**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 MiniBunion® System gives the surgeon a means to address bunion corrections with limited surgical exposure. The MiniBunion® System System includes an intramedullary implant and the related instruments needed for the procedure. The MiniBunion® implants are made of biocompatible titanium. Once implanted, suture (surgeon preference, not provided with the system) can be tied to the implant. The MiniBunion® System Kit components will be provided sterile and are intended for single use only.

The implants require careful seating and adequate bone support.

Instrument System
Instruments used with the MiniBunion® System include the following: K-wires, K-wire guide, sawguide, plate inserter, drill guides, drill bit, screwdriver bit, suture passer assembly. Instruments and instrument kits are provided sterile or non-sterile.

**INDICATIONS**

The MiniBunion® Plating System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

**CONTRAINDICATIONS**
Contraindications for the MiniBunion® 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 implant is only intended to provide a buttress for the healthy bone during the healing process.
- 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.

**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:

- Failure or breakage of the implant or part of the implant
- Infection or painful swollen or inflamed implant site
- 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 MiniBunion® 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 a buttress for stability of healthy bone during the healing process. Abnormal or excessive forces could lead to delayed failure of the implant and suture construct. 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 in order to minimize the potential for complications:

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

Avoid flawing implant surfaces 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, IMPLANTS MAY LOOSEN, FRACTURE, OR CAUSE PAIN AFTER SOFT TISSUE IS HEALED. REMOVAL OF 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 and Instruments

The MiniBunion® System implants and instruments are provided sterile or non-sterile to the end user.

Sterile packaging and components should be inspected to ensure there is no damage. If the 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.

**CARE AND CAUTION**

- All components of the MiniBunion® 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.
- MiniBunion® 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 **reusable instruments** are as follows:

**FOR PREVACUUM STEAM STERILIZATION ONLY:**

1. Double wrap the assembled tray in an 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 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.

**MR SAFETY INFORMATION**

The MiniBunion® System has 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 MIS Bunion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**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.
- Long, narrow, sagittal sawblade

**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 |
|  | Do not reuse |
|  | Lot number |
|  | Manufacturer |
|  | Sterilized using irradiation |
|  | Prescription only - device restricted to use by or on the order of a physician |
|  | Use By:<br>YYYY-MM-DD (YYYY is year; MM is month; DD is day) |

**DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY**

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