English

Skeletal Dynamics FreeFix® Forearm Plating System

INSTRUCTIONS FOR USE

℞: For use by physicians only. Federal Law restricts this device to sale by or on 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 Forearm Plating System; it is not a reference to surgical techniques.

Description

The Skeletal Dynamics FreeFix® Forearm Plating System consists of the following implants made from a medical-grade titanium alloy (ASTM F-136). The FreeFix® Forearm Plates are available in a range of lengths for the radius and for the ulna.

The FreeFix® Forearm Plating System is comprised of:

- Titanium alloy plates and screws
- Stainless steel K-Wires (for provisional fixation; not for implantation)
- System-specific instrumentation

The FreeFix® Forearm Plating System includes instrumentation identified in the system's surgical techniques. Both the FreeFix® Forearm Plating System implants and instrumentation are provided non-sterile and must be sterilized in the user facility.

Intended Use

The FreeFix® Forearm Plating System is intended for fixation, correction and stabilization of bones or bone fragments

Intended Patient Population

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

Indications for Use

The FreeFix® Forearm Plating System is indicated for the treatment of fractures, fusions, and osteotomies of the radius and ulna.

Contraindications

Prior to using the FreeFix® Forearm Plating System, ensure that none of the following patient conditions are present: active or latent infection, sepsis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity, or patients who are unwilling or incapable of following postoperative care instructions.

⚠ 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 implants 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 application of the device during implantation may also increase the possibility of loosening, or migration.
- DO NOT reuse any of the Set 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 Set's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the Set, 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.
- 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 peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- All screws must be implanted and fully tightened into the plate to maintain the integrity and strength of the finished construct. If the screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- 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.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- 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 implantable components, record each of the respective components Lot numbers in the patient records post implantation.
- The set is to be used only with Skeletal Dynamics instruments, implants and accessories.

Potential Adverse Effects

Possible adverse effects associated with FreeFix® Forearm Plating System implants are: infection, nonunion, persistent pain, stiffness, implant failure/break/deformation, loosening or migration of the implants resulting in misalignment.

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MR Safety Information
A person with the FreeFix® Forearm Plating System implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	FreeFix® Forearm Plating System Implants
Static Magnetic Field Strength (B0)	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 FreeFix® Forearm Plating System should only be used by surgeons who have experience with this system being used. Each surgeon must evaluate the appropriateness for the use of the FreeFix® Forearm Plating System based on their clinical experiences.

Please refer to the *FREEFIX® Forearm Plating System Surgical Technique Guide* (MKT-00253-00)) 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, USA.

Implant Removal
In case the physician decides to remove the implants, implants can be removed by using general surgical instruments.

Disposal
Any Skeletal Dynamics implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Cleaning, Sterilization, and Inspection
Instructions for cleaning, disinfection, sterilization, and inspection of GEMINUS ® Volar Distal Radius 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® Forearm Plating System Surgical Technique Guide*** (MKT-00253-00) for proper kitted tray arrangement.

Expected Clinical Benefits
The expected clinical benefits of internal fixation devices of the FreeFix® Forearm Plating System, when used according to instructions for use and recommended technique is stabilization of bones and bone fragments to support bone consolidation.

A summary of safety and clinical performance (IFU-3500-32) 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.

Performance Characteristics of the Device
Skeletal Dynamics has established the performance and safety of FreeFix® Forearm Plating System and that they represent state of the art medical devices intended for the treatment of fractures, fusions, and osteotomies of the radius and ulna. Refer to section Inventory Control Sheet in scope of this IFU for device characteristics such as available lengths and diameters of the subject devices.

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 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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Inventory Control Sheet

Qty.	Midshaft Radius Plate	Qty.	Midshaft Ulna Plate
1	FreeFix® Midshaft Radius Plate, 81mm MRP-081 (01)00841506114576	1	FreeFix® Midshaft Ulna Plate, 81mm MUP-081 (01)00841506115351
1	FreeFix® Midshaft Radius Plate, 97mm MRP-097 (01)00841506112992	1	FreeFix® Midshaft Ulna Plate, 97mm MUP-097 (01)00841506115368
1	FreeFix® Midshaft Radius Plate, 127mm MRP-127 (01)00841506113005	1	FreeFix® Midshaft Ulna Plate, 127mm MUP-127 (01)00841506115382
1	FreeFix® Midshaft Radius Plate, 142mm MRP-142 (01)00841506114590	1	FreeFix® Midshaft Ulna Plate, 142mm MUP-142 (01)00841506113036
1	FreeFix® Midshaft Radius Plate, 173mm MRP-173 (01)00841506115733	1	FreeFix® Midshaft Ulna Plate, 173mm MUP-173 (01)00841506115405
1	FreeFix® Midshaft Radius Plate, 188mm MRP-188 (01)00841506115740	1	FreeFix® Midshaft Ulna Plate, 188mm MUP-188 (01)00841506115412
Qty.	**Cortical Screw, Non-Locking**	**Qty.**	**Cortical Screw, Locking**
2	Screw, Cortical Non-Locking, 3.5mm x 8mm, Ti PANL-35080-TS (01)00841506102771	2	Screw, Cortical, Locking, 3.5mm x 8mm, Ti COLS-35080-TS (01)00841506101071
2	Screw, Cortical Non-Locking, 3.5mm x 9mm, Ti PANL-35090-TS (01)00841506102788	2	Screw, Cortical, Locking, 3.5mm x 9mm, Ti COLS-35090-TS (01)00841506101088
2	Screw, Cortical Non-Locking, 3.5mm x 10mm, Ti PANL-35100-TS (01)00841506102795	2	Screw, Cortical, Locking, 3.5mm x 10mm, Ti COLS-35100-TS (01)00841506101095
6	Screw, Cortical Non-Locking, 3.5mm x 11mm, Ti PANL-35110-TS (01)00841506102801	6	Screw, Cortical, Locking, 3.5mm x 11mm, Ti COLS-35110-TS (01)00841506101101
6	Screw, Cortical Non-Locking, 3.5mm x 12mm, Ti PANL-35120-TS (01)00841506102818	6	Screw, Cortical, Locking, 3.5mm x 12mm, Ti COLS-35120-TS (01)00841506101118
6	Screw, Cortical Non-Locking, 3.5mm x 13mm, Ti PANL-35130-TS (01)00841506102825	6	Screw, Cortical, Locking, 3.5mm x 13mm, Ti COLS-35130-TS (01)00841506101125

