Patient Positioning

Arm Protectors





Materials

- Green Polyurethane (PU) Foam
- O Straps: Composite Sponge and White Velcro Hook

Product Attributes

- 1" thick protective foam
- · Velcro straps secure foam in the closed position

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

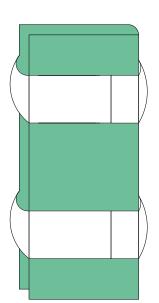
• CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/Registrations

• EN ISO 13485:2016

Storage

· General warehouse conditions















SM-TDS-002 2022 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.





EC REP

GRI-Alleset Limited B.V. Kingsfordweg 151, 1043 GR Amsterdam, The Netherlands www.alleset.com

