English

GEMINUS® Volar Distal Radius Plating System
INSTRUCTIONS FOR USE

℞: For use by physicians only. Federal Law (USA) 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 GEMINUS® Volar Plating System; it is not a reference to surgical techniques.

Description:

The Skeletal Dynamics GEMINUS® Volar Plating System contains bone plates for the repair of distal volar radial fractures. Included in the set are titanium bone screws, fixation pegs, fragment plates, and specialized instrumentation. Also included are a Hook Plate Extension to buttress a volar marginal fragment, and cannulated cobalt chrome polyaxial locking screws for trajectories different than those of the fixed angled bone plates.

The GEMINUS® Volar Plates are available in various sizes and are made of medical grade titanium alloy. Cortical screws affix the plate to the diaphysis and fixed angle pegs are used for distal bone fragments. The system is provided non- sterile and is sterilized in the user facility.

The GEMINUS® Volar Plating System is comprised of:

- Titanium alloy plates, washers and screws
- CoCr Cannulated Polyaxial Locking Screw (PLS)
- Stainless steel K-wires (for provisional fixation; not for implantation)
- System specific instrumentation

Indications:

The GEMINUS® Volar Plating System is intended for the fixation of fractures and osteotomies involving the distal radius.

Contraindications:

Prior to using the GEMINUS® Volar 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.

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⚠ 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 use of power tools for the installation of the screws and pegs is not recommended and may lead to cross treading and damage to the screws and/or plates.
- 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.
- Potential GEMINUS® Volar Plating System 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 postoperative rehabilitation, excessive wrist activities or construct overloading.
- DO NOT reuse any of the GEMINUS® Volar Plating System implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.
- DO NOT open the volar capsule as it may devascularize fracture fragments and destabilize the volar wrist ligaments.
- Use only one 2.7mm Peg (High Compression or Fully Threaded, Non Locking) in each head of the GEMINUS® Volar Plate.
- Use only one 2.5mm PLS in each head of the GEMINUS® Volar Plate.
- DO NOT use the PLS in the most distal hole(s) on the lunate head of the GEMINUS® Volar Plate.
- GEMINUS® Drill Blocks are only compatible with GEMINUS® Volar Plates containing a Gold PDG in the shaft.

⚠ Precautions:

- Protect the GEMINUS® Volar Plating System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the GEMINUS® Volar Plating 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.
- Assure Peg Driver tip does not show any signs of wear or distress such as rounded square edges, excessive depth marks from peg recess insertion, or deformed twisted tip. If such evidence is found for Peg Driver, DO NOT USE and contact your local Skeletal Dynamics representative or the Skeletal Dynamics Customer Care Department for replacement.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are intended to be used during provisional fixation of the GEMINUS® Volar Plate.
- DO NOT permanently implant the pre-loaded Drill Guides, Drill Blocks, or A.I.M.ing Guides; they are intended to be removed prior to peg insertion.
- DO NOT use peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- The maximum angulation of the PLS should not exceed 10° from the trajectory of the respective hole.
- The Non-locking Threaded Pegs are NOT intended to provide subchondral support. Their use should be limited to capture remote bone fragments where partially or fully threaded pegs cannot be used.
- The Skeletal Dynamics GEMINUS® Volar Plating 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, Gap and Screw Gauges are within ± 0.25mm.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.
- To maintain traceability of the GEMINUS® Volar Plating System implantable components, you must record each of the respective components LOT numbers into the patient medical records post implantation.

Potential Adverse Events:

The following are potential risks that have been associated with wrist surgery: infection, nonunion, persistent pain, stiffness of the fingers, loosening or migration of the implants resulting in misalignment.

⚠ MRI Safety Information.

The GEMINUS® Volar Plating System has not been evaluated for safety and compatibility in the MR environment. It has

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not been tested for heating, migration, or image artifact in the MR environment. The safety of the GEMINUS® Volar Plating System in the MR environment is unknown. Scanning a patient who has this device implanted may result in patient injury.

Directions for Use:

The GEMINUS® Volar Plating System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the GEMINUS® Volar Plating System based on their clinical experiences.

Please refer to the GEMINUS® Volar Plating 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, USA.

Cleaning

Upon receipt by the user facility, the GEMINUS® Volar Plating 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, threaded nails, 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 GEMINUS® Volar Plating System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- The System's reusable instruments and accessories, including sterilization tray and tray components, 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, and 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 all components, including instruments, sterilization tray and tray 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 all 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 whenever longer exposure times are recommended.
4. Thoroughly rinse all 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 all 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.
6. Rinse all components thoroughly under reverse osmosis/deionized (RO/DI) 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 all components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on all components using running RO/DI 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 GEMINUS® Volar Plating 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 Times for Dynamic-Air-Removal (Vacuum) Steam Sterilization Cycles

Item	Exposure time at 132°C (270° F)	Minimum Drying Times
Wrapped Sterilization Tray	4 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to the requirements of ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Usage of an FDA cleared 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 GEMINUS Volar Plating System within the 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

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

EC REP

Emergo Europe,
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

MD

CE
2797

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GEMINUS® Volar Plating System Ordering Information: GMN-FSP-SYS

Catalog #	Nomenclature
Volar Distal Radius Plates (Ti)	
GMN-RTN-3HL	GEMINUS Volar Distal Radius Plate, Narrow, 3 Hole, Right
GMN-LTN-3HL	GEMINUS Volar Distal Radius Plate, Narrow, 3 Hole, Left
GMN-RTN-4HL	GEMINUS Volar Distal Radius Plate, Narrow, 4 Hole, Right
GMN-LTN-4HL	GEMINUS Volar Distal Radius Plate, Narrow, 4 Hole, Left
GMN-RTS-3HL	GEMINUS Volar Distal Radius Plate, Standard, 3 Hole, Right
GMN-LTS-3HL	GEMINUS Volar Distal Radius Plate, Standard, 3 Hole, Left
GMN-RTS-4HL	GEMINUS Volar Distal Radius Plate, Standard, 4 Hole, Right
GMN-LTS-4HL	GEMINUS Volar Distal Radius Plate, Standard, 4 Hole, Left
GMN-RTS-7HL	GEMINUS Volar Distal Radius Plate, Standard, 7 Hole, Right
GMN-LTS-7HL	GEMINUS Volar Distal Radius Plate, Standard, 7 Hole, Left
GMN-RTW-4HL	GEMINUS Volar Distal Radius Plate, Wide, 4 Hole, Right
GMN-LTW-4HL	GEMINUS Volar Distal Radius Plate, Wide, 4 Hole, Left
GMN-HP	GEMINUS Hook Plate
GMN-HP-SCRW	GEMINUS Hook Plate, Screw
WBTN-2750-T	Washer, Button, Inside 2.7mm x Outside 5.0mm, Ti
Smooth Pegs, Locking (Ti)	
SPLS-20100-TS	Smooth Peg, Locking, 2.0mm x 10mm
SPLS-20120-TS	Smooth Peg, Locking, 2.0mm x 12mm
SPLS-20140-TS	Smooth Peg, Locking, 2.0mm x 14mm
SPLS-20160-TS	Smooth Peg, Locking, 2.0mm x 16mm
SPLS-20170-TS	Smooth Peg, Locking, 2.0mm x 17mm
SPLS-20180-TS	Smooth Peg, Locking, 2.0mm x 18mm
SPLS-20190-TS	Smooth Peg, Locking, 2.0mm x 19mm
SPLS-20200-TS	Smooth Peg, Locking, 2.0mm x 20mm
SPLS-20210-TS	Smooth Peg, Locking, 2.0mm x 21mm
SPLS-20220-TS	Smooth Peg, Locking, 2.0mm x 22mm
SPLS-20230-TS	Smooth Peg, Locking, 2.0mm x 23mm
SPLS-20240-TS	Smooth Peg, Locking, 2.0mm x 24mm
SPLS-20260-TS	Smooth Peg, Locking, 2.0mm x 26mm
SPLS-20280-TS	Smooth Peg, Locking, 2.0mm x 28mm
SPLS-20300-TS	Smooth Peg, Locking, 2.0mm x 30mm
SPLS-20320-TS	Smooth Peg, Locking, 2.0mm x 32mm
Threaded Peg, Locking (Ti)	
TPLS-23100-TS	Threaded Peg, Locking, 2.3mm x 10mm
TPLS-23120-TS	Threaded Peg, Locking, 2.3mm x 12mm
TPLS-23140-TS	Threaded Peg, Locking, 2.3mm x 14mm
TPLS-23160-TS	Threaded Peg, Locking, 2.3mm x 16mm
TPLS-23170-TS	Threaded Peg, Locking, 2.3mm x 17mm
TPLS-23180-TS	Threaded Peg, Locking, 2.3mm x 18mm
TPLS-23190-TS	Threaded Peg, Locking, 2.3mm x 19mm
TPLS-23200-TS	Threaded Peg, Locking, 2.3mm x 20mm
TPLS-23210-TS	Threaded Peg, Locking, 2.3mm x 21mm
TPLS-23220-TS	Threaded Peg, Locking, 2.3mm x 22mm
TPLS-23230-TS	Threaded Peg, Locking, 2.3mm x 23mm
TPLS-23240-TS	Threaded Peg, Locking, 2.3mm x 24mm
TPLS-23260-TS	Threaded Peg, Locking, 2.3mm x 26mm
TPLS-23280-TS	Threaded Peg, Locking, 2.3mm x 28mm
TPLS-23300-TS	Threaded Peg, Locking, 2.3mm x 30mm
TPLS-23320-TS	Threaded Peg, Locking, 2.3mm x 32mm

