CrossCHECK® Plating System
152236-0

The following languages are included in this packet:

English (en)

For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

CROSSCHECK® PLATING SYSTEM
(152236-0)

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
LOT	Batch code
REF	Catalog number
2	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
STERILE R	Sterilized using radiation
℞ ONLY	For prescription use only
	Do not use if packaging is ripped or damaged.
Abbreviation	**Material**
Ti6Al4V	Titanium Alloy

DESCRIPTION

CrossCHECK® Plating System consists of a variety of bone plates and screws to be used in fixation fractures, osteotomies, and fusions in the small bones of the hand, wrist, foot, and ankle. Surgical instruments are provided to facilitate surgical placement of the implant.

A. INDICATIONS

CrossCHECK® Plating System Plating system is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones in the hand, feet, wrist, ankles, fingers, and toes. The system may be used in both pediatric and adult patients. The device is intended for single use.

B. 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

C. PRECAUTIONS

Pre-operative Precautions

The surgeon must evaluate each situation individually based on the patient's clinical presentation in making any decisions regarding implant selection. The surgeon must be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery. The surgeon should contact Wright for product-specific surgical techniques.

The surgeon should also use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. Implant longevity and stability may be affected by these variables. A heavy-weight patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. The surgeon must consider the ability and willingness of the patient to follow instructions and to control their weight and activity level. Any joint replacement system, including the implant/bone interface, cannot be expected to withstand activity levels and loads as would normal healthy bone and will not be as strong, reliable, or durable as a natural human joint. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Additional conditions presenting increased risk of failure include:

1. uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;

3. metabolic disorders that may impair bone formation;
4. osteomalacia
5. poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).
6. pre-existing conditions commonly considered with any surgery including bleeding disorders, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.

Intra-operative Precautions

Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.

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.

Correct selection of the prosthesis is extremely important. Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Proper implant selection must consider design, fixation, patient weight, age, bone quality, size, activity level, preoperative level of health, and also the surgeon's experience and familiarity with the device. Implant longevity and stability may be affected by these variables. Surgeons should inform the patient about these factors.

Post-operative Precautions

The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred.

Periodic follow-up is recommended to monitor the position and state of the implant components, as well as the condition of the bone. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.

D. WARNINGS

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. In every case, accepted surgical practices should be followed in postoperative care. The patient should be made aware of the limitations of the implant and that physical activity has been implicated in premature failure of similar devices. Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patient sensitivity to implant materials should be considered and assessed prior to surgery.

E. ADVERSE EFFECTS

The following are specific adverse effects, which should be understood by the surgeon and explained to the patient. These do not include all adverse effects, which can occur with surgery in general, but are important considerations specific to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery:

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

F. IMPLANT MATERIALS

The CrossCHECK® implants are manufactured from titanium alloy (Ti -6AI-4V ELI, ASTM F136).

G. PACKAGING AND STERILITY

The medical devices associated with this package insert may be provided sterile or non-sterile; the individual product's labeling will determine whether or not they are packaged sterile. Devices that are presented in trays are provided non-sterile.

Devices provided sterile or non-sterile. Devices provided sterile should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove device from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product. Devices provided non-sterile should be processed according to the recommended cleaning and sterilization parameters below.

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 the following: significant degradation in device performance, cross-infection, and contamination.

An implant should never be re-sterilized or reused after contact with body tissues or fluids, but rather should be discarded. Wright does not take any responsibility for the use of implants re- sterilized after contact with body tissues or fluids.

WARNINGS:

- All packaging materials MUST be removed from the implant prior to implantation.

Implant and Instrument Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove any 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.

Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean 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.

Device Sterilization

The minimum recommended steam sterilization conditions for the non-sterile or reusable medical devices associated with this package insert are as follows:

1. Double wrap the component and/or kit in an FDA-cleared CSR wrap or similar

type non-woven medical grade wrapping material.

2. Autoclave according to the following parameters:

Steam Sterilization		
Sterilizer Type	Parameter	Minimum Set Point
Pre-Vacuum	Temperature	132°C (270°F)
	Full Cycle Time	4 minutes
	Dry Time	45 minutes

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.

H. CAUTION

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

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

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.

This system has not been evaluated for safety and compatibility in the MR environment. This system 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.