

Dorsal Spanning Plate System

INSTRUCTIONS FOR USE FOR THE UNITED KINGDOM AND THE EUROPEAN UNION

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

R: For use by physicians only. 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 Dorsal Spanning Plate System.

Failure to follow instructions may lead to patient injury.

Description

The Skeletal Dynamics Dorsal Spanning Plate System contains bone plates for the repair of distal radius fractures and wrist arthrodesis. Included in the set are titanium bone screws, plates, and specialized instrumentation.

The plates are available in two sizes and are made of medical-grade titanium alloy. Cortical screws affix the plate to the diaphysis of the bone. The system is provided non-sterile and is sterilized in the user facility.

The Dorsal Spanning Plate System is comprised of:

- Titanium alloy plates and screws (Titanium per ASTM F136)
- System-specific instrumentation

Intended Use

The Dorsal Spanning Plate System is intended for fixation, correction, and stabilization of bones or bone fragments.

Indications

The Dorsal Spanning Plate System is intended for the fixation of fractures involving the distal radius and for wrist arthrodesis.

Contraindications

Prior to using the Dorsal Spanning Plate 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.

Intended Patient Population

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

Expected Clinical Benefits

The expected clinical benefit of internal fixation devices of the Dorsal Spanning Plate System, when used according to instructions for use and recommended surgical technique, is the achievement of stabilization of bones and bone fragments to support bone consolidation.

A summary of safety and clinical performance (IFU-01308-32) can be found at the following link:
<http://ec.europa.eu/tools/eudamed>

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 Dorsal Spanning Plate System, and that the system represents state-of-the-art medical devices intended for the treatment of distal radius fractures and wrist arthrodesis. Refer to the section Inventory Control Sheet in the scope of this IFU for device characteristics such as available lengths and diameters of the subject devices.

Device Lifetime

The expected functional lifetime of the Dorsal Spanning Plate System is dependent on bone union. Based on state-of-the-art data, bone union typically occurs within 2-4 months in 99% of cases. Afterward, the plate can be removed for distal radius fractures or kept implanted for wrist arthrodesis. 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.

⚠ Warnings & Precautions

- If the screws are not attached and/or fully tightened, a non-union, delayed union, or construct failure may occur.
- The information in this document should be shared with the patient.
- The patient must be cautioned about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, malunion, 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, the presence of the device, or the failure to remove the device after fracture healing.
- 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.
- Potential construct failures such as implant breakage, loosening, delayed union, or non-union may occur as a result of non-compliance with post-operative rehabilitation, excessive wrist activities, or construct overloading.
- 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 implantable components. Reuse may compromise the structural integrity of the construct.
- If used for fracture fixation, the plate must be removed after fracture healing.
- 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 use screw lengths that will excessively protrude through the far cortex, as it may result in soft tissue irritation.
- DO NOT mix system-specific instrumentation from different 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.
- To maintain traceability of the implantable components, you must record each component's LOT number in the patient records post-implantation.
- Care should be taken to ensure that no implants are placed interfering with the articular surface.

Potential Adverse Events

Possible adverse effects associated with wrist surgery include infection, non-union, pain, stiffness, discomfort, or abnormal sensations, heterotopic ossification, and nerve/bone/ soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break or loosen due to excessive activity, prolonged loading, incomplete healing, or excessive force during insertion. Metal sensitivity, histological, allergic, or adverse foreign-body reactions resulting from implantation of a foreign material may occur. Serious incidents should be reported to Skeletal Dynamics Inc., or an in-country representative, and to the health authority where the incident occurred.



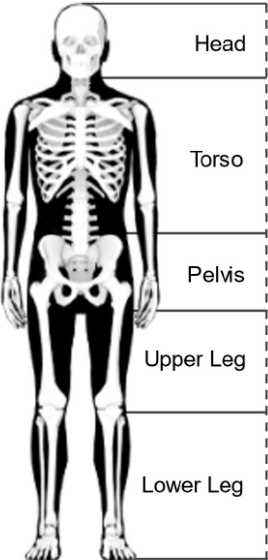
△ MR Safety Information.

