# **Equipment Covers** FCO<sup>2</sup> C-Arm



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
	E46-CARM4	ECO <sup>2</sup> C-Arm Cover, 54" (137cm) Split w/ Tape Tabs, 41x90" (104x229cm)	100	19x15x12" (47x38x30cm)
S	E46-CARM4-S	ECO <sup>2</sup> C-Arm Cover, 54" (137cm) Split w/ Tape Tabs, 41x90" (104x229cm)	50	19x15x12" (47x38x30cm)

## Materials

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

## **Product Attributes**

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

- materials which enhance product biodegradability
- · Clear film helps prevent image distortion
- Versatile design
- Adhesive tab 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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