

Equipment Covers

ECO² C-Arm

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
E46-CARM12	ECO ² C-Arm X-Ray Image Intensifire Drape, 41x64" (104x163cm)	100	20x13x13" (52x32x32cm)
E46-CARM12-S	ECO ² C-Arm X-Ray Image Intensifire Drape, 41x64" (104x163cm)	50	20x13x13" (52x32x32cm)

Materials

- ECO² Clear Polyethylene (PE) Film

Product Attributes

- Certain components of this product incorporate ECO² sustainable materials which enhance product biodegradability
- 2-sided tape included to secure drape to fluoroscope

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

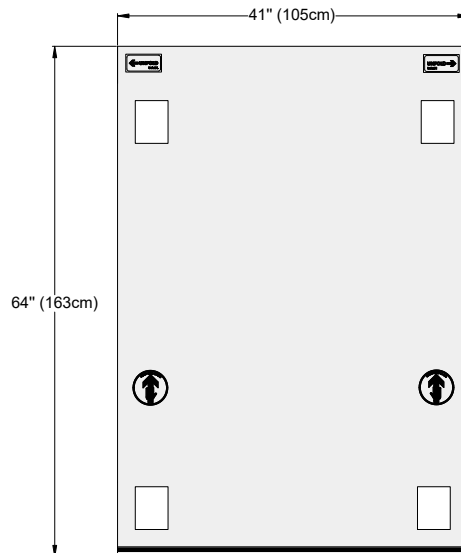
- Sterile: CE certified as Class I, according to MDD93/42/EEC Annex IX, Rule 1
- Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- ASTM D5511-12 Standard Test Method for Determining Anaerobic Biodegradation of Plastics Materials Under High-Solids Anaerobic Digestion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

Manufacturing Certifications/Registrations

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

Storage

- General warehouse conditions



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 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.

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