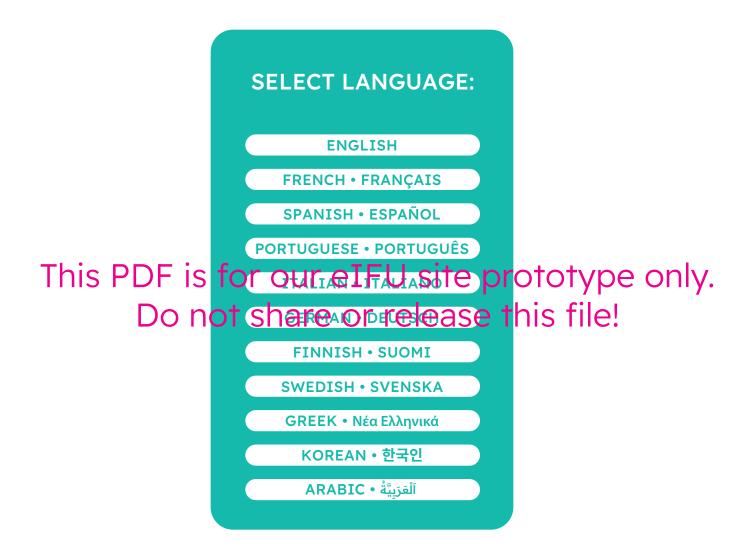
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**⊿**BONE**FOAM**°

## **BLOCK & WEDGE**

**UPPER EXTREMITY POSITIONERS** 

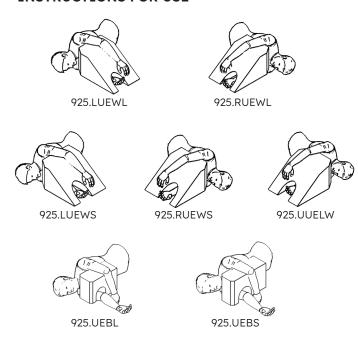




Upper Extremity Blocks & Wedges are reusable freestanding positioners designed to position the patient's upper extremities for upper extremity procedures in the lateral decubitus position.



### **INSTRUCTIONS FOR USE**



### CLEANING AND DISINFECTING INSTRUCTIONS

- Do not sterilize the product. This product is not intended to be sterilized.
- For coated products, wipe the product with a clean wipe and disinfectants after every use. The following disinfecting materials are known to be compatible with coated BoneFoam products:
  - Rubbing alcohol (70% isopropyl alcohol)
  - General purpose/all purpose cleaner
    - Read and follow the cleaning product's instructions.
- Make sure that the coated product is dry before you store it or use it again.

### WARNINGS/PRECAUTIONS/CONTRAINDICATIONS

- Intended to contact intact skin only.
- Incorrect positioning of the patient with this product can increase the risk of:
  - Pressure injury resulting in markings or ulcers
  - Peripheral nerve injury, which can lead to temporary or permanent paralysis
  - Venous pressure, which can lead to ischemia
  - Instability, which can lead to patient falls
- Product is to be used by licensed medical professionals only.
- · Not intended for patient transport.
- This product has a vinyl coating. While this coating is intended to enhance product durability and usability and is safe for skin contact, it may cause allergic reactions in individuals sensitive to vinyl or its derivatives.

- Possibility of artifacts in imaging applications depending on setup and imaging settings.
- Risk of fire. Below are flammability ratings of the materials:
  - Coating: UL 94 HBF
  - Foam: Rated either UL 94 HBF or CAL 117

## CARE, HANDLING AND USEFUL LIFE

- Avoid using the product if package is damaged during transportation.
- Allow coated products to reach room temperature after storage or transportation in cold temperatures.
- Transport and store in dry conditions and out of direct light where possible.
- To prevent patient and/or user injury and/or equipment damage, examine the product for potential damage or wear prior to use. Do not use the product if damage is visible, if parts are missing, or if it does not function as expected.
- Avoid storing where sharp objects could pierce the coating of the product.
- · Avoid stacking items on top of product when storing.
- Do not submerge the product in water. Equipment damage can occur.
- Prior to using this product, read the Instructions for Use.
- Discontinue use if foam has degraded or lost resilience, or if coating is torn, cracked, or loose and wrinkles, as this may lead to acute pressure points.

### SAFE DISPOSAL INSTRUCTIONS

Customers should adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories.

### **PACKAGING**

The product is packaged in a clear polythene bag inside a corrugated cardboard box.

### SAFETY INFORMATION

The techniques detailed in this manual are only manufacturer's suggestions. The final responsibility for patient care with respect to this product remains with the attending physician. Any serious incident that has occurred in relation to this product should be reported to the manufacturer and regulatory authority, where required. Keep this manual available for future reference.

SKU	DESCRIPTION	INTENDED USE	INDICATIONS
925.LUEWL	Wedge   Left Upper Extremity   Large	Nonsterile, reusable upper extremity positioner intended to support, stabilize, and offset the arm in a bent position in the lateral decubitus position.	Indicated for use by healthcare professionals to position the patient's left arm for left arm procedures.
925.LUEWS	Wedge   Left Upper Extremity   Small		
925.RUEWL	Wedge   Right Upper Extremity   Large		Indicated for use by healthcare professionals to position the patient's right arm for right arm procedures.
925.RUEWS	Wedge   Right Upper Extremity   Small		
925.UUELW	Wedge   Universal Upper Extremity	Nonsterile, reusable upper extremity positioner intended to support and stabilize the arm in a bent position in the lateral decubitus position.	Indicated for use by healthcare professionals to position the patient's arm for arm procedures.
925.UEBL	Block   Upper Extremity   Large	Nonsterile, reusable upper extremity positioner intended to support, stabilize, and offset the arm in a bent position in the lateral decubitus position.	
925.UEBS	Block   Upper Extremity   Small		

SYMBOL	DESCRIPTION
MD	Indicates the device is a medical device
•••	Indicates the medical device manufacturer
<b>***</b>	Indicates the country where the medical device was manufactured and date of manufacture
LOT	Indicates the manufacturer's lot number
GTIN	Indicates the medical device Global Trade Item Number
REF	Indicates the manufacturer's catalogue number
UDI	Indicates the unique product identifier information for the device
i	Indicates the need for the user to consult the instruction for use
LATEX	Indicates the device does not contain natural rubber or dry natural rubber latex

SYMBOL	DESCRIPTION
1	Indicates the temperature limits to which the medical device can be stored, transported or used
	Indicates a medical device should not be used if the package has been damaged or opened
QTY	Indicates quantity in package
EC REP	Indicates the European Authorized Representative name and address in the European Community
(€	Signifies European technical conformity
UK	Signifies Great Britain technical conformity
UK RP	Indicates a UK Responsible Person on medical device information supplied by the manufacturer
CH REP	Indicates an Authorized Representative in Switzerland on medical information supplied by the manufacturer