METAL HEMI SYSTEM

152206-0

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CE 0086*
Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

EC REP
Wright Medical UK Ltd.
3rd Avenue
Letchworth
Hertfordshire, SG6 2JF
UK

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

℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

METAL HEMI IMPLANT

(152206-0)

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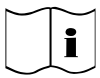
DEFINITIONS

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
	Non-sterile
℞ ONLY	For prescription use only
	Do not use if packaging is ripped or damaged.
Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
Al_2O_3	Alumina

ZrO_2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
$CaSO_4$	Calcium Sulfate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
NiTi	Nitinol (Nickel Titanium)

DESCRIPTION

The Metal Hemi Implant consists of one component to replace the articulation of the proximal phalanx of the first metatarsophalangeal joint, and corresponding instrumentation to facilitate insertion. The Metal Hemi Implant is fixed by means of a stem, which is inserted into the medullary canal of the phalanx. The profile of the metal base plate articulates with the metatarsal head. Instrumentation is provided to assist in the surgical implantation of this great toe system. It is important that instruments and trial implants used are those specifically designed for this device to ensure accurate installation. The base of the stem and under side of the body is plasma sprayed with commercially pure titanium.

A. INDICATIONS

The Metal Hemi Implant is designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidus, painful hallux valgus, revision of failed previous surgery and painful arthritis.

B. CONTRAINDICATIONS

Contraindications for the use of the Metal Hemi Implant include any condition, which would contraindicate the use of the replacement in general, including:

- Poor bone quality, which may affect the stability of the implant
- Severe tendon, neurological, or vascular deficiencies, which would compromise the affected extremity
- Any concomitant disease, which may compromise the function of the implant
- Active infection
- Rheumatoid arthritis

C. WARNINGS

For safe and effective use of this implant system, the surgeon should be familiar with the recommended implantation procedure for this device. Improper selection, placement, positioning, or fixation of implant may result in unusual loading conditions, which could affect the long term service of the implant. In every case, accepted surgical practices should be followed in post-operative care. The patient should be made aware of the limitations of joint reconstruction and cautioned to govern his/her activities accordingly to protect the joint from unreasonable stresses. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture, or wear of the implant. Patient sensitivity to implant materials should be considered and assessed prior to surgery.

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.

Metal Hemi implant has not been evaluated for safety and compatibility in the MR environment. The Metal Hemi implant has 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.

D. ADVERSE EFFECTS

Loosening of similar implant components has been reported. Early loosening may result from improper fixation or latent infection. Late loosening may result in bone resorption or pain due to biological complications or mechanical problems. Dislocation and subluxation of similar implant components has been reported due to improper positioning of the prosthesis. Soft tissue laxity can also contribute to these conditions. Metal sensitivity reactions in patients following joint replacement have been reported infrequently. The significance and effects of sensitization await further clinical evidence for evaluation and may be avoided by preoperative sensitivity testing. Implantation of foreign material in the tissues can result in histological reaction involving various sized macrophages and fibroblasts, or heterotopic bone formation. The actual clinical significance of this effect is uncertain, as similar changes may occur as a normal precursor to, or during, the normal wound healing process.

E. IMPLANT MATERIALS

The Metal Hemi implant is manufactured from cobalt chrome (CoCrMo per ASTM F1537 and ISO 5832-12) and commercially pure titanium plasma spray (CPTi titanium per ASTM F67 and ISO 5832-2).

F. STERILIZATION

The Metal Hemi implants are provided sterile and individually packed according to size. Each implant has been sterilized using gamma irradiation. The instrument system is provided non-sterile and should be steam sterilized at the surgical facility before use. The system must be cleaned prior to sterilization. Clean and inspect all instruments within the system to ensure they are suitable for use. Cracked or bent instruments should be replaced. The system must be steam sterilized using the following process parameters:

Steam Sterilization		
Sterilizer Type	**Parameter**	**Minimum Set Point**
Prevacuum 3 Preconditioning Pulses	Temperature	132°C (270°F)
	Full Cycle Time	4 minutes
	Dry Time	20 minutes
Sample Configuration: Wrapped tray with a towel placed between tray and wrap		

The use of flash sterilization is not recommended.

Remove all packaging materials prior to sterilization. Only implants and instruments should be used in surgery. Immediately clean and re-sterilize all items removed from the surgical field before handling. Surgical implants shall not be re-used. Any implant once used shall be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

G. PRODUCT HANDLING

Store sterile packed implants in their respective protective packages until use. Have a non-sterile team member open the outer packaging and carefully open the inner sterile pouch. The sterile team

member should then remove the hemi implant from the inside of the sterile pouch. Care should be taken to ensure the implant does not come in contact with anything outside the sterile field. Contouring or clamping of implants should be avoided if possible. It is recommended that implants should not be cut, sharply bent or re-bent, notched or scratched. These alterations can produce defects or stresses, which may lead to failure of the implant.

H. ENVIRONMENTAL CONDITIONS

The Metal Hemi implant is intended to be used under normal environmental conditions.

I. CAUTION

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