

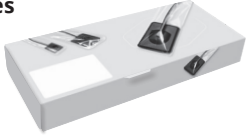



# Instructions for use

## Sensor Sleeves

English (en)

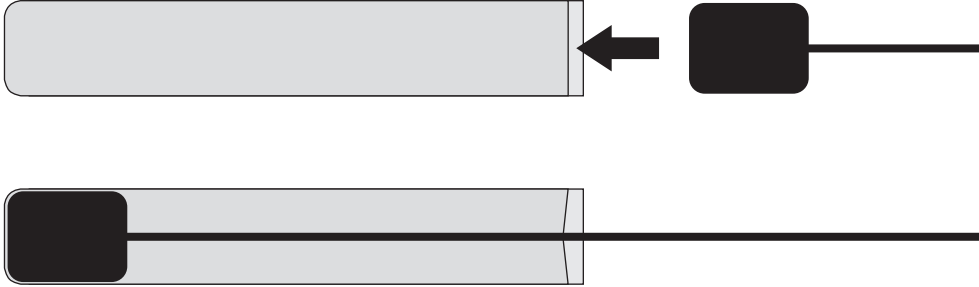


These instructions for use refer to the following articles:

 <p><b>Sensor Sleeves</b></p>			
	REF	70300	70301
Dimensions	3.5 x 21.0 cm	4.0 x 21.0 cm	6.5 x 21.0 cm
Packaging unit	500 pieces	500 pieces	500 pieces

**REF** 70305, 70306, 70307, 70309,  
44774, 44906,  
706300, 706301

**1** Pull the sensor sleeve over the sensor



**2** Dispose of properly after use

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

As of: 30 April 2021



## Intended use

Sensor Sleeves are single-use, transparent plastic protective sleeves to prevent cross-contamination between patients and to protect the intraoral sensors from damage during digital dental radiographs. The protective sleeves are available in 3 sizes and are therefore compatible with the most common sensor sizes 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 sleeves do not affect the performance of the sensors.

The sleeves serve as a support for the dental hygiene measures but do not replace manufacturer specifications for the disinfection or sterilization of the reusable intraoral sensor.

## Safety precautions\*

- The medical device may only be used by (trained) dental personnel.
- The sensor protective sleeves are to be used exclusively with new disposable gloves, this avoids cross-contamination.
- Use a new sensor protective sleeve each time you use the sensors.
- Use only sensor protective sleeves suitable for sensor systems; the protective sleeve should be tight so that it encloses the sensor tightly and prevents the sensor from slipping.
- Hygienic protective sleeves are disposable and must not be reused under any circumstances. Multiple use can cause cross-contamination between patients, this can lead to infections.
- Dispose of the hygienic protective cover after each patient/use.
- Never use a damaged hygienic 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	<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 sensor sleeves per box
	Storage temperature range	<b>CE</b>	CE marking of conformity
	Manufacturer		

\*Literature: <sup>1)</sup>Infectionsprävention 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