FUSEFIX HAMMERTOE IMPLANT AND INSTRUMENT SYSTEM PACKAGE INSERT

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION OF THE MEDICAL DEVICE:

FuseFix System implants:

- The screws are offered in different diameters and lengths.
- The screws have a recess for engaging a driver.
- The screws are designed to be implanted into bone.
- The implants are offered in Titanium alloy within the frame of the standard ISO 5832-3 and ASTM F136.

The implants are shipped sterile.

INDICATIONS FOR USE

The FuseFix System implant is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion appropriate for the size of the device. Screws are intended for single use only.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

MATERIAL

FuseFix System implants are manufactured from a Titanium alloy (ISO 5832-3 and ASTM F136). The specialized instruments are made of surgical grade stainless steel (ISO 7153-1 and ASTM F899) and Radel® polyphenylsulfone (ASTM D6394).

HOW SUPPLIED

The implants and instruments are shipped sterile as specified by the packaging.

All sterile implants are gamma radiation sterilized. All sterile instruments are sterilized using ethylene oxide. The packaging should be inspected prior to use to ensure the sterile barrier has not been compromised.

Do not reprocess.

CONTRAINDICATIONS

The implant should not be used in a patient who has current, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance

WARNINGS and POTENTIAL RISKS

The FuseFix System is designed for **single patient use only and must never be reused.** As with all other orthopedic implants, the CPM Medical components should never be re-implanted under any circumstances.

The FuseFix System can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

The implantation of screw systems should be performed only by experienced surgeons with specific training in the use of this screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be resterilized.

The FuseFix System implants should never be used with dissimilar materials. Specifically, the titanium and stainless steel components offered with this system should not be used together.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of X-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of orthopedic prostheses.

IMPORTANT: The Guidewires included in the FuseFix System is not intended as implants. The Guidewires are only intended for use as instruments to facilitate screw insertion.

POSSIBLE ADVERSE EFFECTS

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Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Bone non-union or delayed union;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

The FuseFix System implant has not been evaluated for safety and compatibility in the MR environment. The FuseFix System implant has not been tested for heating, migration or image artifact in the MR environment. The safety of FuseFix System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

DIRECTIONS FOR USE

To implant the FuseFix System implants, use only the specialized FuseFix System instruments. Do not use implants or instruments from any other system or manufacturer.

Before using the FuseFix System for the first time, the surgeon should be thoroughly familiar with the FuseFix System Surgical Technique Manual as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all FuseFix System implants and instruments, please refer to the FuseFix System Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING

FuseFix System implants and instruments are provided sterile. Do not use if package is damaged.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact CPM Medical Customer Service for return of removed implants.

LABEL SYMBOLS

SYMBOL	MEANING
℞only	Caution: Federal (United States) law restricts this device to sale, distribution, and use by or on the order of a physician.
REF	Reference number
LOT	Lot number
	Expiration date
QTY	Quantity
STERILE R	Sterilized using irradiation
STERILE EO	Sterilized using ethylene oxide
	Single use
	Do not use if package is damaged
	Refer to instructions for use
DIST. BY	Distributed by
	Manufacturer

CUSTOMER SERVICE

For further information regarding the CPM Medical General Instruments, please contact CPM Medical or your local CPM Medical Distributor.

DIST. BY

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