English

Dorsal Spanning Plate System

INSTRUCTIONS FOR USE

℞: 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; it is not a reference to surgical techniques.

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 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
- System specific instrumentation

Indications:
The Skeletal Dynamics 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, 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.

⚠ Warnings:
- 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.
- The information in this document should be shared with the patient.
- 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, 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 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.
- Potential construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, delayed fusion, non-fusion, or incomplete healing may occur as a result of non-compliance to post-operative rehabilitation, excessive wrist activities or construct overloading.
- 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 or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- The components of these systems have not been evaluated for safety and compatibility in the MR environment; nor have they been tested for heating or migration in the MR environment.

IFU-01308-07RAH – June 2022

- DO NOT reuse any of the implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.
- If used for fracture fixation, the plate must be removed after fracture healing.

⚠ Precautions:

- 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 implant components from different manufacturers for metallurgical, biomechanical and functional reasons. The system is to be used only with Skeletal Dynamics instruments, implants and accessories.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth and Screw Gauges are within $\pm$ 1.0mm.
- 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. 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 screws are placed in the joint.

Potential Adverse Events:

Possible adverse effects associated with wrist surgery include infection, non-union, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due 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.

⚠ **MRI 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.

Device Name	Dorsal Spanning Plate 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 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 medical intermediary between the company and the patient, this document contains important medical information provided in this document should be shared to 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 system's Surgical Technique Guide 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:
Upon receipt by the user facility, the Dorsal Spanning Plate 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 Dorsal Spanning Plate System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

⚠ Warnings & Precautions
- System instruments and accessories 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, 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.

Cleaning Instructions

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.

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.

Sterilization:

The Skeletal Dynamics Dorsal Spanning Plate 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
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 Dorsal Spanning Plate System within the GEMINUS Volar Distal Radius Plating System Sterilization Tray. Prior to use, inspect the instrumentation for serviceability.

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.

Dorsal Spanning Plate System Ordering Information: GMN-DSP-SYS

Catalog #	Description
GMN-DSP-SYS	Dorsal Spanning Plate System
GMN-DSP-210	Dorsal Spanning Plate, Long, Ti
GMN-DSP-160	Dorsal Spanning Plate, Short, Ti
MTLS-30060-TS	Screw, Multi-Thread, Locking, 3.0mm x 6mm, Ti
MTLS-30080-TS	Screw, Multi-Thread, Locking, 3.0mm x 8mm, Ti
MTLS-30100-TS	Screw, Multi-Thread, Locking, 3.0mm x 10mm, Ti
MTLS-30120-TS	Screw, Multi-Thread, Locking, 3.0mm x 12mm, Ti
MTLS-30140-TS	Screw, Multi-Thread, Locking, 3.0mm x 14mm, Ti
MTLS-30160-TS	Screw, Multi-Thread, Locking, 3.0mm x 16mm, Ti
MTLS-30180-TS	Screw, Multi-Thread, Locking, 3.0mm x 18mm, Ti
MTNL-30060-TS	Screw, Multi-Thread, Compression, 3.0mm x 6mm, Ti
MTNL-30080-TS	Screw, Multi-Thread, Compression, 3.0mm x 8mm, Ti
MTNL-30100-TS	Screw, Multi-Thread, Compression, 3.0mm x 10mm, Ti
MTNL-30120-TS	Screw, Multi-Thread, Compression, 3.0mm x 12mm, Ti
MTNL-30140-TS	Screw, Multi-Thread, Compression, 3.0mm x 14mm, Ti
MTNL-30160-TS	Screw, Multi-Thread, Compression, 3.0mm x 16mm, Ti
MTNL-30180-TS	Screw, Multi-Thread, Compression, 3.0mm x 18mm, Ti
DRLL-SSC-23040	Drill, 2.3mm x 40mm
TPDG-THD-DG23	Thread-in Drill Guide, 2.3mm
GMN-DSP-HNDL	Assembled, Handle, Dorsal Spanning Plate
IFU-01308-00	Dorsal Spanning Plate System, IFU
GMN-DSP-TRAY	Sterilization Tray, Dorsal Spanning Plate

Skeletal Dynamics, Inc.
Customer Care Center:
7300 N. Kendall Dr. / Suite 400
United States of America, Miami, FL 33156
1-877-753-5396

EC REP **Emergo Europe,**
Prinsessegracht 20
2514 AP, The Hague,
The Netherlands

MD

GEMINUS®

Dorsal Spanning Plate
Inventory Control Sheets

Dorsal Spanning Plates (Ti)[i]	
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, Locking[i]		3.0 mm Screws, Non-Locking[i]	
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

Single Use (Disposable) Instruments[i]	
Drill, 2.3mm x 40mm DRLL-SSC-23040 (01)00841506101262	(01) 00841506101262

Reusable Instruments [ii]			
Thread-in Drill Guide, 2.3mm TPDG-THD-DG23 (01)00841506103334	(01) 00841506103334	Handle, Universal QC, Fixed HNDL-UQC-FXD (01)00841506102108	(01) 00841506102108
Assembled, Handle, Dorsal Spanning Plate GMN-DSP-HNDL (01)00841506101460	(01) 00841506101460	Driver, Universal Quick Connect, T10 DRVR-UQC-T10 (01)00841506101330	(01) 00841506101330
Depth Gauge, Sm. Standard, 30mm DPGA-SMS-030 (01)00841506101187	(01) 00841506101187		
DSP Tray[ii]			
GEMINUS Dorsal Spanning Plate Module GMN-DSP-MOD (01)00841506100487	(01) 00841506100487	GEMINUS Sterilization Tray GMN-FSP-TRAY (01)00841506100401	(01) 00841506100401

CE 2797

[i]

CE

[ii]