, and sterility disposition.

Included With BAROguard® System	Part Number	Item	Sterile	Non-Sterile	Quantity	Check when verified
Yes	PRGNX-7007-001	**BAROguard®** Shipper		X	1 ea	
Yes	PRGNX-7007-002	**BAROguard®** Paragonix SherpaCool® Materials ⚠ **CAUTION: PRECONDITION AT -20°C OR BELOW FOR AT LEAST 48 HOURS PRIOR TO USE**		X	1 ea	

Yes	PRGNX-7007-003	**BAROguard®** Sterile Components	X		1 ea	
No	Varies	4 total Liters of fluids exclusively for packaging the donor lung(s) (e.g. 2L of chilled (4°C), sterile preservation solution for the inner bag and 2L of chilled (4°C), sterile or preservation solution for the middle bag)	X		4 L	
No	Varies	Hemostat (atraumatic DeBakey clamp or similar) or other equivalent airway securement tool	X		1 ea	

3.1 BAROGUARD® 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 BAROguard® immediately to Paragonix Technologies Inc.®
3. When in transit, the Paragonix SherpaCool® Pouches may be stored in the device 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 Paragonix SherpaCool® is set up in the device, place the pouches in the intended locations as shown in section 4.8.**
    - Paragonix SherpaCool® pouches should not be placed in direct contact with the temperature probe.

Figure 1: BAROguard® as shipped in boxes

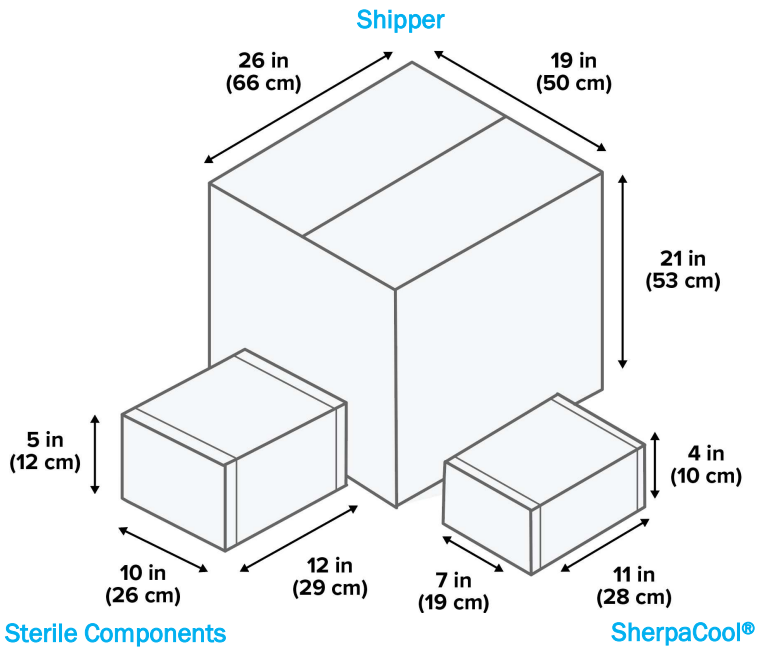


Figure 2: BAROguard® Shipper

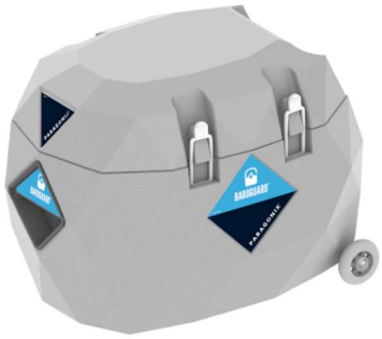


Figure 3: Paragonix SherpaCool® Materials.

