Anker Dental Implant System Instruction manual

For detailed information on the specific surgical and/or prosthetic procedure for the product you are using, please refer to the individual product labels and/or the appropriate manual:

Description:

"Anker Dental Implant System consists of pure titanium, grade 4, and have a SLA (Sand-blasted, Large grit, Acid-etched) surface.

Indications for Use:

Anker Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It is intended for delayed loading.

Contraindications:

Severe uncontrolled systemic diseases, metabolic bone disorders, uncontrolled hemorrhagic diseases, uncooperative/ unmotivated patient, drug or alcohol abuse, psychosis, prolonged treatment-resistant functional disorders, xerostomia, reduced immunity, diseases with periodic use of steroids, titanium allergy, and uncontrolled endocrine diseases.

-Relative contraindications:

Previously irradiated bone, diabetes, mellitus, medical anticoagulation/ hemorrhagic diathesis, bruxism, parafunctional habits, unfavorable bone anatomy, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disease, pathological jaw disease and oral mucosal abnormalities amenable to treatment, pregnancy, inadequate oral hygiene.

-Local contraindications:

Inadequate bone quantity and/ or inadequate bone quality, local residual roots.

Warnings:

The Following may occur after treatment; early low fixation of implant, failure of bone adhesion, or other side effects from an inappropriate design. The low quality and quantity of the bone left, infection, a patient's poor oral hygienic conditions, generalized disease (diabetes, etc.) can be the reason for some side effects. The procedure of implant treatment (surgery) could be dangerous and after treatment the following could be found; swelling of a specific part, rupture, temporary, palpate sensitiveness, edema, hematoma, bleeding. Insensibility of lower lip and some side effects relating to the chin from lower jaw treatment or some tissue around the nose from upper jaw treatment may occur. That is mostly temporary, but rarely permanent paralysis could appear. A gum membrane ulcer or a cell tissue reaction infection could happen, which is an accompanied reaction according to any local treatment.

Instruction Manual & Precautions:

Instruction Manual:

- Expose the implant in aesthetic areas with a semi lunar crestal incision.
- Make split-thickness buccal flap.
- Remove healing plug removal instrument.
- Place appropriate guide pin to check integration and angle.
- Remove excess bone with sulcus reamer corresponding to the chosen abutment with either threaded knob or straight handle.
- Flush and dry implant well with a cotton tip.
- Insert chosen abutment.
- The temporary abutments are to be used for no more than 180 days and should be placed out of occlusion.
- Use a template to confirm appropriateness of abutment prior to engagement of locking taper connection, then tap on abutment in long axis of abutment post to engage locking taper.
- Place an acrylic emergence cuff or temporization sleeve onto abutment and modify, if necessary.
- Inject acrylic around emergence cuff or temporization sleeve and into the vacu-press template.
- Place template to form temporary crown.
- Remove and polish acrylic confluent with emergence cuff or temporization sleeve to help form the gingival sulcus.
- Wait for soft tissue healing prior to taking final impression.

Precautions:

- A patient and product should be thoroughly examined for the treatment.
- Visible examinations such as panoramic images and periapical radiographs are mandatory, to allow visualization of anatomical features, status of occlusion, periodontal status, and suitability of bone.
- Side cephalometric radiograph, CT photo, and tomogram may be useful.
- Even after opening the packing, the product should be checked abnormalities.
- During the period of treatment, the dentist should forbid the patient excessive masticating.

Removal procedure:

- Take X-ray for surgery area.
- Expose surgery area.
- Unscrew the upper structure like cover screw or healing abutment.
- Unscrew the fixture.
- Seal the surgery area.

Potential Adverse Events:

Potential adverse events associated with the use of dental implants may include:

- Failure to integrate.
- Loss of integration.
- Infection, inflammation.
- Pain, paralysis, abnormal feeling.
- Excessive bone loss requiring intervention.
- Implant breakage or fracture.
- Systemic infection.
- Nerve injury.

Precaution:

- Products are supplied sterile and are sterilized by an appropriate validated method.
- As this product is sterilized by radiation, it should not be used under any circumstances if the package is open.
- During the treatment, if the product is contaminated by the operator's mistake, it should not be used.
- Every product is disposable. It should not be reused.
- Refer to individual product labels for sterilization information; all sterile products are labeled "STERILE".
- Do not use when package is damaged.

Storage and Handling:

- Devices should be stored at room temperature.(below 50℃)
- Keep out from water and sun, and store up against the humidity.
- Avoid jolting and extruding.

Caution:

To have a safe and effective use of a Alliance Dental Implant system, the following is strongly recommended:

- The operator should be a medical specialist who learned the required technical skills.
- The operator should be fully aware of the procedure of the treatment and the direction for the use of the product.
- The treatment should be done in an aseptic condition by an operator who wears an aseptic costume.
- Inappropriate selection of patients and operator skills can cause a failure of the treatment and loss of supportive bone.
- Federal law restricts this device to sale by or on the order of a dentist.
- The Anker Dental Implant system has not been evaluated for safety and compatibility in the MR environment. The Anker Dental Impl ant system has not been tested for heating or migration in the MR environment.

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