LASS (Left Arm Support System) Instructions for Use from Radux Devices, LLC
Patient Positioning Set

USA Caution
Federal (USA) law restricts this device to sale by or on the order of a health care professional.

Caution
LASS should be used by physicians or physician extenders with adequate training in the use of the device.

Device Description
LASS is a four (4) piece patient positioning set.

Base Board (LP1001)

Arm Board (LP1002)

Large Foam (LP1003)

Small Foam (LP1004)

LASS is non-sterile and intended for multiple uses, requiring standard cleaning prior to each procedure. It is designed to provide support for a patient's arm during left radial artery access and intervention, or other radiological or surgical procedures.

Intended Use
LASS is intended for patient positioning during radiological and surgical procedures.

Contraindications
None known.

Warnings and Precautions
- Product is non-sterile.
- Sterile drapes required during sterile procedures.
- Do NOT use if the device is damaged in any way. Do NOT drop LASS, as this may result in damage to the device.
- Re-clean all individual LASS parts prior to each use. Cleaning and disinfecting recommendations are listed below.
- Store LASS parts together, away from extreme temperatures.

Potential Complications
- Skin abrasion
- Allergic reaction

Directions for Use

(Note: Photos omit sterile drapes for clearer images of LASS board/foam positioning. Sterile drapes should NOT be omitted during radiological and surgical procedures.)

Steps to Set Up LASS Before Procedure

1. Place the Base Board (LP1001) under the mattress on the left side of the table so that it is 10-12 inches (25-30 centimeters) from the head of the table. Leave 2-3 inches (5-8 centimeters) from the edge of the mattress to the notch on the Base Board. (See Figure 1.)

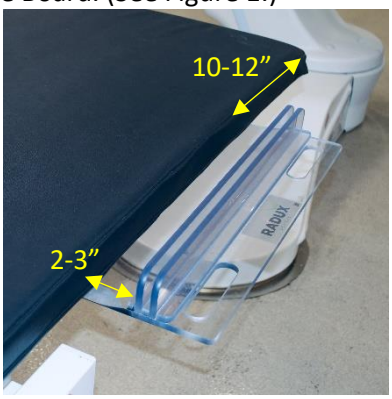

Figure 1.

2. Attach the Arm Board (LP1002) horizontally into the Base Board notch. The labels on the Arm Board should face the floor in this position. (See Figure 2.)

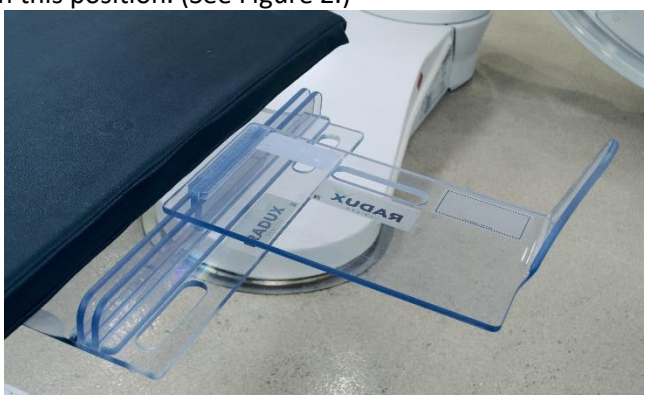

Figure 2.

3. With the patient on the table, extend the patient’s arm on the Arm Board so that it is abducted in a supine position for vascular access in the wrist. (See Figure 3.)

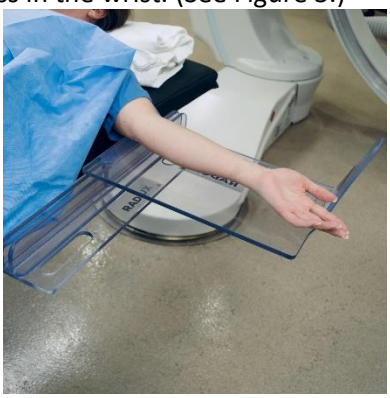

Figure 3.

