

# Equipment Covers

## ECO<sup>2</sup> C-Arm

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
E46-CARM11	ECO <sup>2</sup> Fluoroscope Drape, 36x44" (91x112cm)	100	14x11x8" (36x29x21cm)
E46-CARM11-S	ECO <sup>2</sup> Fluoroscope Drape, 36x44" (91x112cm)	50	14x11x8" (36x29x21cm)

### Materials

- ECO<sup>2</sup> Clear Polyethylene (PE) Film
- 2-Sided Tape

### Product Attributes

- Certain components of this product incorporate ECO<sup>2</sup> 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

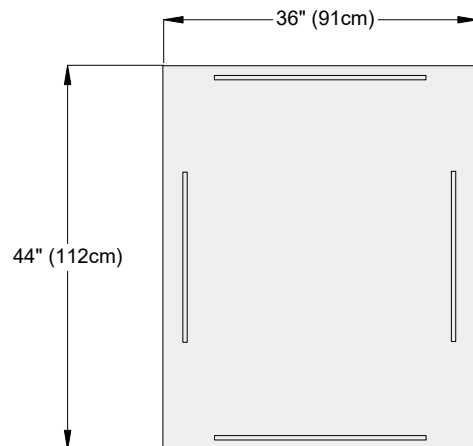
- Sterile: CE certified as Class I, according to MDD93/42/EEC Annex IX, Rule 1
- Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- ASTM D5511-12 Standard Test Method for Determining Anaerobic Biodegradation of Plastics Materials Under High-Solids Anaerobic Digestion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