

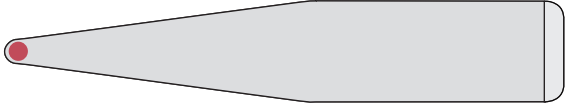

Instructions for use

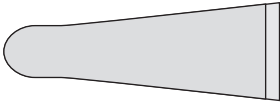

Camera Sleeves

English (en)

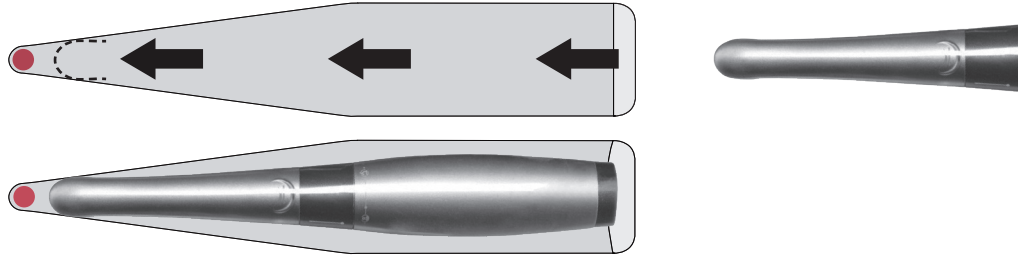

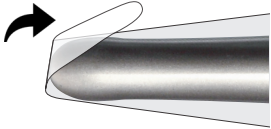
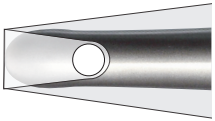


These instructions for use refer to the following articles:

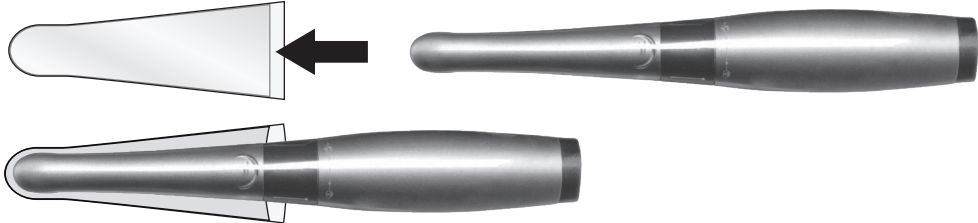
Universal Camera Sleeves Suitable for all commercially available camera systems	
	
REF	70310
Dimensions	4.6 x 23.5 cm
Packaging unit	250 pieces

Shortcam / Small Protective Camera Sleeves Suitable for all commercially available camera systems		
		
REF	70311	70311-A
Dimensions	1.8/3.4 x 9.5 cm	1.8/3.4 x 9.5 cm
Packaging unit	250 pieces	500 pieces

REF 140063, 140064,
352000

- 1** Pull the Universal Camera Sleeve as far as possible over the intraoral camera

- 2** Remove the red cover from the adhesive dot

- 3** Fold back the upper part of the cover, smooth it out and fix it to the back of the camera

- 4** Make sure the film fits tightly and without wrinkles in the optical area of the camera

- 5** Dispose of properly after use

REF 70310

- 1** Pull the Small Protective Camera Sleeve over the intraoral camera

- 2** Dispose of properly after use

REF 70311

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

As of: 30 April 2021



Intended use

Camera Sleeves are single-use, transparent plastic protective sleeves to prevent cross-contamination between patients and to protect the intraoral camera during digital dental radiographs. The protective sleeves are compatible with the most common handheld intraoral cameras on the market.

Performance data

Camera 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 camera systems (lenses).

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 protective camera sleeves are to be used exclusively with new disposable gloves, this avoids cross-contamination.
- Use a new hygienic protective cover each time you use the camera.
- Only use hygienic protective covers that are suitable for camera systems.
- Hygienic 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 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	REF	Catalogue or model number
	Do not reuse	LOT	Batch code
	Non sterile	MD	Medical device
	Keep away from sunlight	UDI	Unique device identifier
	Keep dry		Number of boxes in packaging unit
	Use by		Number of camera sleeves per box
	Storage temperature range		Number of camera sleeves per box (Shortcam)
	Manufacturer	CE	CE marking of conformity

*Literature: ¹⁾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>
²⁾Hygienestandard der Zahnarztpraxen in Greifswald nach Publikation der RKI-Richtlinie 2006 im Vergleich zum Hygienestandard in Greifswald und Magdeburg, S. Handrup - 2011