Procedural information and instructions for use

Description

The OsteoMed OM Orthodontic Anchor System is comprised of implants in diameters of 1.2mm and 1.6mm in thread lengths of 6.0mm to 12.0mm. The instruments include pilot drills, and drivers used to facilitate the placement of implants.

Notes:

- These implants are made from Titanium-Alloy (ASTMF-136). The implant is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications

The Chironom OM Orthodontic Anchor System is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is intended temporarily and is removed after the orthodontic treatment has been completed. The OM Orthodontic Anchors are intended for single patient use only. OsteoMed use device/instrument cannot be shared with the manufacturer's use instructions for sterilization.

For cutting instruments the cutting efficiency may be reduced requiring the surgeon to increase force that might cause potential damage to bone. Therefore, these products have not been validated for multiple uses.

OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications

Use of the Chironom OM Orthodontic Anchor System is contraindicated in cases of acute or suspected infection or in patients with uncontrolled diabetes or who are immunocompromised due to radiation or previously administered chemotherapy. In patients exhibiting disorders which would cause the patient to ignore the limitations of orthodontics. This system is contraindicated in severe systemic diseases, uncontrolled hemorrhagic disorders, bone metabolism disorders; uncooperative or uncoordinated patient, drug, alcohol or tobacco abuse; psychiatric disorders; long standing, therapy use of steroids; and uncontrollable endocrine disorders. The Chironom OM Orthodontic Anchor System implant should not be used when the remaining bone is too diminished to provide adequate width or height to surround the implant.

Failure to do so may result in implant loosening.

Avoid placement of the implant too coronally in the alveolus to prevent interference with surrounding vital structures.

If during insertion the implant cannot be completely seated, it is likely that cementum has been encountered. It is recommended that a pilot hole be extended from the cortical length through the bone to decrease the chances of implant fracture during retrieval.

OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implant site.

The orthodontic mechanics are straightforward with the use of nickel-titanium closed-coil springs or elastic-chain.

Placement Into Attached Gingiva (Exposed Technique):

1. Confirm adequate anesthesia.
2. Use a slow-speed drill with a carbide round bur (#2) passing directly through the tissue and 0.5mm into the underlying cortical bone ("coronal notching"). Adequate irrigation should be used.
3. If adequate space exists between the roots of neighboring teeth, the implant can be inserted perpendicularly to the bone.
4. If there are anatomic barriers to consider (e.g. dental roots), the implant can be placed at an angle to the long axis of the teeth.
5. The thickness of the attached gingiva can be determined prior to placement of the implant. This will help in choosing the appropriate implant length.
6. The radial notch provides a sufficient purchase point for an angled path of insertion for the 1.6mm diameter implant.
7. For the 1.2mm diameter implant, it is recommended that a pilot hole be extended from the cortical length through the bone to decrease the chances of implant fracture during retrieval.

Insert the implant under manual pressure with the implant driver, bringing the bottom of the abutment into contact with the tissue, avoiding severe bending stresses.

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1. Confirm primary stability avoiding rotation of the implant.
2. Orthodontic force can be placed on the implant immediately.
3. If during insertion the implant cannot be completely seated, it is likely that cementum has been encountered. The implant should be reused at a new site if necessary.

Placement Into Unattached Gingiva (Submerged Technique):

1. The protocol is generally the same as with the Exposed Technique but the implant should be submerged for the tissue since the incidence of tissue overgrowth/ulceration is much higher when the implant is inserted through an unattached gingiva.
2. Use a stainless steel engine quieting any implant head resulting in an emerging point of attachment for orthodontic mechanics is preferred in the Submerged Technique.
3. Make a small stab incision through the soft tissue at the desired point of insertion. This will eliminate tissue binding around the implant.
4. Use a slow-speed drill with a carbide round bur (#2) to a depth of 5.0mm into cortical bone with adequate irrigation ("coronal notching").

Insert the implant under manual pressure with the implant driver, bringing the bottom of the abutment into contact with the tissue, avoiding severe bending stresses.

1. Confirm primary stability avoiding rotation of the implant.
2. Proper suturing of the placement site should be done if necessary, allowing the stainless ligature to pass freely into the oral cavity.

If during insertion the implant cannot be completely seated, it is likely that cementum has been encountered. The implant should be reused at a new site if necessary.

Implant Loading/Removal:

- Implants can be loaded immediately after placement. Up to 300 grams of orthodontic force can be applied to 1.6mm diameter implants where as 500 grams can be applied to implants with a diameter of 1.2mm. These numbers should be considered as a guide. The exact amount of force that an implant could withstand depends on many factors that need to be considered.
- The orthodontic mechanics are straightforward with the use of nickel-titanium closed-coil springs or elastic-chain.
- Implants can also be paired with elastic orthodontic force.
- Due to the nature of the smooth surface of the implant and short duration of implantation, osseointegration will not occur, thus retrieval of an exposed implant is easily accomplished with the implant driver. This is often done without the need for local anesthesia and healing is uneventful.

Cleaning

- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound, treatment, etc.) and recommendations for chemical detergents.

OsteoMed recommends the following cleaning and sterilization instructions for Instrumentation:

1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
2. Thoroughly rinse all instruments and the sterilization tray with water.
3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
4. Steam Autosolve per the following Sterilization Instructions.

Sterility

- Implants and Instruments are provided non-sterile and must be sterilized prior to use. OsteoMed shall comply with the manufacturer’s use instructions for sterilization.
- The user facility must clean and disinfet instruments prior to sterilization per standard hospital procedures.
- Non-sterile implants are sterilizable by steam sterilization (autoclaving).

For sterilization of OsteoMed OM Orthodontic Anchor System, the following parameters should be used:

- Pre-Vacuum Steam Sterilization:
  - Minimum Temperature: 270 F (132°C)
  - Full Cycle Time: 8 minutes
  - Minimum Dry Time: 20 Minutes
  - Trapped Whip
  - Wrapping Technique: Tray wrapped with 2 layer of polypropylene wrap (Kingdom KSC90 – STK255A).

- Do not exceed 275°F (135°C) to avoid compromising function of polymeric instrument.

Note: Biological indicator of g. stearothermophilus was used in sterilization validation.

Storage

The OM Orthodontic Anchor System is to be stored at a controlled room temperature between 15°C to 30°C (59°F to 86°F).

Caution

- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed implants or instruments.
- Inspect all components pretoperatively to assure utility. Alternate fixation methods should be available intreproactively.