Instructions for Use

Burrs and reamers Ref.[TF22]

[Accessories] Revision date: [02/10/2023]

Application, activation, deactivation, repairs and regular servicing of CEKA PRECI-LINE products 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With the publication of these instructions for use all previous revisions are no longer valid.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 devices 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 as burrs and reamers do not require any threading/unthreading or activation for handling. All technical procedures will be done according to the professional training of a dentist and/or a dental technician. Burrs and reamers are used in contra-angles. Please refer to the Quick Guide for Use on page 4.

Disinfection

After any fabrication or modification, the prosthetic work, including components or tools, 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 or tools;
- 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.

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 https://www.ckpl.eu/ in the Download Portal section.

ALPHADENT NV
Mannebeekstraat 33
8790 Waregem, Belgium
T +32 56 629 531
E info@ckpl.eu

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DEVICE DESCRIPTION AND INDICATIONS FOR USE

Description of the PRECI-CLIX burrs and reamer

REF / PRODUCT NUMBER	DESCRIPTION	UDI
1226	PRECI-CLIX R BURR SET 3 PCS	04260576940308
1227	PRECI-CLIX PREDRILLING BURR 1 PC	04260576940315
1228	PRECI-CLIX CAVITY BURR 1 PC	04260576940322
1229	PRECI-CLIX PRECISION REAMER 1 PC	04260576940339

Material composition

INOX
C ≤ 0.03 – Si ≤ 1 – Mn ≤ 2 – P ≤ 0.045 – S ≤ 0.015 – N ≤ 0.11 – Cr 17-19 – Mo 2.5-3 – **Ni 12.5-15**

The devices (PRECI-CLIX burrs and reamer) are used to prepare a root canal of a tooth for ulterior cementation of a prefabricated titanium post into the root canal. The tooth root must first be treated endodontically. The tooth and root are prepared according to the dental prosthetic treatment standards. The use of the products depends on the X-ray, anatomy, and length and diameter of the root canal. Once the endodontic procedure is complete, the drills can be used consecutively in a specific order.

In a first stage, the predrilling burr (# 1227) is used. This burr makes the first preparation of the root canal and ensures a correct depth to include the titanium post afterwards.

In a second stage, the cavity burr (diamond burr, # 1228) is used to prepare the exact space for the base of the cementable titanium post.

The last burr, the precision reamer (# 1229), is used to enlarge the root canal to a correct calibrated size to ensure a correct fit of the titanium post.

By following this procedure, the dentist can ensure a stress-free fit of the titanium post (# 1291 C and 1293 C).

The device does not contain any medicinal, human or animal components.

There are no accessories marketed with the device.

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

E info@ckpl.eu

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Description of the PRECI-POST M & PRECI-POST CC reamers

REF / PRODUCT NUMBER	DESCRIPTION	UDI
2004B	PRECI-POST M REAMER BLUE 1 PC	04260576941480
2004G	PRECI-POST M REAMER YELLOW 1 PC	04260576941497
2951A	PRECI-POST CC REAMER A 1 PC	04260576943224
2952B	PRECI-POST CC REAMER B 1 PC	04260576943231
2953C	PRECI-POST CC REAMER C 1 PC	04260576943248
2954D	PRECI-POST CC REAMER D 1 PC	04260576943255

Material composition

INOX
C ≤ 0.03 – Si ≤ 1 – Mn ≤ 2 – P ≤ 0.045 – S ≤ 0.015 – N ≤ 0.11 – Cr 17-19 – Mo 2.5-3 – **Ni 12.5-15**

The devices (PRECI-POST reamers) are used to prepare a root canal of a tooth for ulterior cementation of a cast metal post into the root canal. The tooth root must first be treated endodontically.

The tooth and root are prepared according to the dental prosthetic treatment standards. The use of the products depends on the X-ray, anatomy, and the length and diameter of the root canal.

Once the endodontic procedure is complete, the drill according to the measurements of the X-ray, anatomy, and the length and diameter of the root canal, can be used to prepare the exact width and length of the root canal.

The drills are colour-coded and calibrated, and have different lengths, widths and sizes.

The PRECI-POST M reamers (# 2004B and 2004G) differ from the PRECI-POST CC (# 2951A, 2952B, 2953C and 2954D) in form and size.

The device does not contain any medicinal, human or animal components.

There are no accessories marketed with the device.

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

E info@ckpl.eu

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QUICK GUIDE FOR USE - PRECI-CLIX burrs and reamer

Procedure

The root canal of the tooth must first be treated endodontically. The tooth and root canal are prepared according to the dental prosthetic treatment standards. The use of the products depends on the X-ray, anatomy, and the length and diameter of the root canal.

