Part No. 030-1627
Rev. K

OSTEOMED *Foot Plating System*

Product Information and Instructions for Use

Description

The *OSTEOMED 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 Foot Plating System* includes both 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 or ASTM F 1472). 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 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 Foot Plating System* implants are intended for single use only.

The *OSTEOMED CalFix Calcaneal Plate and Screw System* is indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue type and severely comminuted fractures. The plates and screws are intended for single use only.

The system drills, Steinman pins, guidewires and K-wires 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 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 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. Bending the plate multiple times may weaken the plate and could result in implant failure. It is recommended to place the plate benders in adjacent plate holes during use.
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 ±10° from perpendicular.
10. Excessive 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 pilot drilling.
13. Multiple insertions of a locking screw into the same hole may compromise the locking ability of the screw driving through the plate. If a second insertion is desired, a non-locking screw should be selected for that plate hole, or the surgeon should select a new plate hole location if locking capability is desired.
14. The Osteomed Foot Plating 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.
15. 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 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 driver, insert the driver straight into the screw head with force to engage the screw cruciform. Multiple engagements of the driver into the screw head may damage the self-retention feature. To remove the driver from the screw, rock the driver gently from side to side and lift.
5. On-bone plate benders and vice grip plate benders should be used in adjacent holes whenever possible. Bending across empty plate holes may deform the screw holes and prevent a locking screw from fully seating.
6. The *OSTEOMED Foot Plating System* implants are not intended to endure excessive abnormal functional stresses.
7. The *OSTEOMED Foot Plating System* is intended for temporary fixation only until osteogenesis occurs.
8. All *OSTEOMED 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.
9. Carefully inspect the *OSTEOMED 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.
10. 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.
11. *OSTEOMED* recommends the use of *OSTEOMED* products in a sterile environment.
12. After cutting plate with the plate cutter, utilize diamond file on the top of the plate cutter to remove sharp edges on the plate.
13. Plates and screws are color coded for easy identification. Instruments have colored stripes to indicate size and mating pieces.
14. Depth gauge marking tolerance: 4mm to 14 mm is ±0.13mm, >14mm is ±0.25mm.

Instructions for Use

1. Follow standard rigid fixation techniques (i.e. typical AO technique) for placement of the *OSTEOMED Foot Plating System* implants, whenever possible.
2. Refer to the *OSTEOMED Foot Plating System* Surgical Technique Guide (030-1657) for detailed guidelines on surgical techniques.

Plate Preparation

1. Select the appropriate plate size and configuration for fixation of osteotomy or fracture.
2. If necessary, cut the plate using the FPS™ Plate Cutter Assembly (323-1716). To use the plate cutter;
   a. Determine how many holes need to be removed.
   b. Place the last needed hole around the appropriately sized post.
   c. Pull the plate slightly so that it grasps the post.
   d. Hold the plate securely with one hand and squeeze the handles to cut the plate. The silicone on the cutting tip will hold the discarded part of the plate.
   e. Remove any plate pieces from the silicone before proceeding.
   f. Inspect the plate for burrs and remove them using the diamond file located on the top of the plate cutter.
3. Contour the plate as needed using the plate benders.
   WARNING: Bending the plate multiple times may weaken the plate and could result in implant failure. It is recommended to place the plate benders in adjacent plate holes.

NOTE: Plate cutters and on-bone plate benders are available for use only on the following plates:

Type of Plate	Plate Cutters	Plate Benders
Mini-Fragment	324-10XX	324-10XX
Small Fragment	324-11XX, 324-122X	324-11XX, 324-122X, 324-126X
Hook	324-1270, 324-1271	324-1270, 324-1271
Navicular Cuneiform	324-1292	324-1292
Calcaneal	324-34XX	324-34XX

4. Position the plate over the fracture or osteotomy. The plate may be temporarily held in place using K-wires or the Holding Taks™.

Instrumentation Tip:
When necessary, use the Driver Sleeve to protect soft tissue and to provide stability during screw insertion.

