Instructions for Use
Femoral Locking Plate System

PRIMA™

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

	5.1.1	Manufacturer
	5.1.3	Date of Manufacture
	5.1.4	Use-by-date
LOT	5.1.5	Batch code
REF	5.1.6	Catalogue number
STERILE R	5.2.4	Sterilized using Irradiation
	5.2.6	Do not resterilize
	5.2.8	Do not use if package is damaged
	5.4.2	Do not re-use
	5.4.3	Consult instructions for use
	5.4.4	Caution
	5.2.12	Double Sterile Barrier System
LATEX		Not made with latex
T15		T15 Compatible
T20		T20 Compatible
R_x only		Prescription Use Only

Symbols: ISO 15223-1:2021

CONTENTS
The package contains one or several implants and surgical instrument(s) for the express purpose of fracture management or deformity correction, either as procedure kits or individually sterilized ancillary devices.Implants within this system are made from medical grade stainless steel.

DESCRIPTION
The WishBone Medical Plate and Screw System gives the surgeon a means of bone fixation and helps in the management of fractures and reconstructive surgery; bone plates are not intended to replace normal body structures. The WishBone Medical Plates and Screws are made of stainless steel or titanium alloy.

MRI SAFETY INFORMATION
The MR environment presents risks to patient with metal implants. Physicians should consider the risks when recommending MR imaging for patients with metal implants.

The Femoral Locking Plate System components have not been evaluated for safety in MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Femoral Locking Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

INTENDED USE
The WishBone Medical Plate and Screw System is intended for fixation of fractures.

INDICATIONS
The WishBone Medical Plate and Screw System is indicated for pediatric and adult patients for fractures of the clavicle, scapula, humerus, ulna, radius, middle hand, metacarpals, pelvis acetabulum, femur, fibula, tibia, metatarsals and middle foot bones, and treatment of the calcaneus, and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis.

The system includes Femoral Locking Plates and Screwswhich are indicated for use in infant, child, and adolescent pediatric subgroups and small stature adult patients.

ADVERSE EFFECTS
Possible reactions may include but are not limited to:

- Bone fracture
- Bone necrosis
- Bone removal
- Death
- Delayed or non-union of bone
- Delayed of correction
- Delay of surgery
- Dislocation
- Injury to user
- Growth plate damage
- Pain, ache, or swelling
- Pin tract Infection
- Pulmonary Embolism
- Infection leading to revision
- Infection leading to permanent impairment
- Loss of fixation
- Nerve/Tissue damage
- Component failure
- Limb length discrepancy
- Adverse tissue reaction
- Instability
- Malpositioned component
- Osteolysis in joint space

CONTRAINDICATIONS

- Comminuted bone surface which would mitigate against plate and screw placement.
- Pathologic conditions of bone such as osteopenia which would severely impair the ability to securely fix the plate.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- WishBone Medical Plate and Screw System plates are not intended to cross active growth plates.

STORAGE & HANDLING
The devices are packed in protective packaging that is labeled to its contents. All implants and instruments are supplied sterile.

- Always store the devices in the original protective packaging.
- Store the devices in a dry and dust-free place (e.g. a standard hospital environment).
- Before use, inspect the implant/instrument packaging carefully. Do not use when package is visibly opened or damaged.

STERILE
Procedure kits are sterilized by gamma irradiation, and ancillary components are sterilized via gamma irradiation as indicated on their package label. Caution: Do not resterilize. This is a single-use device.

WARNINGS
A single use medical device or accessory is not intended by its manufacturer to be reprocessed and reused.

