

# Patient Positioning

## Body Wedge

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
50-150401	Body Wedge, 24x8" (61x20cm)	6	24x17x25" (61x43x64cm)

### Materials

- Polyurethane Foam (PU)

### Product Attributes

- Convoluted "egg crate" polyurethane foam
- High density foam

### Sterilization

Non-Sterile: This product is intended to be used non-sterile. If the repackager intends to sterilize this product, a validation must be conducted to demonstrate their sterilization process will meet all the ISO 11135 and EN 10993 requirements to demonstrate sterility and EO/ECH residual compliance. It must be done according to their validated sterilization process.

### Shelf Life

Non-Sterile: Established at 5 years based upon sterile packaged product aging studies and normal warehouse storage conditions. After 5 years, the product should be performance tested to ensure compliance to specifications.

### Product Certifications/Standards

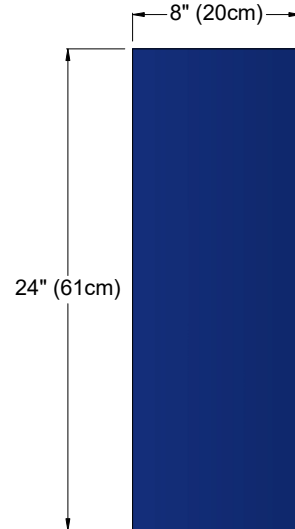
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

### Manufacturing Certifications/Registrations

- EN ISO 13485:2016

### Storage

- General warehouse conditions



Alleset  
 4142 Industry Way  
 Flowery Branch, GA 30542,  
 USA  
[www.alleset.com](http://www.alleset.com)  
 SM-TDS-002 2022  
 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.



Global Resources International Tennessee Foam Inc,  
 910 Callahan Dr #108,  
 Knoxville, Tennessee,  
 37912 UNITED STATES  
[www.alleset.com](http://www.alleset.com)  
 US FDA Establishment Registration #3017728970



Alleset Limited B.V.  
 Kingsfordweg 151,  
 1043 GR Amsterdam,  
 The Netherlands  
[www.alleset.com](http://www.alleset.com)

