METATARSAL DECOMPRESSION IMPLANT (MDI) SYSTEM

152381-1

The following languages are included in this packet:

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Português (pt)
Français (fr)
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CE 0086*

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

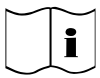
METATARSAL DECOMPRESSION IMPLANT (MDI) SYSTEM (152381-1)

OUTLINE:

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry

	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
STERILE A	Sterilized using aseptic processing techniques
℞ ONLY	For prescription use only
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy

CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

DESCRIPTION

The device is a hemi resurfacing implant intended to replace a portion of the articular surface of the metatarsal head. The device is intended to articulate against the proximal end of the phalanx of the great toe. The implant is available in four sizes. An alphanumeric coding system is used to distinguish sizes. Surgical instruments are provided to facilitate the surgical placement of the implant.

A. PATIENT COUNSELING INFORMATION (SEE ALSO WARNINGS)

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

While the expected life of an implant is difficult to estimate it is finite. These components are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

- Adverse effects of this device may necessitate reoperation, revision, or fusion of the involved joint.

B. INDICATIONS

The Metatarsal Decompression Implant System is intended for use as a hemi-arthroplasty implant for the first metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The device is intended for single use to be used with bone cement or press fit without bone cement.

C. CONTRAINDICATIONS

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Skeletal Immaturity.
- Known metal allergy.
- Diabetes.
- Active infection in the joint.

D. WARNINGS (See also the Patient Counseling Information Section)

- Patients should be made aware of the increased potential for device failure when excessive demands are made upon it. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device.
- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.
- This device is not intended to articulate against anything other than native cartilage.

E. PRECAUTIONS

- Do not re-sterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.

- The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.
- All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.
- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure
- Inspect devices **prior to use** for damage.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition of the fragment (if known);
    b. The size of the fragment (if known);
    c. The location of the fragment;
    d. The potential mechanisms for injury, e.g., migration, infection;

e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Concerning Magnetic Resonance Environments

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

Metatarsal Decompression Implants have not been evaluated for safety and compatibility in the MR environment. Metatarsal Decompression Implants have not been tested for heating or migration in the MR environment. Since these devices have not been tested, Wright cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

These components are passive metallic devices, and as with all passive devices, there is potential for reciprocal interference with certain imaging modalities; including image distortion for MR and X-ray scatter in CT.

F. POTENTIAL ADVERSE EFFECTS

GENERAL SURGERY RELATED RISKS

- Bleeding
- Infection
- Loss of use of the foot
- Permanent disability
- Death

JOINT REPLACEMENT RELATED RISKS

- Pain
- Injury to surrounding nerves, blood vessels, tendons or soft tissue (e.g., numbness)
- Stiffness
- Night and weather related pain
- Loss of motion
- Implant fracture
- Rotation of implant
- Accelerated wear of the device components or bone surface
- Loosening of the implant from the bones
- Dislocation of the joint
- Infection
- Lengthening or shortening of the toe
- Amputation
- Bone weakening around the implant
- Allergic or other reactions to the metal materials
- Additional surgery may be required for reoperation, revision or fusion of the joint
- Surgery may be started but a joint replacement cannot be done resulting in fusion of the joint
- Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

G. MATERIALS

- ASTM F 1537 wrought or ASTM F 75 cast, cobalt chromium
- ASTM F 67 (F 1580 in powder form) commercially pure titanium coating (all but articulating surface)

H. SURGICAL PROCEDURES

A manual is available describing detailed surgical procedures for use of these implant devices. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the implant procedures before use.

I. STERILIZATION

- This component has been sterilized.
- Do not resterilize. The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used.
- Trial sizer components are available to avoid having to open the sterile package prior to prosthesis implantation. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized.

J. SURGICAL INSTRUMENTS

Surgical instruments should be cleaned and sterilized according to the following parameters:

CLEANING AND DISINFECTION

1. **Disassemble** all components if appropriate (use surgical technique for clarification on which components can be separated).

2. **Rinse** in cold water to remove any gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** components 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. **Thoroughly rinse**/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 with cold deionized or reverse osmosis (RO/DI) water.
11. **Dry** with a clean, disposable, absorbent cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean/disinfect until it is visibly clean.

NOTE: Brushes 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.

STERILIZATION

The following Steam Sterilization cycles have been validated for the surgical instrument set.

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

Ensure that instruments are at room temperature prior to use.

These recommendations 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.

K. CAUTION

Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.