Part No. **030-1826**
Rev. **C**

OSTEOMED
OSTEOMED ExtremiLOCK Foot Plating System

Product Information and Instructions for Use

Description
The *OSTEOMED ExtremiLOCK Foot Plating System* is a rigid fixation system consisting of plates and screws in various configurations. The plates are provided in a variety of shapes and sizes, offering surgeons compression and locking hole designs. The *OSTEOMED ExtremiLOCK Foot Plating System* includes angulated locking screws and standard non-locking screws as well as K-wires. Surgical instrumentation is provided to facilitate insertion, modification and/or removal of implants.

Material
The plates are made of titanium (ASTM F 67) or titanium-alloy (ASTM F 136). The screws are made of titanium-alloy (ASTM F 136). K-wires are made of stainless steel (ASTM F 138 or F 139). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymers.

Clinical Indications
The *OSTEOMED ExtremiLOCK Foot Plating System* is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device.
The *OSTEOMED ExtremiLOCK Foot Plating System* implants are intended for single use only.

Contraindications
Use of the *OSTEOMED ExtremiLOCK Foot Plating System* is contraindicated in the following cases:
1. Active or suspected infection or in patients who are immunocompromised;
2. Patients previously sensitized to titanium or stainless steel;
3. Patients with certain metabolic diseases;
4. Patients who have insufficient bone or poor bone quality;
5. Patients exhibiting disorders which would cause the patient to ignore the physician's pre- and/or post-operative instructions and/or the limitations of internal rigid fixation implants;
6. Percutaneous K-wire placement is contraindicated in cases of displaced fractures and compressed fractures.

Warnings
1. The *OSTEOMED ExtremiLOCK Foot Plating System* is recommended for use in patients with sufficient bone quality to sustain effectiveness and benefits of rigid fixation.
2. Use of undersized implants in areas of high functional stress may lead to implant fracture and failure.
3. Plates, screws, wires or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Excessive or multiple bending of plates may weaken the plate and could result in implant failure.
5. Use of screws in highly dense bone may lead to implant fracture or failure upon insertion.
6. When placing additional screws, ensure that subsequent screw placement does not interfere with previously placed screws.
7. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient.
8. K-wires and Holding Taks™ must be removed from the bone fragment prior to compression hole fixation as it will impede the function of the compression hole.
9. The appropriate drill guides for locking screws must be used every time a locking screw is inserted to ensure that the locking angle is within ±20° from perpendicular.
10. Excessive or off-axis torque may compromise the mechanical lock between the screw and the plate.
11. Excessive non-locking screw angulation may cause increased screw head protrusion from the plate. Screw head prominence may cause soft tissue irritation.
12. Drill using the appropriate pilot drill. Note: Use irrigation when drilling.
13. Multiple insertions of a locking screw into the same hole may compromise the locking ability of the screw with the plate. If additional insertions are desired, the ability to lock the screw to the plate may decrease. A non-locking screw may be selected for that plate hole, or the surgeon may select a new plate hole location if locking capability is desired.
14. Evaluation of the safety and compatibility of the device in the MR environment has not been conducted.
15. In considering the evaluation for the safety and compatibility of these devices in the MR environment, the following concerns are raised based on the implant material, per 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 must have specific training, experience, and thorough familiarity with the use of internal rigid fixation devices, surgical techniques and post-operative care. It is recommended to follow standard AO operative techniques whenever possible.
2. The surgeon must exercise reasonable judgment when deciding which plate and screw to use for specific indications.
3. Multi-planar fluoroscopy is recommended throughout screw and plating procedures.
4. When loading a screw onto a driver, insert the driver straight into the screw head with force to engage the screw hexalobe. Multiple engagements of the driver into the screw head may affect the self-retention feature. To remove the driver from the screw, rock the driver gently from side to side and lift.
5. Use of the compression hole is not recommended if the fracture is already reduced.
6. Plate benders should be used between adjacent holes whenever possible. Bending across empty plate holes may deform the screw holes and prevent a locking screw from engaging the plate.
7. After cutting a plate with the plate cutter, utilize the plate file to remove sharp edges on the plate.
8. Instruments have colored stripes to indicate size and mating pieces.
9. The *OSTEOMED ExtremiLOCK Foot Plating System* implants are not intended to endure excessive abnormal functional stresses.
10. The *OSTEOMED ExtremiLOCK Foot Plating System* is intended for temporary fixation only until osteogenesis occurs.
11. All *OSTEOMED ExtremiLOCK Foot Plating System* 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. All implants are held in the organizer block.
12. Carefully inspect the *OSTEOMED ExtremiLOCK Foot Plating System* implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty or damaged and/or suspected to be faulty or damaged should not be used. These instruments should be replaced and sent back to OsteoMed for disposition and repair.
13. Post-operative instructions should be given to the patient by the surgeon, including the potential for secondary injuries to a surgical site if the patient is non-compliant. Patients should be instructed to closely follow the post-operative instructions.
14. OsteoMed recommends the use of OsteoMed products in a sterile environment.
15. Depth gauge marking tolerance: 10mm to 70mm is ±0.25mm.

Instructions for Use
1. Follow standard rigid fixation technique (i.e. typical AO technique) for placement of the *OSTEOMED ExtremiLOCK Foot Plating System* implants.
2. Refer to the *OSTEOMED ExtremiLOCK Foot Plating System* Surgical Technique Guide/User Manual for detailed guidelines on proper screw and plate placement.

