Metallic Internal Fixation Devices

150848-0

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
METALLIC INTERNAL FIXATION DEVICES
(150848-0)

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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
	Authorized EC Representative in the European Community
	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

I. GENERAL PRODUCT INFORMATION

Through the advancement of surgical fusion hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after fusion occurs.

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

In using fusion implants, the surgeon should be aware of the following:

- **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. The implants are not designed to withstand the unsupported stresses of full load bearing.
- **In instances in which delayed healing or nonunion occur, the metallic implant could fail due to metal fatigue.** The stresses of muscular activity of the weight of the limb can result in such failure in the absence of bone healing. Any scratches or nicks in the surface of the implant during the course of surgery may also contribute to breakage of the implant.
- **Corrosion of implants can occur due to the chemical environment of acids, salts, and proteins present in the human body.** The use of dissimilar implants (such as titanium screws with a stainless steel plate) can accelerate the corrosion process due to galvanic corrosion effect.
- **In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:**
    1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
    2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
4. **Underlying chronic disease states.** The healing process may be affected by underlying chronic disease states such as diabetes or rheumatoid arthritis, and this must be considered by the operating surgeon who inserts a metallic implant.

A. 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

See Section II for specific product information.

B. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Decreased union or non-union
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Metal sensitivity or allergic reaction(s) to implant material(s)
- Adverse histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism
- Nerve damage due to surgical trauma
- Bone necrosis

See Section II for specific product information.

C. 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. The decision to remove the implant must be made by the surgeon. It is recommended that whenever possible and practical, metallic implants should be removed once their function as an aid to the healing of the bone has been accomplished. It is imperative that adequate post-operative protection is provided by the surgeon following removal 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 overactivity

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 K-wires and sutures through the implant

It is important that contouring of the implant includes no sharp bends or reverse bends. Scratching or notching must be minimized when contouring is performed by the surgeon so as to prevent metallic corrosion and possible failure of the implant.

NEVER implant a previously used implant as small defects and internal stress patterns may be present in the implant which could lead to failure of the implant.

If complications develop, possible corrective procedures include:

- Implant removal
- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures

such as soft tissue reconstruction or arthrodesis. The patient must be appropriately and adequately instructed as to the limitations of the implant. It is imperative that the patient understand that load bearing and excessive physical activity may lead to delayed union or nonunion of the osteotomy site and possible breakage of the implant. That patient who cannot or will not comply with the post-operative instructions is thus placed at increased risk during the post-operative healing phase.

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 **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

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

See Section II for specific product information.

D. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are provided non-sterile and should be processed according to the recommended parameters for instruments (below).

These implants are for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized

according to the following parameters:

Cleaning & Disinfection

Clean to remove gross contamination and disinfect to reduce the number of viable microorganisms.

1. Place the device in a bin in the ultrasonic machine. Start the ultrasound machine and run it for 15-30 minutes. If the water appears dirty, empty it out, rinse out the machine, and then refill it to the correct level and add 3 ounces of the enzymatic solution.
2. When finished shaking, take the bin out of the ultrasound and rinse the devices thoroughly with plain tap water.
3. Place each separate bin in the surgi-stain soaking solution and soak for a minimum of 15 minutes.
4. Remove the bins from the soaking solution and rinse thoroughly with plain tap water.
5. Place each bin in the lubricant solution, which inhibits rust, for at least 30 seconds. Remove the device from the bin, and shake off any excess solution. Do not rinse.
6. Place equipment in the autoclave.

Sterilization

The metallic internal fixation devices and instruments are packaged non-sterile and must be sterilized prior to surgical use. Gravity displacement steam “flash” sterilization immediately preceding implantion of the fixation device is NOT

recommended. When urgent situations in which patient care requirements preclude other standard sterilization methods, use steam sterilization (High Vac) @ 270 °F (132 °C) for 10 minutes. To assure sterility, a Rapid Readout Biological Indicator/ Monitoring device should be used to verify a negative result. (3M 1-800-228-3957).

Ensure that implants are at room temperature prior to implantation.

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.

For additional information see WMT's Cleaning and Handling of Wright Medical Instruments.

E. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

II. SPECIFIC PRODUCT INFORMATION

A. RAYHACK® OSTEOTOMY SYSTEM

DESCRIPTION

The RAYHACK® Osteotomy System consists of bone plates, non-locking screws, and locking screws for long bone fixation. All implants are made from stainless steel or titanium alloy.

INDICATIONS

The RAYHACK® Osteotomy System is intended for long bone fixation utilized to assist healing but not intended to replace normal body structures. The plate and screws which attach to the bone are temporary internal fixation devices which align the bone surfaces in order to permit bone healing.