English

Ulnar Shortening Plating System

INSTRUCTIONS FOR USE

℞: 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; it is not a reference to surgical techniques. Prior to use of each system in 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, sepsis, osteoporosis, 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 in order to fully understand the possible 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, preferably in writing, 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 loose fixation and/or 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 stress fractures of the bones, loosening of the construct and/or fixation, instability, delayed soft tissue healing, soft tissue irritation, delayed fusion, non-fusion, or incomplete healing 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 for the device, implant, and associated instruments. Potential failures of the system may include delayed union, non-union, loosening of fixation, migration or failure of the device, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance to post-operative rehabilitation.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union, nonunion, or soft tissue healing. 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 and/or lead to failure or infection, which may result in patient injury.
- 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 A.I.M.ing 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 implant components or 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.
- Accuracy of Depth, Gap and Screw Gauges are within ± 0.25mm.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drill handpieces.
- Seek medical help immediately if 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 screws are placed in the joint.
- To maintain traceability of the system implantable components, record each of the respective components Lot numbers in the patient records post implantation.
- All screws must be implanted and fully tightened to maintain the integrity and strength of the finished construct and the positioning established intraoperatively. 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 penetrating the far cortex of the ulna with K-wires or drills as it may result in 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.
- When drilling into the distal ulna, be sure to avoid drilling into the articular surfaces.
- 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.
- 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: discomfort, or abnormal sensations, damage to nerves, vessels, or soft tissue, infection, edema or swelling, joint contractures, reduced or loss of ROM, bone erosion, bone fracture through bone holes, material sensitivity, intraoperative bone perforation, stiffness, nonunion, persistent pain, stiffness, disassociation, loosening or migration of the implants resulting in mal-alignment. Undesirable shortening or lengthening of limb, dislocation or subluxation due to improper positioning, implant failure, fretting and crevice corrosion may occur at interfaces between components, wear and deformation of the articular surfaces. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur.

MRI Safety Information.

A person with the Ulnar shortening Plating System implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Ulnar Shortening Plating System Implants
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant my produce an image artifact.

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 Surgical Technique Guide(s) 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:
Upon receipt by the user facility, the Ulnar Shortening Plating System should be cleaned prior to sterilization. The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

Implant Cleaning:
Implanted plates, screws, or associated components should never be re-used. After each use, unused implants must be cleaned separately from contaminated instruments to prevent cross-contamination utilizing the cleaning instructions provided below.

⇪Warnings & Precautions:
- If the implant has been in contact with the patient, body fluids or tissues or is damaged, it may NOT be reprocessed and MUST be properly discarded.
- Users should wear appropriate personal protective equipment (PPE).
- Users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.

Instrument Cleaning:
The Ulnar Shortening Plating System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

⇪Warnings & Precautions
- Ulnar Shortening Plating System reusable instruments and accessories, including sterilization tray and tray components, should be decontaminated immediately after completion of the surgical procedure. Contaminated instruments should not be allowed to dry prior to cleaning/reprocessing. Excess blood or debris should be wiped off to prevent it from drying.
- Only qualified personnel with documented evidence of training and competency should clean the instruments. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.
- Avoid the use of metal brushes or scouring pads during the cleaning process.
- Instruments should be rinsed of cleaning agents to prevent residue.
- Do not use mineral oil or silicone lubricants on instruments.
- Neutral pH enzymatic and cleaning agents are recommended for cleaning instruments. It is important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
- Prior to sterilization, instruments should be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear. If the product cannot be cleaned after repeated washing or 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.

<u>Cleaning Instructions</u>
Cleaning should begin at the point of use prior to processing. Keep instruments moist after use to prevent soil from drying on them. An enzymatic detergent (Enzol) was used to validate the cleaning process.
1. Disassemble instrumentation, if applicable.
2. Rinse components thoroughly under running cool tap water. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components.

