English

Dorsal Spanning Plate System

INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

℞: For use by physicians only. 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 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 made of medical grade titanium alloy. Cortical screws affix the plate to thediaphysis 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
- System specific instrumentation

Indications

The Skeletal Dynamics Dorsal Spanning Plate System is intended for the fixation of fractures involving the distal radius andfor 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 post operative care instructions.

⚠ Warnings & Precautions

- If the screws are not attached and/or fully tightened, a non-union, delayed union or construct failure mayoccur.
- 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, 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 to post-operative rehabilitation, excessive wrist activities or construct overloading.

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- 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 theconstruct.
- 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 toimplant failure.
- Before using the system, inspect all implants and instruments for wear, disfiguration and physical damage. Ifevidence 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 tissueirritation.
- 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 implant malfunctions.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiringrevision surgery to replace the implant or to carry out alternative procedures. To maintain traceability of the implantable components, you must record each of the respective components LOT numbers into 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 abnormalsensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may breakdue to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant, due to surgical trauma, or from failure to remove the plate after fracture healing.

MR Safety Information

The Dorsal Spanning Plate 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 Dorsal Spanning Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Directions for Use

The Dorsal Spanning Plate 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 medicalintermediary between the company and the patient, this document contains important medical information provided in this document should be shared to the patient.

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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 system's Geminus Distal Radius 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

For instructions on cleaning, disinfection, sterilization and inspection of the Dorsal Spanning Plate System products please refer to cleaning and sterilization instructions for use (IFU-04056-00). Refer to the Geminus Distal Radius Surgical Technique Guide (MKT-00005-00) for proper kitting of tray.

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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Skeletal Dynamics, Inc
7300 N. Kendall Dr. / Suite 800
Miami, FL 33156
Unites States of America
1-877-753-5396

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
	5.2.6 Do not resterilize	Indicates a medical device that is not to be resterilized
	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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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

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