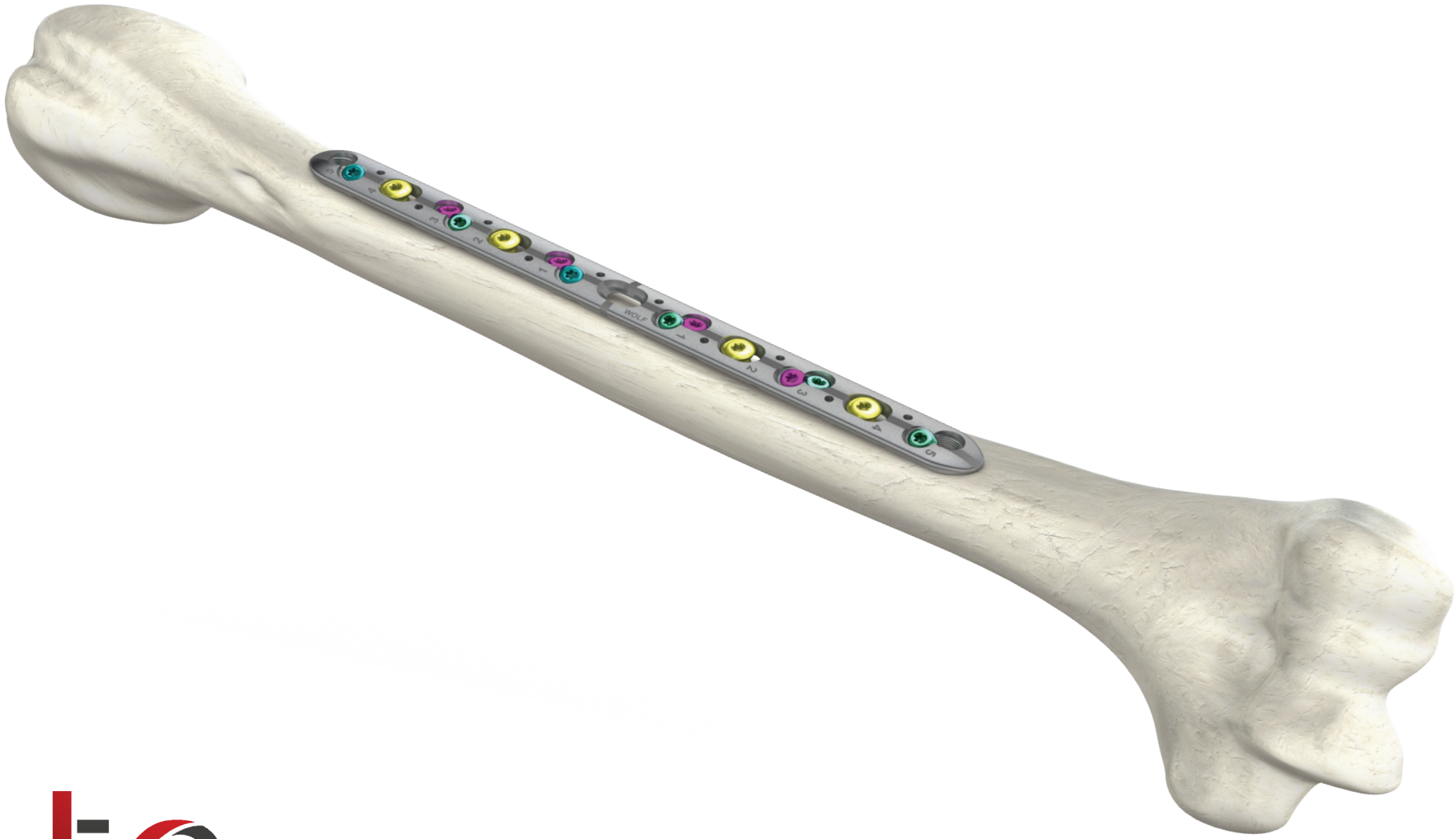
WOLF® Long Bone Plate System
Surgical Technique Guide



TOBY ORTHOPAEDICS

www.tobyortho.com

WOLF® Long Bone Plate System

The WOLF® plating system is indicated for treatment of fractures, osteotomies, and non-unions of the upper extremity diaphyses, with the primary (and most common) use being the open treatment of long bone, or diaphyseal fractures.