Plating with Angulated Locking or Standard Screws

1. Select appropriate plate size and configuration for fixation of osteotomy or fracture.
2. Cut and/or contour the plate as needed (See Plate Preparation).
3. Position the plate over the bone segments to confirm sizing.
4. Use K-wires or Holding Taks™ to temporarily hold the plate in place on the bone.
5. Determine desired screw diameter and type (angulated locking or standard).
6. Select the appropriate drill guide and insert it into the first plate hole nearest the fracture line or osteotomy. Standard and angulated drill guides are available.
7. Drill pilot hole using the appropriate drill size at the desired angle, plus or minus 10° from perpendicular to the plate.
   NOTE: Use irrigation when pilot drilling.
8. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip catches against the bone to determine measurement.
9. Select the desired screw diameter and length accordingly. Verify the screw length with the gauge on the organizer block. Insert the screw into the drilled hole to fixate the plate onto the bone. Fluoroscopy is recommended to ensure correct length and angulation.
10. Repeat steps 5 through 9 for remaining screw placement.
    WARNING: When placing additional screws, ensure that subsequent screw placement does not interfere with other screws.

NOTE: Standard screws are required in all compression and transfixation holes. All remaining plate holes will accept both Standard and Angulated Locking screws.

Compression of Fracture or Osteotomy

Several FPS™ plates contain oblong compression holes.
1. Place standard or locking screws through the plate and into the bone on one side of the fracture.
2. On the opposite side of the fracture, place the compression drill guide in the compression hole closest to the fracture line. The guide should be oriented with the arrow pointing toward the fracture line, in the direction of compression.
3. Drill using the proper drill size.
4. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip catches against the bone to determine measurement. Subtract appropriately for any anticipated interfragmentary compression.
   Select and insert the appropriate standard screw and tighten. Screw insertion will pull the fragment towards the previously retained segment.

Screw diameter	Compression distance
2.0mm	1.2mm
2.4mm	2.2mm
3.0/4.0mm	2.2mm

5. Insert additional Angulated Locking or Standard screws until all necessary holes are filled.

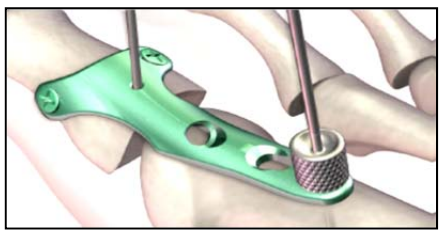
Instructions for Implantation of Hook Plate (324-1270, 324-1271, 324-1272)

1. Expose and reduce the surgical site. Clamp the fractured bones in close apposition.
2. If necessary, cut and/or contour the plate (see Plate Preparation).
3. Position the plate on the clamped bones, ensuring that the hooks will capture the fragment.
   NOTE: If dense cortex is expected, drill burr holes in the bone fragment to allow easier hook penetration.
4. Using the 2.7mm pilot drill guide and drill, drill a pilot hole as distally as possible in the elongated positioning hole.
   NOTE: Use irrigation when pilot drilling.
5. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip catches against the bone to determine measurement.
6. Select the 2.7mm screw of appropriate length. Verify the screw length with the gauge on the block. Insert the screw into the elongated positioning hole without fully seating the head of the screw (see arrow). Fluoroscopy is recommended to ensure correct length and angulation.
7. Impact the hooks into the bone fragment using the hook plate impactor.

8. Select the 2.7mm compression pilot drill guide and insert it into the compression hole nearest the elongated positioning hole.
9. Drill the pilot hole through the compression hole and into the metatarsal, check the length using the depth gauge, and insert and fully seat the appropriately sized 2.7mm screw using the driver.
10. Fully seat the screw previously placed through the elongated positioning hole.
11. Insert any additional screws if desired.
12. Close the treatment site using standard closure techniques.

Instruction for Implantation of 1st MTP/MPJ Fusion Plate with Transfixation Hole (324-1280, 324-1281, 324-1284, 324-1285, 324-1286, 324-1287)

1. Expose and reduce the surgical site. Debride the base of the phalanx and the metatarsal head to bleeding bone.
2. If desired, a range of spherical reamers in a secondary block is available. It is recommended for optimal fit that the final cut for both the metatarsal and the phalanx be done with reamers of matching size.
3. Position the toe with desired dorsiflexion and valgus angle and bring the phalanx and metatarsal in close apposition.
4. Temporarily fixate the plate to the bones with K-wires or Holding Taks™.
5. Select the appropriate pilot drill guide (angulated or standard) and insert it into the first plate hole nearest the joint space on the phalanx side.
6. Drill a pilot hole in the phalanx at the desired angle using the appropriate drill size, within plus or minus 10° from perpendicular to the plate.
7. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip catches against the bone to determine measurement.
8. Select a 2.7mm screw of appropriate length for use in the phalanx. Verify the screw length with the gauge on the block. Insert the screw into the drilled hole to fixate the plate onto the bone.



9. Repeat steps 4 through 7 in the remaining holes over the phalanx.
10. Remove and discard any K-wires or Holding Taks™ positioned through the metatarsal.

