Description of Avita BLP Implant System

Avita BLP implant is designed and made from biocompatible commercially pure titanium (Grade 4) with TiPowerTM surface for dental implant surgery. it might be placed in the maxillary or mandibular alveolar bone through a surgical operation to replace the dental root. The inserted implant supports the prosthetic parts following osseointegration in the bone. After healing period, the abutment stands on the implant and it is covered with other prosthetic parts such as crown. All the auxiliary parts of Avita BLP implant system including the abutment, prosthetic components, and the surgical instruments are compatible with the Avita implant fixture. Refer to the product catalogue or our website (**www.avitads.com**) for details.

Intended Use

The Avita 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 Avita 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. Narrow Implants with diameter of 3.3mm or must be used exclusively for mandibular anterior teeth in order to prevent fracture due to excessive occlusal load.

Storage Condition

Store at room temperature (~25°c) in "protect case" to prevent the package from damage. Do not use the implant if the package is opened, damaged or expired.

General Precautions

The surgical process of dental implant involves an expert and complex procedure. Therefore, formal training is required to perform implant surgery. Careful considerations must be made before the operation in case of bone disorders. Inappropriate treatment technique could contribute to implant
failure and/or loss of supporting bone.

The fixture and cover screw are cleaned 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 with sterilized instruments in a sterilized environment. Re-sterilization or re-use of the product might result in infection and osseointegration failure.

Warning

Do not re-sterilize the fixture or cover screw in any case.

Warning

The use of electro-surgical instruments or lasers around metallic fixture and their abutments is not recommended due to the risk of electric shock and/or burns.

Procedural Precautions

In treatment plan, determine the local anatomy and suitability of the bone characteristics for implant placement. 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.

Avita Implant System is for single or multiple unit restorations only in a 2-stage (delayed loading) surgical procedure. This means that 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.

Before implant placement, try as much as possible to minimize damage to the cell tissue and surgical trauma, pay special attention to removal of the source of contamination and infection. All drills and taps must be sufficiently and continuously irrigated for cooling during use to prevent temperature increase at the implant site. Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended for lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth. Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage to nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Implant placement should be accomplished at very low speed with the Handpiece (maximum speed of 15 rpm is recommended) or manually with the Ratchet. Excessive torque (greater than 55 N.cm) 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. Narrow implant with diameter of 3.3 mm must be used exclusively for mandibular anterior teeth in order to prevent fracture due to excessive occlusal load. Special torque for narrow (lower than other diameters)

Warning

Narrow implant (diameter of 3.3) or implant with diameter of 4.0 or less which integrates with angled abutment may be fractured due to limitations of structural rigidity. They are not recommended for use in a posterior area.
For the placement of the Short Implant (length of 6mm) which is used on the molar region only, clinicians should closely examine the patients for any of the following conditions: 1) periimplant bone loss, 2) changes to implant's response to precautions, 3) radiographic changes in bone to implant contact along the implant's length.

Warning

According to the preimplantitis protocol, if more than %50 of the implant length is affected by preimplantits, your treatment will progress to explanation.

Warning

The selection of inappropriate surgical methods can cause implant failure or loss of bone supporting the implant. Avita 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. Avita implants cannot be used for patients who are allergies or sensitive to the titanium.
The mesiodistal bone availability is an important factor for choosing the implant type and diameter as well as the inter-implant distances where multiple implants are placed. A minimal distance of 1.5mm from the implant shoulder to the adjacent tooth at bone level (mesial and distal) is required. A minimal distance of 3mm between two adjacent implant shoulders (mesiodistal) is also required.

For Avita implants, the facial and palatal bone layer must be at least 1-1.5mm thick in order to ensure stable hard and soft tissue conditions. Within this limitation, a restoration -driven orofacial implant position and axis should be chosen such that screw-retained restorations are possible. In particular, an augmentation procedure is indicated where the orofacial bone wall is less than 1mm or a layer of bone is missing on one or more sides. This technique should be employed only by dentists who have adequate experience in the use of augmentation procedures.

Warning

Avita implant should not be used in cases where the remaining alveolar bone is too diminished to provide adequate width or height to surround the implant.

The cover screw must be locked in a hand-tight procedure thus you might consider the recommended torque between 5-8 N.cm. tightening the cover screw with excessive amount of torque may cause difficulty in reopening after healing time.

Instruction for Use

A. Preparation

1) Check the condition of bone and make a treatment plan.
2) Patient should be aware of the following information: Result of diagnosis, Advantages and side effects of the treatment, Contraindication.
3) Before surgery, check the following information: bone density, oral hygiene, the radiography inspections, CT inspection (according to the condition of soft tissue, hard tissue and occlusion), examine the patient's systemic condition , medicine consumption & smooking.
4) Check the condition of package and the expiration date before opening the pack. If there is any problem do not use the implant and contact the manufacturer at your earliest convenient.

B. Implant Placement

1) The implantation procedure should be done under aseptic conditions with sterile surgical instruments manufactured by Avita.
2) Throughout the drilling sequences, a gentle up and down pumping motion should be continued and external irrigation system should be used to prevent bone heating.
3) The insertion torque of implant should be less than 55 N.cm, because too much insertion torque may cause bone overheating (Recommend Torque 35 N.cm). If an insertion torque of over 35 N.cm is achieved before the implant has assumed its final position, check that the implant bed preparation is correct to avoid bone overcompression.
4) After completing the insertion procedure, place the cover screw into the implant, close and suture the tissue flap.
5) After enough recovery time (which is normally 4 month for maxilla and 2 month for mandible) abutment and prosthetic parts will be placed on the implant.

Warn to Patient

The dentist should warn the patient not to apply too much pressure to the implant, before placing the last prosthesis and completing the treatment process.

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 disorder, insufficient dental arch space, poor bone quality
- Patients who are allergies or sensitive to the titanium material
- Any patient who is not suitable for a surgery

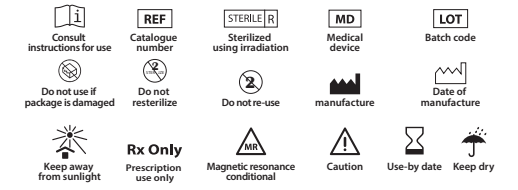
Failure conditions

A few problems may occur after the operation (loss of implant stability, fallout, loosening, fracture, damage of prosthesis). 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.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines. Separation, re-cycling or disposal of packaging material shall follow local legislation on packaging waste.

Symbol Glossary



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