
English

1. Indication for use

- ① This is an implant fixture to be inserted in the human body in order to support prosthesis such as artificial teeth used to regain patients' mastication.
- ② Temporary Fixture is an implant fixture in order to support prosthetic appliance such as artificial teeth used to recover a patient's mastication.

2. Instruction for Use & Order of Procedure

<Preparation before use>

- ① Before clinical use, the doctor must fully understand the order of procedure and the product and must explain the limitation of implant to the patient. Patient must recognize the function and esthetical limitation of the implant.
- ② Appropriate selection and fixation is major factor affecting the life of the implant. It is recommended to strictly abide by the indications, contraindications, precautions and warnings.
- ③ It is recommended to analyze the detailed status of patient, pre surgery diagnosis and treatment planning before the procedure. If not properly followed, it may cause the failure of the implant.
- ④ By reading X-ray images, applicable product may be selected in accordance to each patient's characteristics by reading X-ray image.
- ⑤ Packaging condition, expiration date and any other damages should be observed and confirmed.
- ⑥ This product is supplied in sterilized condition. If packaging is damaged or opened in any way, it is prohibited to use.
- ⑦ Implant failure may be caused by contaminated or infected surgical instruments. Check for the sanitation and availability of the surgical instruments in accordance to each treatment planning.

<Instruction for Use>

- ① X-Ray image of patient is used to determine proper osteotomy site for implant.
- ② On selected surgical site, incision is made on the gum using the scalpel.
- ③ Once bone is exposed, the guide drill is used to position the osteotomy site.
- ④ Initial drill is used to drill initial hole to match the length of the fixture. The depth of the hole may be measured using depth gauge.
- ⑤ If more than one osteotomy site is required, use the positioning guide on the first osteotomy site and continue with the drilling of the next site.
- ⑥ Final drill is selected according to the diameter of the fixture and start drilling by maintaining the appropriate drilling speed.
- ⑦ Confirm the accurate connection between the Driver connector and fixture located within the ampoule. Afterward, fixture is placed by rotating clockwise in the osteotomy site. It is recommended not to exceed 50Ncm of torque.
- ⑧ If unclear about the depth of the osteotomy site, use Torque Wrench to adjust the depth.
- ⑨ After placing fixture, suitable cover screw or closing screw is selected to protect the fixture. Connect the selected screw with the torque below 15Ncm and suture the surgical site.
- ⑩ To prevent contamination and infection in the oral cavity, recommended maintaining the cleanliness and prohibit drinking and smoking.
- ⑪ After 3~6 months of healing time, verify the osseointegration and proceed with the prosthesis.
- ⑫ For operation procedures and detailed instructions and procedures for each product, please see our manual, catalogue, or website.
(www.dioimplant.com/eng/manual.do)

<How to use UF(II)Narrow Fixture>

- ① Products less than 3.25mm in diameter among UF (II) narrow fixtures are fixtures which are inserted into the anterior region.
- ② The implant fixture is placed according to the protocol. The final recommended placement torque is 20 to 40Ncm.
- ③ At this time, the surgical engine torque does not exceed 50Ncm, the maximum one.
- ④ When excessive torque is applied, the internal structure of the fixture may be deformed or damaged and the surgery may consequentially fail.

<Instruction for using Temporary Fixture>

- ① X-Ray image of patient is used to determine proper osteotomy site for implant.
- ② Using Ø1.2 drill, form initial drill by approximately 1/3 length of the fixture.
- ③ Fixture driver length is selected according to the location within the oral cavity and connected to surgical handpiece. (Contra Angle)
- ④ Fixture is removed from its packaging and verified.
- ⑤ Align the fixture and fixture driver and connect until making flush contact.
- ⑥ Fixture is secured into place by rotating clockwise. Set the torque value of surgical engine at 35Ncm.
- ⑦ Once Contra Angle is stopped rotating after reaching the torque limit of 35Ncm, use ratchet driver and torque wrench to finish the placement.
- ⑧ There should be some down time in between each step of placement before completing the placement.
- ⑨ After fixture is placed, prevent contamination and infection by maintaining clean oral cavity and especially prohibit from smoking.
- ⑩ Depending on the patients, it takes maximum of 3~6 months of healing time for the osseointegration to be completed.
- ⑪ Osseointegration and bone formation is verified and temporary fixture is removed.
- ⑫ Using the same driver used to place, fixture is removed slowly at counterclockwise rotation.
- ⑬ Finish by suturing the site.

<How to use UF(II)Wide Fixture>

- ① Products more than 5.0mm in diameter and less than 7mm in length among UF (II) wide fixtures are fixtures which are inserted into the posterior region.

3. Precaution during use

<Contraindication>

- ① Patient with history of heart attack or arteriosclerosis
- ② Non cooperative patient, patient with mental or physical disability, which may cause difficulty with post surgery management and may lead to instability of

prosthesis, fixation failure or any other complication.

- ③ In any state affecting bone formation, microcirculation and blood
- ④ If pregnant
- ⑤ With high blood pressure or diabetes

Warning

- ① Must be performed and handled by skilled professional. Otherwise it may cause damages to the implant and surrounding bone.
- ② Reuse of implant is strictly prohibited. Must be applied to meet the original purpose.
- ③ Damaged or poorly handled implant must be removed.
- ④ Improper selection, location and/or unstable fixation may shorten the life of implant.
- ⑤ Any defective product must be returned.
- ⑥ Implant must be handled with care to prevent any damage or deformation.

<Side effects>

- ① Dehiscence, Delayed healing, Edema
- ② Hematoma, infection, inflammation,
- ③ General hypersensitivity
- ④ After implant is placed, please comply with recommended healing period. After sufficient osseointegration is observed, proceed with the next stage based on doctor's judgment.

4. Insertion torque requirements for placement in the oral cavity

- ① Guide Drill, Initial Drill, Lindemann Drill, Pilot Drill – Recommended Speed: 1200 ~ 1500 rpm, Insertion Torque: 15 Ncm
 - ② Tapered Drill, Profile Drill – Recommended Speed: 700 ~ 800 rpm, Insertion Torque: 15Ncm
 - ③ Tap Drill, Fixture Driver - Recommended Speed: 30 rpm, Insertion Torque: 35 ~ 45 Ncm
 - ④ Torque Wrench - Recommended Speed: Minimum, Insertion Torque: 35 ~ 45 Ncm
- ※ Fixture Driver and Torque Wrench are for Fixture insertion.

5. Maintenance after initial use

For one time use only. Reuse is prohibited.

- Sterilized medical devices.