

Surgical Accessories

Light Handle Covers

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N 25-3611	Light Handle Cover, Flexible, Green	1000	21x21x20" (54x54x50cm)
S 25-3611-S1	Light Handle Cover, Flexible, Green	120	17x11x10" (44x29x25cm)
S 25-3611-S2	Light Handle Cover, Flexible, Green, 2ea pack	120	17x11x10" (44x29x25cm)
S 25-3611-S3	Light Handle Cover, Flexible, Green, 3ea pack	150	20x12x9" (51x30x9cm)
N 25-3613	Light Handle Cover, Universal, Plastic Base, Blue	200	21x17x8" (54x44x20cm)
S 25-3613-S1	Light Handle Cover, Universal, Plastic Base, Blue	100	18x12x12" (45x30x31cm)
N 25-3613GN	Light Handle Cover, Universal, Plastic Base, Blue, Dark Green	200	21x17x8" (54x44x20cm)

Materials

- 25-3611, 25-3611-S1, 25-3611-S2 and 25-3611-S3: Low Density Polyethylene (LDPE)
- 25-3613: Blue Polyethylene (PE) Film, White Polyethylene (PE)
- 25-3613GN: Dark Green Polyethylene (PE) Film, White Polyethylene (PE)

Product Attributes

- Flexible, fits most surgical light handle adapters
- Reduces need to reprocess and sterilize

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-packer. This includes further packaging and sterilization according to the validated processes of the re-packer. These products are to be sterilized by ethylene oxide (EO). Other methods of sterilization have not been validated by Alleset.

Shelf Life

Sterile (25-3611-S1/S2/S3): 5 Years
Non-Sterile (25-3611): Established at 5 years based upon sterile packaged product aging studies and normal warehouse storage conditions. After 5 years, product should be performance tested to ensure compliance to specifications
Non-Sterile (25-3613/GN): Established at 5 years based upon sterile packaged product aging studies and normal warehouse storage conditions. After 5 years, product should be performance tested to ensure compliance to specifications

Product Certifications/Standards

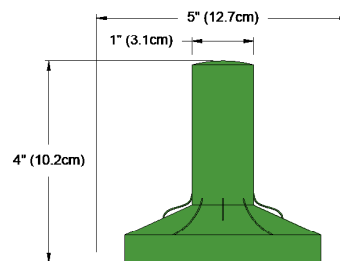
- Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- Sterile: CE certified as Class I, according to MDD93/42/EEC Annex IX, Rule 1

Manufacturing Certifications/Registrations

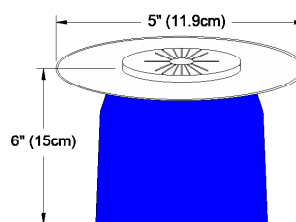
- EN ISO 13485:2016

Storage

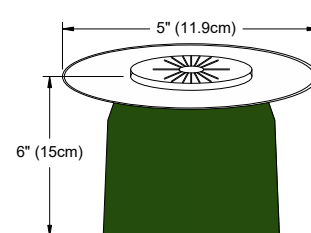
- General warehouse conditions



25-3611, 25-3611-S1, 25-3611-S2 and 25-3611-S3



25-3613



25-3613GN



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

