

These instructions for use refer to the following articles:

TOP Line					
REF	70100	70101	70102	70103	70104
Size	- 0 -	- 1 -	- 2 -	- 3 -	- 4 -
Dimensions	2.0 x 3.0 cm	2.0 x 4.0 cm	3.0 x 4.0 cm	2.7 x 5.4 cm	5.7 x 7.5 cm
Packaging unit	100 pieces	100 pieces	300 pieces	100 pieces	100 pieces

Trend Line					
REF	70400	70401	70402	70403	70404
Size	- 0 -	- 1 -	- 2 -	- 3 -	- 4 -
Dimensions	2.0 x 3.0 cm	2.0 x 4.0 cm	3.0 x 4.0 cm	2.7 x 5.4 cm	5.7 x 7.5 cm
Packaging unit	100 pieces	100 pieces	300 pieces	100 pieces	100 pieces

Standard Line					
REF	70100A	70101A	70102A	70103A	70104A
Size	- 0 -	- 1 -	- 2 -	- 3 -	- 4 -
Dimensions	2.0 x 3.0 cm	2.0 x 4.0 cm	3.0 x 4.0 cm	2.7 x 5.4 cm	5.7 x 7.5 cm
Packaging unit	100 pieces	100 pieces	300 pieces	100 pieces	100 pieces

TAB Line					
REF	70500	70501	70502	70503	70504
Size	- 0 -	- 1 -	- 2 -	- 3 -	- 4 -
Dimensions	2.0 x 3.0 cm	2.0 x 4.0 cm	3.0 x 4.0 cm	2.7 x 5.4 cm	5.7 x 7.5 cm
Packaging unit	100 pieces	100 pieces	300 pieces	100 pieces	100 pieces

Plus Line				
REF	70600	70601	70602	70603
Size	- 0 -	- 1 -	- 2 -	- 3 -
Dimensions	2.0 x 3.0 cm	2.0 x 4.0 cm	3.0 x 4.0 cm	2.7 x 5.4 cm
Packaging unit	100 pieces	100 pieces	300 pieces	100 pieces

- 1 Flip the tab forward
- 2 Slide the imaging plate into the protective envelope
- 3 Peel off the white strip
- 4 Flip back the tab and press firmly
- 5 The inactive side must point to the x-ray device
- 6 To open the protective envelope, peel off the top or bottom strip
- 7 Dispose of properly after use

<b>REF</b>	NPRHB0, NPRHB1, NPRHB2, NPRHB3, NPRHB5	706310, 706311, 706312
	QWU000, QWU001, QWU002, QWU003, QWU004	7302, 7303, 7304, 7305, 7306
	209635, 209636, 209637, 209638, 209639, 235952, 235953	88200, 88201, 88202, 88203, 88204
	322955, 322960, 351990, 351995, 353785, 353790	960002, 960003, 960004, 960005
	6074301, 6074302, 6074303, 6074308, 6074312	

### Intended use

Scan Sleeves are single-use, transparent plastic barrier protection sleeves to prevent the particle contamination from imaging plates, to prevent cross contamination between patients and to protect the imaging plate from light, dust, dirt or physical damage during digital intraoral dental X ray procedures. The imaging plate sleeves are available in 5 sizes (0, 1, 2, 3, 4) and compatible with a variety of typical imaging plates on the market.

### Performance data

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

The sleeves can be used during the x-ray procedure, storage and scanning and support the imaging quality and increase the lifetime of the imaging plates.

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 imaging plates.

### 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, thereby avoiding cross-contamination.
- Use a new protective sleeve with each intraoral imaging plate application.
- Only use well-fitting protective sleeves for your imaging plate size (Size: 0, 1, 2, 3, 4).
- Protective sleeves are single use only and must never be re-used. Cross contamination between patients can occur with multiple use, this can lead to infections.
- Dispose of protective sleeves after each patient use.
- Never use a damaged protective sleeve.
- Tight fit with easy application and removal, see pictures. Due to the ergonomic shape and stable cardboard covering strip you can easily open the Scan Sleeve and insert the imaging plate.

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 scan sleeves 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

