

# Instructions for Use

## **Space maintainers**

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

Application, activation, deactivation, repairs and regular servicing of attachments should only be carried out by professionals/trained personnel only, using original instruments and components. Mechanically cleaning attachments with a toothbrush and toothpaste can cause premature wear and tear of the functional components.

With the publication of these instructions for use all previous revisions are no longer valid.

The manufacturer refuses any liability for damages due to disregard of the instructions for use below.

## **In general**

### **Traceability of lot numbers**

If attachments are assembled from components with different lot numbers, all relevant lot numbers have to be recorded to ensure that they can be traced.

### **Preparation for attachments during use of space maintainers**

There are no special preparation procedures for attachments during use of space maintainers. Please follow the required procedure during assembling of the complete medical device as described in the indications for use on page 3. All technical procedures will be done according to the professional training of a dentist and a dental technician.

### **Metal denture base**

As for bilateral interdental and free-end dentures, the transverse connector should consist of a cast transpalatal plate for uppers and a sublingual bar for lowers. It is important that the denture base is absolutely rigid (will not rebound).

### **Dismantling attachments**

The male and female parts of attachments must be separated prior to heating (casting-on, soldering, laser welding, tempering and firing porcelain) and – if they consist of several components – fully dismantled.

### **Duplicating accessories**

The duplicating accessories are slightly larger than the original components to create an optimum gap for duplicating and resin-bonding.

**Please note:** The duplicating accessory must not be placed in the patient's mouth as a temporary replacement for the female part.



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# Instructions for Use

## **Space maintainers**

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

### **Disinfection**

After any fabrication or modification, the prosthetic work, incl. female part component, must be cleaned and disinfected according to national guidelines. When selecting the disinfectant, it is essential to ensure that:

- it is suitable for cleaning and disinfection of dental prosthetic components;
- it is compatible with the materials of the products to be cleaned and disinfected;
- it has tested efficacy in disinfection.

All parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use.

Recommended: CIDEX® OPA solution. Strictly follow manufacturer's instructions.

### **Further hints**

Further information on processing and techniques, etc. can be accessed on our website [www.CKPL.eu](http://www.CKPL.eu) in the Download section.

### **Warnings**

#### **Allergies**

These products must not be used for patients known to be allergic to one or several of the elements contained in the attachment materials. Please see specific materials on page 9. With patients suspected of being allergic to one or several of the elements contained in any one of the attachment materials, these products can only be used after preliminary allergological testing and proof that no allergy exists.

Please contact your CEKA PRECI-LINE sales representative for further information.

Some space maintainers contain **nickel**.

### **Precautions**

- The parts are delivered non-sterile. Proper preparation of the parts before use in patients is explained in the section 'Disinfection'.
- Ensure the attachment is cleaned regularly to avoid soft tissue inflammation.
- During intraoral use, all products should generally be secured against aspiration.
- No cutting work should be performed in the patient's mouth.

### **DEVICE DESCRIPTION AND INDICATIONS FOR USE**

The device group concerned by this IFU is **CEKA space maintainers, PRECI-CLIX space maintainers and PRECI-BAR space maintainers**. The space maintainers are used in combination with CEKA PRECI-LINE males and females.



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## Instructions for Use

### Space maintainers

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

REF / PRODUCT NUMBER	DESCRIPTION	MD CLASS	IMAGE
1251 B	PRECI-CLIX SPACE MAINTAINER 6 PCS	I	
694 B	CEKA M3 SPACE MAINTAINER 0.3 MM 10 PCS	I	
RA 0055	REVAX M2 SPACE MAINTAINER LARGE 0.4 MM 1 PC	I	
RE 0096	REVAX M2 SPACE MAINTAINER 10 PCS	I	
1101/PH	PRECI-BAR SPACE MAINTAINER LARGE 1 PC	I	
1103/PH	PRECI-BAR SPACE MAINTAINER SMALL 1 PC	I	

### Functional description

The space maintainer is used as a processing part during the working process of the complete attachment or during impression-taking. Intraorally it is only used for a short period of time. It creates a resilience between the assembled parts but is not part of the finalized custom-made prosthesis and attachment during the use of the prosthesis.