High Compression Pegs, Locking (Ti)	
HCLP-27100-TS	High Compression Locking Peg, 2.7mm x 10mm
HCLP-27120-TS	High Compression Locking Peg, 2.7mm x 12mm
HCLP-27140-TS	High Compression Locking Peg, 2.7mm x 14mm
HCLP-27160-TS	High Compression Locking Peg, 2.7mm x 16mm
HCLP-27180-TS	High Compression Locking Peg, 2.7mm x 18mm
HCLP-27190-TS	High Compression Locking Peg, 2.7mm x 19mm
HCLP-27200-TS	High Compression Locking Peg, 2.7mm x 20mm
HCLP-27210-TS	High Compression Locking Peg, 2.7mm x 21mm
HCLP-27220-TS	High Compression Locking Peg, 2.7mm x 22mm
HCLP-27230-TS	High Compression Locking Peg, 2.7mm x 23mm
HCLP-27240-TS	High Compression Locking Peg, 2.7mm x 24mm
HCLP-27260-TS	High Compression Locking Peg, 2.7mm x 26mm
HCLP-27280-TS	High Compression Locking Peg, 2.7mm x 28mm
HCLP-27300-TS	High Compression Locking Peg, 2.7mm x 30mm
HCLP-27320-TS	High Compression Locking Peg, 2.7mm x 32mm
Threaded Pegs, Non-Locking (Ti)	
TPNL-27100-TS	Threaded Peg, Non-Locking, 2.7mm x 10mm
TPNL-27120-TS	Threaded Peg, Non-Locking, 2.7mm x 12mm
TPNL-27140-TS	Threaded Peg, Non-Locking, 2.7mm x 14mm
TPNL-27160-TS	Threaded Peg, Non-Locking, 2.7mm x 16mm
TPNL-27180-TS	Threaded Peg, Non-Locking, 2.7mm x 18mm
TPNL-27200-TS	Threaded Peg, Non-Locking, 2.7mm x 20mm
TPNL-27220-TS	Threaded Peg, Non-Locking, 2.7mm x 22mm
TPNL-27240-TS	Threaded Peg, Non-Locking, 2.7mm x 24mm
TPNL-27260-TS	Threaded Peg, Non-Locking, 2.7mm x 26mm
TPNL-27280-TS	Threaded Peg, Non-Locking, 2.7mm x 28mm
TPNL-27300-TS	Threaded Peg, Non-Locking, 2.7mm x 30mm
TPNL-27320-TS	Threaded Peg, Non-Locking, 2.7mm x 32mm
Polyaxial Screws, Locking (CoCr)	
PALS-25100-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 10mm
PALS-25120-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 12mm
PALS-25140-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 14mm
PALS-25160-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 16mm
PALS-25180-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 18mm
PALS-25200-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 20mm
PALS-25220-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 22mm
PALS-25240-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 24mm
PALS-25260-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 26mm
PALS-25280-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 28mm
PALS-25300-CC	Screw, Cannulated Polyaxial Locking, 2.5mm x 30mm
Cortical Screws, Non-Locking (Ti)	
PANL-35080-TS	Screw, Cortical, Non-Locking, 3.5mm x 8mm
PANL-35090-TS	Screw, Cortical, Non-Locking, 3.5mm x 9mm
PANL-35100-TS	Screw, Cortical, Non-Locking, 3.5mm x 10mm
PANL-35110-TS	Screw, Cortical, Non-Locking, 3.5mm x 11mm
PANL-35120-TS	Screw, Cortical, Non-Locking, 3.5mm x 12mm
PANL-35130-TS	Screw, Cortical, Non-Locking, 3.5mm x 13mm
PANL-35140-TS	Screw, Cortical, Non-Locking, 3.5mm x 14mm
PANL-35150-TS	Screw, Cortical, Non-Locking, 3.5mm x 15mm
PANL-35160-TS	Screw, Cortical, Non-Locking, 3.5mm x 16mm
PANL-35180-TS	Screw, Cortical, Non-Locking, 3.5mm x 18mm

Cortical Screws, Locking (Ti)	
COLS-35080-TS	Screw, Cortical Locking, 3.5mm x 8mm
COLS-35090-TS	Screw, Cortical Locking, 3.5mm x 9mm
COLS-35100-TS	Screw, Cortical Locking, 3.5mm x 10mm
COLS-35110-TS	Screw, Cortical Locking, 3.5mm x 11mm
COLS-35120-TS	Screw, Cortical Locking, 3.5mm x 12mm
COLS-35130-TS	Screw, Cortical Locking, 3.5mm x 13mm
COLS-35140-TS	Screw, Cortical Locking, 3.5mm x 14mm
COLS-35150-TS	Screw, Cortical Locking, 3.5mm x 15mm
COLS-35160-TS	Screw, Cortical Locking, 3.5mm x 16mm
COLS-35180-TS	Screw, Cortical Locking, 3.5mm x 18mm
System Instrumentation	
DPGA-SMS-030 or DPGA-UNV-030	Depth Gauge, Sm. Standard, 30m or Depth Gauge, Universal, 30mm
DRLL-SSC-20040	Drill, Solid Side Cutting, 2.0mm x 40mm
DRLL-SSC-25040	Drill, Solid Side Cutting, 2.5mm x 40mm
DRLL-PLS-20	Drill, Cannulated Polyaxial Locking Screw, 2.0mm x 40mm
DRVR-AOS-S20	Driver, Peg, Torque Limiting
DRVR-UQC-T10	Driver, Universal Quick Connect, T10
DRVR-AOS-PLS	Driver, AO Connection, Polyaxial Locking Screw
HNDL-UQC-FXD or HNDL-AQC-FXD	Handle, Universal Quick Connect, Fixed or Handle, AO QC, Fixed
HNDL-SQC-FXD	Handle, Small Quick Connect, Fixed
FRCP-BHM-RTC	Forceps, Bone Holding Medium, Ratcheting
TPDG-THD-DG20	Thread-in Drill Guide, 2.0mm
TPDG-THD-DG25	Thread-in Drill Guide, 2.5mm
TPDG-DSD-2025	Tissue Protector / Drill Guide, Dual Sided, 2.0mm x 2.5mm
GMN-ID-PLS	Initial Driver, Polyaxial Locking Screw
GMN-CDG-PLS	Cannulated Depth Gauge, Polyaxial Locking Screw
GMN-FSP-PLB	GEMINUS Plate Bender
GMN-FSP-PLH	GEMINUS Plate Holder
PDG-AIM-015	AIMing Guides, 1.6mm
PLS-AIM-0910	PLS AIMing Guide
KWIR-STD-09152	K-wire, Standard Tip, .9mm x 152mm
KWIR-STD-15127	K-wire, Standard Tip, 1.6mm x 127mm
GMN-HP-DG15	GEMINUS Hook Plate, Reduction Tool
Sterilization Trays	
GMN-FSP-TRAY	GEMINUS Volar Distal Radius Plate System Sterilization Tray
GMN-ACC-MOD1	GEMINUS Volar Distal Radius Plate System Accessory Module 1
GMN-TRAY-SST	GEMINUS Volar Distal Radius Plate System Sterilization Tray, 304
GMN-MOD1-SST	GEMINUS Volar Distal Radius Plate System Accessory Module 1, 304
Optional Drill Block System (U.S. ONLY)	
GMN-DBK-RTS	GEMINUS Drill Block, Right, Standard
GMN-DBK-LTS	GEMINUS Drill Block, Left, Standard
GMN-DBK-RTW	GEMINUS Drill Block, Right, Wide
GMN-DBK-LTW	GEMINUS Drill Block, Left, Wide
GMN-DBK-RTN	GEMINUS Drill Block, Right, Narrow
GMN-DBK-LTN	GEMINUS Drill Block, Left, Narrow
TPDG-DBK-DG20	GEMINUS Drill Block, Drill Guide, 2.0mm
DBK-AIM-015	GEMINUS Drill Block, AIMing Guide, 1.5mm
GMN-DBK-MOD	GEMINUS Drill Block, Sterilization Module

