

STERILE SUPPLY

- Light Handle Cover

**Product Function**

The Light Handle Cover is used in theatres to cover the Light Handle Fixture, allowing control of movement & focusing of the light by the surgeon, and preventing cross contamination to the patient.

Product Description

The disposable Light Handle Cover is a single use device, and is supplied sterile.

The Light Handle Cover is durable, light and a snug fit to the Purple Surgical or similar light handle fixtures.

Product Range

PS4611	Light Handle Cover – Single Pack
PS4612	Light Handle Cover – Dual Pack
PS4613	Light Handle Cover – Triple Pack

Standardisation

Device Classification (Defined by 93/42/EEC Directive)	Class 1, Sterile, Rule 1
CE Marking	CE 1639
GMDN	44977
Quality System Certified to	ISO 13485:2016

Sterilisation

Supplied in Sterile Condition	YES
Sterilisation Method	Ethylene Oxide
Product Shelf Life	4 years from date of sterilization

Single Use Warning

These device(s) are designed and sold for single use only as defined in Article 1 (n) of directive 2007/47/EC. As such re-processing and/or re-sterilisation after initial use is not permitted.

The effects of any unauthorized re-processing or re-sterilisation can result in the following complications:

1. Cross contamination due to ineffective re-processing/re-sterilisation.
2. Mechanical fatigue, and associated failure, due to the effects of the re-processing/re-sterilisation method.

Compatibility and Connectivity

The single use Light Handle Cover is designed to fit a Purple Surgical Light Handle Adaptor Fixture.

A range of Purple Surgical Light Handle Adaptor Fixtures (see Adaptor Technical File Summary document) are available to convert theatre lighting handle grips to a standardized dimension, so as to permit the secure use of the standard size Light Handle Cover devices.

Product Materials

Components	Material	Grade	CAS#
Light Handle Cover	ULDPE/LDPE	AP5622 or YZ631DW	9002-88-4

Materials Data

The substances, which are contained in the Device, and require registration under REACH, have been (pre-) registered by our upstream suppliers. Substances, listed in Annex XVII of the EU Regulation No 1907/2006, concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), are not intentionally used or added in the formulation of the Device. However, since the product has not been tested for these substances, we cannot guarantee that there is no trace amount present, as impurity or otherwise.

The Device does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (SVHC) in a concentration above the threshold limit of 0.1 % (w/w) as stated in the REACH (Article 57).

The Device does not contain any of the biocides as stated in the EU Regulation No 528/2012 concerning biocidal products.

Latex Free	YES
Phthalate (DEHP, BBP & DBP) Free	YES

Packaging

Unit Packaging		Pouch: Grid Coated Paper with PA/PE/DS Seal Layer Film. Trade name OCPSxxxx10X/DS120			
Box Packaging		Shelf Box	Shipping Carton		
Product Code	Qty. (Pcs)	Dimensions (mm) (L x W x H)	Qty. (Pcs)	Dimensions (mm) (L x W x H)	Gross Wt. (Kg)
PS4611	N/A	N/A	100	448 x 325 x 166	1.40
PS4612	N/A	N/A	100	431 x 311 x 272	1.90
PS4613	N/A	N/A	100	431 x 311 x 272	2.60

Disposal

After single patient use, the device is to be immediately disposed of as controlled medical waste.

Availability of Instructions for Use:

YES ☐

NO ☒

Storage and Handling Instructions:

Store and Handle with Care



Document Revision History

Revision	Change Detail	Date	Approved
1.	First revision for EO sterilised version of product in new breathable packaging.	2018-11	CW
2.	Box dimensions change on PS4612S & PS4613 (EO only) – PCN 683.	2019-11	EG
3.	Box size change on PS4612 – PCN 748.	2020-01	EG
4.	Label transition from CE 0120 to CE 1639 (UK SGS office to Belgium). Adding (L × W × H) in the Dimensions heading in the Packaging section and updating the Inner Box dimensions of PS4611S from 160 × 160 × 200 to 214 × 153 × 153, and of PS4612S from 160 × 160 × 200 to 264 × 207 × 153, and Shipping Carton dimensions of PS4611 and PS4611S from 180 × 330 × 450 to 448 × 325 × 166, of PS4612 from 200 × 340 × 500 to 431 × 311 × 272, of PS4613 and PS4612S from 280 × 330 × 450 to 431 × 311 × 272. Insertion of REACH compliance statement into the Materials Data section.	2020-11	M. Cihal
5.	Obsolescence of Codes PS4611S & PS4612S – PCN 795.	2021-03	JH