Instruction for Use

1. Product Description

This product is a superstructure that is attached to the dental implant after implant placement, to protect the connection and internal hole and to form an appropriate gingival contour during the healing period. It is designed to be removed after the healing period when the superstructure is attached.

2. Intended Use

It is a superstructure that is attached to the implant after dental implant placement to protect the connection and soft tissue during the healing period. It is removed when the permanent superstructure is placed.

3. Sterility

- Verify the type, size, and expiration date 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.
- Products in open or damaged packages should be disposed of.

4. Procedure

A. Preparation Before Use

- Surgical techniques for dental implants require specialized and complex procedures, so relevant formal education and training for implant procedures are needed.
- Do not use the product if the package is damaged.
- 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) After the implant insertion, use 1.2 Hex driver to connect the cover screw to the implant with 10 Ncm of force. Follow the recommended torque as excessive torque can cause fracturing.
2) After healing of gingiva and osteointegration, turn the cover screw counter-clockwise and remove it.
3) After removing the cover screw, use 1.2 Hex Driver to connect healing abutment to the implant, where the cover screw is removed. Follow the recommended torque(10Ncm) as excessive torque can cause fracturing.
4) After the connection, confirm proper placement by taking radiographs.
5) When soft tissue is healed, remove the healing abutment before connecting the abutment.

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

- 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 use.
- 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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