













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. 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.

### **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.

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 collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant

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

If complications develop, possible corrective procedures include:

- Implant removal
- Bone grafting of cysts
- Replacement of the implant

Over time, metallic implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed.

Removal of metallic implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon.

#### **Recommendations Regarding Device Fragments**

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. 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.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.

5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
6. 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.

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.

#### **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. GENERAL SURGICAL CONTRAINDICATIONS**

- Active infection
- 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

## E. 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*

1. Double wrap the component in an FDA-cleared CSR wrap or a 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 ST79:2010 and A1:2010, Table 5, Row 1 guidelines and 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 Wright's "Cleaning and Handling of Wright Medical Instruments".

**F. 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™ 3Di MIDFOOT/FLATFOOT SYSTEM**

DESCRIPTION

The system contains plates of various styles, sizes and options, each contoured for specific anatomy and designed for specific procedures. All plates feature polyaxial locking screw holes and k-wire holes, and some plates have non-locking slots or compression slots. The plates are made from titanium alloy conforming to ASTM F136 or ISO 5832-3 and accept ORTHOLOC™ 3Di 2.7 mm and 3.5 mm locking screws and ORTHOLOC™ 2.7 mm and 3.5 mm bone screws.

#### INDICATIONS

The ORTHOLOC™ 3Di Midfoot/Flatfoot System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. Specific examples include:

##### Flatfoot Osteotomies

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Medial Displacement Calcaneal Osteotomy (MDCO)

##### Mid / Flatfoot Fusions

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

#### CONTRAINDICATIONS

No product specific contraindications. See Section I.D. for general surgical contraindications.

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