

ORTHOLOC™ 2 Lapidus with Rotation

154817 GLB EN Rev 0




















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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
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	For prescription use only

ISO 15223-1, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied, Part 1: General requirements

Abbr.	Material	Abbr.	Material
Ti	Titanium	SS	Stainless Steel
Ti6Al4V	Titanium Alloy	UHMWPE	Ultra High Molecular Weight Polyethylene
CoCr	Cobalt Chrome Alloy		

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.
- **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.

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. GENERAL SURGICAL CONTRAINDICATIONS

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

There are no contraindications specific to the products.

C. 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
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

See Section II for specific product information.

D. 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.

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 above
- Identify prior pathology
- Stabilize collapsed deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant
- Avoid open wedge osteotomies of the lower tibia which could be a higher load bearing environment.

Avoid flawing implant surfaces to minimize the potential for early fatigue failure. 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.

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.

E. MRI SAFETY INFORMATION

The ORTHOLOC™ 2 Lapidus with Rotation System implants have not been evaluated for safety and compatibility in the MR environment. These implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of the ORTHOLOC™ 2 Lapidus with Rotation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MRI Warnings

There are inherent risks associated with the use of metallic implants in the MR environment: including component migration, heating, and signal interference or image distortion near the component(s). Heating 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 of these adverse effects are unknown for these implants.

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. As with all passive devices, there is potential for interference with certain imaging modalities including image distortion for MR and X-ray scatter in CT.

F. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are either provided sterile or non-sterile; the individual product's labeling will determine whether or not it is packaged sterile. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

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.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning

1. **Disassemble** 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

- Double wrap the component in an FDA-cleared CSR wrap or a similar type non-woven medical grade wrapping material.
- 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

- 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 recommended instructions are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. The recommended instructions provided above have been validated by Wright Medical. It remains the responsibility of the processor to ensure that the processing is performed using appropriate equipment and materials and achieves the desired result. All users should be qualified personnel and properly trained on applicable policies, procedures, and standards.

For additional information see Wright’s “Cleaning and Handling of Wright Medical Instruments”.

G. 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. ORTHOLOC™ 2 Lapidus with Rotation System

DESCRIPTION

The ORTHOLOC™ 2 Lapidus with Rotation System is comprised of plate and screw configurations to facilitate the Lapidus fusion procedure. Plates are left and right specific, include plantar steps for an anatomical fit across the first metatarsal joint, and are manufactured from Titanium Alloy.

INDICATIONS

The ORTHOLOC™ 2 Lapidus with Rotation System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of bones of the feet and toes. Specific examples include: Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion). CAUTION: Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician.

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