Español

GEMINUS® Sistema de Placas Volares para Fracturas del Radio Distal
INSTRUCCIONES DE USO

℞: Para uso médico solamente. Las leyes Federales (EE.UU.) restringen la venta o uso de este dispositivo sólo por autorización u orden médica.

No seguir estas instrucciones de uso puede causar lesiones en el paciente.

El presente prospecto ha sido creado para describir las instrucciones de uso del Sistema GEMINUS® de Placas Volares y no se puede considerar como referencia a Técnicas Quirúrgicas.

Descripción:

El Sistema GEMINUS® de Placa Volares de Skeletal Dynamics contiene placas para la reparación de fracturas del Radio Distal.

El set incluye tornillos de aleación de Titanio, pernos de fijación, placas para fragmentos e instrumentos específicos. También incluye Placas Gancho para soporte especifico del fragmento volar marginal, tornillos canulados poliaxiales de Cromo Cobalto con cabeza para roscar a la placa para trayectorias diferentes a las de ángulo fijo en las placas.

Las Placas Volares GEMINUS® están disponibles en diferentes dimensiones y manufacturadas en aleación de Titanio de grado médico.

Los tornillos corticales fijan la placa a la diáfisis y los pernos de ángulo fijo se usan para los fragmentos de hueso distal. Este sistema se suministra no estéril para ser esterilizado en las instalaciones médicas del usuario.

El sistema GEMINUS®de Placas Volares está compuesto de:

- Placas, arandelas, pernos y tornillos de aleación de Titanio
- Tornillos Canulados poliaxiales roscados de Cromo-Cobalto (PLS)
- Agujas Kirshner (para fijación temporal, no para implantación)
- Sistema específico de instrumentos.

Indicaciones:

El sistema GEMINUS® de Placas Volares está indicado para la fijación de las fracturas u osteotomías que afectan al Radio Distal.

Contraindicaciones:

Previo al uso del Sistema GEMINUS® de Placas Volares asegúrese que el paciente no presenta ninguna de las condiciones siguientes: infección activa o latente, sepsis, insuficiente cantidad o calidad de hueso y/o de los tejidos blandos, intolerancia a los materiales, o pacientes que sean incapaces o no dispuestos a seguir las recomendaciones de cuidado post-operatorio.

⚠Advertencias:

- Todos los pernos y tornillos deben ser implantados y apretados fuertemente a la placa para mantener la integridad y fuerza final del bloque. Si los tornillos y pernos no están sujetos y/o bien apretados podría ocurrir una no unión, retraso en la unión o fallo del bloque.
- El uso de herramientas eléctricas para la instalación de tornillos y pernos no es recomendable y puede dar lugar a roscas cruzadas y daños a los tornillos y placas.
- Información contenida en este documento debe ser compartida con el paciente.
- El paciente debe ser informado de la importancia del seguimiento de la rehabilitación prescrita, para que pueda entender las posibles limitaciones en la actividad diaria. El paciente debe ser advertido de que el no

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seguimiento de las pautas de cuidado post intervención quirúrgica puede hacer que el implante y/o el tratamiento fallen.

- Potencialmente, el Sistema GEMINUS® de Placas Volares puede ocasionar fallos en el bloque tales como fracturas por estrés del hueso, pérdidas de la construcción y/o de fijación retardo en la fusión, no fusión o cicatrización incompleta, como consecuencia de no seguir el proceso de rehabilitación prescrito, exceso de actividad de la muñeca o sobrecargas al bloque.
- NO REUTILIZAR ninguno de los componentes implantables del Sistema GEMINUS® de Placas Volares, la reutilización puede comprometer la integridad estructural del bloque y/o producir un fallo o infección y causar lesiones al paciente.
- NO abrir la capsula volar ya que pueden desvascularizarse fragmentos y desestabilizar ligamentos volares de la muñeca.
- Usar un solo perno de 2,7mm (de alta compresión, roscado bloqueado o roscado no bloqueado) en cada cabeza de la placa volar GEMINUS®.
- Usar solo un tornillo PLS 2,5mm en cada cabeza de la Placa Volar GEMINUS®.
- Usar un solo tornillo Canulado Poliaxial (PLS).
- NO usar ningún tornillo Canulado Poliaxial (PLS) en los orificios distales de la cabeza semilunar de la placa volar GEMINUS®

⚠ Precauciones:

- Proteger los componentes implantables del Sistema GEMINUS® de Placas Volares contra ralladuras o mellado. Este estrés puede causar el fracaso del implante.
- Antes de usar el Sistema GEMINUS® de Placas Volares, inspeccionar el desgaste, deformidad o daño físico de todos los implantes e instrumentos. En caso de observar desgaste deformidad o daño físico NO USAR y contacte con su representante local de Skeletal Dynamics o con el Departamento de Atención al Cliente de Skeletal Dynamics.
- Asegúrese que el destornillador de pernos no muestre signos de desgaste en la punta como los bordes cuadrados redondeados, marcas de profundidad excesivas de uso por inserción o punta torcida o deformada. En caso de observar desgaste deformidad o daño físico NO UTILZAR y contacte con su representante local de Skeletal Dynamics o con el Departamento de Atención al Cliente de Skeletal Dynamics.
- NO implantar ninguna aguja Kirshner de Skeletal Dynamics de forma permanente, estas están indicadas sólo para la fijación temporal durante la implantación de las Placas Volares GEMINUS®
- NO dejar alojadas permanentemente las guías de fresado pre-montadas o las guías A.I.M.ing las cuales han sido diseñadas para ser retiradas antes de la inserción de pernos o tornillos.
- NO usar longitudes de pernos o tornillos que puedan sobresalir excesivamente a través de la segunda cortical ya que puede causar irritación de los tejidos blandos.
- La angulación máxima de los tornillos Canulados Poliaxiales (PLS) no debe exceder de los 10º de la trayectoria del respectivo orificio.
- Los tornillos roscados no bloqueados NO esta indicados para proporcionar soporte subcondral. Su uso debe limitarse a capturar algún fragmento de hueso remoto cuando no pueda usarse un tornillo con rosca parcial o total.
- El Sistema GEMINUS® de Placas Volares está indicado para usarse sólo con los instrumentos y accesorios de Skeletal Dynamics.
- Disponga de los implantes e instrumentos contaminados siguiendo las pautas y protocolos establecidos en sus instalaciones médicas.
- La precisión del medidor de profundidad de los tornillos está en el rango de ± 0,25 mm.
- Se debe tener precaución con las interferencias con los marcapasos causadas durante la cauterización eléctrica o uso de brocas no certificadas.
- Solicite ayuda médica en caso de mal funcionamiento del implante.

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- Para mantener el seguimiento de los componentes implantables del Sistema GEMINUS® de Placas Volares, deben registrarse los números de lote de los respectivos componentes en los expedientes médicos de cada paciente después de su implantación.
- NO usar componentes implantables o instrumentos de diferentes fabricantes por razones de metalurgia, biomecánicas o funcionales.

