

Wrist and Forearm Set

INSTRUCTIONS FOR USE

R: 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 Wrist and Forearm Set; it is not a reference to surgical techniques.

Description

The Skeletal Dynamics Wrist and Forearm Set consists of the following systems:

1. GEMINUS[®] Volar Plating System
2. PROTEAN[®] Fragment Plate System
3. Dorsal Spanning Plate System
4. Forearm Plating System

All components of the system are provided non-sterile to be sterilized in the user facility.

1. GEMINUS[®] Volar Plating System

The GEMINUS[®] Volar Plating System contains bone plates for the repair of distal volar radial fractures. Included in the Set are titanium alloy bone screws, fixation pegs, fragment plates, and specialized instrumentation. Also included are a Hook Plate Extension to buttress a volar marginal fragment, and cobalt chrome cannulated polyaxial locking screws for trajectories different than those of the fixed angled bone plates. The system is provided non-sterile and is sterilized in the user facility.

The GEMINUS[®] Volar Plates are available in various sizes and are made of titanium alloy. Cortical screws affix the plate to the diaphysis and fixed angle pegs are used for distal bone fragments.

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 for Use GEMINUS[®] Volar Plating System

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

2. PROTEAN[®] Fragment Plate System

The PROTEAN[®] Fragment Plate System is a Set of titanium alloy bone plates designed for stabilization and repair of small bone fragments. Included in the Set are titanium alloy bone screws and pegs, cobalt chrome cannulated polyaxial screws, k-wires, and specialized instrumentation.

The PROTEAN[®] Fragment Plates are available in various configurations. The system is provided non-sterile and is sterilized in the user facility.

The PROTEAN[®] Fragment Plate System is comprised of:

- Titanium alloy plates and screws
- Cobalt chrome polyaxial screws
- Stainless steel K-wires (for provisional fixation; not for implantation)
- System specific instrumentation.

Indications for Use PROTEAN® Fragment Plate System

The Skeletal Dynamics PROTEAN® Fragment Plate System is intended for stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstructions of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, and pelvis, particularly in osteopenic bone.

3. Dorsal Spanning Plate System

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 for Use Dorsal Spanning Plate System

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

4. Forearm Plating System

The Forearm Plating System contains bone plates for the repair of midshaft radius and ulna fractures. Included in the Set are titanium alloy bone screws, k-wires, and specialized instrumentation.

The Forearm Plates are available in various sizes and are made of medical grade titanium alloy. The system is provided non-sterile and is sterilized at the user facility.

The Forearm Plating System is comprised of:

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

Indications for Use Forearm Plating System

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

Contraindications

Prior to using the Wrist and Forearm Set, 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.

⚠General Warnings and Precautions

- The information in this document should be shared with the patient.
- The patient should be informed about the importance of following the post-operative rehabilitation prescribed in order to fully understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, device or treatment failure as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.
- Potential construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, instability, delayed soft tissue healing, soft tissue irritation, delayed fusion, non-fusion, or incomplete healing may occur as a result of noncompliance to post-operative rehabilitation, excessive activities, or construct overloading.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Potential failures of the implants may include delayed union, non-union, loosening of fixation, migration or failure of the device, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance to post-operative rehabilitation.

- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union, nonunion, or soft tissue healing. Improper application of the device during implantation may also increase the possibility of loosening, or migration.
- DO NOT reuse any of the Set implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.
- Protect the Set's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the Set, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Skeletal Dynamics representative or the Skeletal Dynamics Customer Care Department.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are only intended to be used during provisional fixation.
- DO NOT permanently implant the pre-loaded Drill Guides or A.I.M.ing Guides; they are intended to be removed prior to screw insertion.
- DO NOT use peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- All screws must be implanted and fully tightened into the plate to maintain the integrity and strength of the finished construct. If the screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- DO NOT mix implant components or system specific instrumentation from different systems or manufacturers for metallurgical, biomechanical and functional reasons.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth, Gap and Screw Gauges are within $\pm 0.25\text{mm}$ or 1.0mm , depending on the system.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures.
- Care should be taken that no screws are placed in the joint.
- To maintain traceability of the implantable components, record each of the respective components Lot numbers in the patient records post implantation.
- The set is to be used only with Skeletal Dynamics instruments, implants and accessories.

⚡GEMINUS® Volar Plating System Warnings and Precautions

- GEMINUS® Drill Blocks are only compatible with GEMINUS® Volar Plates containing a Gold PDG in the shaft.
- 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.
- Use only one 2.5mm PLS in each head of the GEMINUS® Volar Plate.
- The maximum angulation of the PLS should not exceed 10° from the trajectory of the respective hole.
- Use only one 2.7mm Peg (High Compression or Fully Threaded, Non-Locking) 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.
- DO NOT open the volar capsule as it may devascularize fracture fragments and destabilize the volar wrist ligaments.
- 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 use of power tools for the installation of the screws and pegs is not recommended and may lead to cross threading and damage to the screws and/or plates.