Option 1: Transfixation & Compression

The transfixation screw may be inserted prior to the compression screw to obtain both transfixation and compression across the joint with the same screw. The transfixation screw in the *OSTEOMED Foot Plating System* runs from the dorsal side of the metatarsal, through the joint and into the plantar aspect of the phalanx. This screw acts as a tension band and directly resists plantar distraction.
   a. Select the appropriate drill guide and pilot drill through the transfixation screw hole.
   b. Insert the depth gauge until it passes through the distal cortex of the phalanx. Retract the stem until the lip catches against the bone to determine measurement.
      NOTE: K-wires must be removed prior to insertion of compression screw.
   c. Select the 2.7mm standard screw of desired length. Verify the screw length with the gauge on the block. Insert the screw into the drilled hole.
      OPTIONAL: Overdrill the proximal cortex with a clearance drill to create a lag effect.
      OPTIONAL: A 3.0mm cannulated lag screw may be used in the transfixation hole. Please refer to the general instructions for implantation of cannulated screws that accompanies the cannulated system.
   d. Select the standard pilot drill guide and insert it into the compression hole nearest the joint space on the metatarsal side.
      NOTE: Do not use the compression drill guide. Use the standard drill guide and fill this hole with the screw in the neutral position.
   e. Drill the pilot hole through the compression hole into the metatarsal, check the length and insert the appropriately sized 2.7mm standard screw.
   f. Pilot drill the remaining metatarsal plate holes and insert appropriately sized 2.7mm screws.

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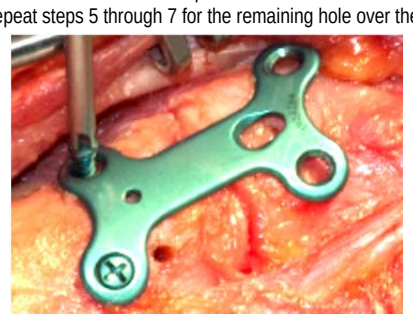
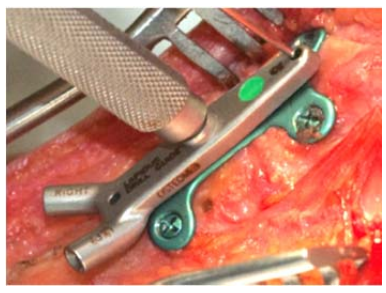
Option 2: Compression & Transfixation

a. Drill pilot hole through the compression hole into the metatarsal, check the length, and insert the appropriately sized 2.7mm standard screw.
   NOTE: K-wires must be removed prior to insertion of compression screw.
b. Pilot drill the remaining metatarsal plate holes and insert appropriately sized 2.7mm screws.
c. Remove and discard remaining K-wires or Holding Taks™.
d. Select the appropriate drill guide and pilot drill through the transfixation screw hole.
   OPTIONAL: Overdrill the proximal cortex with a clearance drill to create a lag effect.
   OPTIONAL: A 3.0mm cannulated lag screw may be used in the transfixation hole. Please refer to the general instructions for implantation of cannulated screws that accompanies the cannulated system.
e. Insert the depth gauge until it passes through the distal cortex of the phalanx. Retract the stem until the lip catches against the bone to determine measurement.
f. Select the 2.7mm standard screw of desired length. Verify the screw length with the gauge on the block. Insert the screw into the drilled hole.

11. Close the treatment site using standard closure techniques.

Instructions for Implantation of Lapidus Plate & Transfixation Screw (324-1290, 324-1291)

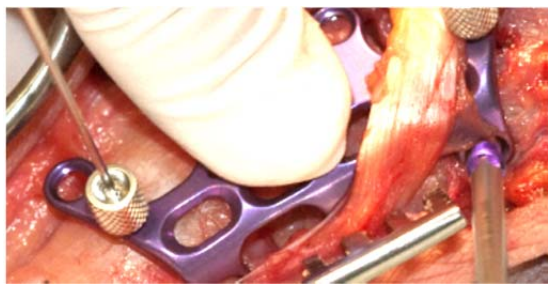
1. Expose and reduce the surgical site. Debride joint surfaces between the bones to be fused.
2. Secure the bones to be fused with K-wires or a bone clamp.
3. Contour the plate as needed using the plate benders (see Plate Preparation).
4. Temporarily attach the plate to the bones with K-wires or Holding Taks™. Additional contouring may be achieved with the use of the on-bone plate benders.
5. Select the 2.7mm pilot drill guide (standard or angled) and insert it into one of the plate holes on the metatarsal. Using the 2.7mm pilot drill, drill a pilot hole at the desired angle, within plus or minus 10° from perpendicular to the plate.
6. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip catches against the bone to determine measurement.
7. Select a 2.7mm screw of appropriate length. Verify the screw length with the gauge on the block. Insert the screw into the drilled hole to fixate the plate to the bone.
8. Repeat steps 5 through 7 for the remaining hole over the metatarsal.

