English

Ulnar Shortening Plating System

INSTRUCTIONS FOR USE (IFU) FOR THE UNITED KINGDOM AND THE EUROPEAN UNION

To ensure use of the most up-to-date revision, refer to www.skeletaldynamics.com/resources/

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

This package insert is designed to provide Instructions for Use of the Ulnar Shortening Plating System. Prior to use of each system in the Ulnar Shortening Plating System, the surgeon should become familiar with all information contained in this pamphlet. **Failure to follow instructions may lead to patient injury.**

Description

The Skeletal Dynamics Ulnar Shortening Plating System contains titanium alloy implantable medical devices available in multiple sizes and configurations.

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

1. Distal Ulnar Shortening Plates (available in left and right orientations)
2. Proximal Ulnar Shortening Plates
3. Screws, K-Wires, and specialized instrumentation

The system is provided non-sterile and is sterilized in the user facility.

Intended Use

The Ulnar Shortening Plating System is intended for stabilization and fixation of bone fragments.

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 Ulnar Shortening Plating 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 postoperative care instructions. The system should not be used in pediatric patients or patients with open growth plates.

Intended Patient Population

The Ulnar Shortening Plating System is intended for skeletally mature patients. The system should not be used in pediatric patients or patients with open growth plates.

Intended User

The Ulnar Shortening Plating System should only be used by surgeons familiar with this system and by facility processing staff trained to handle, clean, and re-sterilize surgical devices. Each surgeon must evaluate the appropriateness of using the Ulnar Shortening Plating System based on their clinical experience.

Expected Clinical Benefits

The expected clinical benefits of internal fixation devices of the Ulnar Shortening Plating System, when used according to the instructions for use and the recommended technique, are the achievement of stabilization of bones and bone fragments to support bone consolidation.

A summary of safety and clinical performance (IFU-02218-32) can be found at the following link: http://ec.europa.eu/tools/eudamed

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Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched. The summary of safety and clinical performance is available upon request. Please refer to the resources section for further information.

Performance Characteristics of the Device

Skeletal Dynamics has established the performance and safety of the Ulnar Shortening Plating System and that the system represents state-of-the-art medical devices intended for the treatment of fractures and osteotomies of the ulna.

Device Lifetime

The expected functional lifetime of the Ulnar Shortening Plating is dependent on bone union. Based on state-of-the-art data, bone union typically occurs within 3-6 months for 97% of cases. The post-therapeutic lifetime of the implant is the remaining lifetime of the patient following bone consolidation. Patient factors such as weight, bone quality, activity level, and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

⚠ 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, 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.
- 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 with 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.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive 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.
- The 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 with pacemakers during electrocautery or by uncertified drill power sources.

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- 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.
- 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 plating system failure 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.
- 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 is completed.
- Protect soft tissue while cutting with the oscillating saw using the Hohman Retractors that are provided in the set.



⚠ **MR Safety Information**

A person with the Skeletal Dynamics' Upper Extremity Systems may be safely scanned at 1.5 T or 3 T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Skeletal Dynamics' Upper Extremity Systems
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m (1,900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	**1.5 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 6.1$ µT) for up to one hour - Lower leg region: Normal Operating Mode for up to one hour **3 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 3.1$ µT) for 6 minutes of scanning, followed by a minimum cooling period of 15 minutes, up to a maximum total scanning/cooling duration of one hour - Lower leg region: Normal Operating Mode for up to one hour
Scan duration	Scan duration as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Scan Regions	Landmark restrictions as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Image Artifact	The presence of Skeletal Dynamics' Upper Extremity Systems may produce an image artifact of 5.1 cm. Some manipulation of scan parameters may be needed to compensate for the artifact
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