The space maintainers are intended to be used as an auxiliary:

- to create a space between the male and female part of the attachment;
- to prevent acrylic to move into the female part while processing the attachment;
- to create a negative of the patient's mouth during the impression.

All CEKA, PRECI-CLIX and PRECI-BAR space maintainers, with the exception of the ring-shaped # 1251 B, are metal discs or metal elongated spacers to be placed between the retentive elements during processing in order to create resilience in the retentive element used with CEKA, PRECI-BAR or PRECI-CLIX components/parts.

The ring-shaped space maintainer # 1251 B is a rubber ring placed on the outside of the PRECI-CLIX female during processing to prevent acrylic resin from flowing into the female part and ensures a pivoting movement after processing the attachment.



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## Instructions for Use

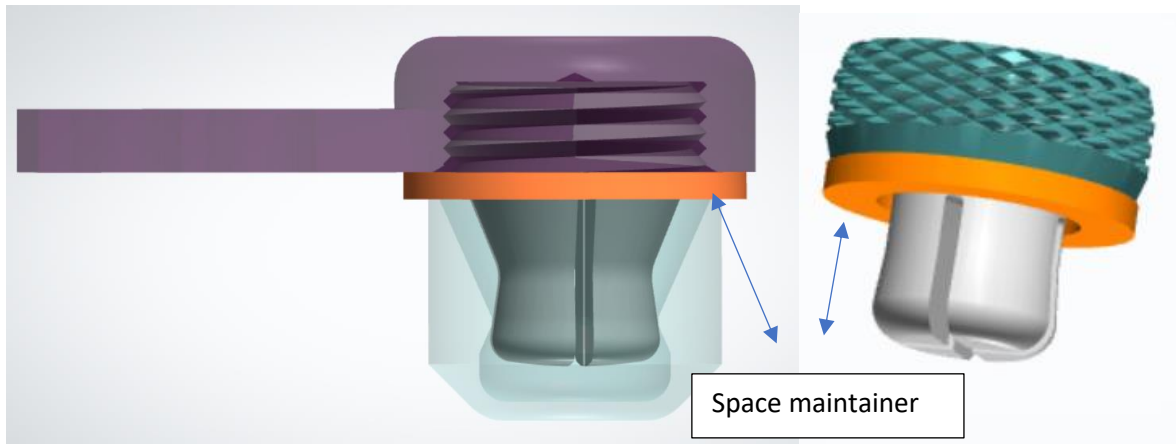
### Space maintainers

[Accessories]

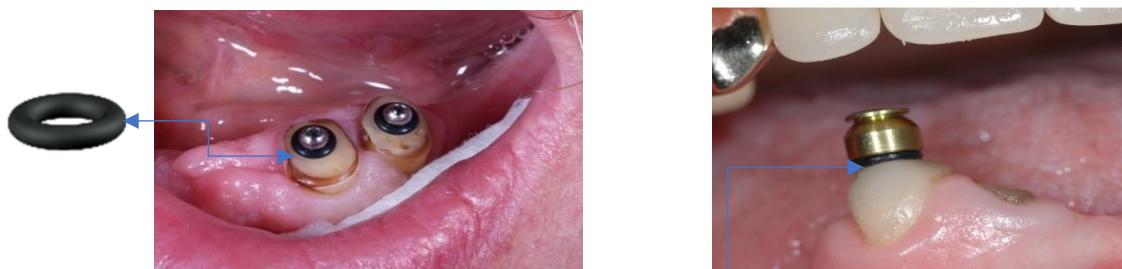
Ref.[TF26]

Revision date: [02/10/2023]