⚡PROTEAN® Fragment Plate System Warnings and Precautions

- 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.

- DO NOT open the volar capsule as it may devascularize fracture fragments and destabilize the volar wrist ligaments.

⚠ Dorsal Spanning Plate System Warnings and Precautions

- If used for fracture fixation, the plate must be removed after fracture healing.

Potential Adverse Effects

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

A person with the Wrist and Forearm Plating System implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Wrist and Forearm Plating System Implants
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

Directions for Use

The Wrist and Forearm Set should only be used by surgeons who have experience with this system being used. Each surgeon must evaluate the appropriateness for the use of the Wrist and Forearm Set based on their clinical experiences.

Please refer to the Surgical Technique Guide(s) 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 Wrist and Forearm Set 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 Wrist and Forearm Set instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- The Wrist and Forearm Set 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. Removal of PDG's prior to sterilization is not required.
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.

Sterilization

The Skeletal Dynamics Wrist and Forearm Set is provided non-sterile. This Set is intended for steam sterilization at the healthcare facility.

1. Place all components and accessories into the designated areas of the sterilization tray. Do not stack trays during sterilization.
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, 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 or sterilization container 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 the Wrist and Forearm within the Sterilization Tray. Prior to use, inspect the instrumentation for serviceability.

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.

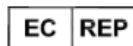
Note: The useful life of these devices is dependent on many factors including, but not limited to the method and duration of each use and the handling of the devices between uses. Routine and careful inspection and functional testing of the device is the best method of determining the serviceable life span for the medical device.

Disclaimer of Warranty and Limited Remedies

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Emergo Europe
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The Netherlands



Wrist and Forearm Set Inventory Control Sheet

Qty.

GEMINUS Volar Distal Radius Plates ¹					
2	GEMINUS Plate, Narrow, 3 Hole, Right GMN-RTN-3HL (01)00841506101620	 (01) 00841506101620	2	GEMINUS Plate, Narrow, 3 Hole, Left GMN-LTN-3HL (01)00841506101569	 (01) 00841506101569
2	GEMINUS Plate, Narrow, 4 Hole, Right GMN-RTN-4HL (01)00841506101637	 (01) 00841506101637	2	GEMINUS Plate, Narrow, 4 Hole, Left GMN-LTN-4HL (01)00841506101576	 (01) 00841506101576
2	GEMINUS Plate, Standard, 3 Hole, Right GMN-RTS-3HL (01)00841506101644	 (01) 00841506101644	2	GEMINUS Plate, Standard, 3 Hole, Left GMN-LTS-3HL (01)00841506101583	 (01) 00841506101583
2	GEMINUS Plate, Standard, 4 Hole, Right ⁺ GMN-RTS-4HL (01)00841506101651	 (01) 00841506101651	2	GEMINUS Plate, Standard, 4 Hole, Left GMN-LTS-4HL (01)00841506101590	 (01) 00841506101590
2	GEMINUS Plate, Standard, 7 Hole, Right GMN-RTS-7HL (01)00841506101668	 (01) 00841506101668	2	GEMINUS Plate, Standard, 7 Hole, Left GMN-LTS-7HL (01)00841506101606	 (01) 00841506101606
2	GEMINUS Plate, Wide, 4 Hole, Right GMN-RTW-4HL (01)00841506101675	 (01) 00841506101675	2	GEMINUS Plate, Wide, 4 Hole, Left GMN-LTW-4HL (01)00841506101613	 (01) 00841506101613
2	GEMINUS Plate, Narrow, 120mm, Right GMN-RTN-120 (01)00841506107455	 (01) 00841506107455	2	GEMINUS Plate, Narrow, 120mm, Left GMN-LTN-120 (01)00841506107462	 (01) 00841506107462
2	GEMINUS Plate, Narrow, 160mm, Right GMN-RTN-160 (01)00841506107479	 (01) 00841506107479	2	GEMINUS Plate, Narrow, 160mm, Left GMN-LTN-160 (01)00841506107486	 (01) 00841506107486
2	GEMINUS Plate, Narrow, 200mm, Right GMN-RTN-200 (01)00841506107493	 (01) 00841506107493	2	GEMINUS Plate, Narrow, 200mm, Left GMN-LTN-200 (01)00841506107509	 (01) 00841506107509
Midshaft Radius Plate ¹			Midshaft Ulna Plate ¹		
1	FreeFix Midshaft Radius Plate, 81mm MRP-081 (01)00841506114576	 (01) 00841506114576	1	FreeFix Midshaft Ulna Plate, 81mm MUP-081 (01)00841506115351	 (01) 00841506115351
1	FreeFix Midshaft Radius Plate, 97mm MRP-097 (01)00841506112992	 (01) 00841506112992	1	FreeFix Midshaft Ulna Plate, 97mm MUP-097 (01)00841506115368	 (01) 00841506115368

