

Surgical Drapes Obstetrics/Gynecology

	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
	80-11114G	GYN Urology Drape w/ Attached Leggings and Pouch, 112x133" (285x338cm)	16	24x16x18" (60x40x45cm)
S	80-11114G-S	GYN Urology Drape w/ Attached Leggings and Pouch, 112x133" (285x338cm)	14	24x16x18" (60x40x45cm)

Materials

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

Product Attributes

- Perineal fenestration
- Absorbent reinforcement material for fluid management
- Tube holders
- · Fluid collection pouch with filtering screen and suction port
- Attached leggings
- 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 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

Manufacturing Certifications/Registrations

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

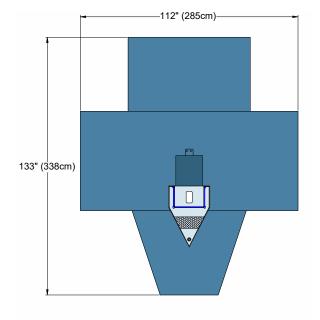
Storage

· General warehouse conditions



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US FDA Establishment Registration #3004911384





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