Products intended for single-use must not be reused in a subsequent procedure. Reuse or reprocessing (e.g., cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

SAFETY PRECAUTIONS

- Prior to use, thoroughly read these instructions. Each surgeon must consider the particular needs of each patient and create a surgical plan that uses the appropriate implant(s) for that patient.
- Keep the instructions for use accessible to all staff.
- Take care not to place screws into the physis, breach the femoral neck cortex, or cross into the joint space.
- The use of surgical instruments for tasks other than those for which they are intended may result in damaged or broken instruments or patient injury.
- The surgeon must be familiar with the instrumentation, method of application, and the recommended surgical technique for adequate fracture repair and protection of soft tissue structures during surgery. Use appropriate drill guide when drilling to protect soft tissues from the edges of drill flutes. The plate must never be unbent or reverted to its original shape once it has been contoured.
- Do not bend plates excessively. Do not use threaded drill guides to bend plates.
- Do not fully tighten the screw to the plate under power. Final tightening should always take place by hand.
- Failure to confirm satisfactory placement of the initial guide wires with fluoroscopy could lead to screws that penetrate the physis, breach the femoral neck cortex, or cross into the joint space.
- Do not bend the guide wires during insertion through the wire guide as this may result in errored correction, or guide wire breakage.
- Incorrect placement of the initial oblique osteotomy may result in non conforming plate to bone contact with the proximal fragment, or the most distal proximal screw on the head of the plate may pass through the osteotomy.
- Failure to adequately lock a locking screw to the plate may lead to the screw backing out.
- Be sure to not cross-thread the guide tower to the plate. This may affect the guide wire trajectory and cause the screws to not lock into the plate
- Always confirm correct drill diameter for desired screw prior to drilling. Progress slowly with drill to prevent plunging through far cortex where vital anatomic structures might be. Fluoroscopy may be needed to confirm desired length.
- Always measure the depth of a pre-drilled hole by carefully inserting the depth gauge first through the plate, and then into the pre-drilled hole. The sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring.
- Threaded drill guides must always fit securely within a locking hole. Using the wrong size or type of drill guide or angulating a threaded drill guide could cause the screw head to pull through the hole. Prior to screw insertion, confirm that the screw type (locking or non-locking), length, and diameter is correct. Fluoroscopy may be needed to confirm desired length.
- Use manual force only with the screwdriver supplied to insert screws. Insert a screw only once. Do not reuse screws as fatigue or damage from a prior insertion may damage the screw.
- Do not use implants of dissimilar metals in contact with one another (i.e. titamiun screws with stainless steel plate) given the potential for corrosion.

- This is a single-use device. Never reuse an implant or instrument. Reuse can result in the transfer of materials including but not limited to bone, tissue, blood or infectious disease. Although the device may appear undamaged, previous stresses may have created nonvisible damage that could result in device failure. The manufacturer accepts no responsibility for a reused implant or instrument.
- WishBone Medical implants should only be used in conjunction with WishBone Medical instruments applicable for the respective sizes.
- After fracture reduction: When using locked plating techniques, reduction should, where possible, be within 1mm to limit fracture fragment motion during healing.
- After closure: For unstable repair constructs, i.e., highly comminuted fractures, post-operative loading should be restricted to a level determined by the physician until callus formation is radiographically documented.

FOR USE BY A TRAINED PHYSICIAN
This description alone does not provide sufficient background for direct use of WishBone Medical products. Instruction by a surgeon experienced in handling these products is highly recommended. It is the responsibility of the surgeon to be familiar with the instrumentation, method of application, and recommended surgical techniques before use of these products by reviewing relevant publications and surgical techniques.

The WishBone Medical Plate and Screw System Surgical Techniques describing the uses of the Femoral Locking Plate System can be found at www.wishbonemedical.com

PRODUCT COMPLAINTS
Any health care professional (e.g. customer or user of this system of products) who has experienced dissatisfaction in this product‘s quality, identity, durability, reliability, safety, effectiveness and/or performance, should either notify their WishBone Medical, Inc. sales representative or contact WishBone Medical, Inc. at WeCare@WishBoneMedical.com. When filing a complaint, please provide the following information:

- Nature of the complaint
- Location of the incident
- Name and address of complainant
- Device name(s) and part number(s)
- Device lot number(s)
- Device UDI (if available)
- Patient name or patient identifier
- Patient age & gender

IMPLANT REMOVAL – ANALYSIS OF IMPLANT
Upon removal of implants, hospital procedures should be followed.

FOR FURTHER INFORMATION
Please contact WishBone Medical, Inc. at www.WishBoneMedical.com or contact your authorized representative for further information about this product.

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