Surgical Drapes Cardiovascular



	CODE	DESCRIPTION		CASE QTY	CASE DIMENSIONS	
	80-02134G	0-02134G Cardiovascular Drape w/ Instrument Pouch, 102x126" (260x320cm)		12	20x12x19" (51x31x47cm)	
Materials						
Multilayered SMS Material with Antistatic Properties and Alcohol Repellency						
l F	lydraGuard® Absor	bent Reinforcement				
Clear Polyethylene (PE) Film						
Product Attributes						
 Absorbent reinforcement material for fluid management Bilateral instrument pouches 		 126" (320cm) 				

Two fenestrations for surgical site access

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 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

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. THINK.MAKE.PROTECT.



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