#### Example of ring-shaped space maintainer # 694 B and # RE 0096

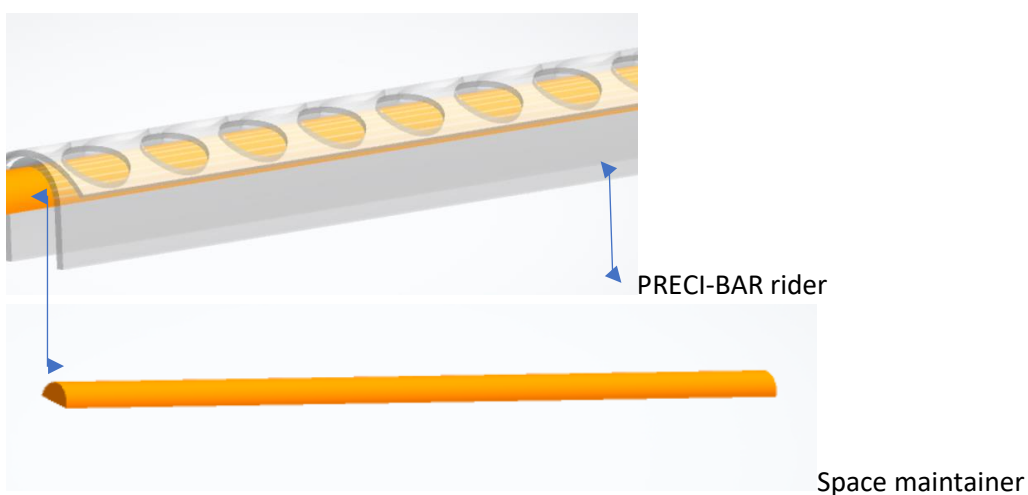


#### Example of ring-shaped space maintainer # 1251 B



Round black space maintainer in EPDM (rubber)

#### Example of metal elongated shaped space maintainer # 1101/PH and 1103/PH



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# Instructions for Use

## Space maintainers

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

### IMPORTANT

These instructions for use are the most recent available. Please read and store them carefully.

### INDICATION FOR USE

Dental and dental-gingival supported dentures:

- Interdental insertion dentures
- Resilient unilateral and bilateral free-end dentures
- Dentures with one interdental saddle and one free-end situation/insertion denture and free-end parts in combination
- Resilient bar constructions

### CONTRAINDICATIONS

- Where patients have an existing allergy to one or more elements of the attachment materials.
- Unwillingness of the patient to correctly follow the aftercare/recall instructions.
- Patients with bruxism or further uncontrolled para-functional habits.
- Unilateral dentures without transverse bracing.

At the date of emission of these instructions for use no undesirable side effects have been reported.

### CAUTION

The choice of the attachment is determined by the dentist or the dental technician according to the prosthetic project.

### EQUIPMENT AND PARTS REQUIRED FOR CORRECT PROCESSING

Product-specific processing accessories and instruments.

### MATERIAL

The materials used for these products are of quality and comply with the international, European and USA/FDA reference standards.

Patients should inform the clinician about potential allergies. In case of allergic events, research the cause and remove it. In case of proven allergy to the materials composing the product, do not use these products.

REF / PRODUCT NUMBER	DESCRIPTION	MATERIAL
1251 B	PRECI-CLIX SPACE MAINTAINER 6 PCS	EPDM (rubber)
694 B	CEKA M3 SPACE MAINTAINER 0.3 MM 10 PCS	Stainless steel 1.4310 according to EN 10088
RA 0055	REVAX M2 SPACE MAINTAINER LARGE 0.4 MM 1 PC	Tin
RE 0096	REVAX M2 SPACE MAINTAINER 10 PCS	Stainless steel 1.4310 according to EN 10088
1101/PH	PRECI-BAR SPACE MAINTAINER LARGE 1 PC	Copper
1103/PH	PRECI-BAR SPACE MAINTAINER SMALL 1 PC	Copper



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# Instructions for Use

## **Space maintainers**

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

### **WARNINGS AND SINGLE USE**

These products are single-use products. Their reuse compromises the mechanical functionality and affects the patient's health, such as the risk of infection through infectious material transmitted from one patient to another. These products can be used only after being washed and sterilized according to the following protocols that do not compromise their correct functionality. ALPHADENT NV assumes no responsibility for any damage derived from an improper use or reuse of these products.