The WOLF® Long Bone Plate system contains bone plates for the repair of fractures of the humerus, radius, and ulna. Included in the sytem 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.

Variations in patient anatomy are significant and variations from humerus long bone to a long bone in the forearm or the leg are vast. This guide is not intended to cover all such variations in regional anatomy or among different patients. Rather, this document is an outline of suggested steps that the surgeon may follow when using WOLF®.

Note: When treating larger bones, such as the humerus, it is recommended to use 3.5mm Cortical Locking Screws and a thicker plate.

Surgeons and other health care professionals must exercise their best judgment in deciding how a diaphyseal fracture or other condition is to be treated. This guide is intended for cases where the surgeon has recommended open management of such fracture or condition, utilizing plate osteosynthesis with TOBY's WOLF® system.

The WOLF® family of plates accepts 3.5mm and 2.7mm screws.

Dual Divergent Fixation

The locking holes in WOLF® are never oriented perpendicular to the plate (See Figure 1).
The divergent orientation of the locking fasteners to the plate is so called because it diverges from the perpendicular line (a line perpendicular to the plane of the plate).

WOLF® includes additional design features to enhance fixation in osteopenic bone. The system offers the possibility to install either one or two Cortical Locking Screws into each locking hole. The surgeon may choose either domain of the locking hole (or both) for the application of a locking fixture to best fit the fracture configuration or local anatomy and circumstance.

WOLF® dual divergent technology provides several advantages, including:

- Greater pullout strength
- Allowing the surgeon to achieve proper bi-cortical screw fixation without creating a cortical defect in cases of slight plate overhang
- Facilitates capturing fracture fragments not directly opposite the screw hole

WOLF® dual divergent fixation is accomplished by installing a partially headed or “Bypass” locking fastener first, leaving room for the adjacent fully headed locking fastener to complete the construct, thereby creating dual divergent fixation to the bone (See Figure 3).

The surgeon may use any combination of Cortical Locking Screws. The Bypass fasteners are clearly identifiable: they are pink and have a partial cutout in the head.

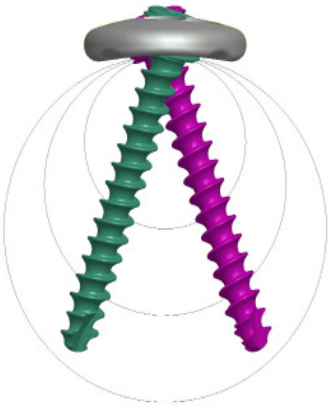


Figure 1

Implant Selection

WOLF® plates are available in 3 thicknesses (2.9mm, 3.8mm and 4.3mm), See Figure 4. Though not anatomically specific, the thinner, low profile plate is generally intended for use in smaller bones, such as the forearm or in smaller patients, such as the pediatric population and small adults. The thicker plates are generally intended for use in larger bones, including a forearm in a large patient, or a humerus in the average patient population.
Curved plates are available to fit curved long bones best.

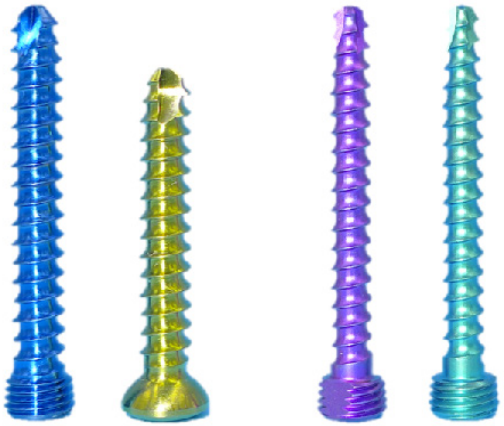


Figure 2

Figure 4

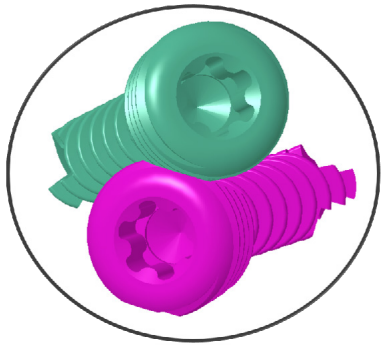


Figure 3

It remains within the discretion of the surgeon to choose the correct implant for a particular application, given the many factors that play into the complex decision-making.