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1	FreeFix Midshaft Radius Plate, 112mm MRP-112 (01)00841506114583  (01)00841506114583	1	FreeFix Midshaft Ulna Plate, 112mm MUP-112 (01)00841506115375  (01)00841506115375
1	FreeFix Midshaft Radius Plate, 127mm MRP-127 (01)00841506113005  (01)00841506113005	1	FreeFix Midshaft Ulna Plate, 127mm MUP-127 (01)00841506115382  (01)00841506115382
1	FreeFix Midshaft Radius Plate, 142mm MRP-142 (01)00841506114590  (01)00841506114590	1	FreeFix Midshaft Ulna Plate, 142mm MUP-142 (01)00841506113036  (01)00841506113036
1	FreeFix Midshaft Radius Plate, 157mm MRP-157 (01)00841506113012  (01)00841506113012	1	FreeFix Midshaft Ulna Plate, 157mm MUP-157 (01)00841506115399  (01)00841506115399
1	FreeFix Midshaft Radius Plate, 173mm MRP-173 (01)00841506115733  (01)00841506115733	1	FreeFix Midshaft Ulna Plate, 173mm MUP-173 (01)00841506115405  (01)00841506115405
1	FreeFix Midshaft Radius Plate, 188mm MRP-188 (01)00841506115740  (01)00841506115740	1	FreeFix Midshaft Ulna Plate, 188mm MUP-188 (01)00841506115412  (01)00841506115412
PROTEAN Plates¹			
2	PROTEAN Fragment Plate, Radial Column Plate, Right PRT-RCP-RT (01)00841506109923  (01)00841506109923	2	PROTEAN Fragment Plate, Radial Column Plate, Left PRT-RCP-LT (01)00841506109930  (01)00841506109930
2	PROTEAN Fragment Plate, Central Column Plate, Right PRT-CCP-RT (01)00841506109947  (01)00841506109947	2	PROTEAN Fragment Plate, Central Column Plate, Left PRT-CCP-LT (01)00841506109954  (01)00841506109954
2	PROTEAN Fragment Plate, Distal Ulna PRT-FSP-DU (01)00841506102900  (01)00841506102900	1	PROTEAN Fragment Plate, Double Hockey Stick PRT-FSP-LR (01)00841506102917  (01)00841506102917
1	PROTEAN Fragment Plate, Y PRT-FSP-YS (01)00841506102931  (01)00841506102931		
Smooth Peg, Locking¹			
4	Smooth Peg, Locking, 2.0mm x 14mm, Ti SPLS-20140-TS (01)00841506102962  (01)00841506102962	6	Smooth Peg, Locking, 2.0mm x 21mm, Ti SPLS-20210-TS (01)00841506103020  (01)00841506103020

