Instructions for Use

CEKA retention parts and base rings Ref.[TF15]

[Attachments] Revision date: [05/10/2023]

Application, activation, deactivation, repairs and regular servicing of attachments should be carried out by professionals/trained personnel only, using original instruments and components. Mechanical cleaning of 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With the publication of these instructions for use all previous revisions are no longer valid.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.

Tooth preparation for extracoronal attachments

No special procedures required. All technical procedures will be done according to the professional training of 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 aids

The duplicating aids (for some components) are slightly larger than the original components to create an optimum gap for duplicating and resin-bonding with CEKA SITE (see bonding technique).
Please note: The duplicating aid must not be placed in the patient's mouth as a temporary replacement for the female part.

Disinfection

After any fabrication or modification, the prosthetic work, including female part component, must be cleaned and disinfected according to national guidelines.

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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. Please read 'Washing and Disinfection' on page 10.

Further hints

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

Warnings

Allergies

This product must not be used for patients known to be allergic to one or several of the elements contained in the attachment materials. With patients suspected of being allergic to one or several of the elements contained in any one of the attachment materials, this product 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.

Auxiliary instruments may contain **nickel**.

Precautions

- The parts are delivered non-sterile and for single use only. Proper preparation of the parts before use in patients is explained in the section 'Disinfection'.
- Ensure that 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

An attachment has mainly 2 functions: first of all as a retainer for the dental prosthesis, secondly to improve aesthetics in comparison to a prosthesis with clasps.

The device group concerned by these instructions for use are the CEKA retention parts and base rings.

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They will be used as a retention part or base ring to thread in males (spring pin or ball attachment). The retention parts and base rings will be incorporated into a dental prosthesis. There are several procedures for incorporating these parts into the prosthesis, namely bonding, acrylic fixation, soldering or cast-on technique. Due to their specific material and shape characteristics the correct method for fixation into the prosthesis will be chosen.

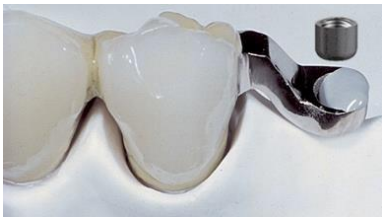
The list here below refers to all the available retention parts of the device group CEKA retention parts and base rings.

REF. / PRODUCT NUMBER	DESCRIPTION	UDI
334 A	RETENTION NUT TI 1 PC	04260576943262
334 AX	RETENTION NUT PA 1 PC	Discontinued product
691 D	CEKA M3 AXIAL BASE RING PA 1 PC	04260576943354
693 D	CEKA M3 AXIAL BASE RING IR 1 PC	04260576943385
694 AKS	CEKA M3 RETENTION PART ACRYLIC 2 PCS	14260576941593
694 AKS2	CEKA M3 RETENTION PART ACRYLIC 2 PCS	14260576941609
694 AS	CEKA M3 RETENTION PART SOLDERING PA 2 PCS	14260576941623
RA 0061	REVAX M2 BASE RING PA 1 PC	04260576943811
RA 0063	REVAX M2 BASE RING IR 1 PC	04260576942043
RE 0061	REVAX M2 RETENTION PART SOLDERING PA 2 PCS	14260576942132
RE 0075	REVAX M2 RETENTION PART ACRYLIC TI 2 PCS	14260576942149
RE 0095	REVAX M2 RETENTION PART ACRYLIC TI 2 PCS	14260576942156
RE 4600 TI	PRECI-CLIX THREADS TI 1 PC	04260576943972

1. Bonding technique (RE 4600 TI)

The bonding technique is a simple and accurate technique to bond metal parts together. An anaerobic bonding composite (CEKA SITE) is recommended to ensure a perfect bonding. Sandblasting and steam cleaning the metal surface before bonding is required.
For a correct handling and cementing procedure, please follow the instructions for use as described inthe according product.

Fig 1. Example: Cementing **RE 4600 TI** into PRECI-CLIX female keeper



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Figs 2-14. Example: Cementing retention part for CEKA spring pin

Insert the green (*M3 size*) or orange (M2 size) duplicating dummy **together with the space maintainer** into the female on the master model. Cover the inclined arm with a thin layer of wax and block out all undercuts. Make sure that the undercut of the duplicating dummy is reproduced in the refractory model (see arrow). Wax up the frame, covering the attachment completely. Cast and finish the frame. Use the REH 20 diamond burr to remove artifacts in the cavity.
The RE H 10 carbide burr is a handy instrument to finish the inside of the metal sleeve (the stop will preserve the retentive ledge).
Sandblast the retention part with coarse aluminium oxide; the H 16 (*M3 size*) or RE H 16 (M2 size) canbe used as a holding instrument.
Sandblast also the cavity in the frame for improved adhesion of the composite. Assemble the sandblasted retention part with the male spring pin and the space maintainer and snap this assembly into the female.
Expel a small amount of CEKA SITE from the automix tip into the cavity of the frame. Seat the frame and hold for 10 minutes. Remove any excess CEKA SITE and polish the cavity.