⚠ **Resonancia Magnética:**

El Sistema GEMINUS® de Placas Volares no ha sido evaluado para compatibilidad y seguridad con la Resonancia Magnética (RM), ni se ha evaluado el calentamiento, migración o artefactos en imágenes en un ambiente de Resonancia Magnética (RM). La seguridad del sistema en un ambiente expuesto a Resonancia Magnética (RM) es desconocido. El someter el paciente con componentes de este Sistema implantados, puede resultar en daño al paciente.

Posibles Eventos Adversos:

Los riesgos potenciales asociados con la cirugía de la muñeca son los siguientes: Infección, no unión, dolor persistente, rigidez de los dedos, aflojado o migración del implante derivados de una mala alineación.

Instrucciones de uso:

El Sistema GEMINUS® de Placas Volares sólo debe ser usado por cirujanos que tengan experiencia con este sistema. Cada cirujano debe evaluar la idoneidad del uso del Sistema GEMINUS® de Placas Volares basado en su experiencia clínica.

Por favor consulte la Técnica Quirúrgica del Sistema GEMINUS® de Placas Volares para revisar el procedimiento quirúrgico descrito por el Dr. Jorge L. Orbay, Doctor en Medicina, del Miami Hand and Upper Extremity Institute localizado en Miami Florida (EE.UU.).

Limpieza:

Los instrumentos del Sistema GEMINUS® de Placas Volares deben de limpiarse para la conseguir su esterilización. El proceso de limpieza comienza en el momento de haber usado el instrumento. Para prevenir que se sequen los fluidos y otros contaminantes, limpie la sangre, partículas y remueva la suciedad de los instrumentos durante el procedimiento quirúrgico. Las instrucciones de limpieza recomendadas son indicadas a continuación. El usuario debe valorar otros métodos de limpieza:

1. Desarme los instrumentos si es aplicable. No es necesario retirar los PDG antes de la esterilización.
2. Enjuague los componentes a fondo bajo una corriente de agua fría del grifo. Al enjuagar, utilice un cepillo de cerdas suaves para aflojar y remover las partículas tanto visible como sea posible de los componentes.
3. Sumerja los componentes en un limpiador enzimático neutro durante un mínimo de diez (10) minutos. Los componentes deben estar inmersos completamente. Siga las instrucciones del fabricante del agente limpiador para la preparación y el tiempo de exposición al agente limpiador.
4. Enjuague los componentes con agua fría. Al enjuagar, utilice cepillos de cerdas suaves, pipetas o un chorro de agua para limpiar lúmenes, agujeros y otras partes de difícil acceso.
5. Fregar manualmente los componentes recién de manera homogénea, usar limpiador enzimático de pH neutro usando cepillos de cerdas suaves o pipetas. Todos los lúmenes, agujeros, componentes bisagras, superficies de contacto, huecos, y componentes de difícil acceso deben ser lavados a fondo.
6. Accionar todas las partes móviles y exponer todas las áreas a un cepillo o una pipeta.
7. Enjuague los componentes a fondo con agua des-ionizada o purificada; utilizando pipetas o un chorro de agua para limpiar lúmenes, agujeros, y otras características de difícil acceso. Accionar todas las características móviles para irrigar totalmente todas las áreas.
8. Inspeccione visualmente las superficies de los componentes. Repita el procedimiento de limpieza hasta que no quede suciedad visible en los componentes.
9. Realizar un enjuague final de los componentes utilizando agua des-ionizada o agua purificada.
10. Secar los componentes limpios usando aire comprimido o con un paño suave y limpio libre de pelusa.

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Comprobar el funcionamiento correcto cuando sea posible:

1. Comprobar el correcto ensamblaje de los dispositivos de acoplamiento.
2. Comprobar el correcto funcionamiento de dispositivos reutilizables con piezas móviles (se puede usar lubricante de grado médico adecuado para la esterilización con vapor).
3. Comprobar la rotación de instrumentos (taladros, fresas y limas) así como de la correcta alineación de los mismos sobre una superficie plana.

NOTA: La vida útil de estos dispositivos depende de muchos factores, incluyendo, pero no limitado a: el método y la duración de cada uso y el manejo de los dispositivos entre usos. La inspección de rutina y cuidado y las pruebas funcionales del dispositivo es el mejor método para determinar la duración de la vida útil del dispositivo médico.

Esterilización:

El Sistema GEMINUS® de Placas Volares de Skeletal Dynamics se suministra no estéril. El Sistema está diseñado para su esterilización por vapor en la instalación sanitaria.

1. Coloque todos los componentes y los accesorios en las áreas designadas de la bandeja de esterilización.
2. La esterilización por vapor se puede realizar usando uno de los ciclos que se indican a continuación:

Tiempos de ciclo para ciclos de esterilización con vapor de eliminación dinámica de aire (vacío)

Artículo	Tiempo de exposición en 132°C (270° F)	Tiempo mínimo de secado
Bandeja de esterilización envuelta	4 minutos (envuelto)	40 minutos

- Siga la guía completa ANSI/AAMI ST79:2006 para la esterilización por vapor y la garantía de esterilidad en instalaciones sanitarias.
- La esterilización rápida no es recomendable, pero en caso de utilizarse debe ser siguiendo las recomendaciones ANSI / AAMI: ST79:2006 para la esterilización por vapor y la garantía de esterilidad en instalaciones sanitarias.
- Se requiere de un envoltorio o contendor de esterilización aprobado por la FDA.
- Las posteriores esterilizaciones de instrumentos deben realizarse en las bandejas proporcionadas del Sistema. Para la reutilización y la esterilización, los instrumentos deben colocarse dentro de la bandeja del sistema en la forma suministrada por la empresa.

Manejo y almacenamiento:

Cuando no esté en uso, guarde el Sistema GEMINUS® de Placas Volares limpios y desinfectados dentro de la bandeja de esterilización. Antes de su uso, inspeccione el funcionamiento de los instrumentos.

Limitación de Garantías y Reclamaciones:

Skeletal Dynamics, Inc. no ofrece ninguna garantía expresa o implícita, incluyendo ninguna garantía implícita de comercialización o adecuación para un propósito en particular sobre el producto (s) descrito en esta publicación. Skeletal Dynamics Inc., no será responsable bajo ninguna circunstancia de ningún daño directo, incidental o consecuente distintos de los previstos expresamente por una ley específica. Ninguna persona tiene autoridad para obligar a Skeletal Dynamics para cualquier representación o garantía, salvo las expresamente mencionadas en esta publicación.

Descripciones o especificaciones proporcionadas por Skeletal Dynamics, Inc, en cualquier publicación sólo se incluyen para describir el producto en general, cuando se fabrica y no constituyen ninguna garantía expresa.

