

Instructions For Use

Product : Dental Orthodontic Implant

Product Description

The screws are manufactured from commercially Ti-6AL-4V ELI (titanium alloy). The screws are available with thread diameter are from 1.4mm to 1.8mm, and total lengths from 6mm to 10mm. There is a pair of self-tapping flutes and self-drilling flutes for easy insertion and removal. The design of smooth curve surface of screw head is comfortable to patients and the screws with or without a 0.65mm diameter hole can supply different orthodontic methods for orthodontists.

Indications for use

The screws are intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. They are used temporarily and are intended to be removed after orthodontic treatment has been completed. The screws are intended for single use only.

Contraindications

- Insufficient bone quantity and/or poor bone quality in the receiving site.
- Poor oral hygiene.
- Heavy smoking, tobacco and alcohol abuse.
- Systemic blood disorders.
- Uncontrolled diabetes.

Warnings

- Placement of surgical screws requires specific knowledge of anatomy and techniques and this procedure must be carried out by qualified and trained people. Improper patient selection and/or incorrect technique can cause placement failure and/or loss of supporting bone.
- An implanted device or used screw should never be reused. Any screws which have been contaminated with blood or bodily fluids should be discarded.

Precautions

- Effective and complete screening of screw application candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are recommended to determine anatomical landmarks and bone adequacy. Lateral telereadiographs and other types of X-ray examination are recommended.
- Detailed instructions, limitations and possible adverse effects of the procedure should be given to the patient.
- Orthodontic Implant application procedures have some risks which include the insult of delicate anatomical structures both of the superior jaw-bone and of mandibular bone, if existing conditions are not carefully considered.
- The Orthodontic Implant has been designed to achieve anchorage with immediate loading and of limited duration. Consequently, the efficiency of this system should not be dependent upon osseointegration. The Orthodontic Implant is highly polished and not designed for osseointegration anchorage (deferred loading).

Adverse Effects

After Orthodontic Implant application, untimely anchorage loss may occur. Potential causes include but are not limited to:

- Bone poor quantity and/or quality, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone leading to non-union.
- Infections
- Poor oral hygiene or patient's cooperation and/or genetic diseases (diabetes).
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Increase fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Inadequate healing.
- Localized swelling, edema and tissue reaction.

Apart from these adverse effects, there are always possible complications such as, but not limited to, infection, nerve damage and pain which may or may not be related to the implant.

Cleaning and Sterilization

It is the responsibility of and incumbent on the user to make certain and to validate that appropriate cleaning and sterilization methods are used.

Sterilization:

The Orthodontic Implant is supplied clean and non-sterile and is intended to be sterilized prior to use. Use of a Sterilization Cassette is recommended to sterilize simultaneously all instruments, components and screws. Components including screws, drivers and shafts may also be sterilized individually using a sterilization pouch.

The validated sterilization procedures as described require the use of FDA cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI.

Those studies confirmed the following recommendations for Steam Sterilization cycles.

Cycle Type	Temperature	Exposure Time
Gravity	121°C	30 minutes
Pre-vacuum	134°C	10 minutes

Sterilization results confirmed for a single micro screw or a fully loaded cassette using one pouch and a dry time.

Direction for use

No pilot drilling is required prior to insertion of Orthodontic Implants with a self-drilling thread in the maxilla. When inserting the Orthodontic Implant, ensure that all the hygiene measures required for invasive surgery are completed, e.g. sterile working area, sterile gloves, face mask etc. Reliable functioning of the Orthodontic Implant depends on rigid anchorage in the bone (primary stability) and placing the head in the region of the attached gingiva (alveolar gingiva). When using the Orthodontic Implant as an anchor, ensure that the head and surrounding tissue are not subjected to any detrimental mechanical effects (e.g. movement of the mucosa, effect of bands and/or tongue, manipulation). Maximum load force is 300G per screw. The direction of force must be perpendicular to the long axis of the implant for immediate loading.

Step 1: Select the insertion area.

Suitable placement sites for the Orthodontic Implant are listed below:

- Retromolar.
- Buccal and lingual interradicular alveolar zone of the mandible and maxilla.
- Mandibular symphysis.

Step 2: Local anesthetic.

Step 3: Punch a hole in the gingiva using a gingival punch.

Step 4: Screw Placement and Insertion

Pick up a sterile Screw and transfer it to the prepared site for placement using the Handle Driver instrument.

Step 5: Screw Placement and Insertion (*cont.*)

In most cases the Orthodontic Implant can be inserted without any drilling depending upon the bone density. It is the responsibility of the professional to determine suitability on a case by case basis before use.

Step 6: Screw Placement and Insertion (*cont.*)

Use Handle Driver for insertion and final height positioning. Always insert the screw to ensure all threaded portions of the screw are sub cortical.

Removal of the Orthodontic Implant:

- Local anesthetic (*optional*).
- Remove all wires, auxiliaries and attachments.
- Unscrew the Orthodontic Implant using the handle driver instrument and head shaft which were used to insert