ORTHOLOC™ 3Di ANKLE FUSION PLATING SYSTEM
150884-0

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

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

℞ ONLY

October 2013
Printed in the U.S.

EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

ORTHOLOC™ 3Di ANKLE FUSION PLATING SYSTEM

(150884-0)

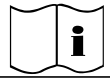
OUTLINE:

- DEFINITIONS
- DESCRIPTION
  - A. INDICATIONS
  - B. CONTRAINDICATIONS
  - C. WARNINGS
  - D. PRECAUTIONS
  - E. ADVERSE EFFECTS
  - F. HANDLING & STERILIZATION
  - G. STORAGE CONDITIONS

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
	Non-sterile
	Do not resterilize
℞ ONLY	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if packaging is ripped or damaged

Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
Al2O3	Alumina
ZrO2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
$CaSO_4$	Calcium Sulfate
CaPO4	Calcium Phosphate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate
PDLLA	Poly D, L-Lactic Acid
PDMS	Silicone 55D
PEEK	Poly Ether Ether Ketone
Al	Aluminum
DBM	Demineralized Bone Matrix

DESCRIPTION

The ORTHOLOC™ 3Di Ankle Fusion Plating System contains plates belonging to 1 of 3 general categories (anterior, lateral and posterior) based on the contouring of each plate and intended surgical approach. All plates feature poly-axial locking screw holes and one or two compression slots. The plates are made from titanium alloy and accept 4.5mm and 5.5mm ORTHOLOC™ 3Di locking screws, 4.5mm and 5.5mm ORTHOLOC™ Fully-Threaded Bone Screws, and 5.5mm ORTHOLOC™ Partially-Threaded Bone Screws. Washers are also available for use with the ORTHOLOC™ Bone Screws.

A. INDICATIONS

Wright's ORTHOLOC™ 3Di Ankle Fusion Plating System is intended to facilitate arthrodesis of the ankle including tibiotalocalcaneal and tibiotalar joints and tibiocalcaneal arthrodeses, in conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

B. CONTRAINDICATIONS

General Surgical Contraindications:

- Active Infection
- Psychologically inadequate patient
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Insufficient quantity or quality of bone to permit stabilization of the arthrodesis
- Suspected or documented metal allergy or intolerance

Product Specific Contraindications:

- None

C. WARNINGS

No product specific warnings

D. 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. The fixation system cannot be expected to withstand activity levels and loads as would normal healthy bone. 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; and
7. rheumatoid arthritis.

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, the prosthesis can break or become damaged as a result of certain activity or trauma, 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 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. Surgeons are encouraged to use their best medical judgment when choosing the most appropriate implant within the system. 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.

The Wright ORTHOLOC™ 3Di Ankle Fusion Plating System has not been evaluated for safety and compatibility in the MR environment. The ORTHOLOC™ 3Di Ankle Fusion Plating System has not been tested for heating or migration in the MR environment.

Recommendations Regarding Device Fragments

1. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
2. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
3. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
4. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition, size, and location of the fragment (if known);
    b. The potential mechanisms for injury, e.g., migration, infection;
    c. 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.

E. ADVERSE EFFECTS

- Allergic reactions to materials; metal sensitivity that may lead to histological reactions, pseudotumor and aseptic lymphocytic vasculitis-associated lesions (ALVAL).
- Delayed would healing; Deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, amputation of the limb may be required.
- Damage to blood vessels or hematoma;

- Temporary or permanent nerve damage, peripheral neuropathies and subclinical nerve damage as possible result of surgical trauma resulting in pain or numbness of the affected limb;
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- Fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, duration of service, loss of fixation, non-union, or excessive weight;
- Dislocation, migration and/or subluxation of prosthetic components from improper positioning, trauma, loss of fixation and/or muscle and fibrous tissue laxity;
- Pain.

F. HANDLING AND STERILIZATION

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 are sterilized by gamma radiation. Irradiated devices have been exposed to a minimum 25 and a maximum 40 kiloGrays of gamma radiation. 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 techniques, 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 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.

Devices provided non-sterile should be processed according to the recommended cleaning and sterilization parameters below.

Device Cleaning

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove 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.
12. **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.

Sterilization

The minimum recommended steam sterilization conditions for Wright Medical devices provided non-sterile are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

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	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and validated 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.

G. STORAGE CONDITIONS

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

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

References:

- EN 980:2008 *Symbols for use in the labeling of medical devices*.
- ANSI/AAMI ST79:2006 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*