Kenko's S&E Orthodontic Mini-screw

- **For Kenko's S&E Orthodontic Mini-screw(YM).**
- **Before clinical use, the operating instructions must be read carefully in their entirety.**
- **Anchorage screws are supplied non-sterile.**
- **Anchorage screws must only be inserted by orthodontists, dentists, oral surgeons and surgeons specializing in maxillofacial surgery.**
- **A comprehensive range of information about Kenko's S&E Orthodontic Mini-screws are available for the user and patient. The range is regularly updated.**
- **All standard hygienic precautions required for invasive procedures such as a sterile working environment, sterile gloves, surgical masks etc. must be taken before and during insertion of Kenko's S&E Orthodontic Mini-screws.**

Description

Kenko's S&E Orthodontic Mini-screw consists of titanium (ASTM F136) and stainless steel (ASTM F138) self-tapping screws with various sizes for applications in the orthodontic field. It is intended to serve as a stable anchorage point for the attachment of orthodontic and pre-prosthetics appliances, in order to facilitate the orthodontic movement of teeth.
Kenko's S&E Orthodontic Mini-screw and associated accessories are supplied non-sterile and should be sterilized before use. The devices are used temporarily with the intention to be removed after orthodontic treatment. Screws are intended for single use only.

Indications

Temporary anchorage screws are intended to provide a stable anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. The screw is used temporarily and is removed after orthodontic treatment has been completed.

Contraindications

Immunodeficiency diseases, thrombus, endocrine disease, rheumatism, cirrhosis and other acute medical history 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.

Warning

Surgical placement of screw requires specific knowledge of anatomy and techniques and this procedure must be carried out by qualified and well-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.

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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 teleradiographs and other types of X-ray examination are also recommended.

- Detailed instructions, limitations and possible adverse effects of the procedure should be given to the patient.

-Kenko's S&E Orthodontic Mini-screw application procedures have some risks which include the insult of delicate anatomical structures both of the maxilla and of mandible, if existing conditions are not carefully considered.

- The Kenko's S&E Orthodontic Mini-screw 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 Kenko's S&E Orthodontic Mini-screw is highly polished and not designed for osseointegration anchorage (deferred loading).

Adverse Effects

After Kenko's S&E Orthodontic Mini-screw 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.

This surgical procedure may cause not only the above-mentioned side-effects and complications but also problems such as injuries to nerves, infections, pain etc., which are not necessarily caused by the implant. If complications occur, they are often the result of incorrect selection of the patient, lack of practice or lack of preoperative planning rather than caused by the screw itself.

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Cleaning and Sterilization

It is the responsibility of the user to make sure and to validate that appropriate cleaning and sterilization. The Kenko's S&E Orthodontic Mini-screw is supplied clean and non-sterile and is intended to be sterilized prior to use. When do sterilization of the Kenko's S&E Orthodontic Mini-screw, use of a "BOMEI" Sterilization Cassette (#BM2901) is recommended.

Steam Sterilization

Steam sterilization shall be completed at a temperature of 121^0C / 249^0F with a minimum hold time of 25 minutes. It is the users' responsibility to validate the recommended sterilization parameters, or any other steam sterilization process than those recommended by Bomei, so that any differences regarding sterilization chambers, wrapping methods and load configurations are taken into account and the obligatory sterility assurance level (SAL) of 10^{-6} can be achieved.

Additional information

The Kenko's S&E Orthodontic Mini-screw is delivered non-sterile, packaging in a steam E.O gas bag .The packaging shall be removed just prior to insertion. Prior to clinical use, non-sterile screw shall again be cleaned and disinfected and then sterilized by the operator.

Storage

To prevent condensation from forming, major temperature fluctuations should be avoided. Prepared sterile instruments must be stored in a suitable reusable sterilizing container in dry, dustproof, low-germ, dark and cool spaces that are vermin-proof. The approved local storage period depends on the type of sterile barrier system and the storage conditions. Operator must specify the approved storage period.

Direction for use

No pilot drilling is required prior to insertion of Kenko's S&E Orthodontic Mini-screw with a self-drilling thread in the maxilla. When inserting the Kenko's S&E Orthodontic Mini-screw, 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 Kenko's S&E Orthodontic Mini-screw depends on rigid anchorage in the bone (primary stability) and placing the head in the region of the attached gingiva. When using the Kenko's S&E Orthodontic Mini-screw 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 screw for immediate loading.

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Step 1: Determine the length of the screws for plate fixation.

Use the BOMEI instrument to pick up the chosen screw for plate fixation.

Step 2: Select the insertion area.

Choose the suitable implantation site for the Kenko's S&E Orthodontic Mini-screw according to the treatment objective and the quality and quantity of bone. Confirm that the implantation site allows adequate clearance from the tooth roots and nerves.

The following positions offer the best conditions for an insertion of the screw:

Maxilla

-The infrazygomatica crest

-The anterior nasal spine

-The palate

Mandible

-The retromolar area

-The symphysis

-The alveolar process

Step 3: Local anesthesis

Step 4: Screw Placement and Insertion

Pick up a sterile Kenko's S&E Orthodontic Mini-screw and insert the screw by using the "Bomei" Handle Driver instrument. ("BOMEI"# YM2901-0 Screwdriver Shaft and #BM2903 handle driver instrument.)

Step 5: Screw Placement and Insertion (cont.)

In most cases the Kenko's S&E Orthodontic Mini-screw can be inserted without any drilling depending upon the bone density. It is the responsibility of the professional users to determine suitability on a case by case basis before use.

Removal of the Kenko's S&E Orthodontic Mini-screw

-Removal of the screw can take place under local anesthesia.

-The screw can be taken out using the exact same instruments that were used for the insertion.

-Remove all wires, auxiliaries and attachments.

-It can be removed with the same instruments that were used for insertion.

-Withdraw the screw using the Bomei handle driver instrument and Bomei head shaft.

-Loosen the screw by carefully turning it anticlockwise; it can then be completely unscrewed.

-Care should be taken to remove any sharp edges after cutting the plate to avoid soft tissue irritation or injury.

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