### **TRANSPORTATION, STORAGE AND EXPIRATION DATE**

Do not damage the packaging during the transportation. Store in a clean, dry place in the original packaging away from sunlight and heat sources. Some of these products have an expiration date, see product label.

**WASHING AND DESINFECTION:** the content of the set is sold as NON-STERILE. It is recommended to wash the prefabricated metal parts with hot water and non-corrosive neutral detergents, along with soft brushes to avoid any damage to the components; any chlorine detergent has to be avoided because they may produce oxides on the laser markings.

The prosthetic work, including male/female part components, must be cleaned and disinfected according to national guidelines, after any fabrication or modification. It is essential to ensure that when selecting the disinfectant:

- it is compatible with the products' materials to be cleaned and disinfected;
- the product has tested efficacy in disinfection;
- it is suitable for cleaning and disinfection of dental prosthetic components.

All parts made of plastic (or metal) must be disinfected with a high EPA-registered disinfectant prior to use. We recommend to use CIDEX® OPA solution. We advise to strictly follow the manufacturer's instructions.

The dentist is responsible for the final cleaning process.

### **TECHNICAL SUPPORT**

ALPHADENT's staff is available for technical questions at the number listed below or check our contact details on our website [www.CKPL.eu](http://www.CKPL.eu). For more information about the use of these products please consult the catalogue, brochures or website

### **MAINTENANCE AND PERIODIC CARE**

Dentists have the responsibility to keep the proper functionality and retention of the attachments assuring the safety of the patient by constant maintenance. In order to maintain the high-quality standard offered by the present products and to avoid the loss of performances, it is suggested to plan a maintenance and periodic care every year.



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# Instructions for Use

## Space maintainers

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

### GUIDELINES FOR THE PATIENTS

Patients are recommended to follow the indications provided by the dentist, to attend periodical controls and to perform a daily, accurate hygiene. These products has not been evaluated for safety and compatibility in the RM environment. The devices have not been tested for heating, migration, or image artifacts in the RM environment.

The safety of these products in the RM environment is unknown. Scanning a patient who has these products could cause injury to the patient.









### DISPOSAL

Follow the local laws for the disposal of medical devices.

### CONTENT OF THE PACKAGES

The present products are sold both as spare parts and as part of a set.

### SYMBOL LEGEND

Symbol	Symbol title	Explanatory text
	Manufacturer	Indicates the medical device manufacturer.
	Manufacturing date	Indicates the manufacturing date of the batch or lot.
	Catalogue or model number	Indicates the manufacturer's catalogue reference number so that the medical device can be identified.
	Unique Device Identification (UDI)	The Unique Device Identification (UDI) is a unique numeric or alphanumeric code related to a medical device.
	Batch code or Lot number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Expiry Date or Use-By Date	Indicates the date after which the medical device is not to be used.
	Quantity	Indicates the number of units in the associated packaging.
	Consult (electronic) instructions for use	Indicates the need for the user to consult the instructions for use.



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## Instructions for Use

### Space maintainers

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

	Caution: US Federal law restricts this device to sale by or on the order of a licensed (healthcare) practitioner.	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	CE-mark	Indicates manufacturer declaration that the product complies with the essential/general safety and performance requirements of the relevant European medical device, health, safety and environmental protection legislations.
	CE-mark with Notified Body number	Indicates manufacturer declaration that the product complies with the essential/general safety and performance requirements of the relevant European medical device, health, safety and environmental protection legislations.
	Do not re-use	Indicates a medical device that is intended for one single use only.
	Do not use if package is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	Temperature range	Minimum and maximum temperatures applicable for the product.
	Medical device	Indicates that product is a medical device.
	Caution, consult accompanying documents	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



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## Instructions for Use

### *Space maintainers*

[Accessories]

Ref.[TF26]

Revision date: [02/10/2023]



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## Instructions for Use

### Space maintainers

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

### TECHNICAL SPECIFICATIONS

Description of all components for positioning, duplicating, in-house fabrication, protection, etc.

