Instruction for Use

1. Product Description

The Abutment & Abutment screw is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations in partially or fully edentulous individuals. It is used to restore a patient's masticatory function. It can be manufactured using a CAD/CAM System milling device to provide customized products for each patient.

2. Intended Use

It serves as the upper structure of a dental implant, acting as a support for a prosthesis that replaces the form of a missing tooth.

3. Sterility

- Verify the type, size stated on the packaging label and packaging condition of the abutment and open the packaging.
- This product must be sterilized in an autoclave at 132°C exposure for 15 minutes with 15 minutes minimum drying time before used in oral cavity.

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

1) Obtain a digital impression using an intraoral scanner.
2) Analyze the scanned data and optimize the digital dental model.
3) Design the prosthesis using CAD or other software based on the acquired data.
4) Generate NC data using CAM software.
5) Manufacture the prosthesis using a CAD/CAM system milling machine.

※ Machining range

Connection	Type	Min. Diameter	Max. Length	Max. Angle
Mini	Straight	4.0 mm	16.5 mm	0°
	Angled	4.0 mm	14.5 mm	17°
Regular	Straight	4.0 mm	14.5 mm	0°
	Angled	4.5 mm	14.5 mm	17°

6) Assemble the final prosthesis with the abutment and check for any abnormalities.
7) When connecting the abutment, follow the recommended insertion torque (Mini 20 Ncm, Regular 30Ncm).

C. Management after use

- All products inserted into the oral cavity are single-use sterile medical devices and must not be reused.
- Used packaging should be disposed.

5. Warning

- Implants must be placed by an experienced dentist, as improper techniques can cause damage to the implant or surrounding bone tissue.
- Improper patient selection and procedure may lead to implant surgery failure or bone loss.
- Movement of the implanted implant, bone loss, and chronic infection can lead to implant surgery failure.
- This product is a single-use sterile medical device and must not be reused.

6. Caution

- When placing an abutment in the patient's oral cavity, the surgeon must confirm the degree of osseointegration of the implanted implant through radiographs and percussion reaction before proceeding with the procedure.
- Contaminated products due to use error during the procedure should not be used.
- This product is a single-use sterile medical device and must not be reused.
- The abutment is a user-sterilized medical device and should be sterilized in an autoclave at 132°C for 15 minutes and dried for 15 minutes before used in oral cavity.
- Use appropriate surgical instruments that meet the specifications of the abutment when attaching it to the implant.

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

- Bone loss, loss of stability, damage to prosthetics, inflammation, and nerve damage can lead to implant surgery failure.
- Local complications such as swelling, hematoma, bleeding, infection, inflammation, ulceration, and wound dehiscence may occur.

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

Store at room temperature (1~30℃).

11. Disposal

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

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