Part No. 030-1551
Rev. J

OSTEOMED
M3-X
Rigid Fixation System
Product Information and Instructions for Use

Description
The *OSTEOMED Rigid Fixation System* is comprised of plates, screws and instrumentation used for fixation of hand and foot osteotomies, fractures, arthrodesis, and reconstructions. The system features plates ranging from 0.25mm to 2.5mm thick, standard screws diameter 1.2 mm to 2.7mm and lengths from 2.0mm to 22.0mm, lag screws in diameters of 1.2mm to 3.0mm in lengths of 6mm to 42mm. The instruments include drill bits, plate bending forceps, plate holding forceps, plate cutters, cannulae, taps, countersinks, plate bending pliers, plate cutters, drill guides 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 Titanium Alloy (ASTM F-136) or 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 M3-X System* is indicated for fixation of small bones and small bone fragments following trauma or osteotomies.

The *OSTEOMED Rigid Fixation 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.

System instruments are reusable.

Contraindications
Use of the *OSTEOMED Rigid Fixation 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 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 appliances 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.
5. Use of screws in high dense bone may lead to implant fracture or failure upon insertion.
6. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient.
7. The *OSTEOMED M3-X 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.
8. 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

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 Rigid Fixation System* plates and screws are not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Rigid Fixation 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: ± 0.38mm.

Instructions for Use, M3-X Lag Screws
1. Place a bone clamp to create the necessary compression across the osteotomy or fusion site (when applicable). Note: This step is very important in arthrodesis and in very dense bone, as the axial force necessary for inserting the lag screw could temporarily distract the fragments at the fracture/arthrodesis line.
2. With the assistance of the drill guide, drill appropriate diameter pilot hole according to the screw size.
3. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip of the device catches onto the distal cortex. Slide the sleeve of the instrument until it is flush against the bone. The measurement can be read on the flat of the device.
4. Countersink if necessary.
5. Retrieve the chosen screw from the visidisk with the appropriate driver stem and insert lag screw.
6. Drive the screw to compress the osteotomy.

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
- Product is supplied NON-STERILE unless expressly labeled as STERILE.
- Select plates and screws are available sterile packaged (Gamma Sterilized) in 5-packs. DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- 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 devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED* implant systems, the following parameters should be used:

  Pre-Vacuum Steam Sterilization:

Temperature:	270°F (132°C)
Time:	4 minutes
Dry Time:	30 minutes
Configuration:	Wrapped tray
Wrapping Technique:	Individually wrap the case in two layers of 1-ply polypropylene wraps (Kimguard KC600 – 510(k) K082554) using sequential envelope techniques with a surgical towel placed between the two wraps and the bottom of the case.

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.

Storage
Sterile packaged implants should be stored at controlled room temperature out of direct sunlight. Product package should be inspected prior to use for signs of damage or tampering.

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
	Use by (Date)		Do not use if sterile package is damaged
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture (MFG Date)	EC REP	Authorized Representative in the European Community
	Manufacturer (MFR)		Attention, See Instructions for Use Caution, Consult Accompanying Documents
STERILE R	Sterile, Method of Sterilization Using Irradiation	Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.

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