English

GEMINUS® Volar Distal Radius Plating System

INSTRUCTIONS FOR USE (IFU) FOR THE UNITED KINGDOM AND THE EUROPEAN UNION

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

R_x: For use by physicians only. Caution: Federal Law restricts this device to sale by or on the order of a physician.

This package insert is designed to provide Instructions for Use of the GEMINUS® Volar Distal Radius Plating System devices. **Failure to follow instructions may lead to patient injury.**

Description

The Skeletal Dynamics GEMINUS® Volar Distal Radius 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-angle bone plates.

The GEMINUS® Volar Distal Radius 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 Distal Radius Plating System is comprised of:

- Titanium alloy plates, washers, and screws
- Cobalt Chrome cannulated Polyaxial Locking Screw (PALS)
- Stainless steel K-Wires (for provisional fixation; not for implantation)
- System-specific instrumentation

Intended Use

The GEMINUS® Volar Distal Radius Plating System is intended for stabilization and fixation of bone fragments.

Indications

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

Contraindications

Prior to using the GEMINUS® Volar Distal Radius Plating System, ensure that none of the following patient conditions are present: active or latent infection, insufficient quantity or quality of bone and/or soft tissue, material sensitivity, or patients who are unwilling or incapable of following postoperative care instructions.

Intended Patient Population

The GEMINUS® Volar Distal Radius Plating System is intended for skeletally mature patients. The system should not be used in pediatric patients or patients with open growth plates.

Intended User

The GEMINUS® Volar Distal Radius Plating System should only be used by surgeons familiar with this system and by facility processing staff trained to handle, clean, and re-sterilize surgical devices. Each surgeon must evaluate the appropriateness of using the GEMINUS® Volar Distal Radius Plating System based on their clinical experience.

Expected Clinical Benefits

The expected clinical benefits of internal fixation devices of the GEMINUS® Volar Distal Radius Plating System, when used according to the instructions for use and the recommended technique, are the achievement of stabilization of bones and bone fragments to support bone consolidation.

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A summary of safety and clinical performance (IFU-00738-32) can be found at the following link: http://ec.europa.eu/tools/eudamed

Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched. The summary of safety and clinical performance is available upon request. Please refer to the resources section for further information.

Performance Characteristics of the Device

Skeletal Dynamics has established the performance and safety of the GEMINUS® Volar Distal Radius Plating System and that the system represents a state-of-the-art medical device intended for the treatment of fractures and osteotomies of the distal radius. Refer to the section Inventory Control Sheet in the scope of this IFU for device characteristics such as available lengths and diameters of the subject devices.

Device Lifetime

The expected functional lifetime of the GEMINUS® Volar Distal Radius Plating is dependent on bone union. Based on state-of-the-art data, bone union typically occurs within 3-6 months in 99% of cases. The post-therapeutic lifetime of the implant is the remaining lifetime of the patient following bone consolidation. Patient factors such as weight, bone quality, activity level, and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

⚠ Warnings & Precautions

- 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 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 Skeletal Dynamics GEMINUS® Volar Distal Radius Plating System is to be used only with Skeletal Dynamics instruments, implants, and accessories.
- Potential GEMINUS® Volar Distal Radius Plating System construct failures, such as implant breakage, loosening, delayed union, or non-union, may occur as a result of non-compliance with postoperative rehabilitation, excessive wrist activities, or construct overloading.
- The patient should seek medical help immediately if the implant malfunctions.
- 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-threading and damage to the screws and/or plates.
- DO NOT reuse any of the GEMINUS® Volar Distal Radius 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® Plate.
- Use only one 2.5mm PALS in each head of the GEMINUS® Plate.
- DO NOT use the PALS in the most distal hole(s) on the lunate head of the GEMINUS® Plate.
- Protect the GEMINUS® Volar Distal Radius Plating System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the GEMINUS® Volar Distal Radius 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 the 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 a 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.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.

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- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are intended to be used during provisional fixation of the GEMINUS® Plate.
- DO NOT permanently implant pre-loaded drill guides or AIMing 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 PALS 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 capturing remote bone fragments where partially or fully threaded pegs cannot be used.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drill power sources.