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4	Smooth Peg, Locking, 2.0mm x 16mm, Ti SPLS-20160-TS (01)00841506102979	 (01)00841506102979	6	Smooth Peg, Locking, 2.0mm x 22mm, Ti SPLS-20220-TS (01)00841506103037	 (01)00841506103037
4	Smooth Peg, Locking, 2.0mm x 17mm, Ti SPLS-20170-TS (01)00841506102986	 (01)00841506102986	6	Smooth Peg, Locking, 2.0mm x 23mm, Ti SPLS-20230-TS (01)00841506103044	 (01)00841506103044
4	Smooth Peg, Locking, 2.0mm x 18mm, Ti SPLS-20180-TS (01)00841506102993	 (01)00841506102993	4	Smooth Peg, Locking, 2.0mm x 24mm, Ti SPLS-20240-TS (01)00841506103051	 (01)00841506103051
6	Smooth Peg, Locking, 2.0mm x 19mm, Ti SPLS-20190-TS (01)00841506103006	 (01)00841506103006	4	Smooth Peg, Locking, 2.0mm x 26mm, Ti SPLS-20260-TS (01)00841506103068	 (01)00841506103068
6	Smooth Peg, Locking, 2.0mm x 20mm, Ti SPLS-20200-TS (01)00841506103013	 (01)00841506103013	4	Smooth Peg, Locking, 2.0mm x 28mm, Ti SPLS-20280-TS (01)00841506103075	 (01)00841506103075
Threaded Peg, Locking¹					
6	Threaded Peg, Locking, 2.3mm x 10mm, Ti TPLS-23100-TS (01)00841506103358	 (01)00841506103358	6	Threaded Peg, Locking, 2.3mm x 23mm, Ti TPLS-23230-TS (01)00841506103457	 (01)00841506103457
6	Threaded Peg, Locking, 2.3mm x 12mm, Ti TPLS-23120-TS (01)00841506103365	 (01)00841506103365	4	Threaded Peg, Locking, 2.3mm x 24mm, Ti TPLS-23240-TS (01)00841506103464	 (01)00841506103464
6	Threaded Peg, Locking, 2.3mm x 14mm, Ti TPLS-23140-TS (01)00841506103372	 (01)00841506103372	4	Threaded Peg, Locking, 2.3mm x 26mm, Ti TPLS-23260-TS (01)00841506103471	 (01)00841506103471
6	Threaded Peg, Locking, 2.3mm x 16mm, Ti TPLS-23160-TS (01)00841506103389	 (01)00841506103389	4	Threaded Peg, Locking, 2.3mm x 28mm, Ti TPLS-23280-TS (01)00841506103488	 (01)00841506103488
6	Threaded Peg, Locking, 2.3mm x 17mm, Ti TPLS-23170-TS (01)00841506103396	 (01)00841506103396	4	Threaded Peg, Locking, 2.3mm x 30mm, Ti TPLS-23300-TS (01)00841506103495	 (01)00841506103495
6	Threaded Peg, Locking, 2.3mm x 18mm, Ti TPLS-23180-TS (01)00841506103402	 (01)00841506103402	2	Threaded Peg, Locking, 2.3mm x 32mm, Ti TPLS-23320-TS (01)00841506103501	 (01)00841506103501
6	Threaded Peg, Locking, 2.3mm x 19mm, Ti TPLS-23190-TS (01)00841506103419	 (01)00841506103419	2	Threaded Peg, Locking, 2.3mm x 34mm, Ti TPLS-23340-TS (01)00841506103983	 (01)00841506103983

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6	Threaded Peg, Locking, 2.3mm x 20mm, Ti TPLS-23200-TS (01)00841506103426  (01)00841506103426	2	Threaded Peg, Locking, 2.3mm x 36mm, Ti TPLS-23360-TS (01)00841506103990  (01)00841506103990
6	Threaded Peg, Locking, 2.3mm x 21mm, Ti TPLS-23210-TS (01)00841506103433  (01)00841506103433	2	Threaded Peg, Locking, 2.3mm x 38mm, Ti TPLS-23380-TS (01)00841506104003  (01)00841506104003
6	Threaded Peg, Locking, 2.3mm x 22mm, Ti TPLS-23220-TS (01)00841506103440  (01)00841506103440	2	Threaded Peg, Locking, 2.3mm x 40mm, Ti TPLS-23400-TS (01)00841506104010  (01)00841506104010
High Compression Locking Peg¹			
1	High Compression Locking Peg, 2.7mm x 10mm, Ti HCLP-27100-TS (01)00841506101682  (01)00841506101682	2	High Compression Locking Peg, 2.7mm x 21mm, Ti HCLP-27210-TS (01)00841506101750  (01)00841506101750
1	High Compression Locking Peg, 2.7mm x 12mm, Ti HCLP-27120-TS (01)00841506101699  (01)00841506101699	2	High Compression Locking Peg, 2.7mm x 22mm, Ti HCLP-27220-TS (01)00841506101767  (01)00841506101767
1	High Compression Locking Peg, 2.7mm x 14mm, Ti HCLP-27140-TS (01)00841506101705  (01)00841506101705	2	High Compression Locking Peg, 2.7mm x 23mm, Ti HCLP-27230-TS (01)00841506101774  (01)00841506101774
2	High Compression Locking Peg, 2.7mm x 16mm, Ti HCLP-27160-TS (01)00841506101712  (01)00841506101712	2	High Compression Locking Peg, 2.7mm x 24mm, Ti HCLP-27240-TS (01)00841506101781  (01)00841506101781
2	High Compression Locking Peg, 2.7mm x 18mm, Ti HCLP-27180-TS (01)00841506101729  (01)00841506101729	2	High Compression Locking Peg, 2.7mm x 26mm, Ti HCLP-27260-TS (01)00841506101798  (01)00841506101798
2	High Compression Locking Peg, 2.7mm x 19mm, Ti HCLP-27190-TS (01)00841506101736  (01)00841506101736	1	High Compression Locking Peg, 2.7mm x 28mm, Ti HCLP-27280-TS (01)00841506101804  (01)00841506101804
2	High Compression Locking Peg, 2.7mm x 20mm, Ti HCLP-27200-TS (01)00841506101743  (01)00841506101743	1	High Compression Locking Peg, 2.7mm x 30mm, Ti HCLP-27300-TS (01)00841506101811  (01)00841506101811
Threaded Peg, Non-Locking¹			
6	Threaded Peg, Non-Locking, 2.7mm x 10mm, Ti TPNL-27100-TS (01)00841506103518  (01)00841506103518	4	Threaded Peg, Non-Locking, 2.7mm x 26mm, Ti TPNL-27260-TS (01)00841506103594  (01)00841506103594