3. Soak components in a neutral enzymatic cleaner for a minimum of ten (10) minutes. Components must be fully immersed in the cleaner. Follow the cleaner manufacturer's instructions for cleaner preparation and exposure time.
4. Thoroughly rinse the components with cool water. While rinsing, use soft bristle brushes, pipettes or a water jet to clean out lumens, holes, and other challenging features.
5. Manually scrub the components thoroughly in newly made, clean, neutral pH enzymatic cleaner using soft bristle brushes or pipettes. All lumens, holes, hinged components, mating surfaces, and crevices, and challenging components should be thoroughly scrubbed. Actuate all moveable features and expose all areas to cleaner and to the brush or pipette.
   Note: When scrubbing rasps, a stiff bristle brush will be required.
6. Rinse components thoroughly with deionized or purified water; using pipettes or a water jet to clean out lumens, holes, and other hard to reach or challenging features. Actuate all movable features to fully irrigate all areas.
7. Visually inspect components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on the components using deionized water or purified water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Sterilization:
The Skeletal Dynamics Ulnar Shortening Plating System is provided non-sterile. This system is intended for steam sterilization at the healthcare facility.

1. Place all components and accessories into the designated areas of the sterilization tray. Do not stack trays during sterilization.
2. Steam sterilization may be accomplished using one of the cycles shown below:

Cycle Type	Temperature	Duration	Drying Time
Pre-Vacuum Autoclave	270°F (132°C)	4-5 minutes (wrapped)	40 minutes
Pre-Vacuum Autoclave	273°F (134°C)	3-5 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Immediate-Use Steam Sterilization (IUSS) not recommended.
- Usage of an FDA approved wrap is required.
- Subsequent instrument sterilization needs to be performed in the tray system provided. For reuse and sterilization, instruments should be arranged within the tray system in the manner supplied by the company.

Handling and Storage:
When not in use, store the clean and disinfected Ulnar Shortening Plating System within the Sterilization Tray. Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect the instrumentation for serviceability.

Functional Checks should be performed where possible:

1. Mating devices should be checked for proper assembly.
2. Reusable devices with moving parts should be operated to check correct operation (medical grade lubricant suitable for steam sterilization can be applied as required).
3. Rotating instruments (e.g. drill bits, reamers) should be checked for straightness. This can be achieved by rolling the instrument on a flat surface.

Note: The useful life of these devices is dependent on many factors including, but not limited to the method and duration of each use and the handling of the devices between uses. Routine and careful inspection and functional testing of the device is the best method of determining the serviceable life span for the medical device.

Disclaimer of Warranty and Limited Remedies:
Skeletal Dynamics, Inc makes no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the product(s) described in this publication. Skeletal Dynamics, Inc shall not be liable under any circumstances for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has authority to bind Skeletal Dynamics, Inc to any representation or warranty except as specifically set forth in this publication. Descriptions or specifications provided by Skeletal Dynamics, Inc in any publication are only included to generally describe the product when manufactured and do not constitute any express warranties.

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Ulnar Shortening Plating System