INFORMACIÓN DE PEDIDOS DEL SISTEMA GEMINUS PLACA VOLAR: GMN-FSP-SYS

Numero de Catálogo	Nomenclatura
Placas Volares, Radio Distal (Ti)	
GMN-RTN-3HL	Placa volar radio distal estrecha GEMINUS, 3 orificios, derecha
GMN-LTN-3HL	Placa volar radio distal estrecha GEMINUS, 3 orificios, izquierda
GMN-RTN-4HL	Placa volar radio distal estrecha GEMINUS, 4 orificios, derecha
GMN-LTN-4HL	Placa volar radio distal estrecha GEMINUS, 4 orificios, izquierda
GMN-RTS-3HL	Placa volar radio distal estándar GEMINUS, 3 orificios, derecha
GMN-LTS-3HL	Placa volar radio distal estándar GEMINUS, 3 orificios, izquierda
GMN-RTS-4HL	Placa volar radio distal estándar GEMINUS, 4 orificios, derecha
GMN-LTS-4HL	Placa volar radio distal estándar GEMINUS, 4 orificios, izquierda
GMN-RTS-7HL	Placa volar radio distal estándar GEMINUS, 7 orificios, derecha
GMN-LTS-7HL	Placa volar radio distal estándar GEMINUS, 7 orificios, izquierda
GMN-RTW-4HL	Placa volar radio distal ancha GEMINUS, 4 orificios, derecha
GMN-LTW-4HL	Placa volar radio distal ancha GEMINUS, 4 orificios, izquierda
GMN-HP	Placa gancho GEMINUS
GMN-HP-SCRW	Tornillo placa gancho GEMINUS
WBTN-2750-T	Arandela botón, Ø interior 2,7 mm, Ø exterior 5,0 mm, Ti
Pernos Lisos Bloqueados (Ti)	
SPLS-20100-TS	Perno liso bloqueo, 2,0 mm x 10 mm, Ti
SPLS-20120-TS	Perno liso bloqueo, 2,0 mm x 12 mm, Ti
SPLS-20140-TS	Perno liso bloqueo, 2,0 mm x 14 mm, Ti
SPLS-20160-TS	Perno liso bloqueo, 2,0 mm x 16 mm, Ti
SPLS-20170-TS	Perno liso bloqueo, 2,0 mm x 17 mm, Ti
SPLS-20180-TS	Perno liso bloqueo, 2,0 mm x 18 mm, Ti
SPLS-20190-TS	Perno liso bloqueo, 2,0 mm x 19 mm, Ti
SPLS-20200-TS	Perno liso bloqueo, 2,0 mm x 20 mm, Ti
SPLS-20210-TS	Perno liso bloqueo, 2,0 mm x 21 mm, Ti
SPLS-20220-TS	Perno liso bloqueo, 2,0 mm x 22 mm, Ti
SPLS-20230-TS	Perno liso bloqueo, 2,0 mm x 23 mm, Ti
SPLS-20240-TS	Perno liso bloqueo, 2,0 mm x 24 mm, Ti
SPLS-20260-TS	Perno liso bloqueo, 2,0 mm x 26 mm, Ti
SPLS-20280-TS	Perno liso bloqueo, 2,0 mm x 28 mm, Ti
SPLS-20300-TS	Perno liso bloqueo, 2,0 mm x 30 mm, Ti
SPLS-20320-TS	Perno liso bloqueo, 2,0 mm x 32 mm, Ti
Pernos Roscados Bloqueados (Ti)	
TPLS-23100-TS	Perno roscado bloqueo, 2,3 mm x 10 mm, Ti
TPLS-23120-TS	Perno roscado bloqueo, 2,3 mm x 12 mm, Ti
TPLS-23140-TS	Perno roscado bloqueo, 2,3 mm x 14 mm, Ti
TPLS-23160-TS	Perno roscado bloqueo, 2,3 mm x 16 mm, Ti
TPLS-23170-TS	Perno roscado bloqueo, 2,3 mm x 17 mm, Ti
TPLS-23180-TS	Perno roscado bloqueo, 2,3 mm x 18 mm, Ti
TPLS-23190-TS	Perno roscado bloqueo, 2,3 mm x 19 mm, Ti
TPLS-23200-TS	Perno roscado bloqueo, 2,3 mm x 20 mm, Ti
TPLS-23210-TS	Perno roscado bloqueo, 2,3 mm x 21 mm, Ti
TPLS-23220-TS	Perno roscado bloqueo, 2,3 mm x 22 mm, Ti
TPLS-23230-TS	Perno roscado bloqueo, 2,3 mm x 23 mm, Ti
TPLS-23240-TS	Perno roscado bloqueo, 2,3 mm x 24 mm, Ti
TPLS-23260-TS	Perno roscado bloqueo, 2,3 mm x 26 mm, Ti
TPLS-23280-TS	Perno roscado bloqueo, 2,3 mm x 28 mm, Ti
TPLS-23300-TS	Perno roscado bloqueo, 2,3 mm x 30 mm, Ti
TPLS-23320-TS	Perno roscado bloqueo, 2,3 mm x 32 mm, Ti
Pernos Bloqueados de Alta Compresión (Ti)	
HCLP-27100-TS	Perno bloqueo alta compresión, 2,7 mm x 10 mm, Ti
HCLP-27120-TS	Perno bloqueo alta compresión, 2,7 mm x 12 mm, Ti
HCLP-27140-TS	Perno bloqueo alta compresión, 2,7 mm x 14 mm, Ti
HCLP-27160-TS	Perno bloqueo alta compresión, 2,7 mm x 16 mm, Ti
HCLP-27180-TS	Perno bloqueo alta compresión, 2,7 mm x 18 mm, Ti
HCLP-27190-TS	Perno bloqueo alta compresión, 2,7 mm x 19 mm, Ti

HCLP-27200-TS	Perno bloqueo alta compresión, 2,7 mm x 20 mm, Ti
HCLP-27210-TS	Perno bloqueo alta compresión, 2,7 mm x 21 mm, Ti
HCLP-27220-TS	Perno bloqueo alta compresión, 2,7 mm x 22 mm, Ti
HCLP-27230-TS	Perno bloqueo alta compresión, 2,7 mm x 23 mm, Ti
HCLP-27240-TS	Perno bloqueo alta compresión, 2,7 mm x 24 mm, Ti
HCLP-27260-TS	Perno bloqueo alta compresión, 2,7 mm x 26 mm, Ti
HCLP-27280-TS	Perno bloqueo alta compresión, 2,7 mm x 28 mm, Ti
HCLP-27300-TS	Perno bloqueo alta compresión, 2,7 mm x 30 mm, Ti
HCLP-27320-TS	Perno bloqueo alta compresión, 2,7 mm x 32 mm, Ti
Pernos Lisos Bloqueados (Ti)	
SPLS-20100-TS	Perno liso bloqueo, 2,0 mm x 10 mm, Ti
SPLS-20120-TS	Perno liso bloqueo, 2,0 mm x 12 mm, Ti
SPLS-20140-TS	Perno liso bloqueo, 2,0 mm x 14 mm, Ti
SPLS-20160-TS	Perno liso bloqueo, 2,0 mm x 16 mm, Ti
SPLS-20170-TS	Perno liso bloqueo, 2,0 mm x 17 mm, Ti
SPLS-20180-TS	Perno liso bloqueo, 2,0 mm x 18 mm, Ti
SPLS-20190-TS	Perno liso bloqueo, 2,0 mm x 19 mm, Ti
SPLS-20200-TS	Perno liso bloqueo, 2,0 mm x 20 mm, Ti
SPLS-20210-TS	Perno liso bloqueo, 2,0 mm x 21 mm, Ti
SPLS-20220-TS	Perno liso bloqueo, 2,0 mm x 22 mm, Ti
SPLS-20230-TS	Perno liso bloqueo, 2,0 mm x 23 mm, Ti
SPLS-20240-TS	Perno liso bloqueo, 2,0 mm x 24 mm, Ti
SPLS-20260-TS	Perno liso bloqueo, 2,0 mm x 26 mm, Ti
SPLS-20280-TS	Perno liso bloqueo, 2,0 mm x 28 mm, Ti
SPLS-20300-TS	Perno liso bloqueo, 2,0 mm x 30 mm, Ti
SPLS-20320-TS	Perno liso bloqueo, 2,0 mm x 32 mm, Ti
Pernos Roscados Bloqueados (Ti)	
TPLS-23100-TS	Perno roscado bloqueo, 2,3 mm x 10 mm, Ti
TPLS-23120-TS	Perno roscado bloqueo, 2,3 mm x 12 mm, Ti
TPLS-23140-TS	Perno roscado bloqueo, 2,3 mm x 14 mm, Ti
TPLS-23160-TS	Perno roscado bloqueo, 2,3 mm x 16 mm, Ti
TPLS-23170-TS	Perno roscado bloqueo, 2,3 mm x 17 mm, Ti
TPLS-23180-TS	Perno roscado bloqueo, 2,3 mm x 18 mm, Ti
TPLS-23190-TS	Perno roscado bloqueo, 2,3 mm x 19 mm, Ti
TPLS-23200-TS	Perno roscado bloqueo, 2,3 mm x 20 mm, Ti
TPLS-23210-TS	Perno roscado bloqueo, 2,3 mm x 21 mm, Ti
TPLS-23220-TS	Perno roscado bloqueo, 2,3 mm x 22 mm, Ti
TPLS-23230-TS	Perno roscado bloqueo, 2,3 mm x 23 mm, Ti
TPLS-23240-TS	Perno roscado bloqueo, 2,3 mm x 24 mm, Ti
TPLS-23260-TS	Perno roscado bloqueo, 2,3 mm x 26 mm, Ti
TPLS-23280-TS	Perno roscado bloqueo, 2,3 mm x 28 mm, Ti
TPLS-23300-TS	Perno roscado bloqueo, 2,3 mm x 30 mm, Ti
TPLS-23320-TS	Perno roscado bloqueo, 2,3 mm x 32 mm, Ti