Surgeons should note that because the thicker plates are intended for larger bones, the angle of divergence between the Cortical Locking Screws is slightly greater, as shown in Figure 5.

It is recommended to select a longer plate whenever possible, over a shorter plate, to avoid possible failure of fixation. Again, it remains within the discretion of the surgeon to choose the correct implant for a particular application.

Caution: The use of a thin plate on a larger bone or patient may result in implant failure and may require revision surgery. The use of a thicker plate on a smaller bone or patient may result in hardware irritation and may result in patient-requested hardware removal after fracture healing. When applying a thicker plate to a smaller bone, it is not advisable to use dual divergent fixation at the risk of removing more bone than is desirable. (See Figure 5) Because the angle of Cortical Locking Screw divergence is greater in thicker plates, there may be an increased risk of creating a cortical defect in smaller bones.

Caution: Whenever possible, use longer plates to bridge the fracture defect to minimize failure of fixation and screw pull out.

Figure 5

SURGICAL STEPS

Step 1 - Fracture Exposure

Exposure of the fracture site is left to the discretion of the surgeon. A standard exposure or a variation may be used to reach the fracture and prepare it for fixation.

Note: Avoid periosteal stripping whenever possible.

The viability of the fracture fragments should be maintained. The soft tissue envelope, including critical structures such as vessels, nerves, muscles and tendons are retracted carefully to reach the fracture itself.

In the case of open fractures, the surgeon may elect to address any contamination initially and stage definitive fixation and soft tissue coverage, as needed.

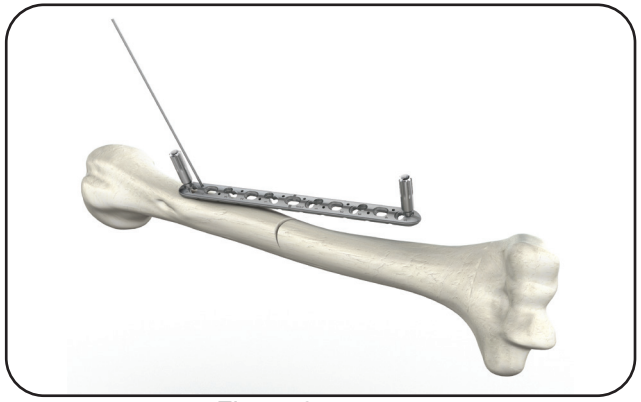


Figure 6

Step 2 - Preliminary Reduction

The tubular nature of long bones allows for some basic generalizations: The fracture fragments are identified under direct or indirect visualization and with intra-operative X-ray imaging. Fracture reduction is achieved using traction and bone clamps. At surgeon discretion, a comminuted fracture may be systematically reduced into a less complex fracture, or may simply be bridged.

The use of circlage wiring for fracture reduction and final fixation of the fracture site is left entirely to the judgment of the treating surgeon.

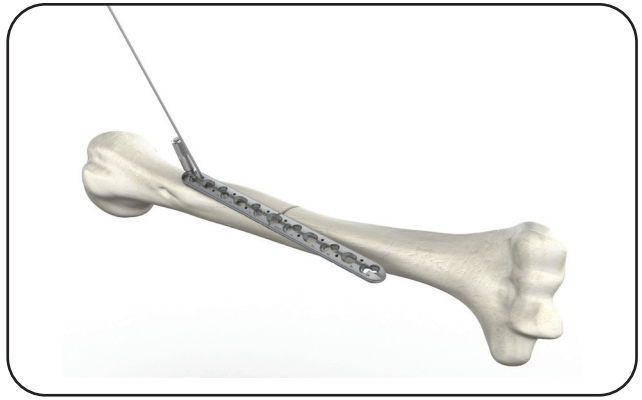


Figure 7

Step 3 - Preliminary Fixation

Once the main fracture fragments are reasonably aligned, position the plate on the surface of the bone.

Note: Whenever possible, try to match the surface of the plate to the surface of the bone.

