

Surgical Drapes

General Surgery

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
80-05829G	Top Drape, 59x94.5" (150x240cm)	26	18x12x22"(46x30x55)

Materials

- ONEZONE® Tri-Laminate Nonwoven Material (PP/PP/PE)
- HydraGuard® Absorbent Reinforcement

Product Attributes

- Absorbent top layer with impermeable film bottom layer for maximum protection

Sterilization

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

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

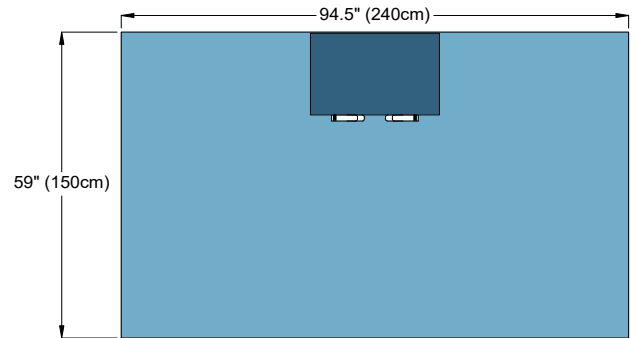
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- Class I Flammability per 16 CFR 1610.4 Standard
- L1 Laser Resistance per ISO 11810-1:2005

Manufacturing Certifications/Registrations

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

Storage

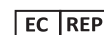
- General warehouse conditions



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SM-TDS-003 2023
Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.



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