

Surgical Drape

General Surgery

	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
	80-01116	Pacing Drape, 81x108" (205x275cm)	16	19x15x14" (47x38x35cm)
	80-01116-S	Pacing Drape, 81x108" (205x275cm)	TBD	TBD

Materials

- Multilayered SMS Material with Antistatic Properties and Alcohol Repellency
- Hydra™ Absorbent Reinforcement

Product Attributes

- Oval fenestration
- Adhesive tape for secure placement
- Absorbent reinforcement material for fluid management

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

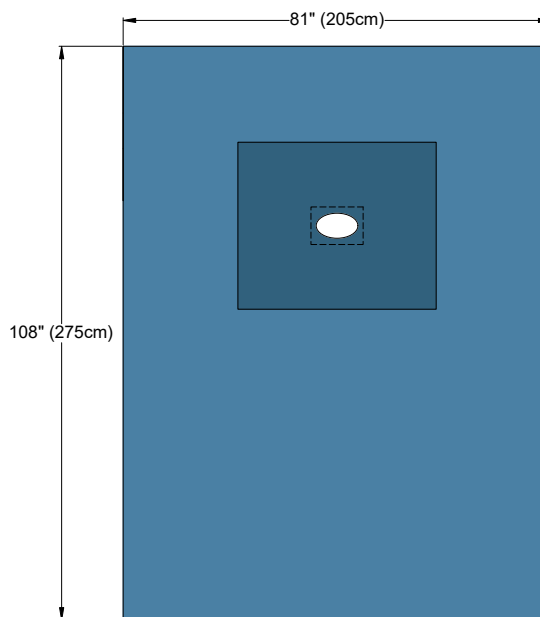
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/Registrations

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

Storage

- General warehouse conditions



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 SM-TDS-002 2022
 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.

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