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

Figure 4: Preservation Solution and/or Saline

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

Figure 5: Sterile Components

⚠ **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 BAROguard®.**

4.2 OVERVIEW USING BAROGUARD®

Using BAROguard® 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 BAROguard® (Section 4.4, optional, recommended)
3. Transport of BAROguard® to the recovery site (Section 4.5)
4. Preparing BAROguard® and Shipper for deployment at recovery site (Section 4.6)
5. Preparing BAROguard® for lungs receipt at recovery site (Section 4.7)
6. Donor lung(s) recovery, packaging, and preservation (Section 4.8)
7. Traveling with BAROguard® to the transplant site (Section 4.9)
8. Removing the lungs from BAROguard® for transplant (Section 4.10)

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 in the sterile field with sterile BAROguard® components.

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

BAROguard® 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 BAROguard® and associated equipment and materials have been prepared for transport.
- Paragonix SherpaCool® Box must be transported to the donor site on ice OR in the device as described in section 3.1.
- 4 total Liters of fluids exclusively for packaging the donor lung(s) (e.g. 2L of chilled (4°C), sterile preservation solution cleared for use with lungs for the inner bag and 2L of chilled (4°C), sterile saline or preservation solution for the middle bag)

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

In order to recover logged temperature data from BAROguard® 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.

Download on the App Store

GET IT ON Google Play

⚠ **NOTE: BAROguard® 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 4.8, Step 20 of this manual) it is possible to visualize the logged data by connecting the BAROguard® device to the Paragonix App.
    - Log in to the Paragonix App on your mobile device.
    - Scan the QR code on the back of the Shipper to pair the device or select the Datalogger

matching the serial number shown at the back of the Shipper from the Paragonix app.

- If prompted enter the Datalogger PassKey provided on the back of the Shipper adjacent to the datalogger serial number.

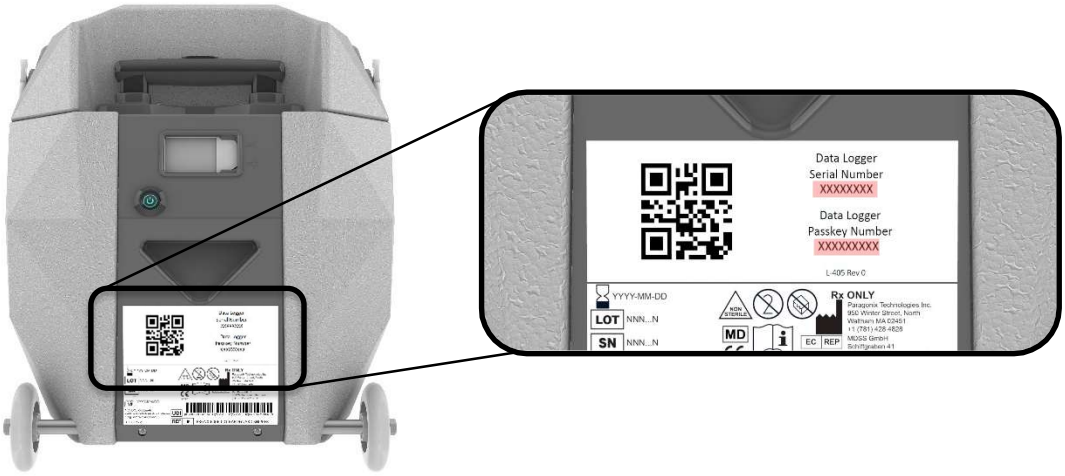


Figure 6: Indication of datalogger Serial Number and PassKey on Shipper

- **Once connected to the datalogger, logged data may be viewed locally and/or uploaded to alternative devices via the Paragonix software application.**
- **For 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 BAROGUARD® TO THE RECOVERY SITE

