English

Skeletal Dynamics Ulnar Shortening Plating System
INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

℞: For use by physicians only. Caution: Federal Law restricts this device to sale by or on the order of a physician.

Failure to follow instructions may lead to patient injury.

This package insert is designed to provide Instructions for Use of the Ulnar Shortening Plating System. Prior to use of the Ulnar Shortening Plating System, the surgeon should become familiar with all information contained in this pamphlet.

Description

The Skeletal Dynamics Ulnar Shortening Plating System consists of the following plate configurations:

1. Distal Ulnar Shortening Plates
2. Proximal Ulnar Shortening Plates
3. Screws, K-Wires, and specialized instrumentation

Distal Ulnar Shortening Plates

The Skeletal Dynamics Distal Ulnar Shortening Plates are titanium alloy designed for fracture fixation, osteotomies, and non-unions of the distal ulna.

The Distal Ulnar Shortening Plates are available in two lengths and in left and right configurations.

Proximal Ulnar Shortening Plates

The Skeletal Dynamics Proximal Ulnar Shortening Plates are titanium alloy plates designed for fracture fixation, osteotomies, and non-unions of the ulna.

The Proximal Ulnar Shortening Plates are available in two lengths.

Indications for Use

The Skeletal Dynamics Ulnar Shortening Plating System is indicated for fractures and osteotomies, in particular for the ulna.

Contraindications

Prior to using the system, ensure that none of the following patient conditions are present: active or latent infection, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post operative care instructions. The system should not be used in pediatric patients or patients with open growth plates.

General Warnings and Precautions

- The information in this document should be shared with the patient.
- The patient should be informed about the importance of following the post-operative rehabilitation prescribed to fully understand the limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- The patient must be cautioned about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, device or treatment failure as a result of loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.

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- Potential construct failures such as implant breakage, loosening, fixation failure, instability, delayed soft tissue healing, soft tissue irritation, delayed union, or non-union may occur as a result of noncompliance to post-operative rehabilitation, excessive activities, or construct overloading.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique, implants, and associated instruments.
- The device is not designed to withstand the stress of excessive weight bearing, load bearing, or physical activity. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- DO NOT reuse any of the system's implantable components. Reuse may compromise the structural integrity of the construct.
- Protect the system's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the system, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Skeletal Dynamics representative or the Skeletal Dynamics Customer Care Department.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are only intended to be used during provisional fixation.
- User should handle K-Wires accordingly during insertion and removal to prevent unintended K-Wire penetration or injury.
- DO NOT permanently implant the pre-loaded Drill Guides or AIMing Guides; they are intended to be removed prior to screw insertion.
- DO NOT use pin/peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- On the distal plate, prevent excessive peg length as this will cause the pegs to violate the distal radioulnar joint (DRUJ) space.
- DO NOT mix system-specific instrumentation from different systems or manufacturers for metallurgical, biomechanical, and functional reasons.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drill power sources.
- Seek medical help immediately if the implant malfunctions.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures.
- Care should be taken that no implants are placed interfering with the articular surface.
- To maintain traceability of the system implantable components, record each of the respective components Lot numbers in the patient records post implantation.
- If the screws are not attached and/or fully tightened, a non-union, delayed union, soft tissue complication, or construct failure may occur.
- Use caution when drilling with K-Wires or drills as it may result in vascular or nerve injury.
- Ensure sufficient space is available for proper application when used in conjunction with other implants to prevent interference. Interference with other prostheses may lead to failure of the plating system or postoperative complications.
- Caution should be taken when contouring plates. Bending the plates may weaken or break the plates.
- The plates cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue prior to healing. Failure of the component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union or excessive loads.

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- Retract and protect the extensor carpi ulnaris (ECU) and dorsal branch of the ulnar nerve during initial dissection.
- Prior to making the osteotomy, do not use a cortical locking screw in the FreeFix™ slot to prevent deformation of the cutting guide rails. If desired, a cortical screw may replace the non-locking screw after the final osteotomy has been achieved.
- Protect soft tissue while cutting with the oscillating saw using the Hohman Retractors that are provided in the set.

Potential Adverse Events

The following are potential risks that have been associated with surgery: infection, nonunion or delayed union, persistent pain, discomfort or abnormal sensations, inflammation, material sensitivity, nerve/bone/soft tissue damage, stiffness, undesirable shortening or lengthening of limb, implant breakage, loosening or migration of the implants resulting in misalignment.

MR Safety Information

The Ulnar Shortening 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 Ulnar Shortening Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Directions for Use

The system should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the system based on their clinical experiences.

The surgeon should select the type and size implant to best meet the patient's needs. Although the surgeon is the medical intermediary between the company and the patient, this document contains important medical information that should be shared with the patient.

It is the responsibility of the surgeon to be familiar with the procedure before use of this device. Additionally, it is the responsibility of the surgeon to be familiar with relevant publications regarding the procedure prior to use. Please refer to the *Freefix ® Ulnar Shortening System Surgical Technique Guide*(MKT-00222-00) to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand and Upper Extremity Institute* located in Miami, Florida.

Cleaning, Sterilization, and Inspection

For instructions on cleaning, disinfection, sterilization, and inspection of the Ulnar Shortening Plating System products please refer to the cleaning and sterilization instructions for use (IFU-04056-00). Refer to the *Freefix ® Ulnar Shortening System Surgical Technique Guide* (MKT-00222-00) for proper kitted tray arrangement.

Resources

The latest version of the Instructions for Use may be requested in a physical format by email (orders@skeletaldynamics.com) or by phone (+1-877-753-5396). The physical copy will be provided within 7 calendar days of receiving a request from the user or at the time of delivery of the device if so requested at the time of order.