Wrist and Forearm Set Inventory Control Sheet

6	Threaded Peg, Non-Locking, 2.7mm x 12mm, Ti TPNL-27120-TS (01)00841506103525  (01)00841506103525	4	Threaded Peg, Non-Locking, 2.7mm x 28mm, Ti TPNL-27280-TS (01)00841506103600  (01)00841506103600
6	Threaded Peg, Non-Locking, 2.7mm x 14mm, Ti TPNL-27140-TS (01)00841506103532  (01)00841506103532	4	Threaded Peg, Non-Locking, 2.7mm x 30mm, Ti TPNL-27300-TS (01)00841506103617  (01)00841506103617
6	Threaded Peg, Non-Locking, 2.7mm x 16mm, Ti TPNL-27160-TS (01)00841506103549  (01)00841506103549	2	Threaded Peg, Non-Locking, 2.7mm x 32mm, Ti TPNL-27320-TS (01)00841506103624  (01)00841506103624
6	Threaded Peg, Non-Locking, 2.7mm x 18mm, Ti TPNL-27180-TS (01)00841506103556  (01)00841506103556	2	Threaded Peg, Non-Locking, 2.7mm x 34mm, Ti TPNL-27340-TS (01)00841506103907  (01)00841506103907
6	Threaded Peg, Non-Locking, 2.7mm x 20mm, Ti TPNL-27200-TS (01)00841506103563  (01)00841506103563	2	Threaded Peg, Non-Locking, 2.7mm x 36mm, Ti TPNL-27360-TS (01)00841506103914  (01)00841506103914
6	Threaded Peg, Non-Locking, 2.7mm x 22mm, Ti TPNL-27220-TS (01)00841506103570  (01)00841506103570	2	Threaded Peg, Non-Locking, 2.7mm x 38mm, Ti TPNL-27380-TS (01)00841506103921  (01)00841506103921
6	Threaded Peg, Non-Locking, 2.7mm x 24mm, Ti TPNL-27240-TS (01)00841506103587  (01)00841506103587	2	Threaded Peg, Non-Locking, 2.7mm x 40mm, Ti TPNL-27400-TS (01)00841506103938  (01)00841506103938
Cortical Screw, Non-Locking¹		Cortical Screw, Locking¹	
6	Screw, Cortical Non-Locking, 3.5mm x 8mm, Ti PANL-35080-TS (01)00841506102771  (01)00841506102771	6	Screw, Cortical, Locking, 3.5mm x 8mm, Ti COLS-35080-TS (01)00841506101071  (01)00841506101071
6	Screw, Cortical Non-Locking, 3.5mm x 9mm, Ti PANL-35090-TS (01)00841506102788  (01)00841506102788	6	Screw, Cortical, Locking, 3.5mm x 9mm, Ti COLS-35090-TS (01)00841506101088  (01)00841506101088
6	Screw, Cortical Non-Locking, 3.5mm x 10mm, Ti PANL-35100-TS (01)00841506102795  (01)00841506102795	6	Screw, Cortical, Locking, 3.5mm x 10mm, Ti COLS-35100-TS (01)00841506101095  (01)00841506101095
6	Screw, Cortical Non-Locking, 3.5mm x 11mm, Ti PANL-35110-TS (01)00841506102801  (01)00841506102801	6	Screw, Cortical, Locking, 3.5mm x 11mm, Ti COLS-35110-TS (01)00841506101101  (01)00841506101101
6	Screw, Cortical Non-Locking, 3.5mm x 12mm, Ti PANL-35120-TS (01)00841506102818  (01)00841506102818	6	Screw, Cortical, Locking, 3.5mm x 12mm, Ti COLS-35120-TS (01)00841506101118  (01)00841506101118

