Surgical Drapes Obstetrics/Gynecology



40" (102cm)

	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
	80-14101	Under Buttocks Drape w/ Fluid Collection Pouch, 40x44" (102x112cm)	100	18x11x19" (45x29x48cm)
S	80-14101-S	Under Buttocks Drape w/ Fluid Collection Pouch, 40x44" (102x112cm)	50	19x13x12" (49x33x30cm)

44" (1¹12cm)

Materials

- Clear Polyethylene (PE) Film
- Blue Polyethylene (PE) Film

Product Attributes

· Fluid collection pouch with 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

Manufacturing Certifications/Registrations

• EN ISO 13485:2016

Medical Device Single Audit Process Certified

Storage

· General warehouse conditions



Alleset 4142 Industry Way Flowery Branch, GA 30542, USA www.alleset.com SM-TDS-003 2023 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.



GRI Medical & Electronic Technology Co., LTD 1805 Honggao Road, 314031 Jiaxing, Zhejiang PEOPLE'S REPUBLIC OF CHINA www.alleset.com US FDA Establishment Registration #3004911384



Emergo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands www.emergobyul.com



