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.

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®.

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.
Dual Divergent Fixation

The locking holes in WOLF® are never oriented perpendicular to the plate. 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 put either one or two Cortical Locking Screws and/or Pegs 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.

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

Implant Selection

WOLF® plates are available in 3 thicknesses (2.9mm, 3.8mm and 4.3mm). 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.
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 and/or Locking Pegs is slightly greater, as shown in Figure 3.

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 3) Because the angle of Cortical Locking Screw / Locking Peg divergence is greater in thicker plates, there may be an increased risk of creating a cortical defect in smaller bones. (See Figure 1)

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

Caution: 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.

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.

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 1.6mm 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.

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.
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.

**Caution:** Avoid over-tightening the Cortical Screw, which may result in stripping of the bone threads and/or loss of fixation. Avoid over manipulating the drill bit or using excessive force, as this may result in damage to the device or harm to the patient.

**Caution:** Ensure that the Drill Guide (i.e. tissue protector) is inserted fully into the plate and not lifted while in use. Failure to keep the tissue protector properly positioned can result in damage to the device or instrumentation, and could result in harm to the patient.

**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.

Extended drill guide (66mm) are left assembled to the plate after drilling, and the extended Depth Gauge is used by placing the tip of the Gauge in the head of the Drill Guide. This allows surgeons to properly measure screw lengths when the hole in the bone is not easy to see.

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

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 than 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.
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 and/or 2.5mm Locking Peg.

Locking Drill Guides are available in both 28mm and 66mm configurations, providing the surgeon ample choices depending on the demands of the situation or surgical preference.

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

Caution: Do not match / use Drill Bits and Cortical Locking Screws and/or Locking Pegs other than in the above configurations. Doing so may result in sub-optimal fixation.

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.

Extended drill guide (66mm) are left assembled to the plate after drilling, and the extended Depth Gauge is used by placing the tip of the Gauge in the head of the Drill Guide. This allows surgeons to properly measure screw lengths when the hole in the bone is not easy to see.

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

When opting for dual divergent fixation, install either a Bypass Cortical Locking Screw (pink) or a Bypass Locking Peg (light pink). Markings on driver are to help align Bypass features to plate. Should final adjustments be necessary, the surgeon can use the hand driver to tighten the Bypass fastener into its optimal position.

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 11.

Drill using the corresponding Drill Bit and then remove the Locking Drill Guide and measure with the depth Gauge. Install the corresponding fully headed fastener (green).
Note: Intra-operative imaging is encouraged throughout the surgical exercise.

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

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.

Caution: Dual divergent fixation is not recommended for long bones of very small diameters, as too much bone may be removed in the process.

Caution: 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.

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 can aid in proper identification of a Bypass fastener (pink) versus a fully headed fastener (green).

Essential Information

Metallic surgical implants provide surgeons a means of fixation to aid in the management of fracture and reconstructive surgery. It should be noted that such implants are not intended to replace normal body structures. All metallic surgical implants are subject to repeated stresses in post-surgical use, even where applied in non-weight bearing situations, and metal fatigue can result. This guide does not include all adverse effects, which might occur during surgical intervention, but are important considerations. 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. Such things are particularly important when treating complex, unstable fractures. It is important that patients are instructed and understand the risks associated with metallic implants.

This sheet does not include all essential information required for selection and use of a surgical device. The surgeon should rely on their own training and experience, as well as consulting the product’s full labeling and Instructions for Use for all necessary information.
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:

- 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.
- 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 long drill guide (66mm) is installed on the plate and used in combination when measuring with the extended depth gauge. Failure to do this will result in incorrect measurements.
- 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.
Cautions Continued:

- Ensure that a bypass screw / peg is installed first into the dual divergent screw hole if an additional locking screw / peg 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 / peg.
- 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.
- Devices may fail when subjected to increased loading associated with delayed union or nonunion.
- Avoid over manipulating the drill bit or using excessive force, as this may result in damage to the device or harm to the patient.
- Ensure that the Drill Guide (i.e. tissue protector) is inserted fully into the plate and not lifted while in use. Failure to keep the tissue protector properly positioned can result in damage to the device or instrumentation, and could result in harm to the patient.

System Components and Ordering Information:

Refer to the current revision of the WOLF® Long Bone Plate System catalog for a full list of the available implants and accessories. Contact TOBY® customer service to request additional information:

Toll Free: 866.979.TOBY (8629)
Tel.: 1.406.556.3260
Fax: 1.305.768.0269

sales@TobyOrtho.com
www.TobyOrtho.com
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Printed in the USA, 500000132-2