Part No. 030-1012
Rev. U

OSTEOMED MINCRO™

Rigid Fixation System

Product Information and Instructions For Use

Description

The *OSTEOMED* MINCRO™ System is comprised of 1.2mm & 1.6mm diameter screws and instrumentation used for fixation and stabilization of bone grafts and the temporary stabilization and fixation of non-resorbable barrier membranes used in guided bone regeneration. The system features 1.6mm diameter standard screws in lengths from 4mm to 14mm, 1.2mm diameter standard screws in lengths from 2mm to 12mm, 1.6mm diameter Auto-Drive screws in lengths from 4mm to 8mm, 1.6mm diameter Auto-Drive partially threaded screws in lengths of 10mm and 12mm, and 1.2mm diameter tenting screws in lengths from 6mm to 10mm. Micro plates are also offered in this sytem in thickess ranging from 0.50mm to 0.55mm. The instruments include drill bits and screwdrivers to facilitate the placement of screws.

Material

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

Indications for Use

Fixation and stabilization of bone grafts and the temporary stabilization and fixation of non-resorbable barrier membranes used in guided bone regeneration. 1.6mm Partially Threaded Auto-Drive Screws are intended for tacking in the dentoalveolar applications only. *Mincro*™ System implants 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. System instruments are reusable.

Contraindications

Use of the Osteomed MINCRO™ Screw System is contraindicated in cases of active or suspected infection or in patients previously sensitized to titanium. The MINCRO™ System is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation screw implants.

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 fractures 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* MINCRO™ 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 screw to use for specific indications.
3. MINCRO™ System screws are not intended to endure excessive abnormal functional stresses.
4. Selection of screw size must be carefully considered by the operating surgeon and should take into consideration the quality of bone, bone type, functional loads exerted on bone(s) and post-operative patient compliance.
5. The MINCRO™ System is intended for temporary fixation only until osteogenesis occurs.
6. 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.
7. 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.
8. 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.

Instructions for use:

1. Remove organizer lid to dispense screws and instrumentation. Retract black distal collar of Taperlock Screwdriver handle to insert appropriate driver shaft. Release collar and align shaft with handle; the collar will lock when extended forward.
2. Prepare bone with appropriate pilot drill, exceeding the length of the intended screw, while avoiding critical structures.
3. Seclect screw length, indicated at the bottom of each column.
4. Engage driver tip lightly into screw cruciform and apply moderate pressure. Vertically retract driver and screw from organizer and verify length with gauge. Drive the screw until the head is seated. Do not overtorque the screw.
5. Replace lid during handling and sterilization.

Sterility

All *Osteomed* MINCRO™ System screws and instruments are packaged non-sterile and must be sterilized prior to surgical use.

Pre-Vacuum Steam Sterilization:

Temperature:	270°F(132°C)
Exposure Time:	8 minutes
Minimum Dry Time:	20 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 introperatively.

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.		

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