

Instructions for Use (AUG. 2017, Ver. 5.5)

Description of Osstem implant system

Osstem Implant is a brand for implant materials for dental practices, and the fixture is made mainly of titanium. The abutment, prosthetic components and tools for the Osstem Implant system are compatible with the Osstem Implant fixture only. 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 the manual or the catalogue or our website (www.osstem.com) for details. See the product label for the product code, specifications, manufacturing date, and expiration date.

Sterility

The fixture, cover screw, and healing abutment are cleansed and sterilized with gamma radiation. This product is a disposable sterilized medical device intended for one-time use. In order to prevent contamination or infection of the product or operated site, the product must be used 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.

Storage condition

Keep the product in a dry place at room temperature (1~30°C). Keep away from direct sunlight.

General precautions

The surgical technology of dental implant involves an expert, complex procedure. Formal training is required to perform implant surgery. Careful considerations must be made before the operation in case of bone disorders (osteoporosis, osteomalacia) or metabolic disorders of the bone.

Precautions

Determine the local anatomy and suitability of the available bone for implant placement. Prepare the implant considering the expected situations and cautions. Excessive occlusal load may cause loosening or fracture of an implant. In order to avoid this condition, the implant must be placed in accurate location and direction considering the relationship between the implant and opposing dentition. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and the adequacy of the bone. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to implant surgery.

Procedural precautions

Osstem Implant System is for single and two stage surgical procedures. As much as possible, try to minimize damage to the cell tissue and surgical trauma, pay special attention to maintaining the temperature at the implant site and removal of the source of contamination and infection. All drills and taps must be sufficiently and continuously irrigated for cooling during use. Implant placement should be accomplished at very low speed (25-30 rpm) or manually. Excessive torque (greater than 55Ncm) in the fixture placement can have adverse effects such as partial fracture or necrosis of the bone. Placing an implant tilted by 30° or higher is not recommended due to possible fracture of implant. Immediate loading to the fixture right after the surgery should be avoided. The bone quality and initial stability after fixture placement are important elements in determining the appropriate loading time. Mini-diameter implant or implant with diameter of 4.0 or less and which integrates with angled abutment may be fractured due to limitations of structural rigidity. They are not recommended for use in a posterior area. The Ultra-Wide fixtures are intended to be used only to replace molar teeth and

that angled abutments are not to be used with the Ultra-Wide fixtures. Evaluate the quantity of bone and radiographs to assess any potential anatomical contraindications to use of the Ultra-Wide fixture. For the placement of the Short Implant (diameter is 5mm or more and length is shorter than 7mm) which is used on the molar region only, clinicians should closely examine the patients for any of the following conditions: 1) perimplant bone loss, 2) changes to implant's response to percussion, 3) radiographic changes in bone to implant contact along the implant's length. If a short implant shows mobility or greater than 50% bone loss, the implant should be considered for possible removal. And clinicians should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer healing periods for osseointegration before fabrication of the prosthesis and avoid immediate loading. Products with diameter of 3.25mm or less must be used exclusively for mandibular anterior teeth in order to prevent fracture due to excessive occlusal load. It is recommended that you should avoid applying HA coated fixture to hard bone, and the insertion torque of the implant should be less than 35Ncm, because cracks or damages might occur in the coated layer during implant placement. The surfaces of CA and SOI have the same physical shape as the SA surface made through blasting and etching treatments. After the SA surface treatment, to prevent the products' exposure to the atmosphere, CA is stored in solution, whereas SOI is stored in water-film coating form; it is designed to maintain the chemically activated state of the SA surface. Thus, CA or SOI products should be implanted in the target region at least within 15 minutes of taking them out of the container.

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.

Indications for use

The Osstem Implant System is an artificial dental root that has been designed for use in dental implant treatment in order to recover lost teeth. The system is implanted via a surgical method in maxillary or mandibular bone to replace natural dental root. 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. Products with diameter of 3.25mm or less must be used exclusively for mandibular anterior teeth in order to prevent fracture due to excessive occlusal load.

Side effects

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.

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

170

USER MANUAL

Manufacturer : Osstem Implant Co., Ltd.
203, Geogje-daero, Yeonje-gu, Busan, Korea
TEL 82-51-850-2500 FAX 82-51-861-4693



DEUTSCHE OSSTEM GmbH.
Mergenthalerallee 35-37
65760 Eschborn, Germany
+49-(0)6196-777-5500

Storage condition

Dry place at room temperature

Rx only

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



2460



Sterilized using irradiation



Use by



Manufacture



Do not reuse



Date of manufacture



Keep away from sunlight



Catalogue number



Non-Sterile



Keep dry



Batch code



Do not resterilize



Caution, Consult accompanying documents