



EN

Laserguard Silicone Ocular Shield



Product Information and Instructions for Use



MEDASIL SURGICAL LIMITED
Medasil House, Hunslet Road
Leeds, LS10 1AU (UK)
Tel: +44 (0)113 243 3491
E-Mail: orders@medasil.com
Website: www.medasil.com



European Healthcare & Device Solutions (Ireland) Ltd
Stratton House, Bishops Town Road,
Cork, Ireland T12 Y9TC
Tel: +353 (86) 228 0846
www.europeandevicesolutions.eu

UK
CA
0120

CE
1639

SYMBOLS					
	Catalogue Number		Lot Number		Use by date (YYYY-MM-DD)
	Manufactured By		Manufactured Date		Do Not Use if Packaging is Open or Damaged
	Keep Dry		Latex Free		Phthalate free
	Keep away from Sunlight		Sterilisation by Gamma Irradiation		Medical Device
	Do Not Reuse		Do Not Resterilize		Consult Instructions For Use
	Sterile Barrier With inner non sterile Barrier		Caution		

INSTRUCTIONS FOR USE

INTENDED USE:

Medasil Laserguard Silicone Ocular Shield is placed directly onto the eyeball to protect the corneal lens during periorbital dermatological and cosmetic laser procedures, to resist accidental exposure to laser light.

Transient use (continuous use less than 60 minutes).

INTENDED PATIENT POPULATION:

Medasil Laserguard Silicone Ocular Shield is intended for use on the general patient population, applied on adults and children.

INTENDED USERS:

Medasil Laserguard Silicone Ocular Shield is intended to be used by Healthcare Professionals (HCP) only within a clinical/ healthcare setting.

DEVICE DESCRIPTION:

Medasil Laserguard Silicone Ocular Shield is manufactured from Silicone Elastomer which is biocompatible, Latex and Phthalate free. Designed to resist laser penetration into the eye, shielding peripheral tissues against potential damage that may be caused during laser therapy. Available in three distinct colours which are associated with different source wavelengths.

INDICATIONS FOR USE:

- Protection of the eyes during periorbital treatments.
- Shield tissues from inadvertent exposure during ophthalmic and plastic procedures.

PERFORMANCE CLAIMS:

Used during periorbital dermatological and cosmetic laser procedures, to protect the eyes and resist laser penetration.

SAFETY CLAIMS:

- Biologically Safe.

CONTRAINDICATIONS:

- Not to be used for LASIK surgery.

POSSIBLE ADVERSE EFFECTS:

- Discomfort and pain to the patient.
- Permanent damage to the patient if the Laserguard Silicone Ocular Shield is not used as defined in the Intended Use
- In the event of any adverse effects, medical attention must be sought immediately, and the device should be removed by a trained Healthcare Professional (HCP).

WARNINGS AND PRECAUTIONS:

Prior to use the (HCP) should consider the following:

- Only a trained (HCP) should fit and use the device.
- Carefully consider the Laser protection level of the device as suitable for the laser power and wavelength.



The ocular shield is intended as protection against accidental laser strikes and should be changed if damaged.



Carefully consider if the Laserguard Silicone Ocular Shield is appropriate to ensure it meets the requirements of the specific clinical procedure while minimising adverse effects.

- The device is not intended for mechanical protection but does offer some protection to the corneal lens against potential scratches.
- The device must not be trimmed or cut.
- Must not be used if the patient has a known allergic reaction to silicone.
- The sterility is only guaranteed in a sealed, undamaged, and unopened pouch.
- Must not be used beyond the expiry date on the label.
- Must not be used if the packaging has been compromised.
- Must be stored in the original unopened packaging.
- Must be stored away from moisture and direct sunlight.
- The Laserguard Silicone Ocular Shield is single-use device.
- In the event of any serious adverse effects, medical attention must be sought immediately.
- Reuse, re-processing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Reuse, re-processing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user

STERILITY:

The device is supplied STERILE, having been terminally sterilized using Gamma Radiation.

SINGLE-USE:

The device has not been validated for reuse. Anyone reusing a single-use device may be held legally liable for the safe performance of the device.

DISPOSAL OF DEVICES:

Biohazardous related waste means related products which were in use and in direct contact with Human Body Fluids and Tissues.

Please note that the proper disposal of products protects the environment. It prevents possible harmful effects on humans and the environment which could be caused by improper handling of the waste.

Disposal of biohazardous waste shall follow local regulations and environmental requirements, taking different contamination levels into account.

Do not dispose biohazardous related waste as unsorted municipal waste.

Waste disposed of in biohazard waste accumulation sites must be collected by service provider for final off-site treatment/incineration/disposal through a biowaste vendor in accordance with local regulations and environmental requirements.

Table 1. Product pouch REF Specifications:

REF	Model	Laser Type	Laser Protection	Max Laser Energy
510-1101-2204	Yellow	Pulse Dye Laser (Yellow/Orange) Light at 585 nm ± 10 nm	585 I LB7	5 J/cm ²
		Nd: Yag 1064 nm	1064 R LB3	0.0005 J/cm ²
510-1101-2205	Red	Ruby Laser (Red) Light at 694.3 nm	694.3 R LB6	0.5 J/cm ²
		Nd: Yag 1064 nm	1064 R LB4	0.005 J/cm ²
510-1101-2206	Green	Nd: Yag Laser (Green) Light at 532 nm	532 R LB7	5 J/cm ²
		Nd: Yag 1064 nm	1064 R LB5	0.05 J/cm ²

All devices have been tested in accordance with EN 207(E) Test method, reported in Paragraph 3.3, Table 1. 315-1400 nm Range.

Box ref 510-1125-2204 Yellow , 510-1125-2205 Red, 510-1125-2206 Green

LIABILITY AND WARRANTY:

Medasil declares that reasonable care has been applied in the design and manufacture of this product. In the event of any alleged damage, please contact Medasil or your supplier. The responsibility of Medasil or your supplier under this warranty is limited to the replacement of the product if faulty. On no account may Medasil or your supplier be held responsible for damage, whether direct, indirect and/or incidental resulting from the misuse and/or manipulation of this device.

NOTES:

This device:

- Is not made with natural rubber latex.
- Does not contain any animal or human cells, tissues and/or derivatives thereof, rendered non-viable; cells, tissues and/or derivatives of microbial or recombinant origin; and/or irradiating components, ionizing or non-ionizing.
- Are not intended for use by lay persons.

SERIOUS INCIDENT:

Any serious incident that has occurred in relation to the Laserguard Silicone Ocular Shield should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.