Non-Sterile Silicone Bite Guard

Product Information and Instructions for Use

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Symbols					
REF	Catalogue Number	LOT	Lot Number		Use by date
	Manufactured By		Manufactured Date		Do Not Use if Packaging is Open or Damaged
	Keep Dry	LATEX	Latex Free	PHT	Phthalate free
	Keep away from Sunlight	NON STERILE	Non Sterile	EC REP	Authorised Representative in the European Community
	Do Not Reuse		Do Not Resterilize		Consult Instructions For Use
MD	Medical Device				

INSTRUCTIONS FOR USE

➢INTENDED USE:

Medasil Silicone Bite Guard is intended to be positioned over the teeth prior to, and during, induction of anaesthesia, intubation, endoscopy, or other surgical or diagnostic procedures involving oral access. It provides protection against accidental damage to loose teeth, dental features such as caps or crowns, or tissues of the buccopharyngeal area, that may result from unintentional or excessive contact with surgical instruments including laryngoscopes and endoscopes. The device is intended for short term use (up to 29 days).

➢INTENDED PATIENT POPULATION

Medasil Silicone Bite Guard is intended for use on the general patient population, applied on adults and children.

➢INTENDED USERS

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

➢DEVICE DESCRIPTION:

Medasil Silicone Bite Guard is manufactured from Silicone elastomer which is biocompatible, Latex and Phthalate free. It is a flexible, durable moulded device, designed to protect the teeth and other oral tissues from damage due to accidental impact and trauma.

- With tape for optional additional security and fixation.
- Without tape.

The device is coloured blue to provide identification against natural tissues and contains Barium Sulphate ($BaSO_4$) which may aid visibility under X-ray. $BaSO_4$ is listed as a medicine, classed as a radiopaque contrast agent in the pharmacopoeia. As used in this device the included $BaSO_4$ does not function as a medicine and no clinical claims are made.

➢INDICATIONS FOR USE:

Include, but are not limited to:

- Protection of the patient's teeth and other oral tissues of the buccopharyngeal area from unintentional or excessive contact with surgical instruments.

➢PERFORMANCE CLAIMS

- Provide protection 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:

Include, but are not limited to:

- Heavy bleeding or active infections within the buccopharyngeal area.
- Must not be used for laser protection.
- Must not be used on Individuals with insufficient dental support for the mouth guard.
- Subjects with contraindications to wearing a mouth guard, such as chronic obstructive pulmonary disease.

➢POSSIBLE ADVERSE EFFECTS:

Include, but are not limited to:

- Ingress of the device caused by accidental dislodgment during use.
- 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.
- Must not be used if the patient has a known allergic reaction to silicone.
- Must not be used if the packaging has been compromised.
- Must not to be used beyond expiry date on the label.
- Must be stored in the original unopened packaging.
- Must be stored away from moisture and direct sunlight.
- Silicone Bite Guard is a single use device.
- 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:

Non-sterile devices must be sterilised by the end user through validated methods.
Do not resterilize.

➢SINGLE USE:

Have 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:

Device **must** be disposed of in accordance with local and national regulations.

Table 1. Product REF Specifications:

REF	Option	Approx. Dimensions
Non-sterile Box Codes		One size Width: 52 mm Length: 46 mm
101-1020-1200	Without Tape	
101-1020-1210	With Tape	

➢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.

Any serious incident that has occurred in relation to the Medasil Silicone Bite Guard must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.