English

PROTEAN® Fragment 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/

℞: For use by physicians only. 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 PROTEAN® Fragment Plating System. **Failure to follow instructions may lead to patient injury.**

Description

The PROTEAN® Fragment Plating System includes titanium alloy and cobalt-chrome implantable medical devices in multiple sizes and configurations.

The PROTEAN® Fragment Plating System is comprised of:

- Titanium alloy plates
- Titanium and cobalt chrome screws
- Stainless steel and cobalt chrome K-Wires (for provisional fixation, not for implantation)
- Specialized Instrumentation

The system is provided non-sterile and is sterilized in the user facility.

Intended Use

The PROTEAN® Fragment Plating System is intended for stabilization and fixation of bone or bone fragments.

Indications for Use

The PROTEAN® Fragment Plating 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 with the appropriate configuration of the device.

Contraindications

Prior to using the PROTEAN® Fragment 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 post-operative care instructions.

Intended Patient Population

The PROTEAN® Fragment 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 PROTEAN® Fragment 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 PROTEAN® Fragment Plating System based on their clinical experience.

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Expected Clinical Benefits

The expected clinical benefit of internal fixation devices of the PROTEAN® Fragment Plating System, when used according to the instructions for use and the recommended technique, is the achievement of stabilization of bones and bone fragments to support bone consolidation.

A summary of safety and clinical performance (IFU-01206-32) 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 PROTEAN® Fragment 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 PROTEAN® Fragment Plating System is dependent on bone union. Based on state-of-the-art data, bone union typically occurs within 2-4 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 and Precautions

- If the screws are not attached and/or fully tightened, a non-union, delayed union, or construct failure may occur.
- The information in this document should be shared with the patient.
- The patient should be informed about the importance of following the postoperative rehabilitation prescribed to fully understand the limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- Potential Fragment Plating System construct failures, such as implant breakage, loosening, fixation failure, delayed union, malunion, or non-union, may occur as a result of non-compliance with post-operative rehabilitation, excessive wrist activities, or construct overloading.
- DO NOT reuse any of the Fragment Plating System implantable components. Reuse may compromise the structural integrity of the construct.
  DO NOT open the volar capsule as it may devascularize fracture fragments and destabilize the volar wrist ligaments.
- Protect the Fragment Plating System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the Fragment 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.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are intended to be used during provisional fixation of the Fragment Plating.
- DO NOT permanently implant the 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 PLS should not exceed 10° from the trajectory of the respective hole.

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- 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.
- The Fragment 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.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drill power sources.
- 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.
- Seek medical help immediately if the implant malfunctions.
- To maintain traceability of the Fragment Plating System implantable components, you must record each of the respective components' LOT numbers into the patient's records.



⚠ 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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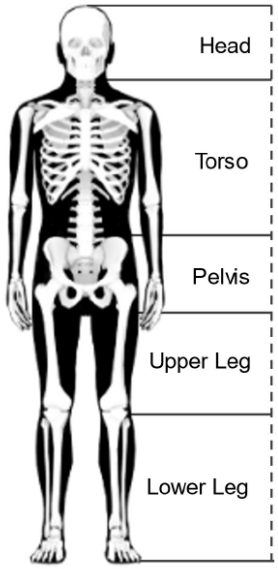
MR Restricted Zone Summary

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 that have been associated with orthopedic surgery: discomfort, nerve/bone/soft tissue damage, infection, swelling, reduced or loss of range of motion, bone fracture, material sensitivity, stiffness, nonunion, persistent pain, loosening/migration/breakage of the implants, implant failure, or damage to the articular surfaces. 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 Use

The PROTEAN® Fragment Plating System should only be used by surgeons who are familiar with this system. Each surgeon must evaluate the appropriateness of using the Fragment Plating System based on their clinical experience. Please refer to the appropriate PROTEAN® Fragment Plating System's Surgical Technique Guide (MKT-00005-00, MKT-00082-00, MKT-00485-00, or MKT-00498-00) 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.