⚠ MR Safety Information

A person with the Skeletal Dynamics' Upper Extremity Systems may be safely scanned at 1.5 T or 3 T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Skeletal Dynamics' Upper Extremity Systems
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m (1,900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	**1.5 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 6.1$ µT) for up to one hour - Lower leg region: Normal Operating Mode for up to one hour **3 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 3.1$ µT) for 6 minutes of scanning, followed by a minimum cooling period of 15 minutes, up to a maximum total scanning/cooling duration of one hour - Lower leg region: Normal Operating Mode for up to one hour
Scan duration	Scan duration as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Scan Regions	Landmark restrictions as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Image Artifact	The presence of Skeletal Dynamics' Upper Extremity Systems may produce an image artifact of 5.1 cm. Some manipulation of scan parameters may be needed to compensate for the artifact
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

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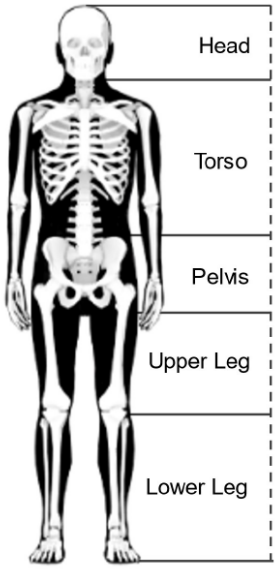
MR Restricted Zone Summary

Skeletal Dynamics' Upper Extremity Systems



Landmark Region	1.5 T Scan Restriction	3 T Scan Restriction
Head	Normal Operating Mode*	Normal Operating Mode*
Torso	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 6.1$ µT	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 3.1$ µT for 6 minutes of scanning followed by a minimum cooling period of 15 minutes
Pelvis		
Upper Leg		
Lower Leg	Normal Operating Mode*	Normal Operating Mode*

Under these conditions, total scanning duration for up to one hour is permitted unless otherwise specified. When a cooling period is recommended, repeated scan/cool sequences are permitted for a total duration of up to one hour. Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
SAR_{wb}: Whole body averaged specific absorption rate
SAR_{head}: Head averaged specific absorption rate
$B_{1+,RMS}$: RMS RF magnetic field (B_{1+})

**Normal Operating Mode limits defined by IEC 60601-2-33 Table 201.104:*
- *SAR_{wb}: 2 W/kg*
- *SAR_{head}: 3.2 W/kg*

Potential Adverse Events

The following are potential risks associated with wrist surgery: infection, nonunion, persistent pain, nerve/bone/soft tissue damage, material sensitivity, stiffness, implant breakage, and loosening or migration of implants, resulting in misalignment. Serious incidents should be reported to Skeletal Dynamics Inc. or an in-country representative and to the health authority where the incident occurred.

Directions for Users

The GEMINUS® Volar Distal Radius Plating System should be used only by surgeons familiar with the system. Each surgeon must evaluate the appropriateness of using the GEMINUS® Volar Distal Radius Plating System during internal fixation procedures based on their experience with the GEMINUS® Volar Distal Radius Plating System.

Please refer to the ***GEMINUS® Volar Distal Radius Plating System's Surgical Technique Guide*** **(**MKT-00005-00) to review the surgical approach as described by Jorge L. Orbay, M.D. of the Miami Hand and Upper Extremity Institute located in Miami, Florida, USA.

You must maintain traceability of the implantable components of the GEMINUS® Volar Distal Radius Plating System. Please record each of the respective components' LOT numbers into the patient's medical records post-implantation.

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Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of GEMINUS ® Volar Distal Radius Plating System products are provided in the Reprocessing IFU, ***Instructions for Reprocessing (Cleaning, Disinfection, and Sterilization) of Skeletal Dynamics Products*** (IFU-04056-00), available at www.skeletaldynamics.com/resources. Refer to the ***GEMINUS® Volar Distal Radius Plating System Surgical Technique Guide*** (MKT-00005-00) for proper kitted tray arrangement.

Resources

The latest version of the Instructions for Use or Summary of Safety and Clinical Performance may be requested in a physical format by email (orders@skeletaldynamics.com) or by phone (+1-877-753-5396). The physical copy will be provided within 7 calendar days of receiving a request from the user or at the time of delivery of the device, if so, requested at the time of order.

For the most current instructions for use visit www.skeletaldynamics.com/resources. Instructions for Use should always be reviewed before using or implanting a device.

