



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

<b>PS4611</b>	Light Handle Cover Single Pack
<b>PS4612</b>	Light Handle Cover Dual Pack
<b>PS4613</b>	Light Handle Cover Triple Pack
<b>PS4611S</b>	Light Handle Cover Single Pack – inner boxed
<b>PS4612S</b>	Light Handle Cover Dual Pack – inner boxed

### Standardisation

Device Classification (Defined by 93/42/EEC Directive)	Class 1 Sterile	Rule 1
CE Marking		CE 0120
GMDN		44977
Quality System Certified to	ISO13485:2003 & ISO9001:2008	

### Sterilisation

Supplied in Sterile Condition	YES
Sterilisation Method	Gamma Radiation
Product Shelf Life	4 years from date of sterilisation

### 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 reprocessing 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 reprocessing / 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**

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

**Sterile Unit Packing – Blister Pouch: EP/Polyolefin/Peel polymer base web, with Polyester/ Polyethylene laminate Peelable Lid.**

Packaging	Shelf Box		Shipping Carton			
	Product Code	QTY. Pcs.	Dimensions, mm	Qty. Pcs.	Dimensions, mm	Gross Wt. Kg
	PS4611	N/A	N/A	100	180 x 330 x 450	1.40
	PS4612	N/A	N/A	100	200 x 340 x 500	1.90
	PS4613	N/A	N/A	100	280 x 330 x 450	2.60
	PS4611S	25	160 x 160 x 200	100	180 x 330 x 450	1.50
	PS4612S	25	160 x 160 x 200	100	280 x 330 x 450	2.00

**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**

<b>Revision</b>	<b>Change detail</b>	<b>Date</b>	<b>Approved</b>
1	First Revision	2005-04	EH
2	Single Use warning added	2009-07	JH
3	New format TFS introduced with added details	2010-10	JH
4	Removal of inner packing boxes on standard range	2012-07	JH
5	Two new codes created for sales with inner boxes	2012-07	JH
6	Material data corrected/explained better on Pouch packaging	2013-11	JH
7	Introduction of Change history table and TFS Numbering system on the TFS template form	2014-02	JH