Part No. 030-1277
Rev. L

OSTEOMED Rigid Fixation System
2.0 Orthognathic System

Product Information and Instructions For Use

Description

The *OSTEOMED 2.0 Orthognathic System* is comprised of plates, screws and instrumentation used for standard orthognathic maxillary and mandibular advancements. The system features zygomatic and pyriform plates 0.8mm thick and BSSO plates 1.0mm thick. The system also features 2.0mm standard screws in lengths from 4mm to 18mm and 2.0mm Auto-Drive Screws in lengths of 4mm to 8mm. The emergency screws to be provided in the system are 2.4mm standard screws in lengths of 5mm to 16mm. The instruments include drill bits, plate bending forceps, plate holding forceps, plate cutters, cannulae, taps, and screwdrivers to facilitate the placement of screws and modification of plates.

Material

The screws are made from Titanium Alloy (ASTM F-136). The plates are made from commercially pure Titanium (ASTM F-67). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications

The *OSTEOMED 2.0 Orthognathic System* is indicated for fracture fixation during cranial and facial trauma reconstruction, orthognathic reconstruction, mandibular reconstruction and surgery involving osteotomies and trauma of small bones of the hand and foot. The *OSTEOMED 2.0 Orthognathic System* implants and drills are intended for single 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. Other system instruments are reusable.

Contraindications

Use of the *OSTEOMED 2.0 Orthognathic System* is contraindicated in cases of active or suspected infection or in patients previously sensitized to titanium. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation plate and screw implants.

Warnings

1. Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
2. Plates and screws, wires, or other applances of dissimilar metals should not be used together in or near the implant site.
3. Multiple bending may weaken the plate and could result in implant fracture and failure.
4. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
5. Use of excessive torque during insertion of screws may lead to implant failure.
6. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.
7. The *OSTEOMED 2.0 Orthognathic System* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of rigid fixation products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.
3. The *OSTEOMED 2.0 Orthognathic System* plates and screws are not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED 2.0 Orthognathic System* is intended for temporary fixation only until osteogenesis occurs.
5. All OsteoMed plates, screws, 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.
6. 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.
7. OsteoMed recommends the use of OsteoMed products in a sterile environment.
8. Depth gauge marking tolerance:± 0.76mm

Instructions for Use, Auto-Drive™ screws

The Auto-Drive screws are self drilling and can be inserted in one step. Insert the screw in a TaperLock™ screwdriver and drive into the bone at a 90° angle using moderate pressure until the head is flush with the surface of the bone/plate. Higher torque may be required to fully engage the threads than when using a normal screw with a pilot drill.

Note: In high density bone, pilot drilling may be necessary.

Instructions for Use, Zygomatic and Pyriform plate tabs

1. Tabs are to be used for identification of plate. They can also be used to aid in placement of plate on bone.
2. Tabs must be broken from plate once fixation is achieved. Bend tabs in opposite directions until broken from plate.

Instructions for Use, Depth Gauge

1. If using bicortical fixation, slide the end of depth gauge through drilled pilot hole to measure screw lenghth.
2. Keeping depth gauge off the center of the pilot hole, pull back until the hook catches the lingual cortex.
3. Slide top sleeve down depth gauge until it rests on the plate or buccal cortex for positional screw placement.
4. Location of sleeve on measurement scale will indicate screw length.

Sterility

All *OSTEOMED 2.0 Orthognathic System* plates, screws and instruments are packaged non-sterile and must be sterilized prior to surgical use.

Pre-Vacuum Steam Sterilization:

Temperature:	270°F(132°C)
Time:	10 minutes
Dry Time:	55 minutes
Configuration:	Wrapped Tray

Wrapping Techinque: Individually wrap in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential wrapping techniques.

Do not exceed 275°F(135°C), to avoid compromising functions of polymeric instrumentation.

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

Since OsteoMed is not familiar with individual hospital handling methods, cleaning methods and bioburden, OsteoMed cannot assume responsibility for sterility even though the guideline is followed.

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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Symbols and Definitions

	Single Use Only	REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.		

Printed in U.S.A.
OSTEOMED August 2014