REF / PRODUCT-NUMBER	DESCRIPTION	DIMENSIONS	DENSITY	STRESS
1251 B	PRECI-CLIX SPACE MAINTAINER	1.8 mm diameter x 0.7 mm	1.12 ± 0.02 g/cm <sup>3</sup>	15.3 MPa
694 B	CEKA M3 SPACE MAINTAINER 0.3 MM	3.8 mm diameter x 0.3 mm		
RA 0055	REVAX M2 SPACE MAINTAINER LARGE 0.4 MM	14 mm diameter x 0.4 mm		
RE 0096	REVAX M2 SPACE MAINTAINER	3.2 mm diameter x 0.3 mm		
1101/PH	PRECI-BAR SPACE MAINTAINER LARGE	50 mm x 1.1 mm x 2 mm	9.0 cm <sup>3</sup>	342 MPa
1103/PH	PRECI-BAR SPACE MAINTAINER SMALL	50 mm x 0.75 mm x 1.5 mm	9.0 cm <sup>3</sup>	342 MPa

APPLIED MATERIAL	COMPOSITION
Copper	Cu – ETP (CW004A) 99.9 rest Bi, Pb, O
Stainless steel	Fe 74.4 – C 0.1 – Cr 17 – Cu 0.2 – Mn 0.9 – Mo 0.1 – <b>Ni 6.7</b> – P 0.03 – S 0.002 – Si 0.6
EPDM	Ethylene Propylene Diene Monomer (synthetic rubber) ISO 1629
Tin alloy	Sn 49.91 – Pb 50.02 – (rest Cu-Ag-Cd-Sb-Bi-Fe-Zn-Al-As-Co-Ni-In-S-Te)

### QUICK GUIDE AND EXAMPLES FOR USE OF SPACE MAINTAINERS

REF / PRODUCT NUMBER	SPACE MAINTAINER TO BE USED WITH PRODUCT GROUP	USE OF SPACE MAINTAINERS
1251 B	Space maintainer for PRECI-CLIX	See IFU PRECI-LINE male-female
694 B	Space maintainer for CEKA	See IFU CEKA spring pin
RA 0055	Space maintainer for PRECI-CLIX or CEKA	See IFU PRECI-LINE male-female/ See IFU CEKA spring pin
RE 0096	Space maintainer for CEKA	See IFU CEKA spring pin
1101/PH	Space maintainer for PRECI-BAR	See IFU PRECI-LINE male-female
1103/PH	Space maintainer for PRECI-BAR	See IFU PRECI-LINE male-female



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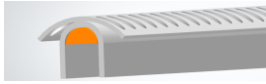




