MANUFACTURER

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CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

DEVICE DESCRIPTION

Implants

The MotoBAND® CP Implant System gives the surgeon a means of bone fixation in the management of bone fractures and reconstruction surgery. The MotoBAND® CP Implant System includes implants, plates and screws, and the related instruments needed for implantation. The MotoBAND® CP implants are made of biocompatible titanium. Prior to implantation, the plate may be contoured for the patient's anatomy. Once implanted the plate may be fixed to the bone using locking and or non-locking screws. MotoBAND® CP Implant components may be provided sterile or non sterile and are intended for single use only. Certain plates of the MotoBAND® CP Implant System are compatible with the MotoCLIP®/HiMAX® Implant System. The MotoBAND®CP Implant System 2-hole plate is not compatible with the MotoCLIP®/HiMAX® Implant System.

The MotoCLIP®/HiMAX®Implant System gives the surgeon a means of bone fixation in the management of bone fractures and reconstruction surgery. The MotoCLIP®/HiMAX® Implant System includes implants and the related instruments needed for implantation. The MotoCLIP®/HiMAX® implants are made of biocompatible nitinol and are designed to exhibit superelastic properties. Prior to implantation, the legs of the MotoCLIP®/HiMAX® implant are held substantially parallel to facilitate insertion into the prepared bone. Once implanted and released from the insertion device, the legs of the implant will move towards each other in a converging fashion. This movement creates compression across the adjoining bone members. The amount of compression will vary depending on the spatial orientation of the bones, bone quality, surgical technique, etc. MotoCLIP®/HiMAX® implant components are provided sterile and are intended for single use only.

Instrument System

Instruments used with the MotoBAND® CP Implant System include the following: Implant Holder/Inserter, Reamer/Drill Guide, Reamers/Drills, Temporary Fixation Pin, Drivers, Plate Benders, Sizing Templates, and Depth Gages. Instruments and instrument kits are provided sterile or non-sterile.

The correct selection and sizing of the implant is extremely important. Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support.

INDICATIONS

The MotoBAND™ CP Implant System includes DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion System, which include plates and screws indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. DynaBunion™ 4D Minimal-incision Bunion System and DynaMet™ Lesser TMT Fusion plates are compatible with fracture fixation staples from the MotoCLIP™/HiMAX™ Implant System cleared in K142727, K181410 and K193452.

CONTRAINDICATIONS

Contraindications for the MotoBAND® CP Implant System are as follows:

- Comminuted bone surface that would prevent proper implant placement
- Pathological bone conditions that would prevent secure implant fixation
- Acute or chronic infections local or systemic
- Physiological or psychological conditions that limit the patient's ability and/or willingness to follow instructions during the healing process.
- Inadequate skin, bone, or neurovascular status
- Known allergies or sensitivity to metals, including titanium and nickel.

Contraindications may be relative or absolute and are left to the discretion of the surgeon.

WARNINGS

- Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
- As with any implant system, the implants cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight-bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods be maintained until bone healing has occurred.
- Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the implant should not be relied upon to achieve closure or reduction of a fracture line.
- Reamers are designed for use specifically with the supplied guides. Re-use or reprocessing may affect the compatibility with other instruments and usability of the instruments.
- If it is suspected that sterilization is compromised prior to implantation, another sterile implant should be used. Product should not be re-sterilized.
- **A single use device (SUD) that comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed**

Dispose of used device in accordance with healthcare facility policy and local regulations.