4. Obtain vascular access in the wrist. Then place the patient's arm across their body in a prone position on top of their abdomen. Hold the patient's arm in place to prevent it from extending or falling aside until the Foam piece is inserted for stabilization.

5. Based on patient size, select either the Large Foam (LP1003) or the Small Foam (LP1004) to insert in the space between the mattress edge and the Base Board notch. Place foam so that the "ELBOW" label faces up and is readable from the left side of the table. The "LARGE" or "SMALL" label with upward-facing arrows on the side of the Foam piece should face outward on the left side of the table. (See Figures 4 and 5.)

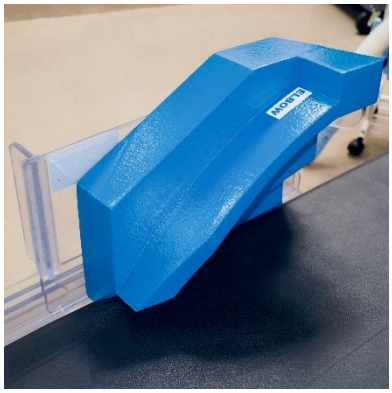

Figure 4.

Figure 5.

6. Once the Foam piece has been properly inserted, it will prevent the patient's elbow from dropping down by their left side. Remove the horizontally placed Arm Board and insert it vertically into the Base Board notch. The curved lip on the Arm Board will wrap around the side of the Foam piece, and the clear "Align foam arrows here" label on the Arm Board will be positioned in front of the "LARGE" or "SMALL" label with upward-facing arrows on the Foam piece. (See Figures 6 and 7.)

Figure 6.

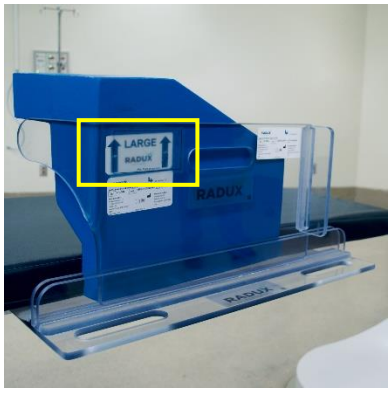

Figure 7.

Steps to Remove LASS After Procedure

1. Hold the patient's arm in position and remove the Arm Board from its vertical position in the notch of the Base Board.
2. Place the Arm Board horizontally into the Base Board notch. The labels on the Arm Board should face the floor in this position.
3. Remove the Foam piece and move the patient's arm from its prone position across their body to be in an abducted, supine position on the horizontal Arm Board allowing for vascular access.

Cleaning and Disinfecting Recommendations

- Follow the guidelines set forth by AORN, HIMA, and AAMI when cleaning and disinfecting LASS.
- Cleaning and disinfecting should be done outside of the sterile field.
- Spray or wipe with facility-approved, compatible cleaning and disinfecting agents.
- Follow all directions and guidelines provided by cleaning/disinfecting solution suppliers.
- Ensure that all solutions have dried before reusing the device.
- Do NOT use abrasive cleaning solutions, scouring pads, or ammonia-based cleaner.

Limited Warranty

Radux Devices warrants that LASS (Left Arm Support System) is free from defects in workmanship and materials for one (1) year from date of sale. Liability under this warranty is limited to refund or replacement of the part which has been found by Radux Devices to be defective in workmanship or materials. Radux Devices shall not be liable for any incidental, special, or consequential damages arising from use of the product. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty. No employee, agent, or distributor has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Radux Devices.

Symbols Legend

Symbol	Definition	Title and Designation # of Standard	Reference #
	Catalog Number	ISO 15223-1:2021 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.6
	Batch Code	ISO 15223-1:2021 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.5
	Consult instructions for use	ISO 15223-1:2021 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.3
	Manufacturer	ISO 15223-1:2021 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.1
	Date of Manufacture	ISO 15223-1:2021 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.3
	Medical Device	ISO 15223-1:2021 Medical devices- Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.7.7

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