BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

The BioPro Foot Plating System Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com.

Federal Law (USA) restricts this device to sale and use by, or on the order of a physician.

Description
A comprehensive plating system used in a variety of procedures throughout the foot and ankle.

Material

Item	Material
Tray	Aluminum
Modules	Polypropylene
Modules	Aluminum
Modules	Radel
Screws	Titanium
Bone Plates	Titanium
Screwdriver Handle	Silicone
General Instruments	Stainless Steel

Indications for use:
The intended use of the BioPro Foot Plating System is to draw two or more aligned bone fragments together to facilitate healing in an adult patient. It is composed of the following bone plate categories:

I. Forefoot System:
The BioPro Forefoot Plating System is Indicated for Use in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient. The Forefoot System is not for Spinal Use.

II. Mid & Hindfoot System:
The BioPro Mid & Hindfoot Plating System is Indicated for Use in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient. The Mid & Hindfoot System is not for Spinal Use.

III. Ankle Fracture System:
The BioPro Ankle Fracture System is Indicated for Use in: 1). Fixation of fractures of the distal tibia including, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures; 2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the metaphyseal and diaphyseal region of the distal fibula;3). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle. The Ankle Fracture System is not for Spinal Use.

Contra-indications Include:
- Infection.
- Patient conditions including blood supply limitations, obesity and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

Adverse Effects:
In all surgical procedures, the potential for complications and adverse reactions exists. The risks and complications with these implants include:
- Fracture of the implant due to excessive loading.
- Incomplete or inadequate healing.
- Implant migration and / or loosening.
- Pain, discomfort, or abnormal sensations due to the presence of an implant.
- Nerve damage resulting from surgical trauma.
- Bone necrosis or bone resorption.
- Delayed or nonunion of bone fragments.
- Allergic reaction to the implant materials.

Warnings & Precautions:
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Implants must not be re-used or re-sterilized.
- Improper insertion of the device during implantation may result in implant loosening or migration.
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, nonunion and incomplete healing may occur.
- Bending or fracture due to applied excessive stresses and load bearing.
- Failure to follow postoperative care instructions may result in procedure complications or failure.
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition may occur.

MR Safety Information:
The BioPro Foot Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the BioPro Foot Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Contact surgeon if a change in performance or pain level is noticed.

Instructions for use:

1. Using standard dissection techniques, expose the surgical site.
2. Perform the intended osteotomy or identify the fracture location.
3. After reduction of the fracture, choose the proper plate based on the size and type of indication.
4. Place the plate on the fracture/osteotomy site, fix with k-wires with stop. If forming/bending the plate to fit the anatomy – use the bending irons for preparation of the proper contour. DO NOT REPEATEDLY BEND THE PLATE – as this will cause a weakened fatigue life of the plate.

5. Utilize the drill guide with proper drill according to screw size for angulation into the most secure bone structure. Drill hole for screw. Repeat hole preparation as necessary for proper fixation of the plate.
6. Utilize the depth gauge for proper length of screw in bone anatomy for firm fixation in the opposite bone cortex.
7. Insert desired size screw matching the plate size and bone anatomy. Repeat process on remaining screw(s) with angulation holes – using either locking or standard screws.
8. Remove k-wires with stop. Check plate/screw tightness on bone anatomy fracture/osteotomy site.
9. Using fluoroscopy, confirm the proper plate and screw placement with the bone anatomy. Correct as warranted & re-check.
10. Clean the surrounding area with a pulse lavage.
11. Use the surgeon's preferred method for closing the surgical site.

Postoperative Management:
The patient is allowed to ambulate with weightbearing to tolerance on the operated fracture site within limits imposed by postoperative discomfort. The progression to normal use of the digit or limb is limited only by the persistence of postoperative swelling and discomfort.

Cleaning and Sterilization

WARNING: Please note that a single use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed of. The instrument tray must be wrapped in FDA cleared wraps or containers for the steam sterilization process.

The modular instrument tray is comprised of the following modules. **Note: all modules may not be present depending on the procedure being performed.**

Item #	Description	Tray Level
22925	Foot Plating System Main Tray	Outside
22926	2.0 Screw-Plate Module	Middle
22927	2.5-2.8 Screw Module	Middle
22928	3.0-3.5 Screw Module	Middle
22929	MTP Plate Module	Middle
22930	2.8 Plate Module	Top
22931	3.0-3.5 Plate Module	Top
22932	Medial Column Plate Module	Top
22933	Calcaneal Plate Module	Top
22934	Osteotomy Plate Module	Bottom

Pre-Cleaning Procedure

Disassemble all multi-component instruments prior to cleaning.

- Prepare an ENZOL® (or equivalent) solution according to the manufacturer's directions.
- Rinse each instrument under cool running tap water (< 35°C) for one (1) minute. Use a nylon bristled brush to remove gross soil.
- Immerse each instrument in the ENZOL® (or equivalent) cleaning solution for two (2) minutes. While immersed, use a nylon bristled brush to remove soil from all areas of the instrument, paying attention to all crevices and cannulations.
- Rinse each instrument under cool running tap water (<35°C) for one (1) minute.
- Prepare an ENZOL® (or equivalent) in a sonicator according to the manufacturer's directions.
- Sonicate each instrument for ten (10) minutes.
- Rinse each instrument by submerging the components into DI water for two (2) minutes, taking care to rinse any lumens.
- Place each instrument back into its specific location.

Automated Cleaning Process

Each tier of the tray will be removed from the outer portion of the system tray.

Treatment Step	Time (mm:ss)	Water Temperature	Cleaning Agent (if applicable)
Pre-Wash	2:00	Unheated Tap Water	N/A
Enzyme Wash	Stage 1: 1:00	122°F (50°C)	Enzymatic Detergent Solution
	Stage 2: 2:00	150°F (65.6°C)	
Wash	1:00	185°F (85°C)	Steris® Prolystica Detergent Solution (or equivalent)
PURW Thermal Rinse	2:00	185°F (85°C)	N/A
Dry	5:30	N/A	N/A
Inspect	As Needed	N/A	N/A

Sterilization:
The BioPro Foot Plating System components are separately packed and are provided non-sterile, thus the implants must be removed from the packaging and properly placed in the instrument tray and **must be sterilized prior to use**. Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline Good Hospital Practice: "steam sterilization and sterility assurance. "The recommended steam sterilization parameters for non-sterile devices are as follows. This is in accordance with ANSI/AAMI ST79:2006 in meeting a Sterility Assurance Level (SAL) of 10^{-6}.

METHOD	TIME	TEMPERATURE	DRY TIME
Pulsed Pre-vacuum	4 minutes	270° F (132° C)	30 Minutes

Unique Device Identification (UDI)
All components in the BioPro Foot Plating System can be identified by M209XXXXX, where "XXXXX= Item #". For a complete listing of BioPro item numbers visit www.bioproimplants.com/udi

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