Part No. 030-2256
Rev. A
EN

OSTEOMED
OSTEOMED Lisfranc Plating System
Product Information and Instructions for Use

Description
The ***OSTEOMED*** *LISFRANC Plating System* is a rigid fixation system consisting of plates and screws. The plates are provided in a variety of shapes and sizes, offering surgeons compression and locking hole designs. The ***OSTEOMED*** *Lisfranc Plating System* when used in conjunction with ExtremiLOCK™ Foot Plating System includes angulated locking screws and standard non-locking screws. ExtremiLOCK™ Foot Plating System includes K-wires and other Surgical instrumentation required to facilitate insertion, modification and/or removal of implants.

Material
The Lisfranc plates are made of titanium (ASTM F 67) 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, titanium, anodized aluminum, and/or medical grade polymers.

Clinical Indications
The ***OSTEOMED*** *Lisfranc Plating System* is indicated for use in trauma, general surgery, and reconstructive procedures of Lisfranc injuries.
The ***OSTEOMED*** *Lisfranc Plating System* implants are intended for single use only.

Contraindications
Use of the ***OSTEOMED*** *Lisfranc 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.

Warnings
1. The ***OSTEOMED*** *Lisfranc 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*** *Lisfranc Plating System* implants are not intended to endure excessive abnormal functional stresses.
10. The ***OSTEOMED*** *Lisfranc Plating System* is intended for temporary fixation only until osteogenesis occurs.
11. All ***OSTEOMED*** ExtremiLOCK™ Foot Plating System instrumentation is 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*** *Lisfranc 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*** *Lisfranc Plating System* implants.
2. Refer to the ***OSTEOMED*** *Lisfranc 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.
2. *If fusion is required, expose Lisfranc fracture/dislocation and prepare affected joint. Reduce using a bone reduction clamp or provisional guide wires.*

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.
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, osteotomy or joint in the case of fusion. 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.
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. Transport contaminated devices for reprocessing as soon as possible after use.
2. 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 manual cleaning and sterilization instructions for re-usable Instrumentation:
1. Rinse the articles to be cleaned under running cool tap water (<40°C) to remove visible soil until visibly clean.
2. Prepare an enzymatic cleaner, STERIS Prolystica 2X Concentrate Enzymatic Presoak and Cleaner, 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.
3. 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.
4. Clean the instruments disassembled if they are designed to be taken apart.
5. 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.
6. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
7. Remove excess moisture from the instruments using a clean, absorbent, non-shedding wipe. Ensure instruments are completely dry.
8. Steam Autoclave per the recommended sterilization Instructions.

Automated Cleaning- Thermal Disinfection
Important: Contaminated instruments require manual cleaning prior to automated cleaning. Follow the washer-disinfector manufacturer's instructions explicitly.
- Process the devices using a standard washing and thermal disinfection cycle in a washer-disinfector compliant with EN ISO 15883-1 and EN ISO 15883-2 or equivalent national standards.
- Remove all implants if a lubrication phase will be used.
- Process all trays removed from the case.
- Attach the following instruments to the minimally invasive surgery (MIS) injector or irrigation ports :
  - 320-2800 Ratcheting Driver Handle.
- Thermal disinfection has been validated* for an A0 ≥ 3000 (at least 5 minutes at 90°C).

*Washer-disinfector processing was validated for fully loaded trays with all parts placed appropriately, with recommended evaluations as listed in EN ISO 15883-1 and EN ISO 15883-2 using a STERIS Reliance® Genfore Washer-Disinfector and STERIS Prolystica 2X Enzymatic Detergent.

Sterility
- The ***OSTEOMED*** ExtremiLOCK™ Foot Plating System *with Lisfranc Plating modules* 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).
- For sterilization of the ***OSTEOMED*** ExtremiLOCK™ Foot Plating System *with Lisfranc Plating modules,* the following parameters shall be used:

Pre-Vacuum Steam Sterilization	ExtremiLOCK™ Foot Plating System Tray with Lisfranc Plating Modules	ExtremiLOCK™ Foot Plating System Tray with Lisfranc Plating Modules
Part No.	**320-2900**	**320-2900**
Temperature[1]	270°F (132°C)	273°F (134°C)
Sterilization Time	4 minutes	3 minutes
Tray Preparation[2]	Wrapped Tray	Wrapped Tray
Wrapped Dry Time Minimum	30 minutes	30 minutes
Tray Preparation[3]	Rigid Containers	Rigid Containers
Rigid Container Dry Time Minimum	30 minutes	30 minutes
1.	**Do not exceed 275°F (135°C) to avoid compromising functions of polymeric instrumentation.**	
2.	**Wrapping technique recommendation: 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.**	
3.	**OsteoMed recommends using Aesculap rigid containers & paper filters. The ExtremiLOCK Foot with Lisfranc Plating System contents need to be split and loaded into 2 Aesculap extra-long rigid containers. The large tray insert from the upper level needs to be loaded into an Aesculap extra-long basket, P/N JF232R, and then the basket is lowered into an extra-long rigid container, P/N JN445/JK490 (bottom/lid). The remaining components from the ExtremiLOCK Foot with Lisfranc Plating System shipping container, the 4 upper modules and the 5 lower modules, are to be loaded into another extra-long basket, P/N JF232R, and then loaded into the second Aesculap extra-long rigid container, P/N JN445/JK490 (bottom/lid). Modules 320-2914, 320-2915 need to be stacked on top of each other. The four smallest modules, 320-2091, 320-2902, 320-2903, & 320-2905 were also stacked up, 2 on 2, so that all 9 modules fit inside the basket. Use 4 Aesculap paper filters, P/N US751, 2 in the lid and 2 in the bottom for each rigid container.**	

Note: Biological Indicator of ***G. stearothermophilus*** was used in the sterilization validations.

Storage
- ***OSTEOMED*** *ExtremiLOCK Foot system with Lisfranc Plating modules* should be stored at controlled room temperature and used in a sterile environment.
- Prior to each use, inspect the contents of ***OSTEOMED*** *ExtremiLOCK Foot system with Lisfranc Plating modules* 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.**

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Symbols and Definitions

Single Use Only		Catalogue Number	
Batch Code (Lot Number)		Consult Instructions for Use	
Date of Manufacture		Manufacturer	
Caution, Consult Accompanying Documents		Non-sterile	
Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.		Use By (Date)	
Do not use if package is damaged and consult instruction for use		Sterile, Method of Sterilization Using Irradiation	

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