Plating General Technique
Preparation

1. Expose and reduce fracture or osteotomy site

Plate Preparation and Positioning
1. Select plate
   a. Select appropriate plate size and configuration
2. Cut plate
   a. Plates may be cut using the plate cutter. The file may be used to blunt any sharp edges.
   b. Note: Do not cut 4 Hole "H" style plates, 1st MTP Arthrodesis plates, 4 Hole Hook plates and Minimally Invasive Calcaneal Plates.
3. Contour plate
   a. Plates are precontoured to anatomically fit bone. If further contouring is necessary, plate benders may be used.
4. Position plate
   a. Position plate over the fracture or osteotomy. Fixate plate to the bone using a screw or holding TAK in a plate positioning hole, positioning slot, or a k-wire hole for temporary fixation during procedure.

Screw Preparation and Insertion Technique
1. Determine desired screw type
   a. Fully Threaded Angled Locking, Fully Threaded Non-Locking, Fully Threaded Lag, or Cannulated Lag Screws
      i. All circular plate screw holes can accept either an angled locking screw or a non-locking screw. Oblong plate screw holes are used for either positioning the plate or providing compression across a fracture or fusion site and must be used with a non-locking screw. A 3.0mm Cannulated Lag screw may be used in the 1st MTP Transfixation plate as the Transfixation screw to provide compression through the plate. Cannulated Lag screws may be used outside the plate.
2. Drill
   a. Fully Threaded Angled Locking Screws
      i. Select the appropriate size angled locking/compression drill guide. Insert the cone-shaped drill guide into the desired plate hole ensuring the guide is firmly against the plate hole. The cone will ensure the drill remains within the 40° angled locking screw range (±20° from center).
   b. Fully Threaded Non-Locking Screws
      i. Select the appropriate size pilot/overdrill guide. Insert the pilot drill side through the desired plate hole ensuring the guide is firmly against the bone.
   c. Drill a pilot hole using the appropriate pilot drill size.
3. Measure
   a. Use the depth gauge to measure for the correct screw length.

Screw Insertion
4. Select & Insert
   a. Select the desired screw diameter and length. Verify screw length with gauge. Insert screw manually using a self-retaining screwdriver shaft until the screw head is seated into the plate. Do not over tighten the screw. Fluoroscopy is recommended during screw insertion to ensure correct length and angle.
   b. Locking screws and plate holes can be used up to 3 times.
5. Repeat steps 1-4 for remaining plate holes
   a. Fill remaining Fully Threaded Angled Locking, Fully Threaded Non-Locking screws until all necessary holes are filled.

Compression Hole Technique
1. Fixate plate
   a. Fixate plate on opposite side of the compression hole.
2. Position Compression Drill Guide
   a. Place drill guide in compression hole. The arrow will be pointing toward fracture/fusion site to drill eccentrically.
3. Drill
4. Measure
5. Insert Screw

Cannulated Lag Screw Technique
1. Expose and reduce fracture/fusion site
2. Insert a K-wire to the appropriate depth under fluoroscopy
3. If necessary or desired, use the countersink to create a recess in the bone to reduce screw head prominence and soft tissue irritation.
4. Slide the cannulated depth gauge over the K-wire until the tip bottoms out on bone; the end of the K-wire will indicate the screw length required. Subtract appropriately for any anticipated interfragmentary compression resulting from screw insertion.
5. ExtremiFix cannulated screws are self-drilling and self-tapping, but drilling is recommended in cases of dense bone. If drilling is desired or necessary, select the appropriate cannulated drill and use over the k-wire to drill a pilot hole. Additionally, for headless screws, the proximal cortex drill is recommended to create a pilot hole for the trailing end of the screw.
6. Select the appropriate screw diameter and length. Verify the screw length with the gauge.
7. Place the screw over the K-wire and use the cannulated driver to implant the screw until the screw is fully seated.
8. Remove and discard the K-wire.
9. Repeat steps 2-8 for additional screw placement.

Cleaning
1. Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
2. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
3. *OSTEOMED* recommends the following cleaning and sterilization instructions for re-usable Instrumentation:
4. Rinse the articles to be cleaned under running cool tap water (<40°C) to remove visible soil until visibly clean.
5. Prepare an enzymatic cleaner, Klenzyme®, or equivalent, per manufacturer's recommendations. Fully immerse the articles in the solution and soak for a minimum of 10 minutes. Actuate the articles while immersed in the solution to ensure complete penetration of cleaning solution.
6. Using a soft bristled brush, clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. A syringe may be used to clean the lumens and other hard to reach areas. Actuate the articles while brushing in order to clean matted surfaces and movable parts.
7. Prepare a mild detergent such as Renu-Klenz™, or equivalent, per manufacturer's recommendations. Fully immerse the articles in the prepared solution and sonicate the articles for a minimum of 10 minutes. Following sonication, remove the articles and proceed to the rinse step.
8. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
9. Steam Autoclave per the recommended sterilization Instructions.

Sterility
- The *OSTEOMED ExtremiLOCK Foot Plating System* is supplied NON-STERILE unless expressly labeled as STERILE.
- 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).
- ExtremiLOCK Foot Plating System Plate/screw modules are sterilized at the same parameters indicated below for the ExtremiLOCK Foot Plating System Tray.
- For sterilization of the *OSTEOMED ExtremiLOCK Foot Plating System*, the following parameters should be used:

Pre-Vacuum Steam Sterilization	ExtremiLOCK Foot System Tray
Wrap Configuration*	Wrapped Block
Temperature	270°F (132°C)
Sterilization Time	4 minutes
Minimum Dry Time	30 minutes
Wrapping Technique	Individually wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554) using sequential techniques with a surgical towel placed between the wraps and the test article.
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
OSTEOMED ExtremiLOCK Foot Plating System should be stored at controlled room temperature and used in a sterile environment.
Prior to each use, inspect the contents of *OSTEOMED ExtremiLOCK Foot Plating System* for signs of damage and/or defects.

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.

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