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6	Screw, Cortical Non-Locking, 3.5mm x 14mm, Ti PANL-35140-TS (01)00841506102832	6	Screw, Cortical, Locking, 3.5mm x 14mm, Ti COLS-35140-TS (01)00841506101132
6	Screw, Cortical Non-Locking, 3.5mm x 15mm, Ti PANL-35150-TS (01)00841506102849	6	Screw, Cortical, Locking, 3.5mm x 15mm, Ti COLS-35150-TS (01)00841506101149
6	Screw, Cortical Non-Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856	6	Screw, Cortical, Locking, 3.5mm x 16mm, Ti COLS-35160-TS (01)00841506101156
6	Screw, Cortical Non-Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863	6	Screw, Cortical, Locking, 3.5mm x 18mm, Ti COLS-35180-TS (01)00841506101163
6	Screw, Cortical Non-Locking, 3.5mm x 20mm, Ti PANL-35200-TS (01)00841506104171	6	Screw, Cortical, Locking, 3.5mm x 20mm, Ti COLS-35200-TS (01)00841506104034
6	Screw, Cortical Non-Locking, 3.5mm x 22mm, Ti PANL-35220-TS (01)00841506104188	4	Screw, Cortical, Locking, 3.5mm x 22mm, Ti COLS-35220-TS (01)00841506104041
4	Screw, Cortical Non-Locking, 3.5mm x 24mm, Ti PANL-35240-TS (01)00841506104195	2	Screw, Cortical, Locking, 3.5mm x 24mm, Ti COLS-35240-TS (01)00841506104058
3	Screw, Cortical Non-Locking, 3.5mm x 26mm, Ti PANL-35260-TS (01)00841506104201	2	Screw, Cortical, Locking, 3.5mm x 26mm, Ti COLS-35260-TS (01)00841506104065
2	Screw, Cortical Non-Locking, 3.5mm x 28mm, Ti PANL-35280-TS (01)00841506104218	2	Screw, Cortical, Locking, 3.5mm x 28mm, Ti COLS-35280-TS (01)00841506104072
General Single Use (Disposable) Instruments			
4	K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504		
General Reusable Instruments			
2	Driver, Universal QC, T10, Reusable DRVR-T10R (01)00841506108827	2	Drill, 2.5mm x 50mm, Reusable DRLL-25050R (01)00841506129525
2	Drill, 2.7mm x 50mm, Reusable DRLL-27050R (01)00841506129518	1	Countersink, 5.6mm, Reusable DRLL-CSK-56R (01)00841506129501

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2	Drill, 3.5mm x 70mm, Reusable DRLL-35070R (01)00841506115719 (01)00841506115719	1	Tissue Protector/Drill Guide, Dual Sided, 2.7mm X 3.5mm TPDG-DSD-2735 (01)00841506117270 (01)00841506117270
1	Handle, Universal Quick Connect, Fixed HNDL-UQC-FXD (01)00841506102108 (01)00841506102108	1	Drill Guide, FreeFix®, 2.7mm TPDG-FF-27ML (01)00841506112732 (01)00841506112732
1	Thread-in Drill Guide, FreeFix® ,3.5mm TPDG-FF-35 (01)00841506115757 (01)00841506115757	1	Bone Holding Forceps FRCP-BHM-LRT (01)00841506109978 (01)00841506109978
1	Depth Gauge, FreeFix® , 50mm DPGA-FF-050 (01)00841506115887 (01)00841506115887	2	Universal Bending Irons, 3.5mm UNV-BND-35 (01)00841506110011 (01)00841506110011
2	Bone Clamp, 135cm OAL, Curved, With Speed Lock CLMP-FRG-135 (01)00841506117140 (01)00841506117140	4	Thread-in Drill Guide, FreeFix®, 1.6mm K-wire TPDG-FF-KW16 (01)00841506117317 (01)00841506117317
Optional			
	Handle, Universal QC, Ratcheting HNDL-UQC-RTC (01)00841506106533 (01)00841506106533		

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