A. **The PRECI-CLIX burrs and reamer are used consecutively in the following order:**
Fig. 1 Prepare the root canal with the predrilling burr (# 1227), and use the cavity burr (# 1228) to prepare the base of the PRECI-CLIX post (# 1291C or 1293 C). Use the reamer (# 1229) to prepare for the diameter of the post.

The following steps are used to complete the prosthetic treatment after the tooth preparation as described in the previous step.

B. **Fig. 2** Thread the black impression tool (# RE H 2) into the post (# 1291C). Check the fit and cement the post. This tool is useful for cementation and protects the threads.
C. **Fig. 3** Take impression with the black impression tool (# RE H 2) and send it together with the analogue (# RE H 14) to the laboratory.
D. **Fig. 4** Assemble the impression tool (# RE H 2) and model analogue (# RE H 14) into the impression and pour a model in stone.
E. **Fig. 5** Thread the male (# 1206C) into the analogue (# RE H 14) using the screwdriver (# IMP-XS-042).
F. **Fig. 6** Place the housing (# 1235) on a flat surface. Place the yellow plastic female (# 1231) over the insertion tool (# 1222) and press it into the housing (# 1235).
G. **Fig. 7** Place the black space maintainer (# 1251B) over the male (# 1206C). Place the female part + housing (# 1231 + 1235) over the male (# 1206 C). Block out any undercuts. The root surface can be relieved with the supplied tinfoil space maintainer (# RA 0055).
H. **Fig. 8** Polymerize the prosthesis over the females.
I. Use the hexagonal screwdriver (# IMP-XS-042) to fix the male (# 1206 C) in the post (# 1291 C). This will guarantee easy replacement in the future, if necessary.

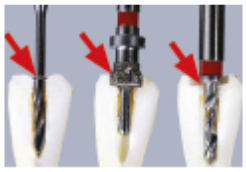
Fig. 1 

Fig. 2 

Fig. 3 

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

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Fig. 4 

Fig. 5 

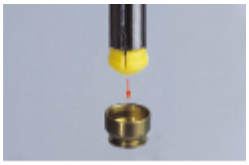
Fig. 6 

Fig. 7 

Fig. 8 

QUICK GUIDE FOR USE - PRECI-POST M reamers

Procedure

The root canal of the tooth must first be treated endodontically. The tooth and root canal are prepared according to the dental prosthetic treatment standards. The use of the products depends on the X-ray, anatomy, and the length and diameter of the root canal.

A. **Preparation of the tooth root canal**
Fig. 9 Prepare the root canal with the standardized # 2004G/2004B yellow or blue root canal reamer.

The following steps are used to complete the prosthetic treatment after the tooth preparation as described in the previous step.

B. **Fig. 10** Place the corresponding # 2002G/2002B yellow or blue opaque impression post in the canal.
C. **Fig. 10** Take impression. The posts are provided with retentions for a proper fit in the impression material.
Whether the impression is plated or an acrylic resin model is made, the opaque impression post does not bond with any of these materials.
D. **Fig. 11** Pour a working model.
E. **Fig. 12** Replace in the laboratory the impression post with the transparent # 2003G/2003B yellow or blue laboratory post.
Fig. 13 Reduce to its correct length and make sure that the top offers a little retention for wax.
F. **Fig. 14** Make the wax pattern, invest, burnout, and cast. The result is always an exactly fitting post-coping without soldering joint.

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8790 Waregem, Belgium
T +32 56 629 531

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Fig. 9

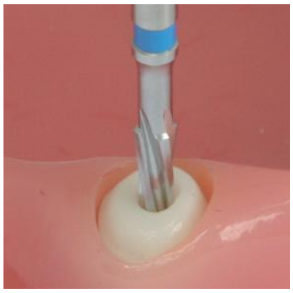

Fig. 10

Fig. 11

Fig. 12

Fig. 13

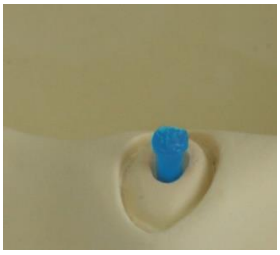

Fig. 14

QUICK GUIDE FOR USE - PRECI-POST CC reamers

Procedure

The root canal of the tooth must first be treated endodontically. The tooth and root canal are prepared according to the dental prosthetic treatment standards. The use of the products depends on the X-ray, anatomy, and the length and diameter of the root canal.

A. **Preparation of the tooth root canal**
   Fig. 15 Prepare the root canal with the standardized # 2951A, 2952B, 2953C, 2954D reamer.

