Part No. 030-1612
Rev. M

OSTEOMED
Hand Plating System

Product Information and Instructions for Use

Description

The *OSTEOMED Hand Plating System* is a rigid fixation system consisting of plates and screws in various configurations. Plates are provided in a variety of shapes and sizes, and offer surgeons compression and locking hole designs. The Hand Plating System includes angulated locking, non-locking, lag, and cannulated screws as well as a buttress pin and K-wire implants. Surgical instrumentation is provided to facilitate modification, insertion, or removal of implants.

Material

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

Clinical Indications

OSTEOMED Hand Plating System is intended for use in trauma, general surgery and reconstructive procedures of the hand, wrist, or other bones appropriate for the size of the device. The OsteoMed Hand Plating System implants are intended for single use only.

OsteoMed Hand Fusion System is intended for use in bone fusion and arthrodesis of phalanges and metacarpals. It is intended for use in trauma, general surgery and reconstructive procedure.
The OsteoMed Hand Fusion 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.

The system Implants, k-wires, drills and taks are intended for single use only.

Contraindications

Use of the OsteoMed Hand Plating System is contraindicated in following cases:

- Active or suspected infection or in patients who are immunocompromised.
- Patients previously sensitized to titanium or stainless steel.
- Patients with certain metabolic diseases.
- Patients exhibiting disorders which would cause the patient to ignore the physician pre- and/or post-operative instructions and limitations of internal rigid fixation implants.
- Patients where there is insufficient bone.

Warnings

1. Use of undersized implants in areas of high functional stress may lead to implant fracture and failure.
2. Plates, screws, K-wires or other devices of dissimilar material should not be used together in or near the implant site. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not mix different metal implants in the same construct.
3. Multiple bending may weaken the plate and could result in implant fracture and failure.
4. Use of screws in high density bone may lead to implant fracture or failure upon insertion. Refer to *OSTEOMED Hand Plating System* User Manual for proper insertion technique(s) (User Manual P/N 030-1616)
5. The *OSTEOMED Hand Plating System* is recommended for use in patients with sufficient bone quality to sustain effectiveness and benefits of rigid fixation.
6. It is recommended to remove any fractured implants from patient during surgery. If unable to remove, notify patient.
7. Locking screws and plate holes can be used up to three times.
8. Use of excessive torque during insertion of screws may lead to implant failure.
9. In patients with a large intramedullary canal, the diameter/length of the Fusion screw provided may not provide adequate compression of the MCP joint.
10. Weight bearing is not recommended following implantation of OsteoMed Hand Fusion until fusion has occurred.
11. The *OSTEOMED Hand 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.
12. 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. Patients must closely follow the post operative instructions from their surgeon.
2. The surgeon must exercise reasonable judgment when deciding which implant or instrument type to use for specific indication.
3. The *OSTEOMED Hand Plating System* implants are not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED Hand Plating System* is intended for temporary fixation only until osteogenesis occurs.
5. All *OSTEOMED Hand Plating System* implants 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 Hand Plating System* implants prior to use.
7. 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.
8. Drills, plate holding taks and K-wires are single use only instruments. Drill using the appropriate pilot drill. Note: Speed and torque parameters must be in accordance with the OsteoMed Power System Instructions for use. Use irrigation when pilot drilling.
9. Multiple engagements of screw cruciform to screwdriver tip may result in loss of retention.
10. Locking screws are intended for use through locking plate holes/slots only.

Instructions for Use

1. Use the *OSTEOMED Hand Plating System* in a sterile environment.
2. Follow standard rigid fixation technique (i.e. typical AO technique) for placement of the *OSTEOMED Hand Plating System* implants.
3. Refer to the *OSTEOMED Hand Plating System* User Manual for detailed instructions on the instrumentation use and/or modification, implantation and removal of the system implants.

⚠	Attention, See *OSTEOMED Hand Plating System* User Manual P/N 030-1616 & 030-1742

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 instructions for the OsteoMed reusable 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.

Sterility

- The *OSTEOMED Hand 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). For sterilization of the *OSTEOMED Hand Plating System*, the following parameters should be used:

Pre-Vacuum Steam Sterilization

Temperature	TRAY (with blocks)	TRAY (without blocks)	BLOCK	POUCH
	270°F (132°C)	270°F (132°C)	270°F (132°C)	270°F (132°C)
Time	4 minutes	4 minutes	4 minutes	4 minutes
Dry Time	50 minutes	25 minutes	25 minutes	10 minutes
Configuration	Wrapped Tray	Wrapped Block	Wrapped Block	Pouch

Wrapping Technique: Individually wrap the case in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential envelope folding techniques with a surgical towel placed between the wraps and the bottom of the case.

Pouch Configuration: Double pouched in FDA cleared sterilization pouch such as Cardinal Health sterilization pouches.

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 Hand Plating* devices should be stored at controlled room temperature, away from moisture and direct sunlight.
- Sterile packaged devices must be stored according to the labeled storage instructions. Do not use sterile packaged devices if the package has been damaged or otherwise tampered.
- Prior to each use, inspect the contents of *OSTEOMED Hand 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.

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

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