# Instructions for Use

## Space maintainers

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

REF/PRODUCT NUMBER	DESCRIPTION	IMAGE	EXAMPLE USE OF SPACE MAINTAINER	DESCRIPTION
1251 B	PRECI-CLIX SPACE MAINTAINER		<div>Fig 1</div>  <div>Fig 2</div> 	Place the black space maintainer (fig 1) over the male. Place the female over the male (fig 2). Block out any undercuts. The root surface can be relieved with the supplied tinfoil space maintainer (RA 0055).
694 B	CEKA M3 SPACE MAINTAINER		<div>Fig 3</div>  <div>Fig 4</div> 	Use the space maintainer during block-out procedure assembled with duplicating dummy (fig 3) or during cementation of metal frame with complete assembled attachment (fig 4).
RE 0096	REVAX M2 SPACE MAINTAINER		<div>Fig 5</div>  <div>Fig 6</div> 	The space maintainer is also used during the service and aftercare during impression-taking (fig 6) to secure the correct placement of the assembling of the attachment.
1101/PH	PRECI-BAR SPACE MAINTAINER LARGE		<div>Fig 7</div> 	Place the metal space maintainer between the bar and the rider (fig 7) during polymerisation of the rider into the prosthesis when resilience is required. Remove the space maintainer afterwards.
1103/PH	PRECI-BAR SPACE MAINTAINER SMALL		<div>Fig 8</div> 	Place the metal space maintainer between the bar and the rider (fig 8) during polymerisation of the rider into the prosthesis when resilience is required. Remove the space maintainer afterwards.
RA 0055	REVAX M2 SPACE MAINTAINER		<div>Fig 9</div> 	Use the space maintainer during the assembling and block-out procedure to secure resilience of the prosthesis afterwards (fig 9). The tinfoil space maintainer can be removed afterwards.

## AFTERCARE

All parts that are part of a prosthetic restoration are subjected to different intraoral influences, such as masticatory forces, bruxism and oral hygiene.

It is important to regularly consult a dental specialist for a thorough check-up of the prosthetic rehabilitation. The goal during the correct periodic follow-up of this prosthetic restoration is to avoid



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# Instructions for Use

## **Space maintainers**

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

excessive wear or breakage of the prosthesis and its components or at least to reduce it to a minimum. An optimal fit of the prosthesis ensures that the quality products used, which serve as a basis for the hold of the assembly, positively influence the wearing comfort as well as the active use of the prosthesis.

The dental specialist is therefore the right person to provide you with all the necessary care to check the prosthesis as well as all the associated components during the check-up.

We recommend to schedule a check-up at least once a year. Further information can be found on our website or you can contact the dental specialist.

## **ACTIVATION / DEACTIVATION**

Space maintainers are used to allow resiliency of assembled attachments during the fabrication process of the prosthetic solutions. The products are not part of the dental attachment once installed and will not be part of the activation or deactivation possibility of the completed attachment.

## **MODIFICATIONS / RELINING**

Space maintainers are used to allow resiliency of assembled attachments and could therefore be used during servicing and aftercare procedures to allow the correct placement or re-integration of the complete attachment.

## **CARE AND CLEANING (PATIENT)**

Space maintainers are not installed in the prosthetic solution, but are only used during the assembling procedure of the complete attachment in the prosthetic device. Please follow the instructions for disinfection when used for service and aftercare.

Ideally you should clean your teeth and your denture after every meal. Cleaning your denture also involves cleaning the connecting element. The gentlest method is to clean the connecting element under running water with a soft toothbrush. For the most thorough cleaning, the denture has to be placed in a small ultrasonic device with a suitable cleaning additive. High-precision attachments must never be cleaned with toothpaste because this can cause damage. You should also be wary of unsuitable cleaning solutions or tablets. These can also damage the high-quality connecting element or interfere with its functioning. The connecting elements fixed in your mouth, e.g. on remaining teeth or on implants, must be cleaned only by using water and a soft toothbrush as well as an interdental brush. Do not use toothpaste in order to avoid premature damage to the connecting element.

Ensure the attachment is cleaned regularly to avoid soft tissue inflammation.

Please contact your CEKA PRECI-LINE agency for advice and additional information.



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## Instructions for Use

### *Space maintainers*

Ref.[TF26]

[Accessories]

Revision date: [02/10/2023]

### **DISCLAIMER**

Upon publication, these instructions for use supersede all previous editions.

The manufacturer is not liable for any damages due to the user disregarding the above instructions for use.

These space maintainers are part of a comprehensive conception and may only be used or combined with the corresponding original components and instruments. If this is not the case, any responsibility by the manufacturer will be refused.

In case of serious incidents, please contact ALPHADENT NV and the competent authority of the Member State in which the user and/or patient is established.

In case of complaints the lot number must always be specified.



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Page 13 of 13