

Surgical Drapes

Obstetrics / Gynecology

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
80-07101	C-Section Drape w/ Fenestrated Incise, 100x120" (254x305cm)	13	18x11x19" (45x29x48cm)
80-07101-S	C-Section Drape w/ Fenestrated Incise, 100x120" (254x305cm)	8	19x12x13" (49x30x33cm)

Materials

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

Product Attributes

- Adhesive incise area with triangular fenestration
- Fluid collection pouch with suction port
- Malleable banded pouch
- Tube holders
- Armboard covers

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-packer. This includes further packaging and sterilization according to the validated processes of the re-packer. 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

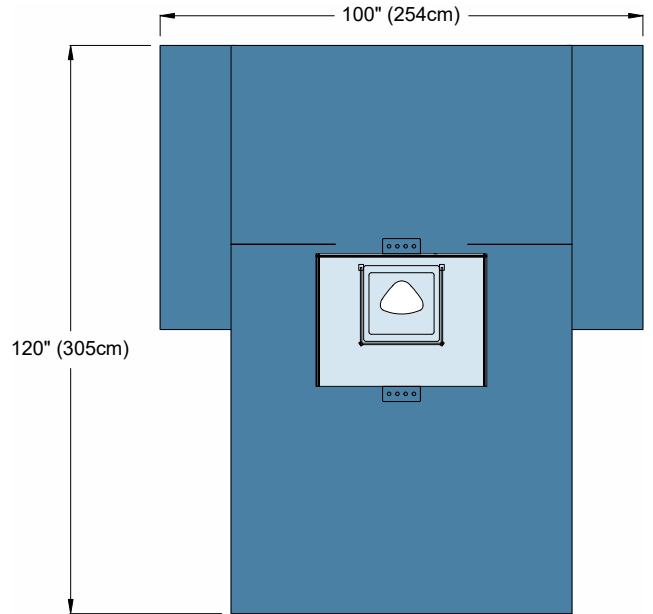
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/Registrations

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

Storage

- General warehouse conditions



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



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