A person with the Dorsal Spanning Plate implant may be safely scanned 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
B_0 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 following 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 Operating Mode section above and in the MR Restricted Zone Summary
Scan Regions	Landmark restrictions as detailed in 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.

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	$SAR_{wb} \leq 1.0 \text{ W/kg}$ OR $B_{1+,RMS} \leq 6.1 \mu T$	$SAR_{wb} \leq 1.0 \text{ W/kg}$ OR $B_{1+,RMS} \leq 3.1 \mu T$ 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

Directions for Use

The Dorsal Spanning Plate System should be used only by surgeons familiar with this system. 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 system's *Geminus Distal Volar System Surgical Technique Guide* (MKT-00005-00) 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. Contact Customer Service (877-753-5396) or your sales representative to obtain a copy of the Guide.

Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of Dorsal Spanning Plate 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 ***GEMINUS® Volar Distal Radius Plating System Surgical Technique Guide*** (MKT-00005-00) for proper kitted tray arrangement.

Resources

The latest version of the Instructions for Use or the 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.

Materials

Basic UDI Code	Basic UDI #s	System Components	Material(s)	Standard(s)
DSP-FAM-TI	0841506142796L	Dorsal Spanning Plates	Ti 6Al-4V ELI	ASTM F136
SCW-FAM-TI	08415061423866	Locking Multi-Thread Screws Compression Multi-Thread 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*

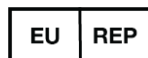
*The percentage of Titanium is determined by the difference and is not determined or certified.

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Geminus®

Dorsal Spanning Plate Inventory Control Sheet

Dorsal Spanning Plates (Ti)	
Dorsal Spanning Plate, Long, Ti GMN-DSP-210 (01)00841506101453  (01) 00841506101453	Dorsal Spanning Plate, Short, Ti GMN-DSP-160 (01)00841506105307  (01) 00841506105307
3.0 mm Screws, Multi-Thread Locking	3.0 mm Screws, Multi-Thread Compression
Screw, Multi-Thread, Locking, 3.0mm x 6mm MTLS-30060-TS (01)00841506102511  (01) 00841506102511	Screw, Multi-Thread, Compression, 3.0mm x 6mm MTNL-30060-TS (01)00841506102580  (01) 00841506102580
Screw, Multi-Thread, Locking, 3.0mm x 8mm MTLS-30080-TS (01)00841506102528  (01) 00841506102528	Screw, Multi-Thread, Compression, 3.0mm x 8mm MTNL-30080-TS (01)00841506102597  (01) 00841506102597
Screw, Multi-Thread, Locking, 3.0mm x 10mm MTLS-30100-TS (01)00841506102535  (01) 00841506102535	Screw, Multi-Thread, Compression, 3.0mm x 10mm MTNL-30100-TS (01)00841506102603  (01) 00841506102603
Screw, Multi-Thread, Locking, 3.0mm x 12mm MTLS-30120-TS (01)00841506102542  (01) 00841506102542	Screw, Multi-Thread, Compression, 3.0mm x 12mm MTNL-30120-TS (01)00841506102610  (01) 00841506102610
Screw, Multi-Thread, Locking, 3.0mm x 14mm MTLS-30140-TS (01)00841506102559  (01) 00841506102559	Screw, Multi-Thread, Compression, 3.0mm x 14mm MTNL-30140-TS (01)00841506102627  (01) 00841506102627
Screw, Multi-Thread, Locking, 3.0mm x 16mm MTLS-30160-TS (01)00841506102566  (01) 00841506102566	Screw, Multi-Thread, Compression, 3.0mm x 16mm MTNL-30160-TS (01)00841506102634  (01) 00841506102634
Screw, Multi-Thread, Locking, 3.0mm x 18mm MTLS-30180-TS (01)00841506102573  (01) 00841506102573	Screw, Multi-Thread, Compression, 3.0mm x 18mm MTNL-30180-TS (01)00841506102641  (01) 00841506102641