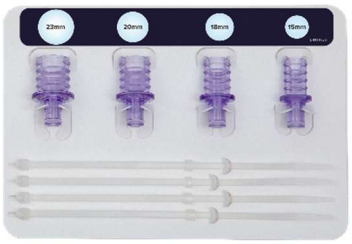
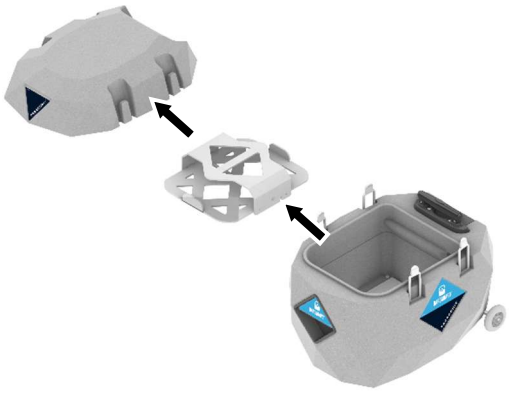
Transport various supplies of BAROguard® to the recovery site by:

- Place Paragonix SherpaCool® Box onto wet ice in an ice chest for transportation OR in the device as described in section 3.1.
  - 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 in original packaging, 18 hours within the device.
- Carry BAROguard® Nested Bag Assembly and (sterile components) in original packaging
- Unbox Shipper prior to transportation to the recovery site.
- Wheel or carry the device to recovery site.

4.6 PREPARATION OF BAROGUARD® FOR DEPLOYMENT AT RECOVERY SITE

1. Using checklist (See Section 3, Table 3), double-check for presence of all BAROguard® components PRIOR to unpacking the components.	NON-STERILE FIELD
2. Open Paragonix SherpaCool® Box, leaving Paragonix SherpaCool® Pouches on ice until installation in the device.	NON-STERILE FIELD

4.7 PREPARING BAROGUARD® FOR LUNGS RECEIPT AT RECOVERY SITE

1. Aseptically remove Sterile Components (nested bags, trachea connectors, cable ties, cable installation tool) and place on sterile table	 Cable Installation Tool  Trachea Connectors (15mm, 18mm, 20mm, 23mm)  Nested Bag Assembly, Cables Ties, Bag Strings	STERILE FIELD
2. Visually inspect all material for damage and discard if necessary.		STERILE FIELD
3. Remove Shipper Lid and Upper Tray from Shipper		NON-STERILE FIELD

4.8 LUNG RECOVERY, PACKAGING, AND PRESERVATION

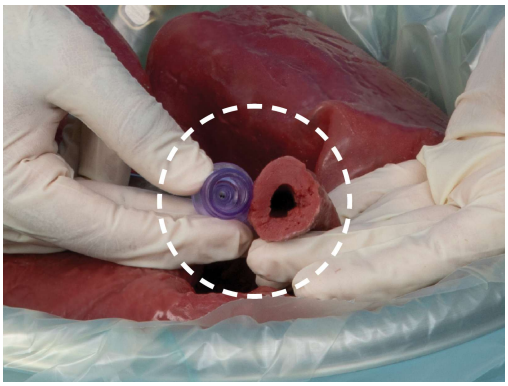
1. Prepare nested bag within back table basin		STERILE FIELD
2. Add 2 liters of chilled (4°C), sterile preservation solution to inner bag.		STERILE FIELD
3. Prepare lungs as appropriate for insertion of trachea connector ⚠ **Note:** Maintain airway pressure during recovery from donor cavity and back table prep airway securement tool (e.g. hemostat, atraumatic DeBakey or similar clamp) ⚠ **Note:** Only package lungs that have been examined and accepted during final assessment without air leaks per institutional protocol.		STERILE FIELD

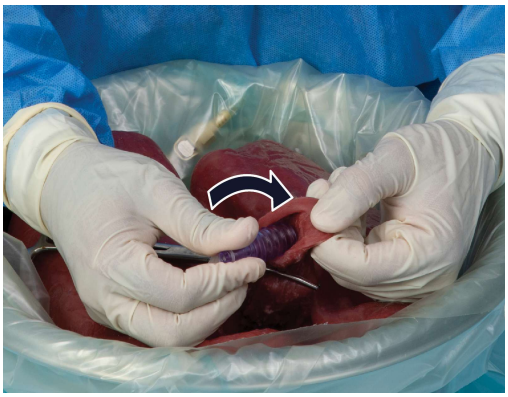
4. Insert appropriate size trachea connector into the trachea and secure with **2 cable ties**

