Silicone Bite Guard

Product Information and Instructions for Use

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CE
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SYMBOLS					
REF	Catalogue Number		Manufactured By	STERILE R	Sterilisation by Gamma Irradiation*
LOT	Lot Number	EC REP	Authorised Representative in the European Community	NON STERILE	Non-Sterile**
	Use by date (YYYY-MM)		Do Not Use if Packaging is Open or Damaged	MD	Medical Device**
LATEX	Latex Free		Keep Dry		Do Not Reuse
PHT	Phthalate Free		Keep away from Sunlight		Do Not Resterilise
	Instructions For Use				

* Applicable to the Sterile product label
** Applicable to the Non-Sterile product label

ENGLISH - INSTRUCTIONS FOR USE

Intended Use:
Medasil Silicone Bite Guards are intended to be positioned over the teeth prior to, and during, induction of anaesthesia, intubation, endoscopy, or other surgical or diagnostic procedure involving oral access. They provide 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 (<30 days).

Device Description:
Bite Guards are manufactured from silicone elastomer which is biocompatible, latex and phthalate free, moulded to protect the teeth and other oral tissues from damage due to accidental impact and trauma.

Silicone Bite Guards are available in four variants:

- Sterile.
- Non-sterile.
- With tape for optional additional security and fixation.
- Without tape.

The device contains Barium Sulphate ($BaSO^4$) which may aid visibility under X-ray, is coloured blue for easy identification and is intended for single use only.

Indications for Use:
Include, but are not limited to:
- Protection of teeth and other oral tissues of the buccopharyngeal area from unintentional or excessive contact with surgical instruments.

Intended Patient Population
The Silicone Bite Guard is intended for use on the general patient population, applied on adults and children.

Intended Users
The Medasil Silicone Bite Guard is intended to be used by healthcare professionals (HCP).

Contraindications:
Contraindications include, but are not limited to:
- Heavy bleeding or active infections within the buccopharyngeal area.
- The device must not be used for laser protection.
- The device 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 Health Care Professional (HCP) or Sterilisation Department personnel 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.
- For devices provided sterile, the sterility is only guaranteed in a sealed, undamaged, and unopened pouch.
- 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.
- The Medasil Silicone Bite Guard is a single use device.

Sterility:
Bite Guards are supplied either non-sterile or sterile. The **STERILE** version has been terminally sterilised using Gamma Radiation. **Do not re-sterilise**.

Non-sterile devices must be sterilised by the end user through validated methods.

Single Use:
Medasil Silicone Bite Guards have not been validated for re-use. Anyone re-using a single use device, may be held legally liable for the safe performance of the device.

Disposal of Devices:
Devices **must** be disposed of in accordance with local and national regulations.

Table 1. Product REF Specifications:

REF	Old REF	Option	Aprox. Dimensions
Non-sterile Box Codes			One size Width: 52 mm Length: 46 mm
101-1020-1200	139	Without Tape	
101-1020-1210	139T	With Tape	
101-GY001	139T Guy's	With 3ft Tape	
Sterile Box Codes			
101-1120-1200	139-STER	Without Tape	
101-1120-1210	139-STER	With Tape	
Individual Sterile Pouch Codes			
101-1101-1200	139-STER	Without Tape	
101-1101-1210	139T-STER	With Tape	