The plate may be held to the bone using standard bone clamps and/or may be initially affixed to the bone with one or more K-wires. WOLF® has small openings along its length to accommodate the passage of K-wires. In general, it is easier to apply a K-wire to one end of the plate and then make any necessary adjustments before applying a K-wire on the opposite end of the plate across the fracture site. The surgeon may elect not to use the K-wire feature of the plate for preliminary fixation.

Note: We recommend using smaller more flexible 1.1mm k-wires to allow accomodation of the plate to the bone.

Caution: K-wire drilling into hard diaphyseal bone can generate heat and may damage the bone immediately surrounding the K-wire. It is recommended to use sharp new K-wires and irrigation in this part of the exercise.

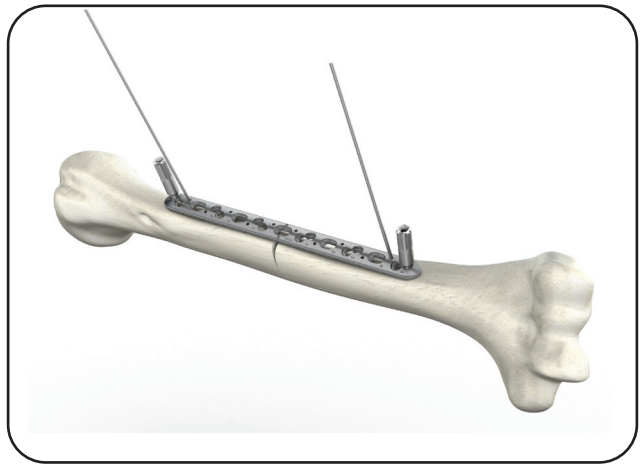


Figure 8

At this stage, it is easy to make adjustments to improve the reduction of the fracture fragments.

Preliminary fixation of the plate across the fracture site may be achieved with screws. In general, the first screw(s) should be Cortical Screws. Use the Drill Guide and the 2.5mm Drill Bit to create a drill hole in a non-locking oblong compression hole. Use the Depth Gauge to measure. Install the corresponding 3.5mm Cortical Screw.

Note: Measuring instrument (Depth Gauge) has +/- .2mm accuracy.

Caution: Avoid over-tightening the Cortical Screw, which may result in stripping of the bone threads and/or loss of fixation.

Note: The use of non-locking compression screws allows a closer apposition of the plate onto the bone surface. This may be or may not be desirable according to fracture pattern and the judgment of the surgeon.

It is left to surgeon discretion whether to compress across the fracture site with one of several dynamic compression techniques or to simply neutralize across the fracture.

Throughout the exercise, after a Drill Bit is used, the surgeon will remove the corresponding Drill Guide and will use the Depth Gauge to determine the proper screw length to be used.

Dynamic compression across a fracture has been described and is well known to anyone engaged in the art of fracture fixation. Briefly, after initial fixation of the plate to a main bone fragment across the fracture site with a 3.5 mm non-locking screw as outlined above, the surgeon then selects a non-locking hole on the plate across the fracture site through which a first screw will be applied to the yet unsecured fracture fragment. The surgeon drills with the 2.5mm drill bit, eccentrically along the specialized oblong hole such that the drill bit perforation will be farther away from the fracture itself. As the non-locking 3.5mm compression screw is installed, the head of the screw and plate interact with the result that the bone fragment being secured slides under the plate toward the fracture, achieving compression. If the surgeon wishes to compress further, the exercise may be repeated once more through another oblong compression hole.

After these initial 3 steps in fixation, the surgeon may continue with any number of options, as outlined in Step 4.

