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# **Laserguard Silicone Ocular Shield**



# Product Information and Instructions for Use



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terile Barrier



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SYMBOLS							
REF	Catalogue Number	LOT	Lot Number	$\subseteq$	Use by date (YYYY-MM-DD)		
<b>~</b>	Manufactured By	<u></u>	Manufactured Date	<b>®</b>	Do Not Use if Packaging is Open or Damaged		
<del>*</del>	Keep Dry	WTE/	Latex Free	<b>***</b>	Phthalate free		
类	Keep away from Sunlight	STERILE R	Sterilisation by Gamma Irradiation	MD	Medical Device		
2	Do Not Reuse	STERRUZE	Do Not Resterilize	[]i	Consult Instructions For Use		
(	Sterile Barrier With inner non	$\wedge$	Caution				

# INSTRUCTIONS FOR USE

#### > INTENDED USE:

Medasil Laserguard Silicone Ocular Shield is placed directly on to 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 is suitable for the laser  $\triangle$  power and wavelength.

 $\ensuremath{\Delta}$  The ocular shield is intended as protection against accidental laser strike 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 towards silicone.
- The sterility is only guaranteed in a sealed, undamaged, and unopened pouch.
- Must not be used beyond 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 are single use devices.
- In the event of any serious adverse effects, medical attention must be sought immediately.
- Reuse, reprocessing, 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, reprocessing, 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. **Do not resterilize.** 

#### > 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 THE DEVICE:

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/cm²
		Nd: Yag <b>1064</b> nm	1064 R LB3	0.0005 J/cm <sup>2</sup>
510-1101- 2205	Red	Ruby Laser (Red) Light at <b>694.3</b> nm	694.3 R LB6	0.5 J/cm <sup>2</sup>
2205		Nd: Yag <b>1064</b> nm	1064 R LB4	0.005 J/cm <sup>2</sup>
510-1101- 2206	Green	Nd: Yag Laser (Green) Light at <b>532</b> nm	532 R LB7	5 J/cm <sup>2</sup>
2206		Nd: Yag <b>1064</b> nm	1064 R LB5	0.05 J/cm <sup>2</sup>

All devices have been tested in accordance to EN 207(E) Test method, reported as 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 declare 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 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.

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.