

Surgical Drapes

Obstetrics/Gynecology

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
80-14104	Under Buttocks Drape, 38x54" (96x137cm)	80	22x12x12" (56x31x31cm)
80-14104-S	Under Buttocks Drape, 38x54" (96x137cm)	30	16x12x14" (40x30x35cm)
80-14104-HB	Under Buttocks Drape, Handi Bin, 38x54" (96x137cm)	TBD	TBD

Materials

- Multilayered SMS Material with Antistatic Properties and Alcohol Repellency
- Grey Polyethylene (PE) Film

Product Attributes

- Film reinforcement

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-packager. 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: Establishes 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

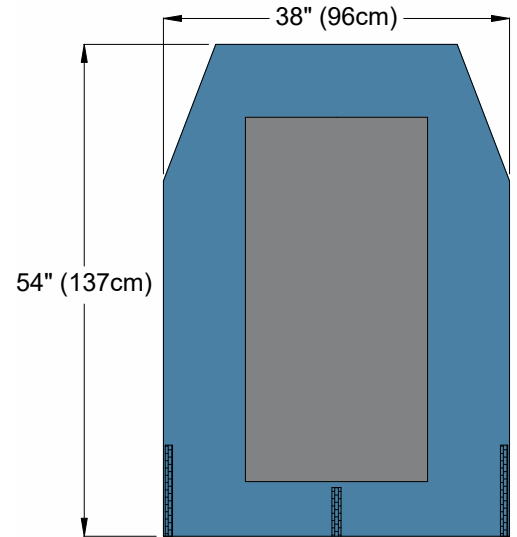
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/Registrations

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

Storage

- General warehouse conditions



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Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.



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