PREXOLID®

English Instructons for Use: PREXOLID Final Abutments and Copings

Eclectic Co., Ltd.
803, 804, 677-10 Dongtan-daero, Hwaseong-si, Gyeonggi-do,
18468, Republic of Korea, https://prexolid.com

English Instructions for Use: Prexolid® Final Abutments

1. Product Description

The Prexolid® prosthetic line offers a range of abutments and copings that are designed to restore Prexolid® dental implants of various types, endosteal diameters, lengths, and platforms. These prosthetic components come in a diverse array of shapes and sizes to cater to the unique needs of individual patients. These instructions for use pertain to the Prexolid® solid, cementable, milling, and CCM abutments, along with their accompanying screws, as well as the final copings.

Material

Titanium-6aluminum-4vanadium alloy (Grade 5):

Chemical components	Composition, %(mass/mass)
Aluminum	6.0
Vanadium	4.0
Residuals(Ta, Fe, O, C, N, H) in total	≤ 1.0
Titanium (Ti)	Balance

Cobalt-chrome alloy:

Chemical components	Composition, %(mass/mass)
Chromium	27 to 30
Molybdenum	5 to 7
Residuals(Mn, Si, Fe, Ni) in total	≤ 2.25
Cobalt	Balance

The sleeve are made from poly-oxymethylene(POM).

Please refer to the product label and the Prexolid® Product Catalog for specific and detailed product specifications.

2. Intended Use

The Prexolid® line of dental implants and abutments are designed to be placed in the oral cavity to serve as a stable foundation for connected prosthetic devices. To support prosthetic restorations such as bridges, crowns, and bar-retained overdentures, final copings are securely attached to the abutments.

3. Indications

The Prexolid® abutments and copings are intended to be placed in Prexolid® dental implants to provide a support structure for oral rehabilitation in patients with partial or complete tooth loss. They are compatible with a range of prosthetic devices, including crowns, bridges, and bar-retained overdentures. Copings are indirectly connected to the dental implant and are indicated for use as an aid in prosthetic rehabilitation. For more information, please consult the product manual.

The Prexolid® dental implant and abutment system is intended for use in patients who are fully or partially edentulous and do not have any of the contraindications listed. In order to use the Prexolid® system safely and effectively, practitioners should have sufficient knowledge and training in dental implantology and familiarize themselves with the product information provided in these instructions for use.

4. Contraindications

Eclectic Co., Ltd.
803, 804, 677-10 Dongtan-daero, Hwaseong-si, Gyeonggi-do,
18468, Republic of Korea, https://prexolid.com

Individuals with known allergies or hypersensitivity to the chemical components present in the following materials should not use the device: titanium (grade 4), titanium-6aluminum-4 vanadium alloy, and Cobalt-chrome alloy.

5. Warning
   - To avoid the risk of accidental ingestion or inhalation of the components of Prexolid® dental implants during intraoral procedures, it is important to ensure that the screwdriver and screw are properly engaged and secured.
   - Titanium, titanium alloy and cobalt chrome secondary parts must not be directly veneered with ceramic.
   - The Prexolid® dental implants must only be restored using compatible components, such as Prexolid® abutments and accessories.
   - Failure to adhere to the proper instructions for use may result in complications, including the accidental aspiration or ingestion of components, which may necessitate additional treatment.
   - During intraoral handling, it is important to take measures to prevent aspiration or ingestion of Prexolid® prosthetic devices.

6. Cautions/ Precautions

   When attaching prosthetic components, it is important to use dental cement or materials as directed by the manufacturer.
   - During placement or removal of prosthetic components, it is crucial to carefully remove any excess cement to prevent complications.
   - To avoid loosening solid or cementable abutments, protective caps and temporary copings should not be removed using a rotary movement.
   - Prexolid® abutments and copings are single-use devices and should be handled with sterile technique to prevent infections.
   - Final abutments should only be placed in occlusion when there is sufficient primary stability or complete osseointegration of the implant.
   - Before placing any prosthetic parts, it is important to ensure that the implant-abutment surface is clean.
   - For the posterior region of the mouth, small diameter implants and angled abutments are not recommended.
   - Magnetic Resonance Imaging (MRI) Safety Information: These products are fabricated from a metal material that may be influenced by MRI energy. Non-clinical testing and MRI simulations have been conducted to evaluate the safety of the system.
   - At this time, it is unknown whether Prexolid® implants are safe for MRI. However, patients with Prexolid® implants may undergo MRI procedures under the prescribed conditions set by their healthcare professionals.
   -

7. Residual risks and side effects

   The effectiveness of dental treatment can be influenced by various factors. The following potential residual risks and side effects are associated with the use of the Prexolid® dental implant system and may require further treatment by a dentist:
   - bone damage
   - discomfort
   - hypersensitivity/allergic reactions
   - gingival injuries
   - loss of implant