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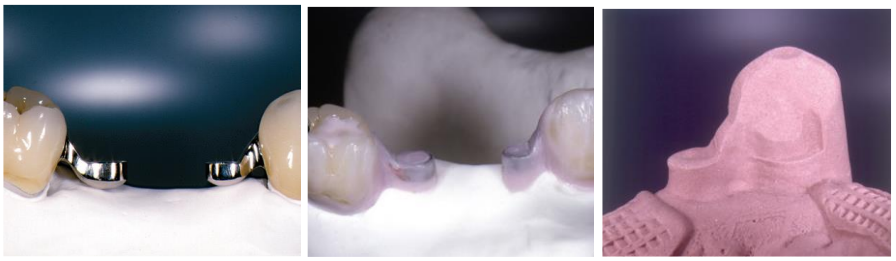
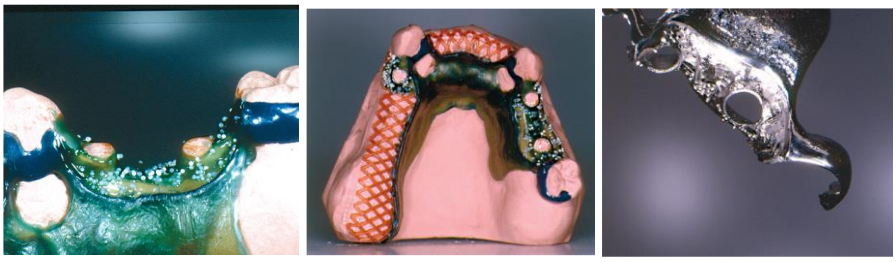
2. Acrylic fixation (334 A, 334 AX, 694 AKS, 694 AKS2, RE 0075, RE 0095)

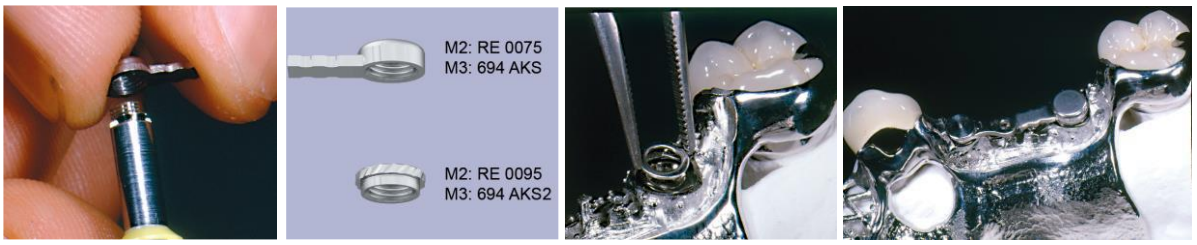
The acrylic fixation technique is used with the according retention parts (together with the male parts)to be fixed into the acrylic of the dental prosthesis. Due to the specific shape of the retention parts (circular, lateral or threadable retention), the parts will be fixed into the acrylic by a mechanical and chemical retention.

Follow the instructions of the manufacturer to ensure a correct adhesion of the parts.

Figs 1-10. Example: CEKA (lateral) retention part, acrylic fixation







Cover the inclined arm with a thin layer of wax, fill the female with wax and duplicate the model. Wax up the frame. Surround the female with wax and leave the occlusal aspect of the female uncovered. Cast and finish the frame. Assemble the retention part with the male spring pin **and the space maintainer**. Press the assembled male into the female on the master cast. The wing of the retention part may be bent, if necessary. The retention part is available for either winged or circular acrylic fixation.

3. Soldering (RE 0061, 691 D, 694 AS)

The soldering technique is a process in which the retentive parts are joined together with the metal frame by using a filler metal (solder), melting it and filling up the joints. The solder needs to have a lower melting point than the adjoining metal. Please follow the instructions for use of the solders and check the solidus-liquidus temperature of the solders according to the retentive parts. The CEKA retention parts **RE 0061, 691 D, 694 AS** are made in PALLAX dental alloy, which has a melting range of 1055-1130 °C (1931-2066 °F).