Implant Materials

The GEMINUS® Volar Distal Radius Plating System consists of several Titanium Alloy implantable plates and screws and Cobalt Chrome screws commonly used for surgical implants.

Basic UDI Codes	Basic UDI #s	System Components	Material(s)	Standard(s)
GDRP-FAM-TI	08415061423764	GEMINUS® Plates	Ti 6Al-4V ELI	ASTM F136
HKP-FAM-TI	0841506142425V	GEMINUS® Hook Plates	Ti 6Al-4V ELI	ASTM F136
WB-FAM-TI	0841506142415T	Washer Buttons	Ti 6Al-4V ELI	ASTM F136
SCW-FAM-TI	08415061423866	Locking Smooth Pegs Locking Threaded Pegs High Compression Locking Pegs Non-Locking Threaded Pegs Non-Locking Cortical Screws Cortical Locking Screws	Ti 6Al-4V ELI	ASTM F136
CS-FAM-TI	0841506142405R	GEMINUS® Hook Plate Screws	Ti 6Al-4V ELI	ASTM F136
SCW-FAM-CC	08415061423968	Polyaxial Locking Screws	CoCrMo	ASTM 1537

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The Titanium implants conform to ASTM F136, which provides the following tolerances for the material:

ASTM F136 Chemical Composition

Element	Composition % (mass)
Nitrogen, Ni	≤ .05%
Carbon	≤ .08%
Hydrogen	≤ .015%
Iron	≤ .25%
Oxygen	≤ .13%
Aluminum	≤ 6.5%
Vanadium	≤ 4.5%
Titanium	balance*

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

Cobalt Chrome polyaxial screws (PALS) conform to ASTM F1537, which provides the following tolerances for the material:

ASTM F1537 Chemical Composition

Element	Composition % (mass)
Carbon	≤ 0.14%
Chromium	≤ 30%
Molybdenum	≤ 7.0%
Nickel*	≤ 1.0%
Iron	≤ 0.75%
Silicon	≤ 1.0%
Manganese	≤ 1.0%
Nitrogen	≤ 0.25%
Cobalt	balance**

* Nickel, classified as skin sensitizer 1: sensitization or allergic reactions to users and/or patients. Classification based on applicable EU legislation for chemical substances

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

 Cobalt	Cobalt Chrome ASTM 1537	This device contains Cobalt in a concentration above 0.1% weight by weight. Current scientific evidence supports medical devices manufactured do not show any significant incidence of adverse events due to the presence of Cobalt.

Polyaxial screws (PALS) will contain nickel and should not be used on any patient with a known allergy.

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GEMINUS®

Volar Distal Radius Plating System

Inventory Control Sheet

GEMINUS® Volar Distal Radius Plates	
GEMINUS® Plate, Narrow, 3 Hole, Right, Ti GMN-RTN-3HL (01)00841506101620 (01) 00841506101620	GEMINUS® Plate, Narrow, 3 Hole, Left, Ti GMN-LTN-3HL (01)00841506101569 (01) 00841506101569
GEMINUS® Plate, Narrow, 4 Hole, Right, Ti GMN-RTN-4HL (01)00841506101637 (01) 00841506101637	GEMINUS® Plate, Narrow, 4 Hole, Left, Ti GMN-LTN-4HL (01)00841506101576 (01) 00841506101576
GEMINUS® Plate, Standard, 3 Hole, Right, Ti GMN-RTS-3HL (01)00841506101644 (01) 00841506101644	GEMINUS® Plate, Standard, 3 Hole, Left, Ti GMN-LTS-3HL (01)00841506101583 (01) 00841506101583
GEMINUS® Plate, Standard, 4 Hole, Right, Ti GMN-RTS-4HL (01)00841506101651 (01) 00841506101651	GEMINUS® Plate, Standard, 4 Hole, Left, Ti GMN-LTS-4HL (01)00841506101590 (01) 00841506101590
GEMINUS® Plate, Standard, 7 Hole, Right, Ti GMN-RTS-7HL (01)00841506101668 (01) 00841506101668	GEMINUS® Plate, Standard, 7 Hole, Left, Ti GMN-LTS-7HL (01)00841506101606 (01) 00841506101606
GEMINUS® Plate, Wide, 4 Hole, Right, Ti GMN-RTW-4HL (01)00841506101675 (01) 00841506101675	GEMINUS® Plate, Wide, 4 Hole, Left, Ti GMN-LTW-4HL (01)00841506101613 (01) 00841506101613
PROTEAN Fragment Plates	
PROTEAN Fragment Plate, Radial Column Plate, Right, Ti PRT-RCP-RT (01)00841506109923 (01) 00841506109923	PROTEAN Fragment Plate, Radial Column Plate, Left, Ti PRT-RCP-LT (01)00841506109930 (01) 00841506109930
PROTEAN Fragment Plate, Central Column Plate, Right, Ti PRT-CCP-RT (01)00841506109947 (01) 00841506109947	PROTEAN Fragment Plate, Central Column Plate, Left, Ti PRT-CCP-LT (01)00841506109954 (01) 00841506109954
PROTEAN Fragment Plate, Distal Ulna, Ti PRT-FSP-DU (01)00841506102900 (01) 00841506102900	PROTEAN Fragment Plate, Double Hockey Stick, Ti PRT-FSP-LR (01)00841506102917 (01) 00841506102917
PROTEAN Fragment Plate, Y, Ti PRT-FSP-YS (01)00841506102931 (01) 00841506102931	