Pernos Bloqueados de Alta Compresión (Ti)	
HCLP-27100-TS	Perno bloqueo alta compresión, 2,7 mm x 10 mm, Ti
HCLP-27120-TS	Perno bloqueo alta compresión, 2,7 mm x 12 mm, Ti
HCLP-27140-TS	Perno bloqueo alta compresión, 2,7 mm x 14 mm, Ti
HCLP-27160-TS	Perno bloqueo alta compresión, 2,7 mm x 16 mm, Ti
HCLP-27180-TS	Perno bloqueo alta compresión, 2,7 mm x 18 mm, Ti
HCLP-27190-TS	Perno bloqueo alta compresión, 2,7 mm x 19 mm, Ti
HCLP-27200-TS	Perno bloqueo alta compresión, 2,7 mm x 20 mm, Ti
HCLP-27210-TS	Perno bloqueo alta compresión, 2,7 mm x 21 mm, Ti
HCLP-27220-TS	Perno bloqueo alta compresión, 2,7 mm x 22 mm, Ti
HCLP-27230-TS	Perno bloqueo alta compresión, 2,7 mm x 23 mm, Ti
HCLP-27240-TS	Perno bloqueo alta compresión, 2,7 mm x 24 mm, Ti
HCLP-27260-TS	Perno bloqueo alta compresión, 2,7 mm x 26 mm, Ti
HCLP-27280-TS	Perno bloqueo alta compresión, 2,7 mm x 28 mm, Ti
HCLP-27300-TS	Perno bloqueo alta compresión, 2,7 mm x 30 mm, Ti
HCLP-27320-TS	Perno bloqueo alta compresión, 2,7 mm x 32 mm, Ti
Pernos Roscados no Bloqueados (Ti)	
TPNL-27100-TS	Perno roscado sin bloqueo, 2,7 mm x 10 mm, Ti
TPNL-27120-TS	Perno roscado sin bloqueo, 2,7 mm x 12 mm, Ti
TPNL-27140-TS	Perno roscado sin bloqueo, 2,7 mm x 14 mm, Ti
TPNL-27160-TS	Perno roscado sin bloqueo, 2,7 mm x 16 mm, Ti
TPNL-27180-TS	Perno roscado sin bloqueo, 2,7 mm x 18 mm, Ti
TPNL-27200-TS	Perno roscado sin bloqueo, 2,7 mm x 20 mm, Ti
TPNL-27220-TS	Perno roscado sin bloqueo, 2,7 mm x 22 mm, Ti
TPNL-27240-TS	Perno roscado sin bloqueo, 2,7 mm x 24 mm, Ti
TPNL-27260-TS	Perno roscado sin bloqueo, 2,7 mm x 26 mm, Ti
TPNL-27280-TS	Perno roscado sin bloqueo, 2,7 mm x 28 mm, Ti
TPNL-27300-TS	Perno roscado sin bloqueo, 2,7 mm x 30 mm, Ti
TPNL-27320-TS	Perno roscado sin bloqueo, 2,7 mm x 32 mm, Ti
Tornillos Poliaxiales Bloqueados (CoCr)	
PALS-25100-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 10 mm, CoCr
PALS-25120-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 12 mm, CoCr
PALS-25140-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 14 mm, CoCr
PALS-25160-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 16 mm, CoCr
PALS-25180-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 18 mm, CoCr
PALS-25200-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 20 mm, CoCr
PALS-25220-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 22 mm, CoCr
PALS-25240-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 24 mm, CoCr
PALS-25260-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 26 mm, CoCr
PALS-25280-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 28 mm, CoCr
PALS-25300-CC	Tornillo bloqueo poliaxial canulado, 2,5 mm x 30 mm, CoCr
Tornillos Corticales no Bloqueados (Ti)	
PANL-35080-TS	Tornillo cortical sin bloqueo, 3,5 mm x 8 mm, Ti
PANL-35090-TS	Tornillo cortical sin bloqueo, 3,5 mm x 9 mm, Ti
PANL-35100-TS	Tornillo cortical sin bloqueo, 3,5 mm x 10 mm, Ti
PANL-35110-TS	Tornillo cortical sin bloqueo, 3,5 mm x 11 mm, Ti
PANL-35120-TS	Tornillo cortical sin bloqueo, 3,5 mm x 12 mm, Ti
PANL-35130-TS	Tornillo cortical sin bloqueo, 3,5 mm x 13 mm, Ti
PANL-35140-TS	Tornillo cortical sin bloqueo, 3,5 mm x 14 mm, Ti
PANL-35150-TS	Tornillo cortical sin bloqueo, 3,5 mm x 15 mm, Ti
PANL-35160-TS	Tornillo cortical sin bloqueo, 3,5 mm x 16 mm, Ti
PANL-35180-TS	Tornillo cortical sin bloqueo, 3,5 mm x 18 mm, Ti

Tornillos Corticales Bloqueados (Ti)	
COLS-35080-TS	Tornillo bloqueo cortical, 3,5 mm x 8 mm, Ti
COLS-35090-TS	Tornillo bloqueo cortical, 3,5 mm x 9 mm, Ti
COLS-35100-TS	Tornillo bloqueo cortical, 3,5 mm x 10 mm, Ti
COLS-35110-TS	Tornillo bloqueo cortical, 3,5 mm x 11 mm, Ti
COLS-35120-TS	Tornillo bloqueo cortical, 3,5 mm x 12 mm, Ti
COLS-35130-TS	Tornillo bloqueo cortical, 3,5 mm x 13 mm, Ti
COLS-35140-TS	Tornillo bloqueo cortical, 3,5 mm x 14 mm, Ti
COLS-35150-TS	Tornillo bloqueo cortical, 3,5 mm x 15 mm, Ti
COLS-35160-TS	Tornillo bloqueo cortical, 3,5 mm x 16 mm, Ti
COLS-35180-TS	Tornillo bloqueo cortical, 3,5 mm x 18 mm, Ti
Sistema de Instrumentos	
DPGA-SMS-030 o DPGA-UNV-030	Medidor profundidad estándar 30 mm o Medidor profundidad universal 30 mm
DRLL-SSC-20040	Broca maciza corte lateral 2,0 mm x 40 mm
DRLL-SSC-25040	Broca maciza corte lateral 2,5 mm x 40 mm
DRLL-PLS-20	Tornillo bloqueo poliaxial canulado de broca 2,0 mm
DRVR-AOS-S20	Destornillador, clavija, limitador de torques
DRVR-UQC-T10	Destornillador conexión rápida universal T10
DRVR-AOS-PLS	Tornillo bloqueo poliaxial de destornillador conexión AO
HNDL-UQC-FXD o HNDL-AQC-FXD	Mango universal fijo conexión rápida o Mango AO fijo conexión rápida
HNDL-SQC-FXD	Mango pequeño fijo conexión rápida
FRCP-BHM-RTC	Pinzas sujeción ósea media con trinquete
TPDG-THD-DG20	Guía fresado roscada 2,0 mm
TPDG-THD-DG25	Guía fresado roscada 2,5 mm
TPDG-DSD-2025	Protector tejidos / Broca doble punta 2,0 mm x 2,5 mm
GMN-ID-PLS	Tornillo bloqueo poliaxial de destornillador iniciador
GMN-CDG-PLS	Tornillo bloqueo poliaxial canulado de medidor profundidad
GMN-FSP-PLB	Moldeador placa GEMINUS
GMN-FSP-PLH	Base placa GEMINUS
PDG-AIM-015	Guías AIMing 1.6mm
PLS-AIM-0910	Guías PLS AIMing, 0,9mm x 10º
KWIR-STD-09152	Aguja Kishner punta estándar 0,9 mm x 152 mm
KWIR-STD-15127	Aguja Kishner punta estándar 1,6 mm x 127 mm
GMN-HP-DG15	Herramienta reductora placa gancho GEMINUS
Bandeja de Esterilización	
GMN-FSP-TRAY	Bandeja esterilización Sistema placa volar radio distal GEMINUS
GMN-ACC-MOD1	Módulo accesorios 1 Sistema placa volar radio distal GEMINUS
GMN-TRAY-SST	Bandeja esterilización Sistema placa volar radio distal GEMINUS, 304
GMN-MOD1-SST	Módulo accesorios 1 Sistema placa volar radio distal GEMINUS, 304