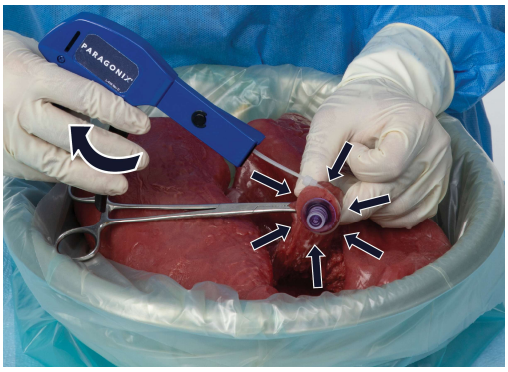
⚠ **Note**: Using less than 2 cable ties may lead to air leaks.

⚠ **Note**: **Keep hemostat applied**. Do not remove airway securement tool (e.g. hemostat, atraumatic DeBakey or similar clamp) until step 7.

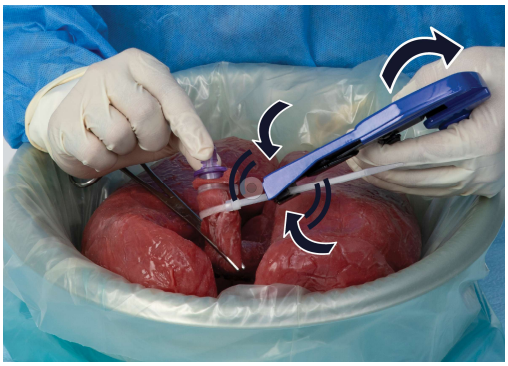
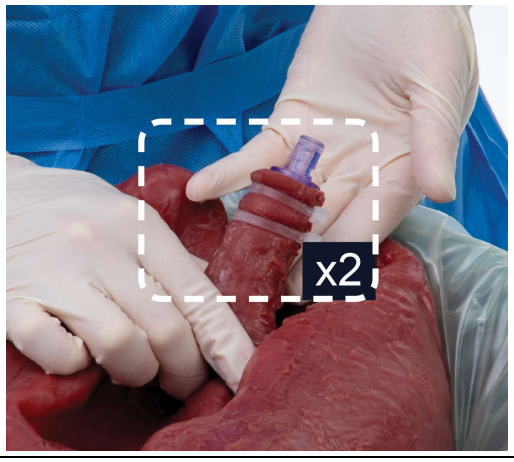
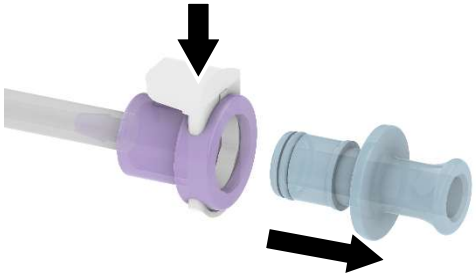
NOTE: DO NOT REMOVE HEMOSTAT