Qty. Inventory Control Sheet

Implants[1]			
2	Ulnar Shortening Plate, Distal, Right USP-DRT (01)00841506114415 (01) 00841506114415	2	Ulnar Shortening Plate, Distal, Left USP-DLT (01)00841506114422 (01) 00841506114422
2	Ulnar Shortening Plate, Distal, Short Right USP-DRS (01)00841506116068 (01) 00841506116068	2	Ulnar Shortening Plate, Distal, Short Left USP-DLS (01)00841506116075 (01) 00841506116075
1	Ulnar Shortening Plate, Proximal USP-PRX (01)00841506114439 (01) 00841506114439	1	Ulnar Shortening Plate, Proximal, Long USP-PRXL (01)00841506114446 (01) 00841506114446
Screws[1]			
4	Threaded Peg, Locking, 2.3mm x 10mm. Ti TPLS-23100-TS (01)00841506103358 (01) 00841506103358	4	Threaded Peg, Locking, 2.3mm x 12mm, Ti TPLS-23120-TS (01)00841506103365 (01) 00841506103365
4	Threaded Peg, Locking, 2.3mm x 14mm, Ti TPLS-23140-TS (01)00841506103372 (01) 00841506103372	4	Threaded Peg, Locking, 2.3mm x 16mm, Ti TPLS-23160-TS (01)00841506103389 (01) 00841506103389
4	Threaded Peg, Locking, 2.3mm x 18mm, Ti TPLS-23180-TS (01)00841506103402 (01) 00841506103402	4	Threaded Peg, Locking, 2.3mm x 20mm, Ti TPLS-23200-TS (01)00841506103426 (01) 00841506103426
4	Threaded Peg, Locking, 2.3mm x 22mm, Ti TPLS-23220-TS (01)00841506103440 (01) 00841506103440	4	Threaded Peg, Non-Locking, 2.7mm x 10mm, Ti TPNL-27100-TS (01)00841506103518 (01) 00841506103518
4	Threaded Peg, Non-Locking, 2.7mm x 12mm, Ti TPNL-27120-TS (01)00841506103525 (01) 00841506103525	4	Threaded Peg, Non-Locking, 2.7mm x 14mm, Ti TPNL-27140-TS (01)00841506103532 (01) 00841506103532
4	Threaded Peg, Non-Locking, 2.7mm x 16mm, Ti TPNL-27160-TS (01)00841506103549 (01) 00841506103549	4	Threaded Peg, Non-Locking, 2.7mm x 18mm, Ti TPNL-27180-TS (01)00841506103556 (01) 00841506103556
4	Threaded Peg, Non-Locking, 2.7mm x 20mm, Ti TPNL-27200-TS (01)00841506103563 (01) 00841506103563	4	Threaded Peg, Non-Locking, 2.7mm x 22mm, Ti TPNL-27220-TS (01)00841506103570 (01) 00841506103570

7	Screw, Cortical Non Locking, 3.5mm x 10mm, Ti PANL-35100-TS (01)00841506102795 (01) 00841506102795	7	Screw, Cortical Non Locking, 3.5mm x 12mm, Ti PANL-35120-TS (01)00841506102818 (01) 00841506102818
7	Screw, Cortical Non Locking, 3.5mm x 14mm, Ti PANL-35140-TS (01)00841506102832 (01) 00841506102832	7	Screw, Cortical Non Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856 (01) 00841506102856
7	Screw, Cortical Non Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863 (01) 00841506102863	3	Screw, Cortical Non Locking, 3.5mm x 20mm, Ti PANL-35200-TS (01)00841506104171 (01) 00841506104171
2	Screw, Cortical Non Locking, 3.5mm x 22mm, Ti PANL-35220-TS (01)00841506104188 (01) 00841506104188	7	Screw, Cortical Locking, 3.5mm x 10mm, Ti COLS-35100-TS (01)00841506101095 (01) 00841506101095
7	Screw, Cortical Locking, 3.5mm x 12mm, Ti COLS-35120-TS (01)00841506101118 (01) 00841506101118	7	Screw, Cortical Locking, 3.5mm x 14mm, Ti COLS-35140-TS (01)00841506101132 (01) 00841506101132
7	Screw, Cortical Locking, 3.5mm x 16mm, Ti COLS-35160-TS (01)00841506101156 (01) 00841506101156	7	Screw, Cortical Locking, 3.5mm x 18mm, Ti COLS-35180-TS (01)00841506101163 (01) 00841506101163
2	Screw, Cortical Locking, 3.5mm x 20mm, Ti COLS-35200-TS (01)00841506104034 (01) 00841506104034		
Single Use (Disposable) Instruments[1]			
6	K-Wire, Single Diamond, 1.6mm x 127mm KWIR-SD-16127 (01)00841506116204 (01) 00841506116204	2	Drill, Solid Side Cutting, 2.0mm x 40mm DRLL-SSC-20040 (01)00841506101255 (01) 00841506101255
2	Drill, 2.7mm x 40mm DRLL-SSC-27040 (01) 00841506105932 (01) 00841506105932	1	Drill, 3.5mm x 40mm DRLL-SSC-35040 (01)00841506116198 (01) 00841506116198
2	Driver, Peg, Torque Limiting DRVR-AOS-S20 (01)00841506101293 (01) 00841506101293	0	Driver, Peg DRVR-S20 (01)00841506109152 (01) 00841506109152
2	Driver, Universal Quick Connect, T10 DRVR-UQC-T10 (01)00841506101330 (01) 00841506101330		
Reusable Instruments[2]			
4	AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870 (01) 00841506102870	2	PROTEAN Plate Bending Pliers, Large PRT-BND-PLL (01)00841506109985 (01) 00841506109985