You must maintain traceability of the implantable components of the PROTEAN® Fragment 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 PROTEAN® Fragment 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 appropriate PROTEAN® Fragment Plating System Surgical Technique Guide (MKT-00005-00, MKT-00082-00, MKT-00485-00, or MKT-00498-00) 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 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 PROTEAN® Fragment 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)
PFP-FAM-TI	0841506145696Y	PROTEAN® Plates	Ti 6Al-4V ELI	ASTM F136
SCW-FAM-TI	08415061423866	Locking Threaded Peg Screw High Compression Locking Screw Non-Locking Threaded Peg	Ti 6Al-4V ELI	ASTM F136
SCW-FAM-CC	08415061423968	Polyaxial Locking Screw	CoCrMo	ASTM 1537
WB-FAM-TI	0841506142415T	Washer Button	Ti 6Al-4V ELI	ASTM F136

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.

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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 and variable angle screws and pegs will contain nickel and should not be used on any patient with a known allergy.

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 is only included to generally describe the product when manufactured and do not constitute any express warranties.

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PROTEAN Fragment Plate	
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, Scapholunate, Short, Right PRT-FSP-SR1 (01)00841506103860 (01)00841506103860	PROTEAN Fragment Plate, Scapholunate, Long, Right PRT-FSP-SR2 (01)00841506103884 (01)00841506103884
PROTEAN Fragment Plate, Scapholunate, Short, Left PRT-FSP-SL1 (01)00841506103877 (01)00841506103877	PROTEAN Fragment Plate, Scapholunate, Long, Left PRT-FSP-SL2 (01)00841506103891 (01)00841506103891
PROTEAN Fragment Plate, Radial Column Plate, Right PRT-RCP-RT (01)00841506109923 (01)00841506109923	PROTEAN Fragment Plate, Central Column Plate, Right PRT-CCP-RT (01)00841506109947 (01)00841506109947
PROTEAN Fragment Plate, Radial Column Plate, Left PRT-RCP-LT (01)00841506109930 (01)00841506109930	PROTEAN Fragment Plate, Central Column Plate, Left PRT-CCP-LT (01)00841506109954 (01)00841506109954
PROTEAN Fragment Plate, Distal Ulna PRT-FSP-DU (01)00841506102900 (01)00841506102900	

Threaded Peg, Locking Screws, 2.3mm	
Threaded Peg, Locking, 2.3mm x 10mm, Ti TPLS-23100-TS (01)00841506103358 (01)00841506103358	Threaded Peg, Locking, 2.3mm x 20mm, Ti TPLS-23200-TS (01)00841506103426 (01)00841506103426
Threaded Peg, Locking, 2.3mm x 12mm, Ti TPLS-23120-TS (01)00841506103365 (01)00841506103365	Threaded Peg, Locking, 2.3mm x 21mm, Ti TPLS-23210-TS (01)00841506103433 (01)00841506103433
Threaded Peg, Locking, 2.3mm x 14mm, Ti TPLS-23140-TS (01)00841506103372 (01)00841506103372	Threaded Peg, Locking, 2.3mm x 22mm, Ti TPLS-23220-TS (01)00841506103440 (01)00841506103440
Threaded Peg, Locking, 2.3mm x 16mm, Ti TPLS-23160-TS (01)00841506103389 (01)00841506103389	Threaded Peg, Locking, 2.3mm x 23mm, Ti TPLS-23230-TS (01)00841506103457 (01)00841506103457