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Hook Plate	
GEMINUS® Hook Plate, Ti GMN-HP (01)00841506101514 (01) 00841506101514	GEMINUS® Hook Plate, Screw GMN-HP-SCRW (01)00841506101545 (01) 00841506101545
General Single Use (Disposable) Instruments	
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
AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870 (01) 00841506102870	PLS AIMing Guides PLS-AIM-0910 (01)00841506102887 (01) 00841506102887
Smooth Peg, Locking	
Smooth Peg, Locking, 2.0mm x 10mm, Ti SPLS-20140-TS (01)00841506102948 (01) 00841506102948	Smooth Peg, Locking, 2.0mm x 20mm, Ti SPLS-20200-TS (01)00841506103013 (01) 00841506103013
Smooth Peg, Locking, 2.0mm x 12mm, Ti SPLS-20160-TS (01)00841506102955 (01) 00841506102955	Smooth Peg, Locking, 2.0mm x 21mm, Ti SPLS-20210-TS (01)00841506103020 (01) 00841506103020
Smooth Peg, Locking, 2.0mm x 14mm, Ti SPLS-20140-TS (01)00841506102962 (01) 00841506102962	Smooth Peg, Locking, 2.0mm x 22mm, Ti SPLS-20220-TS (01)00841506103037 (01) 00841506103037
Smooth Peg, Locking, 2.0mm x 16mm, Ti SPLS-20160-TS (01)00841506102979 (01) 00841506102979	Smooth Peg, Locking, 2.0mm x 23mm, Ti SPLS-20230-TS (01)00841506103044 (01) 00841506103044
Smooth Peg, Locking, 2.0mm x 17mm, Ti SPLS-20170-TS (01)00841506102986 (01) 00841506102986	Smooth Peg, Locking, 2.0mm x 24mm, Ti SPLS-20240-TS (01)00841506103051 (01) 00841506103051
Smooth Peg, Locking, 2.0mm x 18mm, Ti SPLS-20180-TS (01)00841506102993 (01) 00841506102993	Smooth Peg, Locking, 2.0mm x 26mm, Ti SPLS-20260-TS (01)00841506103068 (01) 00841506103068
Smooth Peg, Locking, 2.0mm x 19mm, Ti SPLS-20190-TS (01)00841506103006 (01) 00841506103006	Smooth Peg, Locking, 2.0mm x 28mm, Ti SPLS-20280-TS (01)00841506103075 (01) 00841506103075
Threaded Peg, Locking	
Threaded Peg, Locking, 2.3mm x 10mm, Ti TPLS-23100-TS (01)00841506103358 (01) 00841506103358	Threaded Peg, Locking, 2.3mm x 21mm, Ti TPLS-23210-TS (01)00841506103433 (01) 00841506103433

