OSTEOMED

Rigid Fixation System

OMI Orthodontic Anchor System

Product Information and Instructions For Use

Description

The ***OSTEOMED*** *OMI 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.

Material

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

Clinical Indications

The ***OSTEOMED*** *OMI Orthodontic Anchor System* is indicated to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The OMI Orthodontic Anchor Implants are intended for single patient use only. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications

Use of the ***OSTEOMED*** *OMI Orthodontic Anchor System* is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases; in patients exhibiting disorders which would cause the patient to ignore the limitations of orthodontics. This system is further contraindicated in serious systemic diseases; uncontrolled hemorrhagic disorders; bone metabolism disorders; uncooperative or unmotivated patient; drug, alcohol or tobacco abuse; psychotic diseases; long standing, therapy use of steroids; and uncontrollable endocrine disorders. The *OsteoMed OMI Orthodontic Anchor System* should not be used in cases where the remaining jaw bone is too diminished to provide adequate width or height to surround the implant. Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient available bone or poor bone quality, or medical conditions such as blood disorders, vascular impairment at surgical site, drug or alcohol abuse, current or ongoing anticoagulant therapy.

Warnings:

1. Implant Selection: Choose the longest implant possible for optimal bone purchase considering available bone, thickness of soft tissue and proximity of vital structures. Failure to do so may result in implant loosening.

Cautions:

1. Approaching the height/depth of the vestibule with the implant abutment may cause tissue impingement and ulceration.
2. Avoid placement of the implant too coronally in the alveolus to prevent interference with surrounding vital structures.
3. Overheating of the supporting bone can result in osteonecrosis.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of orthodontic products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which implant to use for specific indications.
3. The ***OSTEOMED*** *OMI Orthodontic Anchor System* implants are not intended to endure excessive abnormal functional stresses.
4. Following placement of implant, avoid applying any rotational or torsional forces.
5. The ***OSTEOMED*** *OMI Orthodontic Anchor System* is intended for temporary implantation until correct placement of teeth has been achieved.
6. Surgeons should be cognizant of the following implant features: Implant groove is 1.3mm wide; diameter of center hole is 0.8mm. These features allow the implant to accept appropriately sized wires and appliances.
7. All OsteoMed implants and instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
8. Carefully inspect the OsteoMed implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition and repair.
9. OsteoMed recommends the use of OsteoMed products in a sterile environment.
10. Patients should be advised not to tamper with or attempt to remove the implant.

Instructions for Use:

Planning Considerations:

- The optimal location for implant placement is based on the assessment of both the anatomic limitations and the orthodontic treatment considerations.
- Implants can be placed anywhere in the maxilla and the mandible in which adequate bone exists, while avoiding surrounding vital structures.
- Vital structures (e.g. dental roots, blood vessels, nerves, maxillary sinus, etc.) should be avoided. The use of radiographs and/or other imaging techniques is recommended. Surgical stents can prove helpful as well.
- Attempts should be made to place the implant through attached gingiva rather than unattached gingiva.
- The thickness of the attached gingiva can be determined prior to placement of the implant. This will help in choosing the appropriate implant length.
- Since the ultimate goal of the implant is to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth, it is paramount to recognize the amount and direction of the desired dental movements prior to placement.
- Placement of the implant should be in an appropriate relationship to the orthodontic appliances and readily available to work with the proposed treatment mechanics.

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 ("cortical notching"). Adequate irrigation should be used.
3. If adequate space exists between the roots of neighboring teeth, the implant can be inserted perpendicular to the bone. If there are anatomical barriers to consider (e.g. dental roots), the implant can be placed at an angle to the long axis of the teeth. The cortical notch provides a sufficient purchase point for an angled path of insertion for the 1.6mm diameter implant. For the 1.2mm diameter implant, it is recommended that a pilot hole be extended from the cortical notch through the cortical bone to decrease the chances of implant fracture during insertion.
4. Insert the implant under manual pressure with the implant driver, bringing the bottom of the abutment into contact with the tissue, avoiding severe blanching.
5. Confirm primary stability avoiding rotation of the implant.
6. Orthodontic force can be placed on the implant immediately.
7. If during insertion the implant cannot be completely seated, it is likely that cementum has been encountered. The implant should be reinserted 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 under the tissue since the incidence of tissue overgrowth/inflammation is much higher when the implant is inserted through an unattached gingiva.
2. Placing a stainless steel ligature around the 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 drill and implant.
4. Use a slow-speed drill with a carbide round bur (#2) to a depth of 0.5mm into cortical bone with adequate irrigation (cortical notching).
5. Insert the implant under manual pressure with the implant driver, bringing the bottom of the abutment to the level of the bone. The same issues concerning pilot drilling and the angle of insertion exist as with the Exposed Technique.
6. Confirm primary stability avoiding rotation of the implant.
7. Proper suturing of the placement site should be done if necessary, allowing the stainless ligature to pass freely into the oral cavity.
8. If during insertion the implant cannot be completely seated, it is likely that cementum has been encountered. The implant should be reinserted 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 1.2mm diameter implants, where as up to 450 grams can be applied to implants with a diameter of 1.6mm. These numbers should serve as a guide only. 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 provide indirect anchorage.
- Due to the nature of the smooth surface of the implant and short duration of implantation, osseiontegration 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.
- Retrieval of a submerged implant requires local anesthesia, exposure of the implant, and unscrewing of the implant with the implant driver. Suturing may be done if necessary; 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 Autoclave per the following Sterilization Instructions.

Sterility

- Implants and Instruments are provided non sterile and must be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of ***OSTEOMED*** *OMI Orthodontic Anchor System*, the following parameters should be used.

Pre-Vacuum Steam Sterilization:
Preconditioning Pulses: 3
Minimum Temperature: 270°F (132°C)
Full Cycle Time: 8 minutes
Minimum Dry Time: 20 Minutes
Configuration: Wrapped Tray
Wrapping Technique: Tray wrapped with 2 layers of 1-ply polypropylene wrap
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

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 instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.**

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CE 0197

Symbols and Definitions

Single Use Only		REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture	EC REP	Authorized Representative in the European Community
	Attention, See Instructions for Use Caution, Consult Accompanying Documents		Manufacturer

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