TOBY ORTHOPAEDICS

INSTRUCTIONS FOR USE - WOLF® Long Bone Plate System

MD

Caution: Federal law restricts this device to sale by or on the order of a physician.

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INTENDED USE

The WOLF® Long Bone Plate System is intended for the internal fixation of bone fragments about the long bones in the upper extremity.

INDICATIONS

The WOLF® Plate system is indicated for fractures, osteotomies, and non-unions of upper extremity diaphysis.

CLINICAL BENEFITS

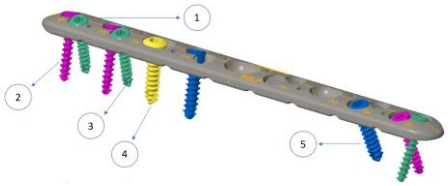
WOLF® is designed to be a versatile plating system, both in ease of application and options available to surgeons for hybrid fixation, including locking and non-locking screws. Due to the rigidity of the locking plates and the tendency for the plate system to move as a whole unit, most commonly in weakened osteoporotic bone, post-surgical complications may arise, including additional fracture site comminution. WOLF® is designed to be less rigid, better matching the modulus of the bone.

CONTRAINDICATIONS

- Diaphysis fractures with significant fragmentation where reconstruction is not possible.
- Open diaphysis fractures with severe contamination.

DESCRIPTION

The WOLF® system contains bone plates for the repair of fractures of the humerus, radius, and ulna. Included in the system are various screws, plates, k-wires, drill bits, and specialized instruments. All components and specialized instruments, which may be purchased independently, are supplied in a non-sterile container suitable for moist heat sterilization.



NOMENCLATURE

1. **WOLF® Long Bone Plate**
2. **2.7mm Bypass Cortical Locking Screw**
3. **2.7mm Cortical Locking Screw**
4. **3.5mm Cortical Screw**
5. **3.5mm Cortical Locking Screw**

Figure 1

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MATERIAL SPECIFICATION

WOLF® implantable components are made of Titanium alloy Ti-6AL-4V ELI. This material meets the requirements of ASTM Designation *F136-02a*, *Standard Specification for Wrought Titanium - 6 Aluminum - 4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

TREATMENT BEFORE DEVICE IS USED

Toby products are supplied in a non-sterile condition and must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Please refer to the Cleaning and Sterilization instruction (Doc. 50000133-04) for further information.

STERILIZATION

WOLF® system components are supplied non-sterile. All non-sterile components are intended to be moist heat sterilized at the health-care facility. Prior to use, the product shall be inspected for any signs of damage or tampering. Any component suspected of damage should be replaced prior to use. If the tray is deemed satisfactory, it should be wrapped in a 510(k)-approved wrap and sterilized following the Dynamic-Air-Removal moist heat sterilization process identified in the table below, or an equivalent sterilization cycle validated for this type of product. The use of flash sterilization is not recommended for WOLF®.

Sterilizer Type	Minimum Temperature	Full Cycle Time	Drying Time	Configuration
Pre-vacuum	135˚C	3 minutes	20 minutes	Wrapped Tray

Any method of moist heat sterilization used should be validated in accordance with the current revision of the following standards to demonstrate a sterility assurance level (SAL) of 10^{-6} or better: *ISO 17664, AAMI TIR 12, AAMI TIR 30, AAMI ST 79, AAMI ST 81*.

WOLF® SYSTEM STORAGE AND INSTRUMENT USE INSTRUCTIONS

When not in use, store the clean and disinfected WOLF® Plate Long Bone system within the Sterilization Tray in a cool, dry place, away from direct sunlight. Prior to use, inspect the product for any signs of damage or tampering. Use the oldest products first. Instrumentation should be disassembled for cleaning and inspection where appropriate (Refer to Doc 50000133). Refer to the WOLF® Surgical Technique Guide for detailed instrumentation usage instructions (Refer to Doc 50000132-06).