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Threaded Peg, Locking, 2.3mm x 12mm, Ti TPLS-23120-TS (01)00841506103365  	Threaded Peg, Locking, 2.3mm x 22mm, Ti TPLS-23220-TS (01)00841506103440 
Threaded Peg, Locking, 2.3mm x 14mm, Ti TPLS-23140-TS (01)00841506103372  	Threaded Peg, Locking, 2.3mm x 23mm, Ti TPLS-23230-TS (01)00841506103457 
Threaded Peg, Locking, 2.3mm x 16mm, Ti TPLS-23160-TS (01)00841506103389  	Threaded Peg, Locking, 2.3mm x 24mm, Ti TPLS-23240-TS (01)00841506103464 
Threaded Peg, Locking, 2.3mm x 17mm, Ti TPLS-23170-TS (01)00841506103396  	Threaded Peg, Locking, 2.3mm x 26mm, Ti TPLS-23260-TS (01)00841506103471 
Threaded Peg, Locking, 2.3mm x 18mm, Ti TPLS-23180-TS (01)00841506103402  	Threaded Peg, Locking, 2.3mm x 28mm, Ti TPLS-23280-TS (01)00841506103488 
Threaded Peg, Locking, 2.3mm x 19mm, Ti TPLS-23190-TS (01)00841506103419  	Threaded Peg, Locking, 2.3mm x 30mm, Ti TPLS-23300-TS (01)00841506103495 
Threaded Peg, Locking, 2.3mm x 20mm, Ti TPLS-23200-TS (01)00841506103426  	
High Compression Locking Peg	
High Compression Locking Peg, 2.7mm x 10mm, Ti HCLP-27100-TS (01)00841506101682  	High Compression Locking Peg, 2.7mm x 21mm, Ti HCLP-27210-TS (01)00841506101750 
High Compression Locking Peg, 2.7mm x 12mm, Ti HCLP-27120-TS (01)00841506101699  	High Compression Locking Peg, 2.7mm x 22mm, Ti HCLP-27220-TS (01)00841506101767 
High Compression Locking Peg, 2.7mm x 14mm, Ti HCLP-27140-TS (01)00841506101705  	High Compression Locking Peg, 2.7mm x 23mm, Ti HCLP-27230-TS (01)00841506101774 
High Compression Locking Peg, 2.7mm x 16mm, Ti HCLP-27160-TS (01)00841506101712  	High Compression Locking Peg, 2.7mm x 24mm, Ti HCLP-27240-TS (01)00841506101781 
High Compression Locking Peg, 2.7mm x 18mm, Ti HCLP-27180-TS (01)00841506101729  	High Compression Locking Peg, 2.7mm x 26mm, Ti HCLP-27260-TS (01)00841506101798 

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High Compression Locking Peg, 2.7mm x 19mm, Ti HCLP-27190-TS (01)00841506101736 (01)00841506101736	High Compression Locking Peg, 2.7mm x 28mm, Ti HCLP-27280-TS (01)00841506101804 (01)00841506101804
High Compression Locking Peg, 2.7mm x 20mm, Ti HCLP-27200-TS (01)00841506101743 (01)00841506101743	High Compression Locking Peg, 2.7mm x 30mm, Ti HCLP-27300-TS (01)00841506101811 (01)00841506101811
Threaded Peg, Non-Locking	
Threaded Peg, Non-Locking, 2.7mm x 10mm, Ti TPNL-27100-TS (01)00841506103518 (01)00841506103518	Threaded Peg, Non-Locking, 2.7mm x 22mm, Ti TPNL-27220-TS (01)00841506103570 (01)00841506103570
Threaded Peg, Non-Locking, 2.7mm x 12mm, Ti TPNL-27120-TS (01)00841506103525 (01)00841506103525	Threaded Peg, Non-Locking, 2.7mm x 24mm, Ti TPNL-27240-TS (01)00841506103587 (01)00841506103587
Threaded Peg, Non-Locking, 2.7mm x 14mm, Ti TPNL-27140-TS (01)00841506103532 (01)00841506103532	Threaded Peg, Non-Locking, 2.7mm x 26mm, Ti TPNL-27260-TS (01)00841506103594 (01)00841506103594
Threaded Peg, Non-Locking, 2.7mm x 16mm, Ti TPNL-27160-TS (01)00841506103549 (01)00841506103549	Threaded Peg, Non-Locking, 2.7mm x 28mm, Ti TPNL-27280-TS (01)00841506103600 (01)00841506103600
Threaded Peg, Non-Locking, 2.7mm x 18mm, Ti TPNL-27180-TS (01)00841506103556 (01)00841506103556	Threaded Peg, Non-Locking, 2.7mm x 30mm, Ti TPNL-27300-TS (01)00841506103617 (01)00841506103617
Threaded Peg, Non-Locking, 2.7mm x 20mm, Ti TPNL-27200-TS (01)00841506103563 (01)00841506103563	
Cortical Screw, Non-Locking	**Cortical Screw, Locking**
Screw, Cortical Non-Locking, 3.5mm x 8mm, Ti PANL-35080-TS (01)00841506102771 (01)00841506102771	Screw, Cortical, Locking, 3.5mm x 8mm, Ti COLS-35080-TS (01)00841506101071 (01)00841506101071
Screw, Cortical Non-Locking, 3.5mm x 9mm, Ti PANL-35090-TS (01)00841506102788 (01)00841506102788	Screw, Cortical, Locking, 3.5mm x 9mm, Ti COLS-35090-TS (01)00841506101088 (01)00841506101088
Screw, Cortical Non-Locking, 3.5mm x 10mm, Ti PANL-35100-TS (01)00841506102795 (01)00841506102795	Screw, Cortical, Locking, 3.5mm x 10mm, Ti COLS-35100-TS (01)00841506101095 (01)00841506101095
Screw, Cortical Non-Locking, 3.5mm x 11mm, Ti PANL-35110-TS (01)00841506102801 (01)00841506102801	Screw, Cortical, Locking, 3.5mm x 11mm, Ti COLS-35110-TS (01)00841506101101 (01)00841506101101

