Surgical Accessories

Light Handle Covers



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
	25-3011	Flexible Light Handle Cover	2400	31x24x20" (79x61x51cm)
S	25-3011-S1	Flexible Light Handle Cover	128	15x12x8" (38x30x20cm)
S	25-3011-S2	Flexible Light Handle Cover	160	15x12x8" (38x30x20cm)
S	25-3011-S3	Flexible Light Handle Cover	240	15x12x8" (38x30x20cm)

Materials

· Low Density Polyethylene (LDPE)

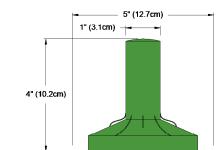
Product Attributes

- · 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 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, 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,

Manufacturing Certifications/Registrations

• EN ISO 13485:2016

Storage

· General warehouse conditions













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SM-TDS-003 2023 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.

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EC REP

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