alleset ®

Surgical Drapes
Ophthalmic

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
(N) 80-04106	Ophthalmic Drape w/ Full Incise, 56x52" (142x132cm)	60	18x14x15" (46x35x38cm)
(S) 80-04106-S	Ophthalmic Drape w/ Full Incise, 56x52" (142x132cm)	44	20x17x20" (50x43x50cm)

Materials

● Multilayered SMS Material with Antistatic Properties and Alcohol Repellency
○ Clear Polyethylene (PE) Film

Product Attributes

• Adhesive incise area
• Fluid collection pouch
• Eye wick
• Malleable breather bar

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.
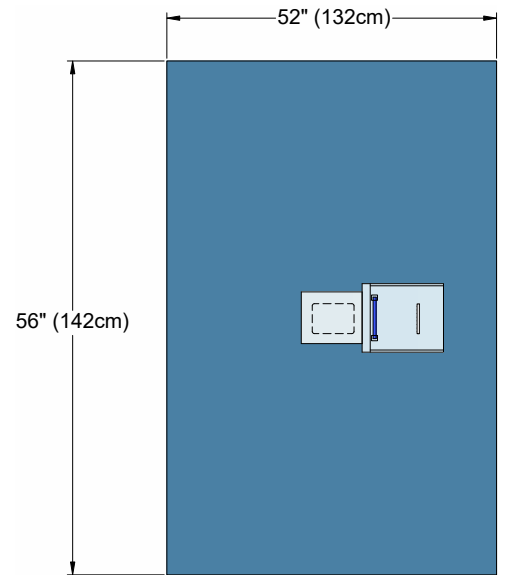
Product Certifications/Standards

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

Manufacturing Certifications/Registrations

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

Storage

• General warehouse conditions

52" (132cm)
56" (142cm)

(N) NON-STERILE
(S) STERILE

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