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 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 Hand Fusion System implants are intended for single use only.

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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 intrinsics of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination. This may lead to 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 cutting 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 the following cases:

- Active or suspected infection in or on patients who are immunocompromised.
- Patients previously sensitized to titanium or stainless steel.
- Patients with certain cardiac pacemakers.
- 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 under-sized 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 contact with each other. 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).
5. The OsteoMed Hand Fusion 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.

Maintaining Device Effectiveness

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 removal and reoperation.
6. Carefully inspect the OsteoMed Hand Plating System implants prior to use.
7. Inspect the implants 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 Plating System User Manual for use. Use irrigation when pilot drilling.
9. Multiple engagements of screw cutout to screwdriver tip may result in loss of retention.
10. Locking screws are intended for use through locking hole slots/slots only.

Instructions for Use

1. Use the OsteoMed Hand Plating System in a sterile environment.
2. Follow standard rigid fixation techniques (i.e., typical AO technique) for placement of the OsteoMed Hand Plating System implants.

Cleanness

- 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 cleaning agents.

OsteoMed recommends the following cleanness 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 instruments in the sterilization case and ensure that the lid is in place and properly closed.