PREXOLID®

English Instructons for Use: PREXOLID Internal Tapered Implants SLA

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 Implants

CAUTION: U.S. federal law restricts this device to sale by or on the order of a dental professional.

1. Product Description
   The Prexolid Dental Implant System is an integrated system of endosseous dental implants with corresponding abutments, closure screws, and other prosthetic parts and surgical instruments.

   Prexolid dental implants are solid screw implants composed of a titanium Gr.4 with SLA surface that is large-grit and acid-etched.

2. Intended Use
   The Prexolid Dental Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of patients with missing teeth.

3. Indications
   The Prexolid Dental Implants are endosteal implantation in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, and terminal or intermediate abutment support for fixed bridgework.

4. Contraindications
   Contraindications include the following, but are not limited to:

- Inadequate bone volume or bone quality, local root remnants
- Serious internal medical problems, uncontrolled bleeding disorders, inadequate wound healing capacity, incomplete maxillary or mandibular growth, poor general state of health
- uncooperative or unmotivated patient, drug or alcohol abuse, psychosis, prolonged therapy-resistant functional disorders
- xerostomia, weakened immune system, illnesses requiring periodic use of steroids, uncontrollable endocrine disorders.
- Allergies or hypersensitivity to chemical ingredients of materials used(titanium)

5. Side effects and precautions
   Immediately after the insertion of dental implants, activities that demand considerable physical exertion should be avoided. Possible complications following the insertion of dental implants are:

- Pain, swelling, phonetic difficulties, gingival inflammation.
- Chronic pain associated with the dental implant, permanent paresthesia, dysesthesia, loss of maxillary ormandibular ridge bone
- localized or systemic infection, oroantral or oronasal fistulae
- Unfavorably affected adjacent teeth, irreversible damage to adjacent teeth
- Fractures of implant, jaw, bone or prosthesis
- Esthetic problems, nerve damage, exfoliation, hyperplasia

6. Warning

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- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
- Avoid approaching the proximity of the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anesthesia, paresthesia and dysesthesia.
- Do not exceed recommended insertion torque as this might cause bone necrosis.

7. Cautions/ Precautions
   - Small-diameter implants are not recommended for the posterior region.
   - The implants should not be placed in bones other than the maxilla or mandible.
   - Special attention should be taken to ensure proper implant alignment where comparatively high loads are expected.
   - Sterile handling is essential. Do not use potentially contaminated components. Contamination may result serious infections.
   - Do not re-sterilize Prexolid implants. Additional cleaning, disinfection and sterilization may compromise material and design characteristics leading to device failure.
   - Special attention should be given to patients who have local or systemic factors that could interfere with either the healing process of bone or soft tissue or the osseointegration process (e.g. bone metabolism disturbances, diabetes mellitus type 1, anticoagulation drugs /hemorrhagic diathesis, bruxism, parafunctional habits, unfavorable anatomic bone conditions, tobacco abuse, untreated periodontal diseases, acute infection of implant site, temporomandibular joint disorders, treatable pathologic diseases of the jaw and changes in the oral mucosa, pregnancy, inadequate oral hygiene).
   - Magnetic Resonance Imaging (MRI) Safety Information: These products are fabricated from a metal material which can be affected by MRI energy. Non-clinical testing and MRI simulations were performed to evaluate the Prexolid Implant System.
   - MRI safety of Prexolid implants is unknown. A patient with an implant from a Prexolid Implant System may be safely in an MR system under the specific conditions prescribed by the professional practitioners.
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8. Storage
   - The implants must be stored in a dry place in the original packaging, protected from direct sunlight and kept at room temperature.
   - Do not re-use Prexolid implants.
   - Do not use Prexolid implants after expiry date indicated on the packaging.

9. Cleaning and disinfection
   Prexolid Implants are provided sterile and for single use only. They must not be cleaned and re-sterilized by the user. This may compromise material and design characteristics leading to device failure. The manufacturer is not responsible for re-sterilized implants.

10. Sterilization

- Prexolid implants and closer screws are delivered sterile by gamma irradiation.The sterile packaging must not be opened until immediately prior to insertion of the implant.
- Implants with damaged sterile packaging must not be used.

11. Procedure
    The general healing time required for osseointegration depends greatly on the individual and treatment. It is the sole responsibility of the surgeon to decide when the implant can be loaded.

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Prexolid Implants are suitable for immediate and early restoration in single missing teeth and in edentulous or partially edentulous jaw. Good primary stability and an appropriate occlusal load are essential. Infection, generalized disease and insufficient or poor remaining bone may be potential causes for failure of osseointegration both immediately after surgery or after osseointegration is initially achieved.

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

12. 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.

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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

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