Figs 1-12. Example: Soldering CEKA retention part into metal frame

Assemble the retention part with the H 1 (*M3 size*) or RE H 1 (M2 size) dummy male spring pin. Snap the assembled male into the female on the master model.
Cover the inclined arm with a thin layer of wax, block out all undercuts and prepare the model for duplication. Wax up the frame, covering the attachment completely except for the solder access hole. Cast and finish the frame.
Grind undercuts in the stud of the retention part for the pick-up procedure. Enlarge the solder access hole of the frame and pick up the male with cold-cure acrylic. Replace the dummy spring pin with the H 16 (*M3 size*) or RE H 16 (M2 size) soldering accessory. Invest for soldering.

4. Cast-on technique (RA 0061, RA 0063, 693 D)

The cast-on technique is a process based on a technique called lost-wax technique. The created wax pattern with the incorporated retention part is placed into a heat-resistant mould and investment material in which a dental alloy is melted and cast into this mould. The retention part is made of a dental alloy suitable for cast-on alloys used in general dentistry and dental technics. The retention parts have a higher melting temperature than the alloy used for casting-on, as this procedure requiresa heating procedure.

Figs 1-8. Example: CEKA base ring cast-on procedure on a post-coping

Model a wax structure. Use a paralleling mandrel to position the base ring using a paralleling gauge. Once the wax structure is modelled, it is embedded in a muffle with refractory embedding compound.

Make sure that no air bubbles are embedded in the metal parts. This muffle is placed in a preheated oven and the wax is melted out by heating (lost-wax technique). The metal cast-on base ring is poured with a dental alloy. Once the metal structure has cooled down, it can be further finished according to the rules of the art. At the end the male part can be threaded in.

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

INDICATIONS FOR USE
Dental and dental-gingival supported dentures:
- Interdental insertion dentures;
- Rigid unilateral and bilateral free-end dentures;
- Dentures with one interdental saddle and one free-end situation / Insertion denture and free-end parts in combination.

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- Attachments can only be used (processed) by dental professionals such as a dental technician, dentist, implantologist.
- Patients can be children, adolescents and adults, depending on the clinical needs.
- The dental professional has the final responsibility of the prosthesis.

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 parafunctional 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.

CEKA PRECI-LINE parts are subject to a technical assemblage procedure. The correct fitting and functionality of the final prosthesis must be checked and approved by the dental professional in association with the patient.

These CEKA PRECI-LINE spare parts need to be used in combination with other CEKA PRECI-LINE spare parts and accessories.

EQUIPMENT AND PARTS REQUIRED FOR CORRECT PROCESSING

Simple parallelometer, product-specific processing aids and instruments.

MATERIAL

The materials used for these products are of quality and comply with the European reference standards.

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

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REF. / PRODUCT NUMBER	DESCRIPTION	MATERIAL
334 A	RETENTION NUT TI 1 PC	TITANAX
334 AX	RETENTION NUT PA 1 PC	PALLAX
691 D	CEKA M3 AXIAL BASE RING PA 1 PC	PALLAX
693 D	CEKA M3 AXIAL BASE RING IR 1 PC	IRAX
694 AKS	CEKA M3 RETENTION PART ACRYLIC 2 PCS	TITANAX
694 AKS2	CEKA M3 RETENTION PART ACRYLIC 2 PCS	TITANAX
694 AS	CEKA M3 RETENTION PART SOLDERING PA 2 PCS	PALLAX
RA 0061	REVAX M2 BASE RING PA 1 PC	PALLAX
RA 0063	REVAX M2 BASE RING IR 1 PC	IRAX
RE 0061	REVAX M2 RETENTION PART SOLDERING PA 2 PCS	PALLAX
RE 0075	REVAX M2 RETENTION PART ACRYLIC TI 2 PCS	TITANAX
RE 0095	REVAX M2 RETENTION PART ACRYLIC TI 2 PCS	TITANAX
RE 4600 TI	PRECI-CLIX THREADS TI 1 PC	TITANAX

- **IRAX: For the cast-on technique with precious alloys only**
  White - Au 60 - Pt 24 - Pd 15 - Ir 1
  Melting range: 1400-1460 °C

Mechanical properties	Values
Type	4 (high resistant)
Colour	White
Density (g/cm^3)	18.1
Hardness (HV)	180 - 240
Proof stress Rp$_{0.2}$ (MPa)	400 - 700
Elastic modulus	115’000
Tensile strength Rm (MPa)	560 - 800
Elongation (%)	15 - 20