Eclectic Co., Ltd.
803, 804, 677-10 Dongtan-daero, Hwaseong-si, Gyeonggi-do,
18468, Republic of Korea, https://prexolid.com

- loss of prosthetic components
- other toxicity reactions
- poor esthetic outcome
- recall to the dentist's office
- risk of surgical implant explantation
- risk of swallowing/inhaling small parts during
- the procedure
- longer recovery/healing time than expected
- paresthesia
- dysesthesia
- swelling
- local inflammation
- bruising
- maxillary/mandibular ridge bone resorption
- local infection
- minor bleeding
- local pain

8. Compatibility Information

Our Prexolid® dental implants and prosthetic components are available in two configurations: mini and regular. The label on each product indicates compatibility with specific components, using abbreviations to show the connection identifier.

9. Cleaning and disinfection

Prexolid® abutments and components delivered non-sterile must undergo cleaning and disinfection before use. The product's packaging system must be removed before processing.

10. Sterilization

Prexolid® abutments and components delivered non-sterile must be sterilized prior to intra-oral use. We recommend a sterilization procedure that includes individually double-pouching the abutment and abutment screw in sterilization pouches prior to sterilization.

Method	Conditions	Drying time
Moist Heat (Autoclave) Fractionated vacuum	132 °C (270 °F) to 134 °C (273 °F) at least for 3 min	Local practice(or 30min)

Sterilized Prexolid® abutments and components should be used immediately after sterilization. If storage is necessary, carefully adhere to the manufacturer's instructions for sterilization accessories and storage containers.

11. Procedure

Find Prexolid® Implant system, user guide at our website or brochures for a detailed procedure.

11.1 Use and handling of Prexolid® stock abutments for the dental technician

To create a coping or crown, please follow the standard procedures recommended by the material manufacturer.

11.2 Use and handling of Prexolid® stock abutments for the clinician

Once the dental lab sends the master cast with the original abutment, the clinician should remove any temporary restoration, healing cap, or closure screw from the implant and clean and dry the

Eclectic Co., Ltd.
803, 804, 677-10 Dongtan-daero, Hwaseong-si, Gyeonggi-do,
18468, Republic of Korea, https://prexolid.com

implant connection. Then, remove the restoration from the working model and follow the instructions provided in the "Cleaning and disinfection" and "Sterilization" sections of the instructions for use to clean, disinfect, and sterilize the dental restoration before use.

12. Storage

Prexolid® devices should be stored in a dry and cool place in their original packaging and protected from direct sunlight. Proper storage is crucial to maintaining the essential material and design characteristics of the device, which could otherwise lead to device failure.

13. Disposal

Disposal of Prexolid® devices should be handled in an environmentally sustainable manner according to local regulations. Hazardous waste from contaminated devices or sharps should be disposed of in appropriate containers that meet specific technical requirements. It is important to follow proper disposal procedures to ensure the safety of the environment and those who handle the waste.

14. Information to be provided to the patient

For Prexolid® devices, it is important to provide the patient with information on contraindications, warnings, precautions, side effects, and potential complications. The patient should also be informed about the MRI compatibility of the Prexolid® products used. It is the responsibility of the dental professional to provide this information to the patient in a clear and understandable manner, and to answer any questions or concerns that the patient may have.

15. Symbol

The following table describes the symbols that may be printed on the packaging label. Please refer to the packaging label for the applicable symbols related to the product.

Eclectic Co., Ltd.
803, 804, 677-10 Dongtan-daero, Hwaseong-si, Gyeonggi-do,
18468, Republic of Korea, https://prexolid.com

.

Symbol	Symbol Description	Symbol Source
	Product Code	ISO 15223-1
	Batch Code	ISO 15223-1
	U.S federal law restricts this device to sale by or on the order of a dental professional	21 CFR 801.109(b)(1)
	Non-sterile	ISO 15223-1
	Consult instructions for use	ISO 15223-1
	Do not re-use	ISO 15223-1
	Manufacturer	ISO 15223-1
	Date of manufacture	ISO 15223-1
	Sterilized using irradiation	ISO 15223-1
	Do not re-sterilize	ISO 15223-1
	Do not use if package is damaged	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
	Use-by date	ISO 15223-1
	Temperature limit (e.g.: min 5 °C / max. 20 °C)	ISO 15223-1
	Keep away from sunlight	ISO 15223-1
	Caution	ISO 15223-1

Eclectic Co., Ltd.
803, 804, 677-10 Dongtan-daero, Hwaseong-si, Gyeonggi-do,
18468, Republic of Korea, https://prexolid.com