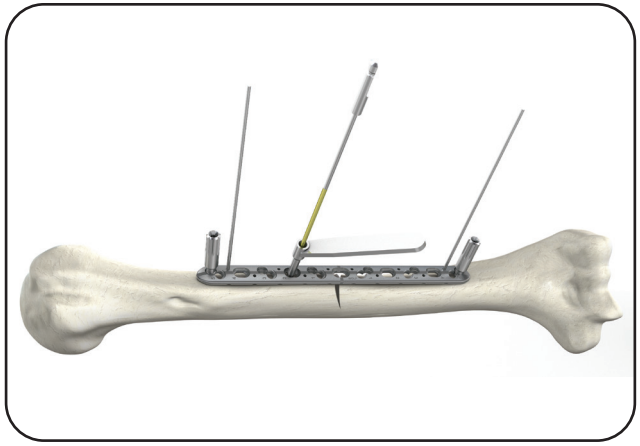


Figure 9

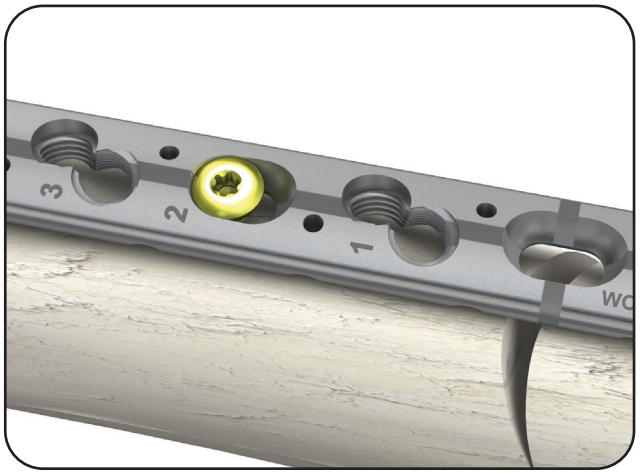


Figure 10

Step 4 - Final Fixation

WOLF® has Locking Drill Guides specifically designed to accommodate a 2.0mm Drill Bit and other Locking Drill Guides designed to accommodate a 2.5mm Drill bit.

Use the 2.0mm Locking Drill Guide when the intention is to implant a 2.7mm Cortical Locking Screw.

Use the 2.5mm Locking Drill Guide when the intention is to implant a 3.5mm Cortical Locking Screw.

Caution: Do not use a 2.5mm Drill bit when implanting a 2.7mm Cortical Locking Screw. Do not use a 2.0mm Drill bit when implanting a 3.5mm Cortical Locking Screw.

Thread the Locking Drill Guide(s) to either domain of the locking hole(s) along the plate. Proceed to drill with the corresponding drill bit.

Remove the Locking Drill Guide and use the Depth Gauge to determine the proper fastener length.
Implant the corresponding fastener.

Note: Measuring instrument, Depth Gauge, has +/- .2mm accuracy.

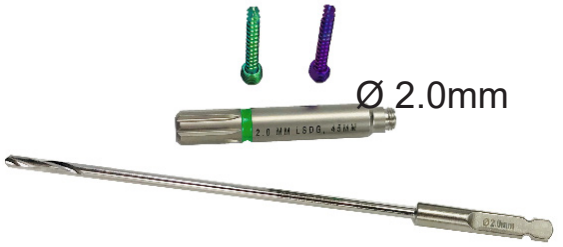


Figure 11

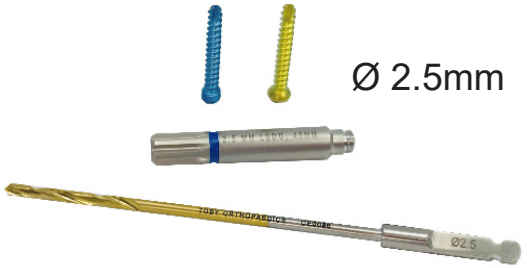


Figure 12

Dual Divergent Fixation

Note: Dual divergent fixation is ideal along the broader metaphyseal bone ends. We do not recommend dual screw fixation along narrow diaphyseal bone.

When opting for dual divergent fixation, install a Bypass Cortical Locking Screw (pink screw). Implant the corresponding fastener. Once the first Bypass fastener is installed, confirm that the adjacent opening is unimpeded, meaning a full circular opening is available for the next fastener. If necessary, the surgeon may again make adjustments here using the driver. Next, thread the corresponding Locking Drill Guide for the desired second fastener. (See Figure 13).

Drill using the corresponding Drill Bit and then remove the Locking Drill Guide and measure with the depth gauge. Implant the corresponding fully headed fastener (green).

Figure 13

Note: Intra-operative imaging is encouraged throughout the surgical exercise.