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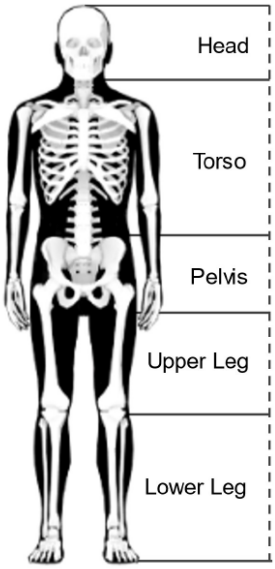
MR Restricted Zone Summary

Skeletal Dynamics' Upper Extremity Systems



Landmark Region	1.5 T Scan Restriction	3 T Scan Restriction
Head	Normal Operating Mode*	Normal Operating Mode*
Torso	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 6.1$ µT	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 3.1$ µT for 6 minutes of scanning followed by a minimum cooling period of 15 minutes
Pelvis		
Upper Leg		
Lower Leg	Normal Operating Mode*	Normal Operating Mode*

Under these conditions, total scanning duration for up to one hour is permitted unless otherwise specified. When a cooling period is recommended, repeated scan/cool sequences are permitted for a total duration of up to one hour. Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
SAR_{wb}: Whole body averaged specific absorption rate
SAR_{head}: Head averaged specific absorption rate
$B_{1+,RMS}$: RMS RF magnetic field (B_{1+})

**Normal Operating Mode limits defined by IEC 60601-2-33 Table 201.104:*
- *SAR_{wb}: 2 W/kg*
- *SAR_{head}: 3.2 W/kg*

Potential Adverse Events

The following are potential risks that have been associated with surgery: discomfort, nerve/bone/soft tissue damage, infection, swelling, reduced or loss of range of motion, bone fracture, material sensitivity, stiffness, nonunion, persistent pain, loosening/migration/breakage of the implants, undesirable shortening or lengthening of the limb, implant failure, or damage to the articular surfaces. Serious incidents should be reported to Skeletal Dynamics Inc. or an in-country representative and to the health authority where the incident occurred.

Directions for Use

The system should be used only by surgeons familiar with it. Each surgeon must evaluate the appropriateness of using the system based on their clinical experience.

The surgeon should select the type and size of 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 surgeon's responsibility to be familiar with the procedure before using this device. Additionally, it is the surgeon's responsibility to be familiar with relevant publications on the procedure prior to use. Please refer to the *FreeFix Ulnar Shortening System Surgical Technique* (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.

You must maintain traceability of the implantable components of the Ulnar Shortening Plating System. Please record each component's LOT number in the patient's medical records post-implantation.

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Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of Ulnar Shortening Plating System products are provided in the Reprocessing IFU, **Instructions for Reprocessing (Cleaning, Disinfection, and Sterilization) of Skeletal Dynamics Products** (IFU-04056-00), available at www.skeletaldynamics.com/resources. 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 or Summary of Safety and Clinical Performance 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 the user's request, or at the time of device delivery if 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

Implant Materials

Basic UDI Codes	Basic UDI #s	System Components	Material(s)	Standard(s)
USP-FAM-TI	0841506143886S	Ulnar Shortening Plates	Ti 6Al-4V ELI	ASTM F136
SCW-FAM-TI	08415061423866	Locking Threaded Pegs Non-Locking Threaded Pegs Non-Locking Cortical Screws Cortical Locking Screws	Ti 6Al-4V ELI	ASTM F136

The Titanium implants conform to ASTM F136, which provides the following tolerances for the material:

ASTM F136 Chemical Composition

Element	Composition % (mass)
Nitrogen, Ni	≤ .05%
Carbon	≤ .08%
Hydrogen	≤ .015%
Iron	≤ .25%
Oxygen	≤ .13%
Aluminum	≤ 6.5%
Vanadium	≤ 4.5%
Titanium	balance*

*The percentage of Titanium is determined by the difference and is not determined or certified.

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Ulnar Shortening Plating System

Inventory Control Sheet

Implants[1]	
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	
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
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

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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	
Single Use (Disposable) Instruments[1]	
K-Wire, Single Diamond, 1.6mm x 127mm KWIR-SD-16127 (01)00841506116204 (01) 00841506116204	

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