Wrist and Forearm Set Inventory Control Sheet

6	Screw, Cortical Non-Locking, 3.5mm x 13mm, Ti PANL-35130-TS (01)00841506102825  (01)00841506102825	6	Screw, Cortical, Locking, 3.5mm x 13mm, Ti COLS-35130-TS (01)00841506101125  (01)00841506101125
6	Screw, Cortical Non-Locking, 3.5mm x 14mm, Ti PANL-35140-TS (01)00841506102832  (01)00841506102832	6	Screw, Cortical, Locking, 3.5mm x 14mm, Ti COLS-35140-TS (01)00841506101132  (01)00841506101132
6	Screw, Cortical Non-Locking, 3.5mm x 15mm, Ti PANL-35150-TS (01)00841506102849  (01)00841506102849	6	Screw, Cortical, Locking, 3.5mm x 15mm, Ti COLS-35150-TS (01)00841506101149  (01)00841506101149
6	Screw, Cortical Non-Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856  (01)00841506102856	6	Screw, Cortical, Locking, 3.5mm x 16mm, Ti COLS-35160-TS (01)00841506101156  (01)00841506101156
6	Screw, Cortical Non-Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863  (01)00841506102863	6	Screw, Cortical, Locking, 3.5mm x 18mm, Ti COLS-35180-TS (01)00841506101163  (01)00841506101163
6	Screw, Cortical Non-Locking, 3.5mm x 20mm, Ti PANL-35200-TS (01)00841506104171  (01)00841506104171	6	Screw, Cortical, Locking, 3.5mm x 20mm, Ti COLS-35200-TS (01)00841506104034  (01)00841506104034
6	Screw, Cortical Non-Locking, 3.5mm x 22mm, Ti PANL-35220-TS (01)00841506104188  (01)00841506104188	6	Screw, Cortical, Locking, 3.5mm x 22mm, Ti COLS-35220-TS (01)00841506104041  (01)00841506104041
4	Screw, Cortical Non-Locking, 3.5mm x 24mm, Ti PANL-35240-TS (01)00841506104195  (01)00841506104195	4	Screw, Cortical, Locking, 3.5mm x 24mm, Ti COLS-35240-TS (01)00841506104058  (01)00841506104058
4	Screw, Cortical Non-Locking, 3.5mm x 26mm, Ti PANL-35260-TS (01)00841506104201  (01)00841506104201	4	Screw, Cortical, Locking, 3.5mm x 26mm, Ti COLS-35260-TS (01)00841506104065  (01)00841506104065
4	Screw, Cortical Non-Locking, 3.5mm x 28mm, Ti PANL-35280-TS (01)00841506104218  (01)00841506104218	4	Screw, Cortical, Locking, 3.5mm x 28mm, Ti COLS-35280-TS (01)00841506104072  (01)00841506104072
Washer¹			
2	Washer, Button (Bronze) WBTN-HCLP (01)00841506105963  (01)00841506105963	2	Washer, Button (Blue) WBTN-2750-T (01)00841506103730  (01)00841506103730

Wrist and Forearm Set

Inventory Control Sheet

General Single Use (Disposable) Instruments¹

2	Drill, Solid Side Cutting, 2.0mm x 40mm DRLL-SSC-20040 (01)00841506101255	 (01) 00841506101255	6	K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504	 (01) 00841506102504
2	Drill, Solid Side Cutting, 2.5mm x 40mm DRLL-SSC-25040 (01)00841506101279	 (01) 00841506101279	2	Drill, 2.7mm x 50mm DRLL-SSC-27050 (01)00841506114705	 (01) 00841506114705
2	Driver, Peg, Torque Limiting DRVR-AOS-S20 (01)00841506101293	 (01) 00841506101293	1	Countersink, 5.6mm DRLL-CSK-56 (01)00841506105956	 (01) 00841506105956
2	Driver, Peg DRVR-S20 (01)00841506109152	 (01) 00841506109152	2	Drill, 3.5mm x 70mm DRLL-SSC-35070 (01)00841506106540	 (01) 00841506106540
2	Driver, Universal Quick Connect, T10 DRVR-UQC-T10 (01)00841506101330	 (01) 00841506101330	2	Drill, 2.5mm x 50mm DRLL-SSC-25050 (01)00841506117133	 (01) 00841506317137

