Instruction for Use

1. Product Description

Dental Implant: This product is a dental implant designed to replace missing teeth and restore dental functionality by being implanted into the alveolar bone. It is a root-form osseointegrated implant made of Grade 4 titanium (ASTM F 67) with a threaded structure. The connection with the superstructure is achieved through an internal hex (HEX) connection.
The surface is treated using the SLA (Sand Blasting with Large grit and Acid etched) method, which involves blasting the surface with Al2O3 powder to create a fine roughness, followed by acid treatment with hydrochloric acid (HCl) and sulfuric acid (H2SO4). The process concludes with a cleaning stage to remove any residual substances.

Cover Screw: This product is a superstructure for dental implants that connects to the internal threading of the hex portion that is exposed above the alveolar bone after implant placement, preventing the infiltration of soft tissue and foreign materials during the osseointegration period.

2. Intended Use

Dental Implant: A substructure inserted into the human body as an implant inserted to support prosthesis such as artificial teeth used to restore the patient's mastication function.

Cover Screw: A superstructure of a dental implant that protects the implant’s inner hole and superstructure connection from soft tissue growth and foreign substance penetration.

3. Sterility

- The Implant and Cover Screw are cleaned and sterilized by gamma irradiation.
- This product is a sterilized medical device and should be used in a sterilized environment using sterilized tools.
- Opened or damaged package product and expired product should be disposed.
- This product should not be re-sterilized or re-used.

4. Procedure

A. Preparation Before Use

- Surgical techniques for dental implants require specialized and complex procedures, so relevant formal education and training for implant procedure is needed.
- The decision for surgery is made considering the suitability of the bone and appropriate surgical methods.
- Prepare suitable implants considering foreseeable scenarios and precautions.
- Radiographs and various examinations provide essential information for the procedure, conditions of adjacent teeth, and assessment of bone condition.
- Preoperative planning, adequate imaging, and investigation of various implant sites are necessary before surgery.

B. Applications

For the placement of dental implant, surgery should be performed on patients who have sufficient bone quality. After adequate disinfection of oral and external areas and surgical instruments, local anesthesia should be administered. The surgical site is then incised to sufficiently expose the area for implantation surgery.

1) Confirm the location for implant placement. Consider factors such as the height of the bone adjacent to the cervical contact area of the adjacent teeth, distance from adjacent teeth, and position of nerves.

2) Disinfect the oral cavity and make an incision in the gingiva at the desired implantation site.
3) Drill the cortical bone to an appropriate depth using a guided drill.
4) Select a drill diameter matching the implant diameter and drill to the appropriate depth according to the surgical guide.

※ The length of the drill should be considered, as it may be up to 1mm longer than the implant length.

※ To minimize bone damage due to heat during drilling, it is recommended to drill under adequate irrigation.

Primary Surgery

5) Verify the type, size, and expiration date stated on the packaging label and packaging condition of the implant and open the sterilized packaging.
6) Secure the implant driver attached to the handpiece in line with the implant

   ※ Ensure the hex direction of the implant and implant driver are properly engaged.
7) Bend and detach the implant connected to the implant driver from the support base. (Discard the implant if the end is not smooth.)
8) Handle the implant carefully to avoid contamination with metal or saliva, place it in the pre-drilled location in the oral cavity, and rotate it at 25-35rpm to place the implant into the bone.
9) Use the torque wrench attached to the implant driver to fully fix the implant into the bone at the recommended torque value of 35-45Ncm.
10) Remove the implant driver after implantation.

    ※ When inserting the implant using the implant driver or torque wrench, excessive force should not be applied. Excessive insertion torque exceeding 50Ncm can cause necrosis of the alveolar bone and various defects. If excessive torque occurs during implantation, remove the implant, drill one step wider, and then implant again.
11) According to the surgeon's protocol, screw the cover screw or healing abutment manually with a force of 10Ncm and suture the soft tissue.

Secondary Surgery

1) After the gingival mucosa has healed and osteointegration has occurred, incise the upper soft tissue at the implantation site to expose the cover screw.
2) Remove the cover screw and connect the healing abutment to the implant.
3) Suture the surrounding soft tissue around the healing abutment.

Healing Period

Sufficient healing period is needed following implantation. Depending on the nature of the bone, a healing period of at least 3 months for the mandible and 6 months for the maxilla is necessary before connecting the abutment. In cases where the bone is very soft, an additional healing period of 1-2 months may be necessary.

C. Management after use

1) All products inserted into the oral cavity are single-use sterile medical devices and must not be reused.
2) Once opened, even if not used, the product must be discarded as sterility cannot be maintained.
3) Used packaging should be disposed.
4) After the procedure, all used surgical instruments must be immediately cleaned with alcohol, detergent, distilled water, etc., then sterilized, dried, and stored. However, the use of hydrogen peroxide is not recommended.

5. Warning

- Implants must be placed by an experienced dentist, as improper techniques can cause damage to the implant or surrounding bone tissue.
- Implants should not be reused and must be applied according to their intended purpose.
- Damaged or improperly handled implants should be removed.
- The lifespan of the implant may be shortened if the implant is improperly selected, positioned, or if the fixation is unstable.
- Defective products must be returned.
- Implants should be handled with care to prevent damage or deformation.

6. Caution

- In cases of bone diseases (osteoporosis, osteomalacia), metabolic bone disorders, etc., careful consideration of these conditions should precede the procedure.
- There is a possibility of failed osteointegration due to infection, mobility, or bone loss. Failed implants should be removed as soon as possible, and all tissue in the form of particles must be removed from the implantation site.
- Bone suitability should be determined through X-rays, visual inspection, and palpation of the proposed implant site. To initiate the implant procedure, the location of all anatomical characteristics must be established.
- Adhere to the healing period after procedure, perform the next step according to the surgeon's judgment after sufficient osteointegration, and ensure that no pressure such as bite force is applied to the fixed body during the healing period.

7. Contraindication

Do not use in the following patients:

- Patients with a history of heart attack or arteriosclerosis
- Patients who are uncooperative or who have mental or physical disabilities that may cause instability, fixation failure or other complications regarding the implant during post-surgical management.
- Patients with conditions affecting bone formation, microcirculation, or blood.
- Pregnant patient.
- Patients with hypertension or diabetes.

8. Side Effects

- Complications such as malocclusion, paresthesia caused by neurological damage, infection, edema, hypodermal bleeding, pain, soft tissue ulcer can arise.
- Loosening of a screw, fracture of implant or abutment.
- Bone defect around the implant and mucositis.

9. MR Safety Information

This product has not been evaluated for safety and compatibility in a magnetic resonance (MR) environment. Tests for heating, migration, and image artifacts in the MR environment have not been conducted. Therefore, the safety of this product in the MR environment is unknown. Scanning patients with this medical device implanted may result in patient injury.

10. Storage

The device should be stored in a dry condition away from direct light at room temperature (1~30℃).

11. Disposal

Follow local regulations and laws for the disposal of medical devices.

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