   The following steps are used to complete the prosthetic treatment after the tooth preparation as described in the previous step.
B. **Fig. 16** Place the corresponding impression post (not available from ALPHADENT) in the root canal.
C. Take impression.
D. **Fig. 17** Pour a working model.
E. **Fig. 18** Replace in the laboratory the impression post with the corresponding color-coded laboratory post (# 2951A, 2952B, 2953C, 2954D).
   Fig. 19 Reduce to its correct length and make sure that the top offers a little retention for wax.
F. **Fig. 20** Make the wax pattern, invest, burnout, and cast. The result is always an exactly fitting post-coping without soldering joint.

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Mannebeekstraat 33
8790 Waregem, Belgium
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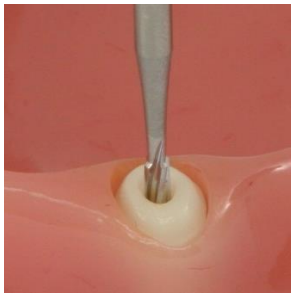

Fig. 15

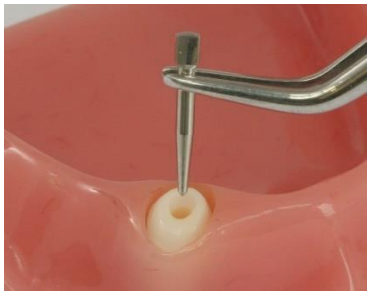

Fig. 16

Fig. 17

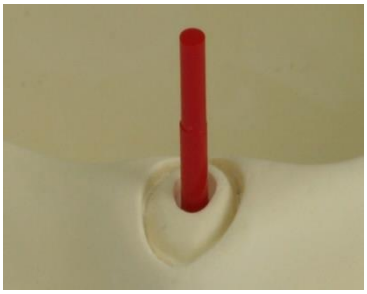

Fig. 18

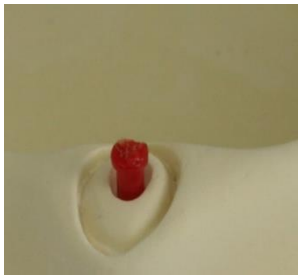

Fig. 19

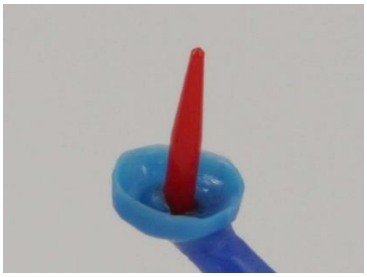

Fig. 20

IMPORTANT

Please read this instruction for use and store it carefully for reference.

INDICATIONS FOR USE

The devices (PRECI-POST reamers & PRECI-CLIX burrs and reamer) are used to prepare a root canal of a tooth for ulterior cementation of a cast metal or prefabricated titanium post into the root canal. The tooth root must first be treated endodontically.

The tooth and root are prepared according to the dental prosthetic treatment standards. The use of the products depends on the X-ray, anatomy, and the length and diameter of the root canal.

Once the endodontic procedure is complete, the drill according to the measurements of the X-ray, anatomy, and the length and diameter of the root canal can be used to prepare the exact width and length of the root canal.

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

E info@ckpl.eu

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The drills are color-coded and calibrated, and have different lengths, widths and sizes.

CONTRAINDICATIONS

- Where patients have an existing allergy to one or more elements of the materials.
- Unwillingness of the patient to correctly follow the aftercare/recall instructions.
- Patients with bruxism or further uncontrolled parafunctional habits could affect the prosthetic rehabilitation.
- 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 PRECI-CLIX burrs and reamer and PRECI-POST reamers is determined by the dentist or the dental technician according to the prosthetic project and clinical situation.

CEKA PRECI-LINE parts are subject to a technical assembly 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 PRECI-POST reamers and PRECI-CLIX burrs and reamer need auxiliary instruments for correct processing. Please read the information in the section ‘Device description & indications for use’ starting on page 2. Please find the corresponding colour-coded impression posts and burn-out laboratory posts in section ‘Quick Guide for Use’.

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.

Detailed information on the materials and their classification is given in the specific Material Safety Data Sheet, catalogue, and in the table below.

