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Laserguard Silicone Bite Guard



Product Information and Instructions for Use



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Symbols					
	Catalogue Number		Lot Number		Use by date
	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		Authorised Representative in the European Community
	Do Not Reuse		Do Not Resterilize		Consult Instructions For Use
	Medical Device		Single Sterile Barrier		Warning

INSTRUCTIONS FOR USE

- **INTENDED USE:**
Medasil Laserguard Silicone Bite Guard is intended to protect the teeth and oral tissues from damage due to accidental laser contact, impact or trauma. The device is intended for short-term use (up to 29 days).
- **INTENDED PATIENT POPULATION:**
Laserguard Silicone Bite Guard is intended for use on the general patient population, applied on adults and children.
- **INTENDED USERS:**
Laserguard Silicone Bite Guard is intended to be used by Healthcare Professionals (HCP) only within a clinical/healthcare setting.
- **DEVICE DESCRIPTION:**
The Laserguard Silicone Bite Guard is manufactured from Silicone elastomer which is biocompatible, Latex and Phthalate free. It is a flexible preformed device designed to resist laser penetration and protect the teeth and oral tissues.
The device is coloured blue for easy identification against natural tissues.
- **INDICATIONS FOR USE:**
Protection of the patient's teeth and oral tissues from damage due to accidental laser contact, impact or trauma during dental, dermatological or cosmetic laser therapy.
- **PERFORMANCE CLAIMS:**
 - A flexible, durable, preformed device designed to shield tissues from inadvertent laser exposure during laser therapy procedures to resist laser penetration and protect the teeth and oral tissues.
 - Provide protection of the patient's teeth against accidental damage to loose teeth, dental features such as caps or crowns, or tissues of the buccopharyngeal area during oral surgeries.
- **SAFETY CLAIMS:**
Biologically Safe.
- **CONTRAINDICATIONS:**
 - Heavy bleeding or active infections within the buccopharyngeal area.
 - The device should not be used on individuals with insufficient dental support for the mouth guard.
 - Patients with contraindications to wearing a mouth guard, such as chronic obstructive pulmonary disease.
- **POSSIBLE ADVERSE EFFECTS:**
Discomfort and/or unwanted movement of the device caused by an imperfect fit.
- **WARNINGS AND PRECAUTIONS:**
Prior to use the HCP should consider the following:
 - Only a trained HCP should fit and use the device.
 - The device is only appropriate for Er: YAG lasers with a wavelength of 2940 nm.

Carefully consider the Laser protection level of the device to ensure that it is suitable for the laser power and wavelength of the equipment to be used.
 - Must not be used if the patient has a known allergic reaction to silicone.
 - Device is sterile only in a sealed, undamaged and unopened pouch.
 - Must not be used if the packaging has been compromised.
 - Must not be used beyond the expiry date on the label.
 - Must be stored in the original unopened packaging.
 - Must be stored away from moisture and direct sunlight.
 - The Laserguard Silicone Bite Guards are single-use devices.
 - 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. 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 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 REF Specifications:

Product	REF	Laser Protection	Max Laser Power
Box of 20	520-1120-0002	2940 I LB3 Tested for Er:YAG 2940 nm	0.0005 J/cm ²
Individual Pouch	520-1101-0002		

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

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 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 the 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 Medasil Laserguard Silicone Bite Guard should be reported to Medasil and/or the competent authority of the member state in which the user and/or patient is established.