9. Select the 2.7mm compression pilot drill guide and insert it into the compression hole over the first cuneiform.
10. Using the 2.7mm pilot drill, drill the pilot hole, check the length with the depth gauge and insert the appropriately sized 2.7mm screw.
11. Repeat steps 5 through 7 for the remaining holes over the first cuneiform.
12. Position the Lapidus Drill Guide on the plate by inserting the locating pins on the guide through the relevant holes in the plate and secure with Holding Taks™ (see picture above). A threaded handle is available to insert into the guide for additional control.
13. Use the 2.7mm pilot drill to drill the transfixation hole from the dorsal side of the metatarsal base to the plantar side of the first cuneiform. Ensure the correct barrels on the guide are used: RIGHT when used with the right Lapidus plate and LEFT used with the left Lapidus plate.
14. Remove the Lapidus Drill Guide.
15. Insert the depth gauge until it passes through the distal cortex of the first cuneiform. Retract the stem until the lip catches against the bone to determine measurement.
16. Select a 2.7mm screw of appropriate length. Verify the screw length with the gauge on the block. Insert the screw into the drilled hole.
17. Close the treatment site using standard closure techniques.

Instructions for Implantation of the Medial Column Plate (324-1296, 324-1297)

1. Expose and reduce the surgical site. Debride joints between the bones to be fused.
2. Select the appropriately sized plate. Contour the plate as need (see Plate Preparation).
3. Temporarily position the bones using K-wires or a bone clamp.
4. Temporarily fixate the plate to the bones, under the tibialis anterior tendon, using K-wires or Holding Taks™. The side of the plate with four holes is to be positioned dorsally.



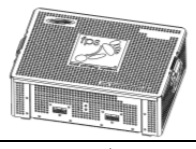
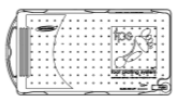
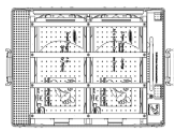
5. Screw insertion progresses from proximal to distal. Select the 3.5/4.0mm pilot drill guide (standard or angled) and insert it into the plate hole above the most proximal bone to be fixated.
   NOTE: After the plate holes over the most proximal bone are filled, compression holes should be filled before the outlying holes on the plate. This is to be done in each subsequent bone to be fused, moving proximal to distal.
6. Drill a pilot hole at the desired angle using the 3.5/4.0mm pilot drill, within plus or minus 10° from perpendicular to the plate.
7. Remove the distal K-wires or Holding Taks™ prior to using compression holes.
8. Insert the depth gauge until it passes through the distal cortex. Retract the stem until the lip catches against the bone to determine measurement.
9. Select a 3.5/4.0mm standard screw of appropriate length. Verify the screw length with the gauge on the block. Insert the screw into the drilled hole to fixate the plate onto the bone.
10. Repeat steps 5 through 9 to fill all necessary plate holes.
11. Close the treatment site using standard closure techniques.

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 instructions for the OsteoMed reusable instrumentation:
   a. 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.
   b. Thoroughly rinse all instruments and the sterilization tray with water.
   c. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.

Sterility

1. The *OSTEOMED Foot Plating System* is supplied NON-STERILE unless expressly labeled as STERILE.
2. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
3. The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
4. Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of the *OSTEOMED Foot Plating System*, the following parameters should be used:

Pre-Vacuum Steam Sterilization	FPS™ Tray (loaded)	FPS™ Organizer Block (single)	FPS™ Small Fragment Tray with Medium Fragment Instrument Block (loaded)
Tray Configuration			
Wrap Configuration*	Wrapped Tray	Wrapped Block	Wrapped Tray
Temperature	270°F (132°C)	270°F (132°C)	270°F (132°C)
Sterilization Time	8 minutes	4 minutes	4 minutes
Dry Time	50 minutes	25 minutes	60 minutes
Do not exceed 275°F (135°C) to avoid compromising functions of polymeric instrumentation.			

* 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 ad the test article.

Storage

OSTEOMED 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 Foot Plating System* for signs of damage and/or defects.

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 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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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.		

Attention: Instructions for Use are in the Surgical Technique Guide (030-1657)

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