CAUTIONS

- WOLF® instrumentation does not have an infinite functional life. Because the instrumentation is subjected to repeated stresses related to impaction, bone contact, routine cleaning, and sterilization processes, all re-usable instrumentation should be carefully inspected before each use to ensure that they are fully functional. Scratches and/or dents may result in breakage during use. Dullness of cutting edges can result in poor functionality. All damaged instrumentation and those suspected to not perform as required should be replaced to prevent any potential patient injury such as metal fragments falling into the surgical site. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instruments. It is important that the surgeon and operating theater staff be fully conversant with the appropriate surgical technique for the WOLF® system.
- Dispose of contaminated implants and instruments per established Healthcare facility precautions for the handling of containment / biohazardous materials.
- Safe disposal of Reuseable devices that have been inspected and have reached the end of their lifetime should be disposed of according to institutional procedures.
- Safety precautions Personal Protective Equipment (PPE) should be worn when handling or working with contaminated devices. Universal precautions are standards of infection control practices designed to reduce the risk of transmission of bloodborne infections. Universal precautions should be observed by all Healthcare Facility Personnel that work with contaminated or potentially contaminated devices.
- Exercise caution when handling devices with sharp points and cutting edges.
- All implantable devices must never be reused. Previous stresses from prior use may cause imperfections that can potentially lead to device failure.
- All implantable devices should be protected from scratches, nicking, or dents that may lead to stress concentrations that would potentially result in failure.
- The patient shall be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this device.
- Exercise caution to avoid damaging the vasculature of the bone fragments.
- Use caution to match the thickness of the plate to the bone size in question, taking into account the size of the defect needing repair. Lower profile plates should not be used in larger bones or larger patients. Where used, hardware failure may occur and may require revision surgery. The low-profile plates are preferable for use on small bones. The use of a thicker plate in a small bone can lead to hardware irritation. The patient may request hardware removal after fracture healing in such cases.
- Dual divergent screw fixation is recommended along the broad metaphyseal region of the bone.
- When using K-wires to affix the plate to the bone, use only sharp K-wires and irrigation to avoid local burn injury to the bone.
- Use a drill guide whenever using a drill bit to minimize potential injury to the surrounding tissue.
- Use caution to match the use of drill bits and corresponding screws to ensure optimal fixation.
- Exercise caution to ensure that the drill guide (45 mm) is installed on the plate and used in combination when measuring with the depth gauge. Failure to do this will result in incorrect measurements. Note: measuring instruments have ± 1mm accuracy.
- Avoid drilling past the far cortex; the drill bit can produce significant soft tissue damage.
- Exercise caution to avoid creating a cortical defect when the incorrect side of the dual locking screw is used.

- Ensure that a *bypass* screw is installed first into the dual divergent screw hole if an additional locking screw is to be installed into the adjacent hole. Failure to use a bypass screw or failure to properly align the bypass screw head will result in difficulty with installation of the secondary screw.
- During hardware removal, never try to remove the bypass fastener first; it may be impossible to remove and the surgeon risks stripping the head of the screw. The color-coding on the fasteners should aid in the proper identification of a bypass fastener (light pink / purple) and a fully headed fastener (light green / dark green).
- Do not use fasteners other than those provided within the WOLF® system. Such usage may result in device failure and/or corrosion.
- Use caution to ensure sufficient bone stock is available to use dual divergent fixation, especially in smaller bones, to avoid creating cortical defects, and when choosing fasteners, as the dual divergent feature is not recommended for locking screw diameters larger than 2.7mm.
- Whenever a 3.5mm Cortical Locking Screw is used, it is to be used by itself and not in combination with a bypass screw to avoid excessive bone loss or stress riser.
- Devices may fail when subjected to increased loading associated with delayed union or nonunion.
- The WOLF® Long Bone Plate System Implants have been evaluated for MR Safety. Non-clinical testing of the worst-case scenario has demonstrated that the implants of the system are MR Conditional. These implants can be scanned safely under the following Conditions:

MRI Safety Information:

A patient with a Toby Orthopaedics Wolf® Long Bone Plate implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	**Toby Orthopaedics Wolf® Long Bone Plate System**
Nominal value(s) of Static Magnetic Field [T]	**1.5 T or 3 T**
Maximum Spatial Field Gradient [T/m and gauss/cm]	**30 T/m (3000 gauss/cm)**
RF Excitation	**Circularly Polarized (CP)**
RF Transmit Coil Type	**Whole body transmit coil, Head RF transmit-receive coil**
Maximum Whole Body SAR [W/kg]	**2.0 W/kg (Normal Operating Mode)**
Limits on Scan Duration	**2.0 W/kg whole body average SAR for 30 minutes of continuous RF (a sequence or back-to-back series/scan without breaks), followed by a 15-minute resting period, followed by an additional 15-minute scan.**
MR Image Artifact	**The presence of this implant may produce an image artifact of 19 mm.**
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

ADVERSE EFFECTS

Potential complications/adverse events associated with the use of implantable bone plates include, but are not limited to, the following:

- Postoperative pain and/or discomfort
- Prominent screws
- Hardware failure
- Numbness
- Inflammation
- Failure of fracture healing
- General infection

For more information, questions or to report a complaint and/or an adverse event please contact Toby Orthopaedics, Inc. by:

Phone: 305.665.8699

Email: sales@tobyortho.com

Mail: 6355 SW 8th Street, Unit 101

Miami, FL 33144 USA

CE 2797

TOBY ORTHOPAEDICS

SYMBOL LEGEND

	**Single Use**
	**Medical Device**
	**Keep Dry**
	**Keep away from sunlight**
 www.tobyortho.com	**eIFU**
	**MRI conditional**
	**Non-Sterile**
	**Refer to Instructions for Use.**

	**Unique Device Identifier**
	**Manufacturer**
	**Manufacture date**
	**CE mark in compliance with directive on Class IIA or IIb medical devices.**
	**EU Authorized Representative**
	**UK Authorized Representative**
	**Lot number**
	**Catalogue Reference number**

Toby Orthopaedics, Inc.
6355 SW 8th Street, Suite 101
Miami, FL 33144 USA
Tel: 305.665.8699
Fax 305.768.0269
sales@tobyortho.com

Atlantico Systems
LTD
34 Oldfield,
Kingston
Galway, Ireland