



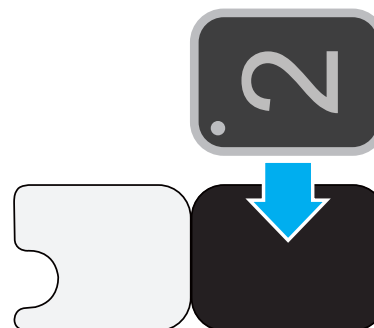


These instructions for use refer to the following articles:

<b>Bite Cover</b> Made of black and white cardboard				
<b>REF</b>	70130	70131	70132	70133
<b>Size</b>	- 0 -	- 1 -	- 2 -	- 3 -
<b>Dimensions</b>	2.0 x 3.0 cm	2.0 x 4.0 cm	3.0 x 4.0 cm	2.7 x 5.4 cm
<b>Packaging unit</b>	200 pieces	200 pieces	200 pieces	200 pieces

**REF** 202325, 202326, 202327, 202328,  
6075049, 6075050, 6075051, 6075053,  
97-93856, 988-2202,  
QWU010, QWU011, QWU012, QWU013

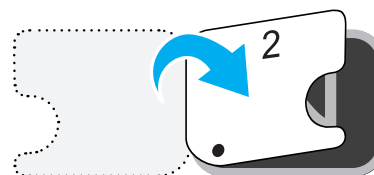
1 Place the imaging plate in the bite cover



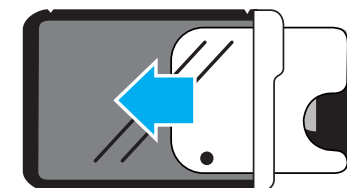
2 Pay attention to the orientation: The filled round marking of the imaging plate must correspond to the filled round marking of the bite cover



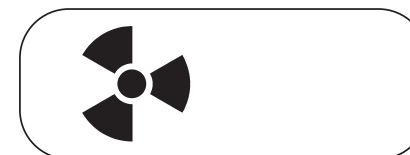
3 Close the bite cover at the fold



4 Slide the bite cover with the imaging plate into the barrier envelope of correct size



5 Take an X-ray image (according to the instructions for use/manufacturer's instructions of the X-ray unit)



6 Remove the bite cover before reading the imaging plate

Ref-no may differ from trader's article no. For reorder, please refer to trader's code.

As of: 30 April 2021



Intended use

Bite covers of M. G. Kurth GmbH are single use articles to protect dental image plates of most common sizes from influences such as light, dust, dirt, physical damage (e.g. caused by biting during fixation) during interoral x-ray imaging. By reducing the risk of damaged image plates, they indirectly protect the patient of toxic particles released by damaged image plates. They do not replace requirements for disinfection or sterilization of reusable image plates.

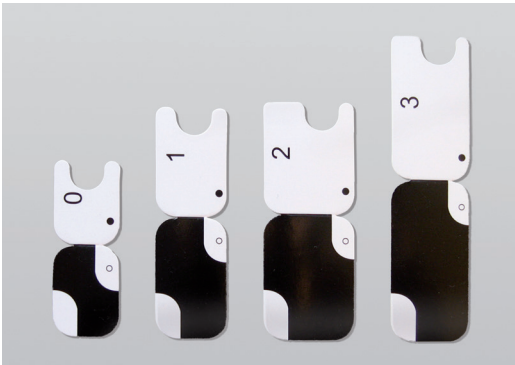
Performance data

The bite cover is made of printed cardboard. The material has been tested for possible skin irritation. The bite cover can be used during imaging, storage and scanning to maintain good image quality and increase the life of the imaging plates.

Safety precautions\*

- The medical device may only be used by (trained) dental personnel.
- The bite cover is to be used exclusively with new disposable gloves. This prevents contamination and damage to the imaging plate.
- Use a new bite cover each time you use an imaging plate.
- Only use matching bite covers (size 0, 1, 2, 3) for imaging plates.
- The bite cover is a disposable item and must not be reused under any circumstances. In case of multiple use, the stability of the product is no longer guaranteed.
- Dispose of the bite cover after each use (household waste).
- Never use a damaged bite cover.
- Use according to the illustrations overleaf.
- Also observe the instructions for use of the imaging plates and protective sleeves.
- The bite block protector does not replace the protective cover and hygiene measures necessary for the use of imaging plates.
- Store the product in a dark and dry place between 5 and 35 °C.

Any serious incidents related to the product must be reported to the manufacturer and the competent authority of your country.



Symbol designation – Explanation of the symbols used on packaging and labelling according to EU medical device standard DIN EN ISO 15223-1:2017-04			
	Consult instructions for use	<b>REF</b>	Catalogue or model number
	Do not reuse	<b>LOT</b>	Batch code
	Non sterile	<b>MD</b>	Medical device
	Keep away from sunlight	<b>UDI</b>	Unique device identifier
	Keep dry		Number of boxes in packaging unit
	Use by		Number of bite covers per box
	Storage temperature range	<b>CE</b>	CE marking of conformity
	Manufacturer		

\*Literature: <sup>1)</sup>Infektionsprävention in der Zahnheilkunde - Anforderungen an die Hygiene1 - Mitteilung der Kommission für Krankenhaushygiene und Infektionsprävention beim Robert Koch-Institut Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2006, 49, S1-16, <http://www.bonath-dental.com/RKI-Zahnmedizin2006.pdf>  
<sup>2)</sup>Hygienestandard der Zahnarztpraxen in Greifswald nach Publikation der RKI-Richtlinie 2006 im Vergleich zum Hygienestandard in Greifswald und Magdeburg, S. Handrup - 2011

