English (en)

Hygiene Sleeves for Bite Block

These instructions for use refer to the following articles:

Hygiene Sleeves for Bite Block Continuous in dispenser box			
REF	70302	70303	70308
Dimensions	2.1 x 5.1 cm	4.0 x 8.0 cm	2.1 x 4.6 cm
Packaging unit	500 pieces	500 pieces	200 pieces

REF

07311F, 07312F,

352005,

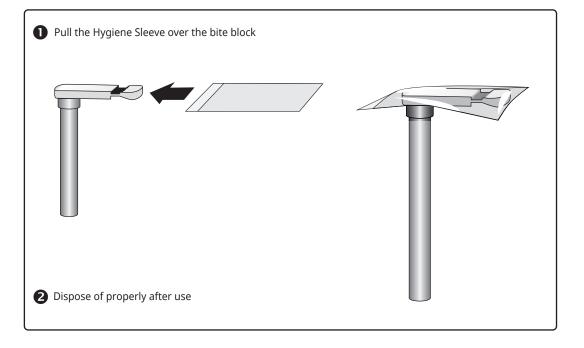
42860F, 66636F, 70093,

706262, 706263,

07311F, 7311F, 7312F

QWU020, QWU021,

2680875



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



















MGK

Hygiene Sleeves for Bite Block

Intended use

The hygienic sleeves for bite blocks are single-use, transparent plastic protective sleeves to prevent cross-contamination between patients and to protect bite blocks in digital intraoral dental radiographs. The hygienic protective sleeves are compatible with the most common holder systems on the market.

Performance data

Sensor Sleeves are made out of latex-free, odorless plastic and the material was tested not to provoke skin irritation.

The protective covers do not affect the function of the bite block.

The disposable protective cover serves as a support for the dental hygiene measures, but does not replace the manufacturer's specifications for disinfection or sterilisation of the reusable bite blocks.

Safety precautions*

- The medical device may only be used by (trained) dental personnel.
- The protective sleeves are to be used exclusively with new disposable gloves, thus avoiding cross-contamination.
- Use a new protective cover each time the bite block is used.
- Use only matching protective covers; the protective cover should be tightly fitted so that it
 encloses the bite block firmly.
- Protective covers are disposable and must not be reused under any circumstances. In case of
 multiple use, cross-contamination between patients may occur, this may lead to infections.
- Dispose of the protective cover after each patient/use.
- · Never use a damaged protective cover.
- Easy application and removal according to the illustrations overleaf.

All 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	REF	Catalogue or model number	
(2)	Do not reuse	LOT	Batch code	
NON STERILE	Non sterile	MD	Medical device	
紫	Keep away from sunlight	UDI	Unique device identifier	
**	Keep dry	\Diamond	Number of boxes in packaging unit	
	Use by		Number of hygiene sleeves per box	
	Storage temperature range	CE	CE marking of conformity	
•••	Manufacturer			

^{*}Literature: ¹JInfektionsprävention in der Zahnheilkunde - Anforderungen an die Hygiene1 - Mitteilung der Kommission für Krankenhaushygiene und Infektionsprävention beim Robert Koch-Institut Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2006, 49, 51-16, http://www.bonath-dental.com/RKI-Zahnmedizin2006.pdf ²JHygienestandard der Zahnarztpraxen in Greifswald nach Publikation der RKI-Richtlinie 2006 im Vergleich zum Hygienestandard in Greifswald und Magdeburg, S. Handrup - 2011