Note: Bypass fasteners are generally recommended to be used in combination with fully headed fasteners. However, they may be used alone in instances where a surgeon decides not to drill the second hole for the fully headed fastener. This decision should be made according to the surgeon's best judgment.

Implant Removal

Removal of WOLF® proceeds similarly to any other long bone plate system, except when dual divergent fixation has been used.

Where the surgeon has opted for dual divergent fixation, always remove the fully headed fastener (green) first and only then proceed to remove the partially headed Bypass fastener (pink).

Caution: Never try to remove the partially headed Bypass fastener first, as it will be impossible to remove and the head of the fastener may be stripped. The color-coding on the fasteners aids in proper identification of a Bypass fastener (pink) versus a fully headed fastener (green).

Figure 14

Essential Information

Metallic surgical implants provide surgeons a means of fixation to aid in the management of fracture and reconstructive surgery.
All metallic surgical implants are subject to repeated stresses in post-surgical use, and metal fatigue can result. . All surgical risks should be explained to patients prior to surgery.

Post-operative care and the patient's understanding and willingness to follow rehabilitation instructions are important aspects of successful healing.

Intended Use

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

Indications For Use

WOLF® is indicated for fractures, osteotomies, and non-unions of upper extremity diaphyses.

Contraindications For Use

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

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

Cautions

- When not in use, store the clean and disinfected WOLF® Long Bone Plate 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. Instruments should be disassembled for cleaning and inspection where appropiate (Refer to Doc. 50000013-04).
- 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 suspect 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 contanminated / 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 the 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.
- Excersise 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.
- 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 (45mm) is installed on the plate and used in combination when measuring with the depth gauge. Failure to do this will result in incorrect measurements.

Cautions Continued:

- 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. Dual divergent screw fixation is recommended along the broadmetaphyseal region of the bone.
- 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 stree riser.
- Devices may fail when subjected to increased loading associated with delayed union or nonunion.
- For additional cautions and instructions for use, refer to WOLF® Instructions for Use (Doc. 60000024).
- The Wolf Long Bone Plate System Implants have been evaluated for MRI safety. Non-Clinincal testing of the worst case scenario has demonstrated that the implants of the system are MR Conditional. A patient with a Toby Orthopaedics WOLF® Long Bone Plate implant can be scanned safely under the following scenario, failure to follow these condtions may result in injury to the patient:

Name / Identification of device	Toby Orthopaedics WOLF® Long Bone Plate System
Nominal value (s) of Statid Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (300 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 os Scan Duration	2.0 W/kg. whole body average SAR for 30 minutes of continous RF (a sequence or back-to-back series/scan without breaks), followed by an additional 15-minute scan.
MRI Image Artifact	The presence of this implant may produce an image artifact of 19 min.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

SYSTEM COMPONENTS- IMPLANTABLES

CATALOGUE NO.	DESCRIPTION
TO-LBP-070	WOLF® Plate, 70mm, 5 Hole
TO-LBP-096	WOLF® Plate, 96mm, 7 Hole
TO-LBP-122	WOLF® Plate, 122mm, 9 Hole
TO-LBP-148	WOLF® Plate, 148mm, 11 Hole
TO-LBP-174	WOLF® Plate, 174mm, 13 Hole
TO-LBP-200	WOLF® Plate, 200mm, 15 Hole
TO-LBP-226	WOLF® Plate, 226mm, 17 Hole
TO-LBP-252	WOLF® Plate, 252mm, 19 Hole
TO-LBP-278	WOLF® Plate, 278mm, 21 Hole
TO-LP-LBP-070	WOLF® Plate, Low Profile, 70mm, 5 Hole
TO-LP-LBP-096	WOLF® Plate, Low Profile, 96mm, 7 Hole
TO-LP-LBP-122	WOLF® Plate, Low Profile,122mm, 9 Hole
TO-LP-LBP-148	WOLF® Plate, Low Profile, 148mm, 11 Hole
TO-CLP-LBP-174	WOLF® Plate, Curved, 174mm, 13 Hole
TO-CLP-LBP-200	WOLF® Plate, Curved, 200mm, 15 Hole
TO-CLP-LBP-226	WOLF® Plate, Curved, 226mm, 17 Hole

