Equipment Covers

FCO² C-Arm



41" (104cm)-

125" (318cm)

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	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
	E46-CARM6	ECO ² C-Arm Cover, Universal, w/ Rubber Bands and Clips, 41x125" (104x318cm)	50	18x16x10" (45x41x26cm)
S	E46-CARM6-S	ECO ² C-Arm Cover, Universal, w/ Rubber Bands and Clips, 41x125" (104x318cm)	50	18x16x10" (45x41x26cm)

Materials

ECO² Clear Polyethylene (PE) Film

Product Attributes

- Certain components of this product incorporate ECO2 sustainable materials which enhance product biodegradability
- · Clear film helps prevent image distortion
- · Versatile design
- · Rubber band and clip securement

Sterilization

Sterile: Sterilized by EO (ethylene oxide). Product is sterile unless the package has been damaged or opened.

Non-Sterile: If a product is delivered non-sterile and is ultimately for use in sterile environments, it is intended to be sterilized by the re-packager. This includes further packaging and sterilization according to the validated processes of the re-packager. These products are to be sterilized by ethylene oxide (EO). Other methods of sterilization have not been validated by Alleset.

Shelf Life

Sterile: 5 years

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

- · Sterile: CE certified as Class I, according to MDD93/42/EEC Annex IX, Rule 1
- Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII. Rule 1
- ASTM D5511-12 Standard Test Method for Determining Anaerobic Biodegradation of Plastics Materials Under High-Solids Anaerobic **Digestion Conditions**

Manufacturing Certifications/Registrations

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

Storage

· General warehouse conditions



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Flowery Branch, GA 30542, www.alleset.com SM-TDS-003 2023 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.