Skeletal Dynamics, Inc/
Centro de Asistencia al Cliente:
7300 N. Kendall Dr. / Suite 400
Miami, FL 33156
1-877-753-5396

EC REP

Emergo Europe,
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

MD

CE
2797

IFU-00738-00RBF – May 2023

GEMINUS™

Volar Plating System

Inventory Control Sheet

Quantity			Quantity		
GEMINUS Volar Distal Radius Plates					
	GEMINUS Plate, Narrow, 3 Hole, Left GMN-LTN-3HL (01)00841506101569	(01) 00841506101569		GEMINUS Plate, Narrow, 4 Hole, Left GMN-LTN-4HL (01)00841506101576	(01) 00841506101576
	GEMINUS Plate, Narrow, 3 Hole, Right GMN-RTN-3HL (01)00841506101620	(01) 00841506101620		GEMINUS Plate, Narrow, 4 Hole, Right GMN-RTN-4HL (01)00841506101637	(01) 00841506101637
	GEMINUS Plate, Standard, 3 Hole, Left GMN-LTS-3HL (01)00841506101583	(01) 00841506101583		GEMINUS Plate, Standard, 4 Hole, Left GMN-LTS-4HL (01)00841506101590	(01) 00841506101590
	GEMINUS Plate, Standard, 3 Hole, Right GMN-RTS-3HL (01)00841506101644	(01) 00841506101644		GEMINUS Plate, Standard, 4 Hole, Right GMN-RTS-4HL (01)00841506101651	(01) 00841506101651
	GEMINUS Plate, Standard, 7 Hole, Left GMN-LTS-7HL (01)00841506101606	(01) 00841506101606		GEMINUS Plate, Wide, 4 Hole, Left GMN-LTW-4HL (01)00841506101613	(01) 00841506101613
	GEMINUS Plate, Standard, 7 Hole, Right GMN-RTS-7HL (01)008415061016	(01) 00841506101668		GEMINUS Plate, Wide, 4 Hole, Right GMN-RTW-4HL (01)008415061016	(01) 00841506101675
PROTEAN Fragment Plates					
	PROTEAN Fragment Plate, Double Hockey Stick PRT-FSP-LR (01)00841506102917	(01) 00841506102917		PROTEAN Fragment Plate, Y PRT-FSP-YS (01)00841506102931	(01) 00841506102931
	PROTEAN Fragment Plate, Distal Ulna PRT-FSP-DU (01)008415061029	(01) 00841506102900			
GEMINUS Hook Plate					
	GEMINUS Hook Plate GMN-HP (01)008415061015	(01) 00841506101514		GEMINUS Hook Plate Screw GMN-HP-SCRW (01)008415061015	(01) 00841506101545
Single Use (Disposable) Instruments					
	A.I.M.ing Guides, 1.5mm PDG-AIM-015 (01)00841506102870	(01) 00841506102870		PLS AIMing Guides, .9mm x 10° (Cone Tool) PLS-AIM-0910 (01)008415061028	(01) 00841506102887
	K-Wire, Standard Tip, 0.9mm x 152mm KWIR-STD-09152 (01)00841506102498	(01) 00841506102498		K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504	(01) 00841506102504
	Drill, Solid Side Cutting, 2.0mm x 40mm DRLL-SSC-20040 (01)00841506101255	(01) 00841506101255		Drill, Solid Side Cutting, 2.5mm x 40mm DRLL-SSC-25040 (01)00841506101279	(01) 00841506101279
	Drill, Cannulated, Polyaxial Locking Screw, 2.0mm DRLL-PLS-20 (01)00841506101248	(01) 00841506101248		Driver, AO Connection, Square Tip 2.0mm DRVR-AOS-S20 (01)00841506101293	(01) 00841506101293
	Driver, AO Connection, PLS DRVR-AOS-PLS (01)00841506101286	(01) 00841506101286		Driver, Universal Quick Connect, T10 DRVR-UQC-T10 (01)00841506101330	(01) 00841506101330

Smooth Pegs, Locking (Ti) - Gray			
	Smooth Peg, Locking, 2.0mm x 10mm SPLS-20100-TS (01)00841506102948		Smooth Peg, Locking, 2.0mm x 20mm SPLS-20200-TS (01)00841506103013
	Smooth Peg, Locking, 2.0mm x 12mm SPLS-20120-TS (01)00841506102955		Smooth Peg, Locking, 2.0mm x 21mm SPLS-20210-TS (01)00841506103020
	Smooth Peg, Locking, 2.0mm x 14mm SPLS-20140-TS (01)00841506102962		Smooth Peg, Locking, 2.0mm x 22mm SPLS-20220-TS (01)00841506103037
	Smooth Peg, Locking, 2.0mm x 16mm SPLS-20160-TS (01)00841506102979		Smooth Peg, Locking, 2.0mm x 23mm SPLS-20230-TS (01)00841506103044
	Smooth Peg, Locking, 2.0mm x 17mm SPLS-20170-TS (01)00841506102986		Smooth Peg, Locking, 2.0mm x 24mm SPLS-20240-TS (01)00841506103051
	Smooth Peg, Locking, 2.0mm x 18mm SPLS-20180-TS (01)00841506102993		Smooth Peg, Locking, 2.0mm x 26mm SPLS-20260-TS (01)00841506103068
	Smooth Peg, Locking, 2.0mm x 19mm SPLS-20190-TS (01)00841506103006		Smooth Peg, Locking, 2.0mm x 28mm SPLS-20280-TS (01)00841506103075
High Compression Locking Pegs (Ti) -			
	High Compression Locking Peg, 2.7mm x 10mm HCLP-27100-TS (01)00841506101682		High Compression Locking Peg, 2.7mm x 21mm HCLP-27210-TS (01)00841506101750
	High Compression Locking Peg, 2.7mm x 12mm HCLP-27120-TS (01)00841506101699		High Compression Locking Peg, 2.7mm x 22mm HCLP-27220-TS (01)00841506101767
	High Compression Locking Peg, 2.7mm x 14mm HCLP-27140-TS (01)00841506101705		High Compression Locking Peg, 2.7mm x 23mm HCLP-27230-TS (01)00841506101774
	High Compression Locking Peg, 2.7mm x 16mm HCLP-27160-TS (01)00841506101712		High Compression Locking Peg, 2.7mm x 24mm HCLP-27240-TS (01)00841506101781
	High Compression Locking Peg, 2.7mm x 18mm HCLP-27180-TS (01)00841506101729		High Compression Locking Peg, 2.7mm x 26mm HCLP-27260-TS (01)00841506101798
	High Compression Locking Peg, 2.7mm x 19mm HCLP-27190-TS (01)00841506101736		High Compression Locking Peg, 2.7mm x 28mm HCLP-27280-TS (01)00841506101804
	High Compression Locking Peg, 2.7mm x 20mm HCLP-27200-TS (01)00841506101743		High Compression Locking Peg, 2.7mm x 30mm HCLP-27300-TS (01)00841506101811
Threaded Pegs, Locking (Ti) - Pink			
	Threaded Peg, Locking, 2.3mm x 10mm TPLS-23100-TS (01)00841506103358		Threaded Peg, Locking, 2.3mm x 21mm TPLS-23210-TS (01)00841506103433
	Threaded Peg, Locking, 2.3mm x 12mm TPLS-23120-TS (01)00841506103365		Threaded Peg, Locking, 2.3mm x 22mm TPLS-23220-TS (01)00841506103440
	Threaded Peg, Locking, 2.3mm x 14mm TPLS-23140-TS (01)00841506103372		Threaded Peg, Locking, 2.3mm x 23mm TPLS-23230-TS (01)00841506103457
	Threaded Peg, Locking, 2.3mm x 16mm TPLS-23160-TS (01)00841506103389		Threaded Peg, Locking, 2.3mm x 24mm TPLS-23240-TS (01)00841506103464
	Threaded Peg, Locking, 2.3mm x 17mm TPLS-23170-TS (01)00841506103396		Threaded Peg, Locking, 2.3mm x 26mm TPLS-23260-TS (01)00841506103471
	Threaded Peg, Locking, 2.3mm x 18mm TPLS-23180-TS (01)00841506103402		Threaded Peg, Locking, 2.3mm x 28mm TPLS-23280-TS (01)00841506103488
	Threaded Peg, Locking, 2.3mm x 19mm TPLS-23190-TS (01)00841506103419		Threaded Peg, Locking, 2.3mm x 30mm TPLS-23300-TS (01)00841506103495