CONCERNING MAGNETIC RESONANCE ENVIRONMENT

The MotoBAND® CP Implant system and the MotoCLIP®/HiMAX® Implant System have not been evaluated for safety and compatibility in the MR environment. These systems have not been tested for heating, migration, or image artifact in the MR environment. The safety of the MotoBAND® CP Implant system and the MotoCLIP®/HiMAX® Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exist. Surgical procedures involving these devices should not be attempted by physicians unfamiliar with possible adverse clinical events which may occur during or after the procedure and could require additional surgery for implant revision. The risks and complications with this system include:

- Infection or painful, swollen or inflamed implant site
- Failure or breakage of the implant or part of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Damage to nerves and vessels
- Delayed union or malunion; Prolonged healing
- Edema
- Muscle tendon impalement and excessive operative bleeding
- Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
- Venous thrombosis, pulmonary embolism, cardiovascular problems
- Inability to compress the bone surface due to poorly fixated implant

The anticipated adverse device effects are the same as those associated with the currently available fixation procedures.

No additional risks are associated with the MotoBAND® CP Implant System

PATIENT SELECTION
Use of surgical fusion hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of post-operative therapy
- Cooperative patient

PRECAUTIONS
Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

The main goal of surgery with this implant is to establish bony fusion. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant. Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or over activity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device. Some preventative measures to consider to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided below
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant

Avoid flawing implant surfaces or excessive bending to minimize the potential for early fatigue failure. If complications develop, possible corrective procedures include:

- Implant removal
- Bone grafting of cysts
- Replacement of the implant

OVER TIME, METALLIC IMPLANTS MAY LOOSEN, FRACTURE, OR CAUSE PAIN AFTER BONE FRACTURE OR OSTEOTOMY IS HEALED. REMOVAL OF METALLIC IMPLANTS IS AT THE SURGEON'S DISCRETION, AND THE APPROPRIATENESS OF THE SELECTED PROCEDURE WILL BE BASED ON THE SURGEON'S PERSONAL MEDICAL TRAINING AND EXPERIENCE. IT IS IMPERATIVE THAT ADEQUATE POST-OPERATIVE CARE AND PROTECTION BE PROVIDED BY THE SURGEON.

HOW SUPPLIED, CLEANING AND STERILIZATION
Implants
The MotoBAND® CP implants are provided sterile or non sterile to the end user. The MotoCLIP®/HiMAX® implants are provided sterile to the end user.

Sterile packaging and implants should be inspected to ensure there is no damage. If the implants' packaging or implants' integrity has been compromised use an alternate item and contact the manufacturer for further instructions.

Implants are for single use only. A single use device (SUD) that comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed

Instrument System
Instruments are provided sterile or non-sterile to the end user. Instrument packaging and instruments should be inspected to ensure there is no damage. If the instruments' packaging or instruments' integrity has been compromised, contact the manufacturer for further instructions.

CARE AND CAUTION

- All components of the MotoBAND® CP Implant System are provided sterile for single use only or non-sterile.
- Inspect the sterile packaging used for the implants and instruments prior to use. If the packaging and/or seal is damaged, sterilization may be compromised and the implant and/or instrument should not be used.
- MotoBAND® CP Implant System implants and instruments may be stored at room temperature.

Some instruments and implants may be provided non-sterile to the end user and must be cleaned and sterilized before each use in accordance with the instructions below.

Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).**Open** all hinged instruments.
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Rinse thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens; however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

The minimum recommended steam sterilization conditions for **non-sterile implants and reusable instruments** are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:
1. Double wrap the assembled tray in a FDA cleared wrap or FDA cleared sterilization container.

2. Autoclave according to the following parameters:
Steam Sterilization – PREVACUUM

Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 ˚F (132 ˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20-30 minutes

3. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79:2010 guidelines and have been developed and tested using specific equipment.

Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

OTHER SUPPLIES AND EQUIPMENT NEEDED
- Standard OR equipment used in patient preparation and surgical exposure.
- Power drill with pin driver attachment and AO quick connect attachment.

SYMBOLS
Refer to package labels to determine which symbols are relevant to the device in the package.

	Caution consult accompanying documents
	Catalogue number
	Consult instructions for use
	Contents of package
	Do not reuse
	Lot number
	Manufacturer
Sterile R	Sterilized using irradiation
	Prescription only - device restricted to use by or on the order of a physician
	Use By: YYYY-MM-DD (YYYY is year; MM is month; DD is Day)

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