For the most current instructions for use visit www.skeletaldynamics.com/resources. Instructions for Use should always be reviewed before using or implanting a device

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MD NON STERILE

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SYMBOLS GLOSSARY

Symbols that follow BS EN ISO 15223-1 / Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Symbol Reference Number and Title	Description
	5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	5.1.6 Catalogue Number	Indicates the manufacturer's catalogue number so the medical device can be identified
	5.4.3 Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	5.1.5 Batch Code	Indicates the manufacturer's batch code or lot can be identified
	5.4.2 Do Not Re-use	Indicates a medical device that is intended for one single use only
	5.1.1 Manufacturer	Indicates the medical device manufacturer
	5.2.8 Do Not Use If Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.1.4 Use-by-date	Indicates the date after which the medical device is not to be used
	5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	5.7.7 Medical device	Indicated the item is a medical device
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured

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Ulnar Shortening Plating System

Inventory Control Sheet

Ulnar Shortening Plates	
Ulnar Shortening Plate, Distal, Right USP-DRT (01)00841506114415 (01) 00841506114415	Ulnar Shortening Plate, Distal, Left USP-DLT (01)00841506114422 (01) 00841506114422
Ulnar Shortening Plate, Distal, Short Right USP-DRS (01)00841506116068 (01) 00841506116068	Ulnar Shortening Plate, Distal, Short Left USP-DLS (01)00841506116075 (01) 00841506116075
Ulnar Shortening Plate, Proximal USP-PRX (01)00841506114439 (01) 00841506114439	Ulnar Shortening Plate, Proximal, Long USP-PRXL (01)00841506114446 (01) 00841506114446
Ulnar Shortening Plate, Proximal, Short USP-PRXS (01)00841506135267 (01) 00841506135267	
Titanium Screws	
Threaded Peg, Locking, 2.3mm x 10mm, Ti TPLS-23100-TS (01)00841506103358 (01) 00841506103358	Threaded Peg, Locking, 2.3mm x 12mm, Ti TPLS-23120-TS (01)00841506103365 (01) 00841506103365
Threaded Peg, Locking, 2.3mm x 14mm, Ti TPLS-23140-TS (01)00841506103372 (01) 00841506103372	Threaded Peg, Locking, 2.3mm x 16mm, Ti TPLS-23160-TS (01)00841506103389 (01) 00841506103389
Threaded Peg, Locking, 2.3mm x 18mm, Ti TPLS-23180-TS (01)00841506103402 (01) 00841506103402	Threaded Peg, Locking, 2.3mm x 20mm, Ti TPLS-23200-TS (01)00841506103426 (01) 00841506103426
Threaded Peg, Locking, 2.3mm x 22mm, Ti TPLS-23220-TS (01)00841506103440 (01) 00841506103440	Threaded Peg, Non-Locking, 2.7mm x 10mm, Ti TPNL-27100-TS (01)00841506103518 (01) 00841506103518
Threaded Peg, Non-Locking, 2.7mm x 12mm, Ti TPNL-27120-TS (01)00841506103525 (01) 00841506103525	Threaded Peg, Non-Locking, 2.7mm x 14mm, Ti TPNL-27140-TS (01)00841506103532 (01) 00841506103532

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Threaded Peg, Non-Locking, 2.7mm x 16mm, Ti TPNL-27160-TS (01)00841506103549 (01)00841506103549	Threaded Peg, Non-Locking, 2.7mm x 18mm, Ti TPNL-27180-TS (01)00841506103556 (01)00841506103556
Threaded Peg, Non-Locking, 2.7mm x 20mm, Ti TPNL-27200-TS (01)00841506103563 (01)00841506103563	Threaded Peg, Non-Locking, 2.7mm x 22mm, Ti TPNL-27220-TS (01)00841506103570 (01)00841506103570
Screw, Cortical Non Locking, 3.5mm x 10mm, Ti PANL-35100-TS (01)00841506102795 (01)00841506102795	Screw, Cortical Non Locking, 3.5mm x 12mm, Ti PANL-35120-TS (01)00841506102818 (01)00841506102818
Screw, Cortical Non Locking, 3.5mm x 14mm, Ti PANL-35140-TS (01)00841506102832 (01)00841506102832	Screw, Cortical Non Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856 (01)00841506102856
Screw, Cortical Non Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863 (01)00841506102863	Screw, Cortical Non Locking, 3.5mm x 20mm, Ti PANL-35200-TS (01)00841506104171 (01)00841506104171
Screw, Cortical Non Locking, 3.5mm x 22mm, Ti PANL-35220-TS (01)00841506104188 (01)00841506104188	Screw, Cortical Locking, 3.5mm x 10mm, Ti COLS-35100-TS (01)00841506101095 (01)00841506101095
Screw, Cortical Locking, 3.5mm x 12mm, Ti COLS-35120-TS (01)00841506101118 (01)00841506101118	Screw, Cortical Locking, 3.5mm x 14mm, Ti COLS-35140-TS (01)00841506101132 (01)00841506101132
Screw, Cortical Locking, 3.5mm x 16mm, Ti COLS-35160-TS (01)00841506101156 (01)00841506101156	Screw, Cortical Locking, 3.5mm x 18mm, Ti COLS-35180-TS (01)00841506101163 (01)00841506101163
Screw, Cortical Locking, 3.5mm x 20mm, Ti COLS-35200-TS (01)00841506104034 (01)00841506104034	
Guides	
AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870 (01)00841506102870	

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K-Wires	
K-Wire, Single Diamond, 1.6mm x 127mm KWIR-SD-16127 (01)00841506116204 (01)00841506116204	

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