Abutment

Abutment and Prosthetic Components

User Manual

OSSTEM IMPLANT

Storage Condition :
Dry place at room temperature(1℃~30℃)

Caution, Consult accompanying Documents

Rx only For USA Only : Federal law restricts this device to sale by or on the order of a dentist

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English Abutment Instruction for Use

1. Description of Osstem Implant

Osstem Implant is a brand for implant materials for dental practices. Abutment materials include Titanium, Gold alloy, Polymer, Stainless steel, Cobalt Chrome Alloy, and Ceramic material. Prosthetic and dental laboratory materials are polymer, titanium, and stainless steel. Osstem Implant Abutment and prosthetic components are only compatible with the OSSTEM Fixture. Using this product in combination with products from other manufacturers may cause various problems including loosening and fracture due to incomplete locking and compatibility issues. Refer to Osstem's manual, catalogue or our website (www.osstem.com) for details. For the product code, specification, manufacturing date, and expiration date see the product label.

2. Sterility

Cover screw and healing abutment are cleansed and sterilized with gamma radiation. To prevent contamination or infection of the product or operated site, the product must be utilized using a sterilized instrument in a sterilized environment. Damaged products, products with open packaging, or expired products must be discarded due to potential risks of contamination, infection, or osseointegration failure. Re-sterilization or re-use of the product may result in infection, osseointegration failure, or implant damage due to reduced accuracy. The unsterilized prosthetic components must be sterilized in an autoclave at 132°C for 15 minutes before use. After the steam sterilization, the abutments should be dried for 15 minutes before use.

3. Storage Condition

Keep the product in a dry place at room temperature. Keep away from direct sunlight.

4. General Precautions

The surgical technology of dental implant involves an expert, complex procedure. Formal training is required to perform implant surgery.

5. Precautions

Determine the local anatomy and suitability of the available bone for implant placement. Prepare the implant considering the expected situations and cautions. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone.

6. Procedural Precautions (Surgery)

The implant operation requires high accuracy and careful attention, we must try to minimize damage to the cell tissue and pay special attention to the temperature, surgical trauma, and/or removal of the source of contamination and infection.

7. Procedural Precautions (Prosthetics)

All operation tools must be maintained in excellent condition. Since implant constructs, prosthetic structures, and tools are small in size, caution must be taken to prevent swallowing or asphyxiation by the patient. System information (TS, SS, US, KS) and compatibility information (Mini, Regular, Wide) of the abutment and fixture must be confirmed before use in order to prevent loosening or fracture caused by erroneous locking. After locking the abutment to the fixture, confirm
the validity of locking through radiographical image. The screw must be locked using the torque indicated on the Tyvek packaging. Tightening 2~3 times repeatedly is recommended in order to prevent loosening. Excessive tightening torque may cause screw fracture. Angled abutment may be fractured due to limitations in

implant rigidity. It is not recommended for use in the posterior area. When fabricating a prosthesis, it is important to disperse stress adequately. In case of bridge, compatibility between prosthesis and abutment must be confirmed, and occlusal adjustment must be made. Excessive cantilever may cause fracture of the implant system. The fabrication of prosthesis using ceramic abutment requires special technique, and the technician must be trained appropriately. Port Abutment and Port Angled Abutment are intended for overdentures and not for single tooth restorations.

8. Cautions for Patients

Keep the oral cavity thoroughly clean. Do not apply excessive stress on the teeth until the last prosthesis is placed.

9. Warning

The selection of inappropriate patients and surgical methods can cause implant failure or loss of bone supporting the implant. Osstem implants must not be used for purposes other than the recommended use and must not be remodeled. Implant mobility, bone loss, and chronic infection can result in failure of the implant surgery. Osstem implants cannot be used for patients who are allergies or sensitive to the raw material.

10. Indications for Use

The Osstem Implant System was designed for dental implant surgery; it is placed on the maxillary or mandibular alveolar bone through a surgical operation to replace the dental root. The inserted implant can replace lost teeth by connecting the abutment post following osseointegration with the alveolar bone. The Osstem Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. The abutment system is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.

11. Side Effect

A few problems may occur after the operation (loss of implant stability, damage of prosthesis, etc.). Deficient quality and quantity of the remaining bone, infection, allergic reaction, inferior oral hygiene or uncooperativeness of patient, implant mobility, partial deterioration of tissue, and improper position or arrangement of implants may cause the above mentioned problems.

12. Contraindications

Contraindications include the following, but are not limited to:

- Patients with hemophilia or difficulties related to bone or wound treatment.
- Patients with uncontrollable diabetes, heavy smoker or alcoholic.
- Patients whose immunity system is inactive due to chemical therapy or radiation therapy.
- Patients with oral infection or inflammation. (improper oral hygiene, bruxism)
- Patients with untreatable occlusion/joint disorder, insufficient dental arch space.
- Any patient who is not suitable for an surgery.
- Osstem implants cannot be used for patients who are allergies or sensitive to the raw material.