CATALOGUE NO.	DESCRIPTION
TO-35-T10-CS-10	3.5mm T10 Cortical Screw, 10mm
TO-35-T10-CS-12	3.5mm T10 Cortical Screw, 12mm
TO-35-T10-CS-14	3.5mm T10 Cortical Screw, 14mm
TO-35-T10-CS-16	3.5mm T10 Cortical Screw, 16mm
TO-35-T10-CS-18	3.5mm T10 Cortical Screw, 18mm
TO-35-T10-CS-20	3.5mm T10 Cortical Screw, 20mm
TO-35-T10-CS-22	3.5mm T10 Cortical Screw, 22mm
TO-35-T10-CS-24	3.5mm T10 Cortical Screw, 24mm
TO-35-T10-CS-26	3.5mm T10 Cortical Screw, 26mm
TO-35-T10-CS-28	3.5mm T10 Cortical Screw, 28mm
TO-35-T10-CS-30	3.5mm T10 Cortical Screw, 30mm
TO-35-T10-CS-32	3.5mm T10 Cortical Screw, 32mm
TO-35-T10-CS-34	3.5mm T10 Cortical Screw, 34mm
TO-35-T10-CLS-10	3.5mm T10 Cortical Locking Screw, 10mm
TO-35-T10-CLS-12	3.5mm T10 Cortical Locking Screw, 12mm
TO-35-T10-CLS-14	3.5mm T10 Cortical Locking Screw, 14mm

CATALOGUE NO.	DESCRIPTION
TO-35-T10-CLS-16	3.5mm T10 Cortical Locking Screw, 16mm
TO-35-T10-CLS-18	3.5mm T10 Cortical Locking Screw, 18mm
TO-35-T10-CLS-20	3.5mm T10 Cortical Locking Screw, 20mm
TO-35-T10-CLS-22	3.5mm T10 Cortical Locking Screw, 22mm
TO-35-T10-CLS-24	3.5mm T10 Cortical Locking Screw, 24mm
TO-35-T10-CLS-26	3.5mm T10 Cortical Locking Screw, 26mm
TO-35-T10-CLS-28	3.5mm T10 Cortical Locking Screw, 28mm
TO-35-T10-CLS-30	3.5mm T10 Cortical Locking Screw, 30mm
TO-35-T10-CLS-35	3.5mm T10 Cortical Locking Screw, 35mm
TO-27-T10-CLS-10	2.7mm T10 Cortical Locking Screw, 10mm
TO-27-T10-CLS-12	2.7mm T10 Cortical Locking Screw, 12mm
TO-27-T10-CLS-14	2.7mm T10 Cortical Locking Screw, 14mm
TO-27-T10-CLS-16	2.7mm T10 Cortical Locking Screw, 16mm
TO-27-T10-CLS-18	2.7mm T10 Cortical Locking Screw, 18mm
TO-27-T10-CLS-20	2.7mm T10 Cortical Locking Screw, 20mm