Burrs and reamers Ref.[TF22]

[Accessories] Revision date: [02/10/2023]

REF / PRODUCT NUMBER	DESCRIPTION	MD CLASS	MATERIAL
1226	PRECI-CLIX R BURR SET 3 PCS	I	Stainless steel
1227	PRECI-CLIX PREDRILLING BURR 1 PC	I	Stainless steel
1228	PRECI-CLIX CAVITY BURR 1 PC	I	Stainless steel
1229	PRECI-CLIX PRECISION REAMER 1 PC	I	Stainless steel
2004B	PRECI-POST REAMER BLUE 1 PC	I	Stainless steel
2004G	PRECI-POST REAMER YELLOW 1 PC	I	Stainless steel
2951A	PRECI-POST CC REAMER A 1 PC	I	Stainless steel
2952B	PRECI-POST CC REAMER B 1 PC	I	Stainless steel
2653C	PRECI-POST CC REAMER C 1 PC	I	Stainless steel
2954D	PRECI-POST CC REAMER D 1 PC	I	Stainless steel

Stainless steel: for preparation of a root canal

C ≤ 0.03 – Si ≤ 1 – Mn ≤ 2 – P ≤ 0.045 – S ≤ 0.015 – N ≤ 0.11 – Cr 17 – 19 – Mo 2.5 – 3 – **Ni 12.5 – 15**

Mechanical properties of stainless steel

Properties	Units	Temperature °C				
		20	200	300	400	500
Density	g cm^{-3}	7.70				
Young modulus E	GPa	215	205		190	
Electrical resistance	Ω mm^2 m^{-1}	0.60				
Thermal expansion	m m^{-1} K^{-1} 10^{-6}	20-200 °C 11.0	20-200 °C 11.0	20-300 °C 12.0	20-400 °C	20-500 °C
Thermal conductivity	W m^{-1} K^{-1}	24.9				
Specific heat	J kg^{-1} K^{-1}	460				
Melting range	Average melting range: 1500-1420 °C					
Magnetisms	Ferromagnetic, can be magnetized					

Please find further documentation on our website www.CKPL.eu or request the information from our worldwide dealer network, available free of charge.

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Mannebeekstraat 33
8790 Waregem, Belgium
T +32 56 629 531
E info@ckpl.eu

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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.

Allergies

This product must not be used for patients known to be allergic to one or several of the elements contained in the tool materials. With patients suspected of being allergic to one or several of the elements contained in any one of the tool 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' on page 1.
- Ensure that the parts are 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.

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 plastic parts with water and non-corrosive neutral detergents, along with soft brushes to avoid any damage to the components.

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 when selecting the disinfectant that:

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

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

E info@ckpl.eu

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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 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. 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.

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

E info@ckpl.eu

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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 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.
	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.

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

E info@ckpl.eu

	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.

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

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TECHNICAL SPECIFICATIONS

REF/ PRODUCT NUMBER	DESCRIPTION	MATERIAL	IMAGE	DIMENSIONS	MATERIAL/ ALLOY SPEC.
1226	PRECI-CLIX R BURR SET 3 PCS	Stainless steel		See # 1227, 1228, 1229	See alloy specifications
1227	PRECI-CLIX PREDRILLING BURR 1 PC	Stainless steel		Ø 1.2 mm	See alloy specifications
1228	PRECI-CLIX CAVITY BURR 1 PC	Stainless steel		Ø 3.6 mm	See alloy specifications
1229	PRECI-CLIX PRECISION REAMER 1 PC	Stainless steel		Ø 1.4 mm	See alloy specifications
2004B	PRECI-POST REAMER BLUE 1 PC	Stainless steel		Tip 0.8 mm	See alloy specifications
2004G	PRECI-POST REAMER YELLOW 1 PC	Stainless steel		Tip 1.00 mm	See alloy specifications
2951A	PRECI-POST CC REAMER A 1 PC	Stainless steel		Tip 0.65 mm	See alloy specifications
2952B	PRECI-POST CC REAMER B 1 PC	Stainless steel		Tip 0.7 mm	See alloy specifications
2953C	PRECI-POST CC REAMER C 1 PC	Stainless steel		Tip 0.75 mm	See alloy specifications
2954D	PRECI-POST CC REAMER D 1 PC	Stainless steel		Tip 0.8 mm	See alloy specifications

Note: All PRECI-POST M & CC reamers and PRECI-CLIX burrs and reamer have the best durability and functionality once processed as described above. Please follow the guidelines and indications for use for correct processing.

See catalogue or website https://www.ckpl.eu for further information about auxiliary instruments.

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

E info@ckpl.eu

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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 PRECI-POST M/CC reamers and PRECI-CLIX burrs are used by dental professionals as part of a calibrated post-coping system after an endodontic treatment, to transfer the width, depth and length of the root canal by using a pre-defined calibrated color-coded burr and/or reamer. These burrs and reamers are not suitable to be activated/deactivated. All auxiliary parts of the PRECI-POST M/CC and PRECI-CLIX burrs and reamer can be found on the website www.CKPL.eu or please follow the instructions for use. Please see device description on page 2, followed by indications for use on same page

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.

These burrs and reamers are part of a comprehensive concept 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.

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

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