Instructions for Use

Screwdriver and screwdriver + activating tool Ref.[TF7]

[Accessories] Revision date: [05/09/2023]

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With the publication of these instructions for use all previous revisions are no longer valid.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

Threading/unthreading or activating

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

Disinfection

After any fabrication or modification, the prosthetic work, including 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, techniques, etc. can be accessed on our website http://www.CKPL.eu/ in the Download section.

ALPHADENT NV
Mannebeekstraat 33
8790 Waregem, Belgium
T +32 56 629 531

E info@ckpl.eu

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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. 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

The device group concerned by these instructions for use is the activating tool (# A 1) and screwdriver (# IMP-XS-042). The activating tool (# A 1) is composed of two parts, a screwdriver and an activating tool. The screwdriver part is used as a tool to thread or unthread CEKA spring pins in the patient's mouth or in the prosthesis, depending on the clinical situation. The activating part of the tool is used as a device to activate the retentive elements of a CEKA spring pin in the patient's mouth or in the prosthesis.
The screwdriver (# IMP-XS-042) is used as a tool to thread or unthread male parts with a hexagonal opening on top of the male part, in this case ball attachments used for the PRECI-BALL, PRECI-CLIX and PRECI-SAGIX product range.

REF / PRODUCT NUMBER	DESCRIPTION	MD CLASS	TF NUMBER
A 1	ACTIVATING TOOL A 1 - 1 PC	I	7
IMP-XS-042	HEX SCREWDRIVER 0.9 MM - 1 PC	I	7

Activating tool + screwdriver # A 1

Screwdriver # IMP-XS-042

ALPHADENT NV
Mannebeekstraat 33
8790 Waregem, Belgium
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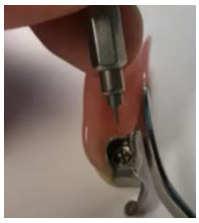
1. **Activating tool + screwdriver # A 1**
   The activating tool is used as a screwdriver to thread CEKA spring pins into retention parts and base rings or unthread them for replacement of the CEKA spring pins. The crossed blade of the accessory is used as the screwdriver part of the tool. The part with the single conical blade is used as the activating tool.

   Activating the spring pin:
   - Use only the conical blade (fig 1) of the tool to increase retention on all CEKA spring pins.
   - Press the conical blade of the accessory vertically, progressively and crosswise between the four segments of the spring pin.
   - Activate step by step and check if the spring pin has obtained adequate retention.
   - Never make lateral or bending movements to avoid segments to break off the spring pin.

Fig 1



   Screwdriver part:
   - Clean the spring pin with compressed air to allow for a perfect fit of the accessory between the segments. This will prevent breaking or torquing of the segments when loosening or unthreading the spring pin.
   - Place the protruding part (fig 2) of the crossed blade of the screwdriver diagonally between two segments before pressing it completely over the spring pin (fig 3).

Fig 2

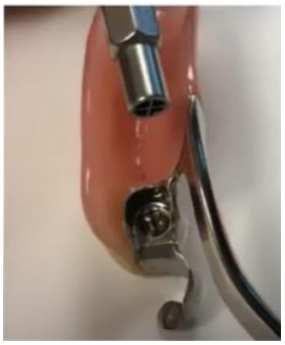


Fig 3

ALPHADENT NV
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8790 Waregem, Belgium
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E info@ckpl.eu

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2. Screwdriver # IMP-XS-042

The screwdriver is used for threading or unthreading dental attachments with a hexagonal opening of 0.9 mm to allow for a perfect fit of the screwdriver head. The threadable PRECI-BALL, PRECI-SAGIX and PRECI-CLIX attachments from the CEKA PRECI-LINE range are provided with a hexagonal opening on top of the attachment.

- Clean the opening of the attachment with compressed air.
- Insert the head of the screwdriver into the hexagonal opening of the male part (fig 4) and thread or unthread the male part of the attachment.

Fig 4 Example

IMPORTANT

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

INDICATIONS FOR USE

The activating tool + screwdriver (# A 1) and the screwdriver (# IMP-XS-042) are auxiliary tools especially made for the CEKA PRECI-LINE product range.

- Use the activating tool + screwdriver for all CEKA spring pins.
- Use the screwdriver for the following product ranges: PRECI-BALL, PRECI-CLIX, PRECI-SAGIX threadable male parts.
- 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.

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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

The activating tool + screwdriver and the screwdriver are tools that do not need auxiliary instruments for correct processing. Please read the section 'Device description and indications for use' starting on page 2.

MATERIAL

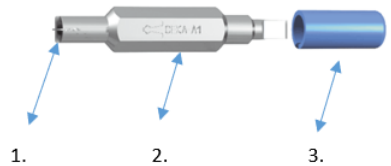
The materials used for these products are of quality and comply with the European reference standards.

Patients should inform the clinician about potential allergies. In case of allergic events, research 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
A 1	ACTIVATING TOOL	Stainless steel, CoCr, plastic
IMP-XS-042	HEX SCREWDRIVER 0.9 MM	Stainless steel, CoCr, plastic

Activating tool + screwdriver # A 1

1. CoCr (Phynox): Co 40% - Cr 20% - Fe 16% - **Ni** 16% - Mo 7%
2. Stainless steel: C 0.1% - Si 1% - Mn 2% - P 0.045% - S 0.35% - Cr 19% - **Ni** 10% - Mo 0.7% - Cu 1% - N 0.10% - Fe balance
3. 1-butene: polymer with ethene



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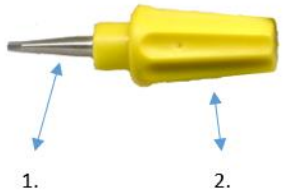
Screwdriver # IMP-XS-042

1. Stainless steel: C 0.50% - Si 1% - Mn 1.25 - P 0.04% - S 0.35% - Cr 14% - Mo 0.6%
2. Thermoplastic polyester resin



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 according to 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 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.

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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 plan a 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.

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 t.

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.

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	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-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.

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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.

TECHNICAL SPECIFICATIONS

Ref / product number	Description	Material	Image	Available sizes	Material/alloy specifications	Fixation technique
A 1	Activating tool + screwdriver	Stainless steel		M2 and M3 spring pins	See alloy specifications	Double function: activating and threading by turning
IMP-XS-042	Screwdriver	Stainless steel		0.9 mm hexagonal	See alloy specifications	Threading by turning

Note: All screwdrivers and activating tools + screwdrivers have the best durability and functionality once processed as 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.

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.

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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 screwdriver and activating tool + screwdriver are auxiliary instruments that are needed when assembling the dental attachment. The screwdriver is needed for threading and unthreading parts and the activating part is needed as an activating tool to increase the retention of the CEKA spring pins. These parts are not intended for being activated/deactivated. All suitable parts for use with the screwdriver and the activating tool can be found on the website www.CKPL.eu or please follow the instructions for use. Please see read the indications for use on page 2.

CARE AND CLEANING (PATIENT)

Please follow the instructions for 'Disinfection' on page 1.

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 tools 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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E info@ckpl.eu

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