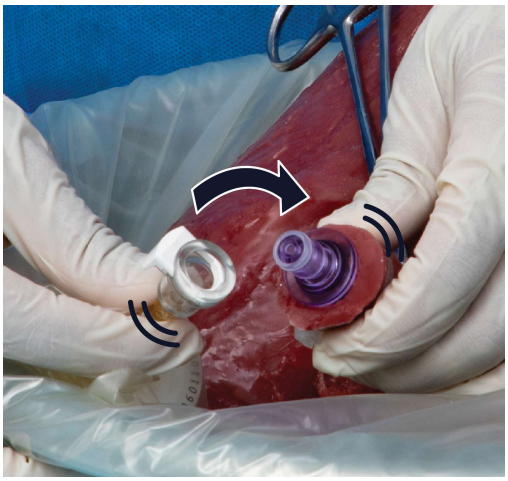
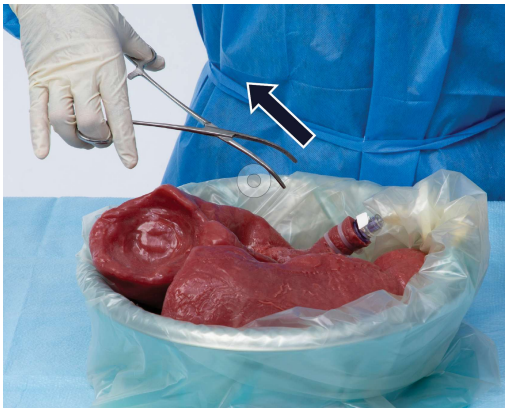






STERILE FIELD

Step 4 continued ⚠ **Note**: **Keep hemostat applied**. Do not remove airway securement tool (e.g. hemostat, atraumatic DeBakey or similar clamp) until step 7	 NOTE: DO NOT REMOVE HEMOSTAT 	
5. Remove cap from bag tubing connector while depressing the white button ⚠ **Note**: This may require two hands.		STERILE FIELD
6. Insert trachea connector into bag tubing connector ⚠ **Note**: **Keep hemostat applied**. Do not remove airway securement tool (e.g. hemostat, atraumatic DeBakey or similar clamp) until step	NOTE: DO NOT REMOVE HEMOSTAT	STERILE FIELD

		STERILE FIELD
7. Remove airway securement tool (e.g. hemostat, atraumatic DeBakey or similar clamp).		STERILE FIELD
8. Remove air from inner bag and close using institutional protocol with either woven ties or cable ties. ⚠ **Note:** Consider institutional protocol at recipient center for unpackaging donor lung(s) when selecting closure method.	**OPTION 1: WOVEN TIES**  **OPTION 2: CABLE TIES**	STERILE FIELD

STERILE FIELD

9. Add 2 liters of chilled (4°C) sterile saline or chilled (4°C) sterile preservation solution to the middle bag.

⚠ **Note**: Do not use sterile slush or ice.

STERILE FIELD

10. Remove air from <u>middle bag</u> and close using institutional protocol with either woven ties or cable ties.

⚠ **Note:** Consider institutional protocol at recipient center for unpackaging donor lung(s) when selecting closure method.

STERILE FIELD

11. Remove air from <u>outer bag</u> and close using institutional protocol with either woven ties or cable ties.

⚠ **NOTE:** Consider institutional protocol at recipient center for unpackaging donor lung(s) when selecting closure method.

STERILE FIELD

12. Turn on pump by depressing the indicated button. ⚠ **NOTE:** Turn on pump prior to connecting bags to the shipper to ensure lungs remain inflated. Illuminated blue LED switch and audible tone will confirm pump operation.		NON-STERILE FIELD
13. Lift only the front edge of the Bottom Tray towards the datalogger. ⚠ **NOTE:** Use caution, temperature probe is affixed to Bottom Tray. Do not pull.		NON-STERILE FIELD
14. Place Paragonix SherpaCool® Pouch 1 underneath the Bottom Paragonix SherpaCool® Tray and lower the tray.		NON-STERILE FIELD

15. Place the packaged donor lungs within the device and connect the tubing to the airline port within the shipper.

⚠ **NOTE: Ensure the pump is ON <u>prior</u> to connecting the tubing within the device to prevent potential partial lung deflation.**

ENSURE PUMP IS TURNED ON

NON-STERILE FIELD

16. Load the 2 Paragonix SherpaCool® Pouch "2" materials into the Upper Paragonix SherpaCool® Tray.

NON-STERILE FIELD

17. Replace the Upper Tray in the Shipper.		NON- STERILE FIELD
18. Close the lid of the device.		NON-STERILE FIELD
19. Seat and lock each of the 4 Shipper latches securely.		NON-STERILE FIELD

20. Press and hold Button 1 on the datalogger for 10 seconds to power on the datalogger and initiate the logging of temperature, airway pressure, and time.