General Reusable Instruments²

6	AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870	 (01) 00841506102870	2	Fragment Bone Clamp, 135cm OAL, Curved CLMP-FRG-135 (01)00841506117140	 (01) 00841506317144
1	Handle, Universal Quick Connect, Fixed HNDL-UQC-FXD (01)00841506102108	 (01) 00841506102108	4	Thread-in Drill Guide, FreeFix, 1.6mm K-wire TPDG-FF-KW16 (01)00841506117317	 (01) 00841506317311
2	Handle, Small QC, Fixed HNDL-SQC-FXD (01)00841506102078	 (01) 00841506102078	1	Tissue Protector/Drill Guide, Dual Sided, 2.0mm x 2.5mm TPDG-DSD-2025 (01)00841506103310	 (01) 00841506103310
1	Forceps, Bone Holding Medium, Ratcheting FRCP-BHM-RTC (01)00841506101354	 (01) 00841506101354	1	Drill Guide, FreeFix, 2.7mm TPDG-FF-27ML (01)00841506112732	 (01) 00841506112732
1	Bone Holding Forceps FRCP-BHM-LRT (01)00841506109978	 (01) 00841506109978	1	GEMINUS Plate Bender GMN-FSP-PLB (01)00841506101484	 (01) 00841506101484
1	Thread-in Drill Guide, 2.0mm TPDG-THD-DG20 (01)00841506103327	 (01) 00841506103327	1	GEMINUS Plate Holder GMN-FSP-PLH (01)00841506101491	 (01) 00841506101491

Wrist and Forearm Set Inventory Control Sheet

1	Thread-in Drill Guide, FreeFix ,3.5mm TPDG-FF-35 (01)00841506115757  (01)00841506115757	2	PROTEAN Plate Bending Pliers PRT-BND-PLR (01)00841506102894  (01)00841506102894
1	Depth Gauge, FreeFix , 50mm DPGA-FF-050 (01)00841506115887  (01)00841506115887	2	Universal Bending Irons, 3.5mm UNV-BND-35 (01)00841506110011  (01)00841506110011
1	Depth Gauge, Universal, 30mm DPGA-UNV-030 (01)00841506101194  (01)00841506101194	2	Instrument, Mini-Hohmann Retractor, Standard INST-MHR-STD (01)00841506102467  (01)00841506102467
1	Tissue Protector / Drill Guide, Slot, 2.5mm TPDG-GTS-25 (01)00841506109121  (01)00841506109121	1	Instrument, Sharp Hook Probe, Standard INST-SHP-STD (01)00841506102474  (01)00841506102474
1	Tissue Protector / Drill Guide, Dual Sided, 2.7mm x 3.5mm TPDG-DSD-2735 (01)00841506117270  (01)00841506317274	1	Instrument, Key Periosteal Elevator, Standard INST-KPE-STD (01)00841506102450  (01)00841506102450
Hook Plate¹			
2	GEMINUS Hook Plate GMN-HP (01)00841506101514  (01)00841506101514	4	GEMINUS Hook Plate, Screw GMN-HP-SCRW (01)00841506101545  (01)00841506101545
Hook Plate – Polyaxial Screw, Locking (Cannulated)¹			
2	Screw, Polyaxial Locking, 2.5mm x 10mm Cannulated PALS-25100-CC (01)00841506102665  (01)00841506102665	2	Screw, Polyaxial Locking, 2.5mm x 20mm Cannulated PALS-25200-CC (01)00841506102719  (01)00841506102719
2	Screw, Polyaxial Locking, 2.5mm x 12mm Cannulated PALS-25120-CC (01)00841506102672  (01)00841506102672	2	Screw, Polyaxial Locking, 2.5mm x 22mm Cannulated PALS-25220-CC (01)00841506102726  (01)00841506102726
2	Screw, Polyaxial Locking, 2.5mm x 14mm Cannulated PALS-25140-CC (01)00841506102689  (01)00841506102689	2	Screw, Polyaxial Locking, 2.5mm x 24mm Cannulated PALS-25240-CC (01)00841506102733  (01)00841506102733
2	Screw, Polyaxial Locking, 2.5mm x 16mm Cannulated PALS-25160-CC (01)00841506102696  (01)00841506102696	2	Screw, Polyaxial Locking, 2.5mm x 26mm Cannulated PALS-25260-CC (01)00841506102740  (01)00841506102740
2	Screw, Polyaxial Locking, 2.5mm x 18mm Cannulated PALS-25180-CC (01)00841506102702  (01)00841506102702	2	Screw, Polyaxial Locking, 2.5mm x 28mm Cannulated PALS-25280-CC (01)00841506102757  (01)00841506102757

Wrist and Forearm Set

Inventory Control Sheet

Hook Plate - Single Use (Disposable) Instruments¹

4	K-Wire, Standard Tip, 0.9mm x 152mm KWIR-STD-09152 (01)00841506102498		(01)00841506102498	2	K-Wire, Standard Tip, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504		(01)00841506102504
2	Drill, Cannulated, Polyaxial Locking Screw, 2.0mm DRLL-PLS-20 (01)00841506101248		(01)00841506101248	2	PLS AIMing Guides PLS-AIM-0910 (01)00841506102887		(01)00841506102887
2	Driver, AO Connection, Polyaxial Locking Screw DRVR-AOS-PLS (01)00841506101286		(01)00841506101286				

