

# Patient Positioning

## Patient Positioning Strap

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
50-AB3010	Arm Board Strap, 1.5x32" (4x81cm)	48	15x11x7" (37x27x18cm)

### Materials

- Hook Material
- Three-Layered Construction:
  - Top and Bottom Layers: Polyester Fiber Cloth
  - Middle Layer: Polyurethane (PU) Foam

### Product Attributes

- One piece design
- Hook and loop securement

### 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

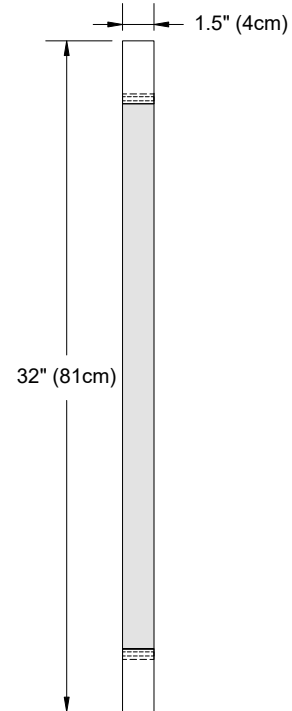
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

### Manufacturing Certifications/Registrations

- EN ISO 13485:2016
- Medical Device Single Audit Process Certified

### Storage

- General warehouse conditions



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 SM-TDS-003 2023  
 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.



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