- **TITANAX: For the bonding technique**
  Titanium grade 5 (Ti6 A/4V ELI, ISO 22674:2016, Ti 90%, Al6%,V 4%)
  Melting range: 1663-1682 °C

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Mechanical properties	Values
Proof stress $Rp_{0.2}$ (MPa)	944 (±21)
Elongation at break A	14.2 (±0.9)
Elastic modulus E	107 (±2)
Density (g/cm^3)	4.415 (±0.007)
Total metal ion release (µg/cm)	4
Solidus temperature (°C)	1663
Liquidus temperature (°C)	1682

- **PALLAX: For soldering to precious and non-precious alloys**
  Au 2% - Ag 37% - Pt 9.5% - Pd 37% - Cu 12.5% - Co 2%
  Melting range: 1067-1220 °C

Mechanical properties	Values
Proof stress $Rp_{0.2}$ (MPa)	585 (±5 type A)
Elongation at break A	43.5 (±2.5 type A)
Elastic modulus E	182 (±2.5 type A)
Density (g/cm^3)	7.90 (±0.02)
Total metal ion release (µg/cm)	100
Solidus temperature (°C)	1415 (±5)
Liquidus temperature (°C)	1450 (±5)

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 disinfected accordingto the national regulations 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 transportation. Store in a clean, dry place in the original packaging away from sunlight and heat sources. The shelf-life of the devices is 10 years. See product label for expiry date.

WASHING AND DISINFECTION

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.

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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 thatwhen 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. The castable parts do not need to be sterilized because of the transformation process (casting) done by the laboratory technician.

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. 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 plana maintenance and periodic care every year.

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 have 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. The patient should contact the dental professional every year for maintenance.

DISPOSAL
Follow the local laws for the disposal of medical devices.

CONTENT OF THE PACKAGES
The present products are sold both as single parts and as part of a set.

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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 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.
	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 0197	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.
MD	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.

CEKA retention parts and base rings Ref.[TF15]

[Attachments] Revision date: [05/10/2023]

TECHNICAL SPECIFICATIONS

Ref. / Product number	Description	Material	Image	Available sizes	Material / alloy specs	Fixation technique
334 A	RETENTION NUT TI 1 PC	TITANAX		M3 threading	see alloy specification	Acrylic fixation
334 AX	RETENTION NUT PA 1 PC	PALLAX		M3 Threading	see alloy specification	Acrylic fixation
691 D	CEKA M3 AXIAL BASE RING PA 1 PC	PALLAX		M3 threading	see alloy specification	Soldering
693 D	CEKA M3 AXIAL BASE RING IR 1 PC	IRAX		M3 threading	see alloy specification	Cast-On
694 AKS	CEKA M3 RETENTION PART ACRYLIC 2 PCS	TITANAX		M3 threading	see alloy specification	Acrylic fixation
694 AKS2	CEKA M3 RETENTION PART ACRYLIC 2 PCS	TITANAX		M3 threading	see alloy specification	Acrylic fixation
694 AS	CEKA M3 RETENTION PART SOLDERING PA 2 PCS	PALLAX		M3 threading	see alloy specification	Soldering
RA 0061	REVAX M2 BASE RING PA 1 PC	PALLAX		M2 threading	see alloy specification	Soldering
RA 0063	REVAX M2 BASE RING IR 1 PC	IRAX		M2 threading	see alloy specification	Cast-on
RE 0061	REVAX M2 RETENTION PART SOLDERING PA 2 PCS	PALLAX		M2 threading	see alloy specification	Soldering
RE 0075	REVAX M2 RETENTIONPART ACRYLIC TI 2 PCS	TITANAX		M2 threading	see alloy specification	Acrylic fixation
RE 0095	REVAX M2 RET.PART ACRYLIC TI 2 PCS	TITANAX		M2 threading	see alloy specification	Acrylic fixation
RE 4600 TI	PRECI-CLIX THREADS TI 1 PC	TITANAX		M2 threading	see alloy specification	Bonding

Note: All CEKA retention parts and base rings have the best durability and functionality once processedas described here above. Please follow the guidelines and indications for use for correct processing.

See catalogue or website http://www.CKPL.eu/ for further information about auxiliary instruments.

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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 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

The CEKA retention parts and base rings are not suitable for activation or deactivation as these parts are needed as a basis into which male parts will be threaded. The activation or deactivation of the corresponding male parts can be found on our website http://www.CKPL.eu/ or please follow the instructions for use.

CARE AND CLEANING (PATIENT)

Please follow the instructions of the dental professional.

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.

This attachment is 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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