	Threaded Peg, Locking, 2.3mm x 20mm TPLS-23200-TS (01)00841506103426 		
Threaded Pegs, Non-Locking (Ti) -			
	Threaded Peg, Non-Locking, 2.7mm x 10mm TPNL-27100-TS (01)00841506103518 		Threaded Peg, Non-Locking, 2.7mm x 22mm TPNL-27220-TS (01)00841506103570 
	Threaded Peg, Non-Locking, 2.7mm x 12mm TPNL-27120-TS (01)00841506103525 		Threaded Peg, Non-Locking, 2.7mm x 24mm TPNL-27240-TS (01)00841506103587 
	Threaded Peg, Non-Locking, 2.7mm x 14mm TPNL-27140-TS (01)00841506103532 		Threaded Peg, Non-Locking, 2.7mm x 26mm TPNL-27260-TS (01)00841506103594 
	Threaded Peg, Non-Locking, 2.7mm x 16mm TPNL-27160-TS (01)00841506103549 		Threaded Peg, Non-Locking, 2.7mm x 28mm TPNL-27280-TS (01)00841506103600 
	Threaded Peg, Non-Locking, 2.7mm x 18mm TPNL-27180-TS (01)00841506103556 		Threaded Peg, Non-Locking, 2.7mm x 30mm TPNL-27300-TS (01)00841506103617 
	Threaded Peg, Non-Locking, 2.7mm x 20mm TPNL-27200-TS (01)00841506103563 		
Cannulated Polyaxial Screws, Locking (CoCr) -			
	Screw, Polyaxial Locking, 2.5mm x 10mm, Cannulated PALS-25100-CC (01)00841506102665 		Screw, Polyaxial Locking, 2.5mm x 22mm, Cannulated PALS-25220-CC (01)00841506102726 
	Screw, Polyaxial Locking, 2.5mm x 12mm, Cannulated PALS-25120-CC (01)00841506102672 		Screw, Polyaxial Locking, 2.5mm x 24mm, Cannulated PALS-25240-CC (01)00841506102733 
	Screw, Polyaxial Locking, 2.5mm x 14mm, Cannulated PALS-25140-CC (01)00841506102689 		Screw, Polyaxial Locking, 2.5mm x 26mm, Cannulated PALS-25260-CC (01)00841506102740 
	Screw, Polyaxial Locking, 2.5mm x 16mm, Cannulated PALS-25160-CC (01)00841506102696 		Screw, Polyaxial Locking, 2.5mm x 28mm, Cannulated PALS-25280-CC (01)00841506102757 
	Screw, Polyaxial Locking, 2.5mm x 18mm, Cannulated PALS-25180-CC (01)00841506102702 		Screw, Polyaxial Locking, 2.5mm x 30mm, Cannulated PALS-25300-CC (01)00841506102764 
	Screw, Polyaxial Locking, 2.5mm x 20mm, Cannulated PALS-25200-CC (01)00841506102719 		
Cortical Screws, Locking (Ti) - Bronze			
	Screw, Cortical Locking, 3.5mm x 8mm COLS-35080-TS (01)00841506101071 		Screw, Cortical Locking, 3.5mm x 13mm COLS-35130-TS (01)00841506101125 
	Screw, Cortical Locking, 3.5mm x 9mm COLS-35090-TS (01)00841506101088 		Screw, Cortical Locking, 3.5mm x 14mm COLS-35140-TS (01)00841506101132 
	Screw, Cortical Locking, 3.5mm x 10mm COLS-35100-TS (01)00841506101095 		Screw, Cortical Locking, 3.5mm x 15mm COLS-35150-TS (01)00841506101149 
	Screw, Cortical Locking, 3.5mm x 11mm COLS-35110-TS (01)00841506101101 		Screw, Cortical Locking, 3.5mm x 16mm COLS-35160-TS (01)00841506101156 
	Screw, Cortical Locking, 3.5mm x 12mm COLS-35120-TS (01)00841506101118 		Screw, Cortical Locking, 3.5mm x 18mm COLS-35180-TS (01)00841506101163 
Cortical Screws, Non-Locking (Ti) -			
	Screw, Cortical Non-Locking, 3.5mm x 8mm PANL-35080-TS (01)00841506102771 		Screw, Cortical Non-Locking, 3.5mm x 13mm PANL-35130-TS (01)00841506102825 
	Screw, Cortical Non-Locking, 3.5mm x 9mm PANL-35090-TS (01)00841506102788 		Screw, Cortical Non-Locking, 3.5mm x 14mm PANL-35140-TS (01)00841506102832 
	Screw, Cortical Non-Locking, 3.5mm x 10mm PANL-35100-TS (01)00841506102795 		Screw, Cortical Non-Locking, 3.5mm x 15mm PANL-35150-TS (01)00841506102849 

	Screw, Cortical Non-Locking, 3.5mm x 11mm PANL-35110-TS (01)00841506102801		Screw, Cortical Non-Locking, 3.5mm x 16mm PANL-35160-TS (01)00841506102856
	Screw, Cortical Non-Locking, 3.5mm x 12mm PANL-35120-TS (01)00841506102818		Screw, Cortical Non-Locking, 3.5mm x 18mm PANL-35180-TS (01)00841506102863
Washers (Ti) - Blue			
	Washer, Inside Ø2.7mm, Outside Ø5.0mm WBTN-2750-T (01)00841506103730		

Reusable Instruments	
Handle, Universal Quick Connect, Fixed HNDL-UQC-FXD (01)00841506102108	Tissue Protector / Drill Guide, Dual Sided, 2.0mm x 2.5mm TPDG-DSD-2025 (01)00841506103310
Handle, Small QC, Fixed HNDL-SQC-FXD	GEMINUS Plate Bender GMN-FSP-PLB
Forceps, Bone Holding Medium, Ratcheting FRCP-BHM-RTC (01)00841506101354	GEMINUS Plate Holder GMN-FSP-PLH
Thread-in Drill Guide, 2.0mm TPDG-THD-DG20 (01)00841506103327	Cannulated Depth Gauge, PLS GMN-CDG-PLS (01)00841506101378
Thread-in Drill Guide, 2.5mm TPDG-THD-DG25 (01)00841506103341	Initial Driver, Polyaxial Locking Screw GMN-ID-PLS (01)00841506101552
Depth Gauge, Sm. Standard, 30mm DPGA-SMS-030 (01)00841506101187	GEMINUS Hook Plate, Reduction Tool GMN-HP-DG15 (01)00841506101521
GEMINUS Tray	
GEMINUS Sterilization Tray GMN-FSP-TRAY (01)00841506100401	GEMINUS Lid GMN-TRAY-LID
GEMINUS Base GMN-TRAY-BASE	GEMINUS Accessory Module 1 GMN-ACC-MOD1 (01)00841506100456
GEMINUS Instrument Tray Insert GMN-TRAY-INSRT (01)00841506100425	GEMINUS Hook Plate Snap-in Block GMN-ACC-MOD1A (01)00841506100463
GEMINUS Screw Caddy GMN-TRAY-CAD	
Optional	
Handle, Small QC, Ratcheting HNDL-SQC-RAT (01)00841506102085	Instrument, Sharp Hook Probe, Standard INST-SHP-STD (01)00841506102474
Instrument, Mini-Hohmann Retractor, Standard INST-MHR-STD (01)00841506102467	Handle, AO QC, Fixed HNDL-AQC-FXD
Instrument, Key Periosteal Elevator, Standard INST-KPE-STD (01)00841506102450	Protean Bending Pliers PRT-BND-PLR