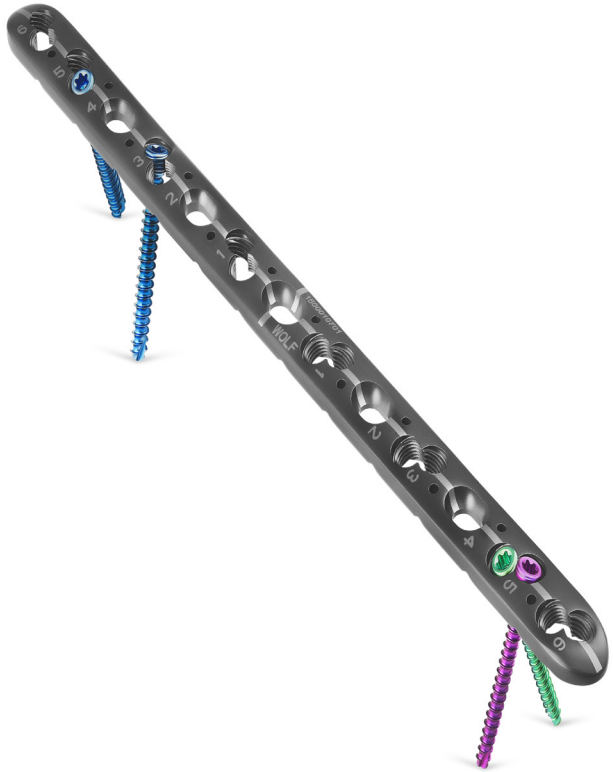
CATALOGUE NO.	DESCRIPTION
TO-27-T10-CLS-22	2.7mm T10 Cortical Locking Screw, 22mm
TO-27-T10-CLS-24	2.7mm T10 Cortical Locking Screw, 24mm
TO-27-T10-CLS-26	2.7mm T10 Cortical Locking Screw, 26mm
TO-27-T10-CLS-28	2.7mm T10 Cortical Locking Screw, 28mm
TO-27-T10-CLS-30	2.7mm T10 Cortical Locking Screw, 30mm
TO-27-T10-CLS-32	2.7mm T10 Cortical Locking Screw,32mm
TO-27-T10-CLS-34	2.7mm T10 Cortical Locking Screw, 34mm
TO-27-T10-BLS-10	2.7mm T10 Bypass Cortical Locking Screw, 10mm
TO-27-T10-BLS-12	2.7mm T10 Bypass Cortical Locking Screw, 12mm
TO-27-T10-BLS-14	2.7mm T10 Bypass Cortical Locking Screw, 14mm
TO-27-T10-BLS-16	2.7mm T10 Bypass Cortical Locking Screw, 16mm
TO-27-T10-BLS-18	2.7mm T10 Bypass Cortical Locking Screw, 18mm
TO-27-T10-BLS-20	2.7mm T10 Bypass Cortical Locking Screw, 20mm
TO-27-T10-BLS-22	2.7mm T10 Bypass Cortical Locking Screw, 22mm
TO-27-T10-BLS-24	2.7mm T10 Bypass Cortical Locking Screw, 24mm

IMPLANTABLE COMPONENTS - CONTINUED

CATALOGUE	DESCRIPTION
TO-27-T10-BLS-26	2.7mm T10 Bypass Cortical Locking Screw, 26mm
TO-27-T10-BLS-28	2.7mm T10 Bypass Cortical Locking Screw, 28mm
TO-27-T10-BLS-30	2.7mm T10 Bypass Cortical Locking Screw, 30mm
TO-27-T10-BLS-32	2.7mm T10 Bypass Cortical Locking Screw, 32mm
TO-27-T10-BLS-34	2.7mm T10 Bypass Cortical Locking Screw, 34mm

INSTRUMENT COMPONENTS

INSTRUMENT CATALOGUE NO.	DESCRIPTION
TO-DB20-110	2.0mm Drill bit x 110mm
TO-DB25-110	2.5mm Drill Bit x 110mm
TO-20-LSDG-45	2.0mm Locking Screw Drill Guide, 45mm
TO-25-LSDG-45	2.5mm Locking Screw Drill Guide, 45mm
TO-DG-2535	2.5mm/3.5mm Drill Guide
TO-DRI-10P	T-10 Driver with Quick Connect
TO-PH-DG-50	Depth Gauge, 50mm
TO-DRI-S-CQCH	Cannulated Universal Quick Connect Handle
TO-KW-16-130	1.6mm K-wire x 130mm
TO-WOLF-27-SC	WOLF® 2.7mm Screw Caddy
TO-WOLF-35-SC	WOLF® 3.5mm Screw Caddy
TO-WOLF-LP-27-SC	WOLF® Low-Profile 2.7mm Screw Caddy
TO-WOLF-LP-35-SC	WOLF® Low-Profile 3.5mm Screw Caddy
TO-WOLF-STL	WOLF® Sterlization Lid
TO-WOLF-ST	WOLF® Sterilization Tray
TO-WOLF-INS-ST	WOLF® Instrument Sterilization Tray
TO-WOLF-LP-ST	WOLF® Instrument Low Profile Plate Sterilization Tray



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

TOBY ORTHOPAEDICS

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Federal law restricts this device to sale by or on the order of a Physician.

This surgical technique is intended as an educational tool to assist a properly licensed medical professional in the usage of Toby Orthopaedics products, and is not meant to replace professional judgment as to product usage and technique.
Prior to use, medical professionals should consult the product's Instructions for Use and rely on their own training and experience.

MD

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