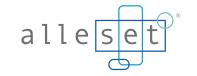
Patient Positioning

Head Cradles



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N	50-150101	Head Cradle, Adult, 9x8x4.25" (23x20x10.8cm)	36	24x17x25" (61x43x64cm)
N	50-150102	Head Cradle with Trach Slit, Adult, 9x8x4.25" (23x20x10.8cm)	36	24x17x25" (61x43x64cm)
	50-150104	Head Cradle, Stacked with Trach Slit, Adult,8x8.5x4" (20x22x10cm)	36	24x17x25" (61x43x64cm)
N	50-150105	Head Rest, Donut, 9x2" (23x5cm)	36	20.5x18x19" (52x46x49cm)
	50-150106	Head Rest, Donut Multiple, 9x2" (23x5cm)	36	20.5x18x19" (52x46x49cm)
N	50-150109	Head Cradle, Pediatric, 6.25x7x3.5" (16x18x8cm)	36	20.5x18x19" (52x46x49cm)

Materials

Polyurethane Foam

Product Attributes

· High density polyurethane 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

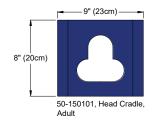
• CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

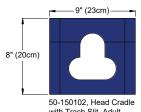
Manufacturing Certifications/Registrations

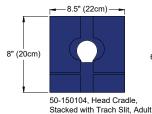
• EN ISO 13485:2016

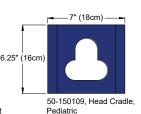
Storage

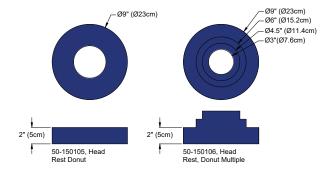
• General warehouse conditions























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







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