Part No. 030-1294
Rev. M

OSTEOMED

Orthognathic Supra Advancement (OSA) System

Product Information and Instructions For Use

Description

The *OSTEOMED OSA (Orthognathic Supra Advancement) System* is comprised of various plates and screws. Plates, .8mm through 1.0mm thick are provided in various pre-manufactured shapes and sizes. The LeFort plates are pre-bent with a step ranging from 2mm to 12mm and are provided in both left and right versions. The ISO plates are pre-bent with steps ranging from 4mm to 14mm. The system also includes buttress plates and sagittal split (BSSO) plates. Auto-Drive screws are provided in 1.6mm and 2.0mm diameter in lengths of 4.0mm through 8.0mm. Standard screws are provided in 2.0mm diameter in lengths of 8.0mm to 14.0mm. Safety screws are 1.9mm and 2.3mm diameter. The instruments include screwdrivers, countersinks, pilot drills and preparation instruments to facilitate the placement of plates and screws.

Material

Plates are made of Titanium (ASTM-F-67). The screws 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 OSA (Orthognathic Supra Advancement) System* is intended for a variety of pan facial indications. Specifically, the system is intended for selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and mandible. Implants are 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.

Contraindications

Use of the *OSTEOMED OSA (Orthognathic Supra Advancement) 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. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation.

Warnings

1. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
2. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
3. Use of screws in high density bone may lead to implant fracture or failure upon insertion.
4. Use of excessive torque during insertion of screws may lead to implant failure.
5. 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.
6. The *OSTEOMED OSA (Orthognathic Supra Advancement) System* 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 OSA (Orthognathic Supra Advancement) System* plates and screws are not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED OSA (Orthognathic Supra Advancement) 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.

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.

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

- *OSTEOMED OSA (Orthognathic Supra Advancement) System* plates, screws, and instruments are supplied 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 devices prior to sterilization per standard hospital procedures.
- Non-sterile instruments are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED* OSA system instruments, the following parameters should be used.

Pre-Vacuum Steam Sterilization

Temperature:	273°F (134°C)
Time:	30 minutes
Dry Time:	55 minutes

Tray wrapped with two layers of 1-ply poly propylene wrap (Kimguard KC600 – 510(k) K082554).

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.

Caution

- Federal (United States) law restricts this device for sale by or on the order of 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.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001 USA
Customer Service: 800/456-7779
Outside USA: 972/677-4600

EC REP
Shotwell & Carr, LLC
2 St. Paul's Road
Clifton Bristol
BS8 1LT, U.K.
Tel: +44 (0) 117 9738944

CE 0086

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