1	Handle, Universal Quick Connect, Fixed HNDL-UQC-FXD (01)00841506102108 (01) 00841506102108	1	Handle, Small QC, Fixed HNDL-SQC-FXD (01)00841506102078 (01) 00841506102078
1	Thread-in Drill Guide, 2.0mm TPDG-THD-DG20 (01)00841506103327 (01) 00841506103327	1	Thread-in Drill Guide, FreeFix, 3.5mm TPDG-FF-35 (01)00841506115757 (01) 00841506115757
1	Depth Gauge, Universal, 30mm DPGA-UNV-030 (01)00841506101194 (01) 00841506101194	1	FreeFix Depth Gauge DPGA-FF-050 (01)00841506115887 (01) 00841506115887
1	Forceps, Bone Holding Medium, Compression, Right FRCP-BHM-COMR (01)00841506117560 (01) 00841506117560	1	Forceps, Bone Holding Medium, Compression, Left FRCP-BHM-COML (01)00841506117577 (01) 00841506117577
1	Forceps, Bone Holding Medium, Ratcheting FRCP-BHM-RTC (01)00841506101354 (01) 00841506101354	1	Drill Guide, FreeFix, Ulnar Shortening TPDG-FF-USP (01)00841506117614 (01) 00841506117614
1	Oblique Compression Hole Guide TPDG-CHG (01)00841506116037 (01) 00841506116037	1	Ulnar Shortening, Cutting Guide, Proximal, Right CUTG-PRX-R (01)00841506116082 (01) 00841506116082
1	Ulnar Shortening, Cutting Guide, Proximal, Left CUTG-PRX-L (01)00841506116099 (01) 00841506116099	1	Ulnar Shortening, Cutting Guide, Oblique, Proximal, Right CUTG-OPRX-R (01)00841506116105 (01) 00841506116105
1	Ulnar Shortening, Cutting Guide, Oblique, Proximal, Left CUTG-OPRX-L (01)00841506116112 (01) 00841506116112	1	Ulnar Shortening, Cutting Guide, Distal, Right CUTG-DIST-R (01)00841506116129 (01) 00841506116129
1	Ulnar Shortening, Cutting Guide, Distal, Left CUTG-DIST-L (01)00841506116136 (01) 00841506116136	0	Ulnar Shortening Plate Bending Irons US-BND (01)00841506116143 (01) 00841506116143
0	Instrument, Mini-Hohmann Retractor, Standard INST-MHR-STD (01)00841506102467 (01) 00841506102467	1	Cottle Osteotome, 2.0mm C-OST-20 (01)00841506116167 (01) 00841506116167
2	Instrument, Hohmann Retractor, Double Ended INST-HR-DBL (01)00841506117690 (01) 00841506117690	0	Driver, Peg, Torque Limiting, Reusable DRVR-AOS-S20R (01) 00841506108834 (01) 00841506108834
0	Driver, Peg, Reusable DRVR-S20R (01)00841506109114 (01) 00841506109114	0	Removal Driver, Peg DRVR-RM-S20 (01)00814506108865 (01) 00841506108865

0	Driver, Universal Quick Connect, T10, Reusable DRVR-T10R (01)00841506108827 (01)00841506108827		

[1] CE 2797

[2] CE