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Screw, Cortical Non-Locking, 3.5mm x 12mm, Ti PANL-35120-TS (01)00841506102818	Screw, Cortical, Locking, 3.5mm x 12mm, Ti COLS-35120-TS (01)00841506101118
Screw, Cortical Non-Locking, 3.5mm x 13mm, Ti PANL-35130-TS (01)00841506102825	Screw, Cortical, Locking, 3.5mm x 13mm, Ti COLS-35130-TS (01)00841506101125
Screw, Cortical Non-Locking, 3.5mm x 14mm, Ti PANL-35140-TS (01)00841506102832	Screw, Cortical, Locking, 3.5mm x 14mm, Ti COLS-35140-TS (01)00841506101132
Screw, Cortical Non-Locking, 3.5mm x 15mm, Ti PANL-35150-TS (01)00841506102849	Screw, Cortical, Locking, 3.5mm x 15mm, Ti COLS-35150-TS (01)00841506101149
Screw, Cortical Non-Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856	Screw, Cortical, Locking, 3.5mm x 16mm, Ti COLS-35160-TS (01)00841506101156
Screw, Cortical Non-Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863	Screw, Cortical, Locking, 3.5mm x 18mm, Ti COLS-35180-TS (01)00841506101163
Washer	
Washer, Button (Blue), Ti WBTN-2750-T (01)00841506103730	
Hook Plate – Polyaxial Screw, Locking (Cannulated)	
Screw, Polyaxial Locking, 2.5mm x 10mm Cannulated, CoCr PALS-25100-CC (01)00841506102665	Screw, Polyaxial Locking, 2.5mm x 22mm Cannulated, CoCr PALS-25220-CC (01)00841506102726
Screw, Polyaxial Locking, 2.5mm x 12mm Cannulated, CoCr PALS-25120-CC (01)00841506102672	Screw, Polyaxial Locking, 2.5mm x 24mm Cannulated, CoCr PALS-25240-CC (01)00841506102733
Screw, Polyaxial Locking, 2.5mm x 14mm Cannulated, CoCr PALS-25140-CC (01)00841506102689	Screw, Polyaxial Locking, 2.5mm x 26mm Cannulated, CoCr PALS-25260-CC (01)00841506102740
Screw, Polyaxial Locking, 2.5mm x 16mm Cannulated, CoCr PALS-25160-CC (01)00841506102696	Screw, Polyaxial Locking, 2.5mm x 28mm Cannulated, CoCr PALS-25280-CC (01)00841506102757

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Screw, Polyaxial Locking, 2.5mm x 18mm Cannulated, CoCr PALS-25180-CC (01)00841506102702  (01)00841506102702	Screw, Polyaxial Locking, 2.5mm x 30mm Cannulated, CoCr PALS-25280-CC (01)00841506102764  (01)00841506102764
Screw, Polyaxial Locking, 2.5mm x 20mm Cannulated, CoCr PALS-25200-CC (01)00841506102719  (01)00841506102719	

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