    Press Button 1 to toggle between airway pressure, lung cavity probe temperature, battery voltage, and internal BAROguard® system temperature.

⚠ **NOTE:** For the first hour following assembly of BAROguard® you may experience transient temperatures.. This is due to system stabilization immediately following final assembly.

⚠ **NOTE:** Time to target pressure stabilization may vary depending on initial pressure maintained during procurement from donor cavity.

NON-STERILE FIELD

4.9 TRAVELING WITH BAROGUARD® TO THE TRANSPLANT SITE

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

In the event of transport by vehicle, roll BAROguard® to the vehicle and place BAROguard® in a flat location secured against shifting or tipping during transit. Secure BAROguard® as necessary to accomplish this. If transported by air, either on a helicopter or airplane, follow the crew's instructions and secure BAROguard® to prevent shifting or tipping during transit.

⚠ **NOTE:** Use caution when loading and unloading BAROguard® to ensure device power remains ON.

Upon arrival at the recipient transplant site, follow institutional protocol for moving equipment into the transplant OR. Identify a non-sterile surface in the OR for staging BAROguard®. Continue use of BAROguard® until the recipient has been prepared to accept the donor lungs and that the device is securely closed with all 4 latches in place.

4.10 REMOVING THE LUNGS FROM BAROGUARD® FOR TRANSPLANT

1. Remove the device lid and the Upper Tray containing Paragonix SherpaCool® materials. ⚠ **Note: DO NOT TURN OFF PUMP**	 	NON-STERILE FIELD
2. Disconnect nested bag assembly using the quick connect. ⚠ **NOTE: DO NOT TURN OFF PUMP** ⚠ **NOTE:** Disconnect tubing **PRIOR** to lifting the package donor lung(s).		NON-STERILE FIELD

3. **AFTER** disconnecting the quick connect, remove the packaged donor lung(s) from the device.		
4. Touching ONLY the outer bag, a nonsterile operator will open it such that a sterile operator can remove the middle bag per institutional protocol.		NON-STERILE FIELD STERILE FIELD
5. Using appropriate aseptic technique, the sterile operator will disconnect the outer bag from the middle bag. Carefully remove the middle bag assembly and bring to a basin on the sterile table.		STERILE FIELD

6. Open the middle bag per institutional protocol ⚠ **NOTE:** Middle bag and inner bag remain connected	STERILE FIELD
7. Open the inner bag per institutional protocol.	STERILE FIELD
8. Remove first lung from inner bag for preparation of transplant per institutional protocol.	STERILE FIELD
9. As the first lung is being transplanted, repackage second lung back into shipper per institutional protocol.	STERILE FIELD
10. Unpack the second donor lung per institutional protocol once it is ready for transplant.	STERILE FIELD
11. Following use, dispose of lungs preservation solution, and discard the entire BAROguard® per institutional protocol via the biohazard waste stream.	

5 TROUBLESHOOTING

Table 4. Troubleshooting

Trouble	Probable Cause	Action
No temperature or pressure 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 2. If the datalogger does not activate and display temperature, contact Paragonix immediately via the phone for further assistance.
Datalogger alert is going off	Pressure in airway is less than 10cmH_2O	1. Ensure the quick connector of the nested bags is connected to the quick connect in the Shipper wall 2. If the alert continues for another minute disconnect the quick connect of the nested bags from the quick connect in the wall of the shipper and press Button 2 to silence the alert

6 STORAGE

Unopened BAROguard® 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 for at least 48 hours in preparation for use.

NOTES