



# Instruction for use

Disposable Bite-Block



Educational recommendation:  
Please read this IFU carefully before the first application of the product and keep it safe for later consultations.

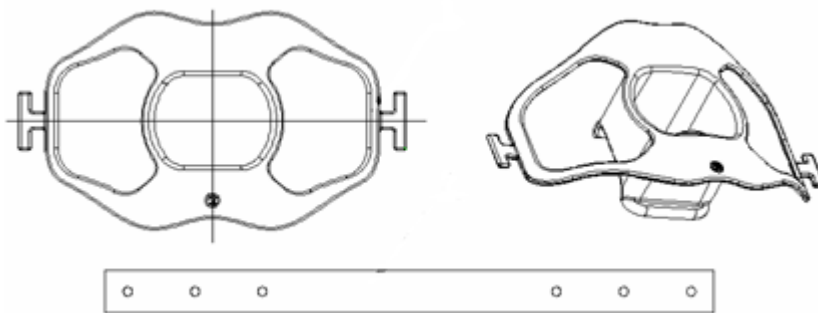
## 1.0 General information:

**Manufacturer:**  
**Key Surgical GmbH**  
**Zum Windpark 1**  
**23738 Lensahn**  
**phone: + 49 4363 905900**  
**telefax: + 49 4363 90590590**

## 2.0 Intended use / product description

For the use during gastroscopic and bronchoscopic treatments. The Bite-Block is used to protect the endoscope insertion tube from being bitten by the patient.

The Bite-Blocks are constructed as follows:



## 3.0 Measurements of the Bite-Blocks

Model	Bite-Block (mm)	Length (mm)	Length Head-Strap (mm)	Width Head-Strap (mm)
26004/ 26003	31x30x24,5	86,4	550	20
26002	24x22x21	71	550	20

## 4.0 Composition / Product specification

1. The Bite-Blocks are smooth, clean, without unevenness and burrs.
2. The head-straps are soft, elastic and latex free.
3. Wide openings at the side / atraumatic geometry

## 5.0 Materials

The following raw materials are used for the Bite-Blocks:

No.	Part of the device	Material description	Standard No.
1	Bite-Block	PP	YY/T 0242-2007
2	Head Strap	Spandex (Elastan), TPE, Terylene (Polyester)	-

## 6.0 Specification of auxiliary instruments

- Endoscopes

## 7.0 Advices before first application

1. Examine the packaging for any possibility of damage and Bite-Block for usability.
2. Examine the Bite-Block for damages, contaminations etc. Do not use the Bite-Block in case of irregularities.

## 8.0 Handling and Operation

1. Unpack the Bite-Block and remove it from the pouch.
2. Place the Bite-Block carefully in the patient's mouth and avoid placing your fingers between the bite-Block and the patient's teeth. Pass the strap around the patient's neck and attach it again to the bite block while belaying the patient's head.
3. Remove the Bite-Block carefully from the patient's mouth after the examination and discard the device as medical waste according to the national regulations.

## 9.0 Hazard note

1. This device is for single use only. Discard the Bite-Blocks after the first use. The reuse of single-use devices might present risks to the safety of the user or patient, due to possible uncontrolled contamination and / or unreliability of the device performance.
2. Should sharp edges be examined, discard the Bite-Block to prevent the patient from being hurt.

## 10.0 Packaging and storage

Single packaging in PE pouch. 50 pouches in protective carton. Store cool and dry (humidity below 80%). Do not expose the device to direct or indirect sunlight or other ultra-violet rays!

### 11.0 Application symbols



Keep away from sunlight



Store dry



Attention (reference to warning notices / preventive measures in the IFU)



Attend to the information for use



Manufacturer



Single-use



Non-sterile