Surgical Drapes

Laparotomy



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N	80-05174G	Laparoscopic/Pelviscopy Drape w/ Attached Leggings and Fluid Collection Pouch, 30x111x124" (76x283x314cm)	10	23x14x17" (58x36x43cm)
S	80-05174G-S	Laparoscopic/Pelviscopy Drape w/ Attached Leggings and Fluid Collection Pouch, 30x111x124" (76x283x314cm)	10	24x16x18" (60x40x45cm)

Materials

- Multilayered SMS Material with Antistatic Properties and **Alcohol Repellency**
- HydraGuard® Absorbent Reinforcement
- Clear Polyethylene (PE) Film

Product Attributes

- · Trapezoidal abdominal fenestration
- Perineal fenestration
- Attached leggings
- · Absorbent reinforcement material
- Armboard covers
- · Hook and loop tube and line control
- · Fluid collection pouch with filtering screen and suction port

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 repackager. 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

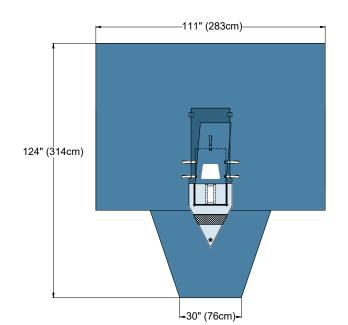
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- US FDA: Class II

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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EC REP

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