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Threaded Peg, Locking, 2.3mm x 17mm, Ti TPLS-23170-TS (01)00841506103396 (01)00841506103396	Threaded Peg, Locking, 2.3mm x 24mm, Ti TPLS-23240-TS (01)00841506103464 (01)00841506103464
Threaded Peg, Locking, 2.3mm x 18mm, Ti TPLS-23180-TS (01)00841506103402 (01)00841506103402	Threaded Peg, Locking, 2.3mm x 26mm, Ti TPLS-23260-TS (01)00841506103471 (01)00841506103471
Threaded Peg, Locking, 2.3mm x 19mm, Ti TPLS-23190-TS (01)00841506103419 (01)00841506103419	Threaded Peg, Locking, 2.3mm x 28mm, Ti TPLS-23280-TS (01)00841506103488 (01)00841506103488
High Compression Locking Screws, 2.7mm	
High Compression Locking Peg, 2.7mm x 10mm, Ti HCLP-27100-TS (01)00841506101682 (01)00841506101682	High Compression Locking Peg, 2.7mm x 21mm, Ti HCLP-27210-TS (01)00841506101750 (01)00841506101750
High Compression Locking Peg, 2.7mm x 12mm, Ti HCLP-27120-TS (01)00841506101699 (01)00841506101699	High Compression Locking Peg, 2.7mm x 22mm, Ti HCLP-27220-TS (01)00841506101767 (01)00841506101767
High Compression Locking Peg, 2.7mm x 14mm, Ti HCLP-27140-TS (01)00841506101705 (01)00841506101705	High Compression Locking Peg, 2.7mm x 23mm, Ti HCLP-27230-TS (01)00841506101774 (01)00841506101774
High Compression Locking Peg, 2.7mm x 16mm, Ti HCLP-27160-TS (01)00841506101712 (01)00841506101712	High Compression Locking Peg, 2.7mm x 24mm, Ti HCLP-27240-TS (01)00841506101781 (01)00841506101781
High Compression Locking Peg, 2.7mm x 18mm, Ti HCLP-27180-TS (01)00841506101729 (01)00841506101729	High Compression Locking Peg, 2.7mm x 26mm, Ti HCLP-27260-TS (01)00841506101798 (01)00841506101798
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

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Threaded Pegs, Non-Locking, 2.7mm	
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	
Polyaxial Locking Screws, 2.5mm	
Screw, Polyaxial Locking, 2.5mm x 10mm, CoCr PALS-25100-CC (01)00841506102665 (01)00841506102665	Screw, Polyaxial Locking, 2.5mm x 20mm, CoCr PALS-25200-CC (01)00841506102719 (01)00841506102719
Screw, Polyaxial Locking, 2.5mm x 12mm, CoCr PALS-25120-CC (01)00841506102672 (01)00841506102672	Screw, Polyaxial Locking, 2.5mm x 22mm, CoCr PALS-25220-CC (01)00841506102726 (01)00841506102726
Screw, Polyaxial Locking, 2.5mm x 14mm, CoCr PALS-25140-CC (01)00841506102689 (01)00841506102689	Screw, Polyaxial Locking, 2.5mm x 24mm, CoCr PALS-25240-CC (01)00841506102733 (01)00841506102733
Screw, Polyaxial Locking, 2.5mm x 16mm, CoCr PALS-25160-CC (01)00841506102696 (01)00841506102696	Screw, Polyaxial Locking, 2.5mm x 26mm, CoCr PALS-25260-CC (01)00841506102740 (01)00841506102740
Screw, Polyaxial Locking, 2.5mm x 18mm, CoCr PALS-25180-CC (01)00841506102702 (01)00841506102702	Screw, Polyaxial Locking, 2.5mm x 28mm, CoCr PALS-25280-CC (01)00841506102757 (01)00841506102757

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Washer Button	
Washer, Button WBTN-2750-T (01)00841506103730 (01) 00841506103730	
Guides	
AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870 (01) 00841506102870	PLS AIMing Guides, .9mm x 10° PLS-AIM-0910 (01)00841506102887 (01) 00841506102887
K-Wires	
K-Wire, Standard Tip, .9mm x 152mm KWIR-STD-09152 (01)00841506102498 (01) 00841506102498	K-Wire, 1.6mm x 127mm KWIR-STD-15127 (01)00841506102504 (01) 00841506102504

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