Hook Plate - Reusable Instruments²

1	GEMINUS Hook Plate, Reduction Tool GMN-HP-DG15 (01)00841506101521		(01)00841506101521	1	Initial Driver, Polyaxial Locking Screw GMN-ID-PLS (01)00841506101552		(01)00841506101552
1	Cannulated Depth Gauge, Polyaxial Locking Screw GMN-CDG-PLS (01)00841506101378		(01)00841506101378				

Dorsal Spanning Plates¹

2	Dorsal Spanning Plate, Short, Ti GMN-DSP-160 (01)00841506105307		(01)00841506105307	2	Dorsal Spanning Plate, Long, Ti GMN-DSP-210 (01)00841506101453		(01)00841506101453
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Multi-Thread Screw, Locking¹

Multi-Thread Screw, Compression¹

4	Screw, Multi-Thread, Locking, 3.0mm x 6mm, Ti MTLS-30060-TS (01)00841506102511		(01)00841506102511	4	Screw, Multi-Thread, Compression, 3.0mm x 6mm, Ti MTNL-30060-TS (01)00841506102580		(01)00841506102580
4	Screw, Multi-Thread, Locking, 3.0mm x 8mm, Ti MTLS-30080-TS (01)00841506102528		(01)00841506102528	4	Screw, Multi-Thread, Compression, 3.0mm x 8mm, Ti MTNL-30080-TS (01)00841506102597		(01)00841506102597
4	Screw, Multi-Thread, Locking, 3.0mm x 10mm, Ti MTLS-30100-TS (01)00841506102535		(01)00841506102535	4	Screw, Multi-Thread, Compression, 3.0mm x 10mm, Ti MTNL-30100-TS (01)00841506102603		(01)00841506102603
6	Screw, Multi-Thread, Locking, 3.0mm x 12mm, Ti MTLS-30120-TS (01)00841506102542		(01)00841506102542	6	Screw, Multi-Thread, Compression, 3.0mm x 12mm, Ti MTNL-30120-TS (01)00841506102610		(01)00841506102610
6	Screw, Multi-Thread, Locking, 3.0mm x 14mm, Ti MTLS-30140-TS (01)00841506102559		(01)00841506102559	6	Screw, Multi-Thread, Compression, 3.0mm x 14mm, Ti MTNL-30140-TS (01)00841506102627		(01)00841506102627

Wrist and Forearm Set Inventory Control Sheet

6	Screw, Multi-Thread, Locking, 3.0mm x 16mm, Ti MTLS-30160-TS (01)00841506102566  (01) 00841506102566	6	Screw, Multi-Thread, Compression, 3.0mm x 16mm, Ti MTNL-30160-TS (01)00841506102634  (01) 00841506102634
4	Screw, Multi-Thread, Locking, 3.0mm x 18mm, Ti MTLS-30180-TS (01)00841506102573  (01) 00841506102573	4	Screw, Multi-Thread, Compression, 3.0mm x 18mm, Ti MTNL-30180-TS (01)00841506102641  (01) 00841506102641
Dorsal Spanning Plate – Single Use (Disposable) Instrument¹			
2	Drill, 2.3mm x 40mm DRLL-SSC-23040 (01)00841506101262  (01) 00841506101262		
Dorsal Spanning Plate - Reusable Instrument²			
1	Thread-in Drill Guide, 2.3mm TPDG-THD-DG23 (01)00841506103334  (01) 00841506103334		
Optional²			
	Handle, Small QC, Ratcheting HNDL-SQC-RAT (01)00841506102085  (01) 00841506102085		Driver, Peg, Torque Limiting, Reusable DRVR-AOS-S20R (01)00841506108834  (01) 00841506108834
	Handle, Universal QC, Ratcheting HNDL-UQC-RTC (01)00841506106533  (01) 00841506106533		Driver, Peg, Reusable DRVR-S20R (01)00841506109114  (01) 00841506109114
	Handle, AO QC, Fixed HNDL-AQC-FXD (01)00841506105406  (01) 00841506105406		Drill, Solid Side Cutting, 2.0mm x 40mm, Reusable DRLL-20040R (01)00841506108841  (01) 00841506108841
	GEMINUS Drill Block System GMN-DBK-SYS (01)00841506101446  (01) 00841506101446		Drill, Solid Side Cutting, 2.5mm x 40mm, Reusable DRLL-25040R (01)00841506108858  (01) 00841506108858
	Handle, AO QC, Fixed HNDL-AQC-FXD (01)00841506105406  (01) 00841506105406		Driver, Universal QC, T10, Reusable DRVR-T10R (01)00841506108827  (01) 00841506108827

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