

Patient Positioning

Patient Positioning Straps

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
50-KB2030	Patient Positioning Straps, 4x33" (10x84cm)	12	12x11x10" (31x28x26cm)

Materials

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

Product Attributes

- Hook and loop securement
- Foam strap design
- Plastic buckle

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

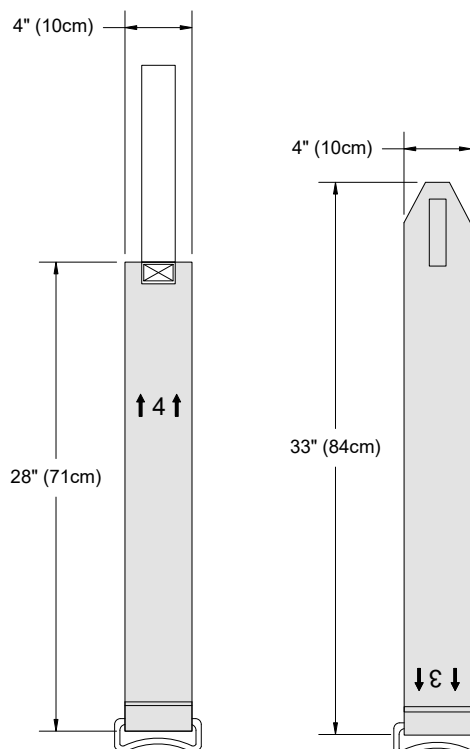
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

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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