PROTEAN® Radial Head Plate Module

INSTRUCTIONS FOR USE

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

Failure to follow instructions may lead to patient injury.

This package insert is designed to provide Instructions for Use of the PROTEAN Radial Head Plate Module;
It is not a reference to surgical techniques. Prior to use of the PROTEAN Radial Head Plate Module the surgeon should become familiar with all information contained in this pamphlet.

Description

The Skeletal Dynamics PROTEAN® Radial Head Plate Module consists of titanium alloy plates (right and left), screws, and specialized instrumentation. The screws are available in both locking and non-locking configurations and are provided in lengths from 10mm – 40mm, with increments of 2mm.

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

Indications

The Skeletal Dynamics PROTEAN Radial Head Plates are intended for fixation of fractures, fusions, osteotomies and non-unions of the radius, particularly in osteopenic bone.

Contraindications

Prior to using the PROTEAN Radial Head Plates, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions.

Warnings & Precautions

- All screws must be implanted and fully tightened into the plate to maintain the integrity and strength of the finished construct. If the screws are not attached and/or fully tightened, a non-union, delayed union or construct failure may occur.
- The information in this document should be shared with the patient.
- The patient 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.
- 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 PROTEAN Radial Head Plates may result of include delayed union, non-union, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or non-compliance 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 or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- Potential PROTEAN Radial Head Plate Module construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, delayed fusion, non-fusion, or incomplete healing may occur as a result of non-compliance to post-operative rehabilitation, excessive elbow activities or construct overloading.
- 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.
- DO NOT reuse any of the PROTEAN Radial Head Plate Module implantable components. Reuse may compromise the structural integrity of the plate and screws and/or lead to failure, which may result in patient

IFU-01400-07RAD – June.2022
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injury.

- Before using the PROTEAN Radial Head Plate Module, 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 for provisional fixation and guidance.
- DO NOT permanently implant the Pre-loaded Drill Guides or AIMing Guides; they are intended to be removed prior to peg insertion.
- Caution should be taken when contouring the PROTEAN Radial Head Plates. Bending the plates may weaken or break the plates.
- DO NOT mix implant components from different manufacturers for metallurgical, biomechanical and functional reasons.
- DO NOT use peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- The Non-locking Threaded Pegs are NOT intended to provide subchondral support. Their use should be limited to capture remote bone fragments where pegs cannot be used.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures.
- To maintain traceability of the PROTEAN Radial Head Plate Module implantable components, record each of the respective components LOT numbers in the patient records post implantation.
- Care should be taken that no screws are placed in the joint.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of depth gauge is within ± .5 mm.
- Caution should be taken for interference to pacemakers do electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.

Potential Adverse Events

The following are potential risks that have been associated with elbow surgery: infection, nonunion, persistent pain, stiffness of the elbow, loosening or migration of the implants resulting in mal-alignment.

⚠ **MRI Safety Information.**

A person with the Protean Radial Head implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Protean Radial Head Implants
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant my produce an image artifact.

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Directions for Use
The PROTEAN Radial Head Plate Module should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the PROTEAN Radial Head Plate Module based on their clinical experiences.

It is the responsibility of the surgeon to be familiar with the procedure before use of this device. Additionally, it is the responsibility of the surgeon to be familiar with relevant publications regarding the procedure prior to use. Please refer to the PROTEAN Radial Head Plate Module Surgical Technique Guide to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

Cleaning
Upon receipt by the user facility, the PROTEAN Radial Head Plate Module should be cleaned prior to sterilization. Processing begins at the point of use. To prevent drying of soil and other contaminants, wipe blood, debris and remove gross soil from the instruments during the procedure. 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 PROTEAN Radial Head Plate Module instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- PROTEAN Radial Head Plate Module 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.

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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 with reverse osmosis or distilled 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 reverse osmosis or distilled 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 byrolling 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 PROTEAN Radial Head Plate Module 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. 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 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.

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Handling and Storage
When not in use, store the clean and disinfected PROTEAN Radial Head Plate Module 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.

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Inventory Control Sheet

PROTEAN Radial Head Plating System

General Instrumentation[2]

2	Handle, Small QC, Fixed HNDL-SQC-FXD (01)00841506102078 (01) 00841506102078	2	PROTEAN Plate Bending Pliers PRT-BND-PLR (01)00841506102894 (01) 00841506102894
1	Forceps, Bone Holding Medium, Ratcheting FRCP-BHM-RTC (01)00841506101354 (01) 00841506101354	1	Depth Gauge, Universal, 30mm DPGA-UNV-030 (01)00841506101194 (01) 00841506101194

IMPLANTS

PROTEAN Plates[1]

1	Assembled, PROTEAN Radial Head Plate, Right PRT-RHP-RT (01)00841506104669 (01) 00841506104669	1	Assembled, PROTEAN Radial Head Plate, Left PRT-RHP-LT (01)00841506104652 (01) 00841506104652

Threaded Peg, Cortical Non-Locking, 2.7mm[1]		Threaded Peg, Fluted, Locking, 2.3mm[1]	
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 10mm, Ti PANL-27100-TS (01)00841506105970 (01) 00841506105970	3	Threaded Peg, Fluted, Locking, 2.3mm x 10mm, Ti TPFL-23100-TS (01)00841506104713 (01) 00841506104713
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 12mm, Ti PANL-27120-TS (01)00841506105987 (01) 00841506105987	3	Threaded Peg, Fluted, Locking, 2.3mm x 12mm, Ti TPFL-23120-TS (01)00841506104720 (01) 00841506104720
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 14mm, Ti PANL-27140-TS (01)00841506105994 (01) 00841506105994	3	Threaded Peg, Fluted, Locking, 2.3mm x 14mm, Ti TPFL-23140-TS (01)00841506104737 (01) 00841506104737
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 16mm, Ti PANL-27160-TS (01)00841506106007 (01) 00841506106014	3	Threaded Peg, Fluted, Locking, 2.3mm x 16mm, Ti TPFL-23160-TS (01)00841506104744 (01) 00841506104744
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 18mm, Ti PANL-27180-TS (01)00841506106014 (01) 00841506106014	3	Threaded Peg, Fluted, Locking, 2.3mm x 18mm, Ti TPFL-23180-TS (01)00841506104751 (01) 00841506104751
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 20mm, Ti PANL-27200-TS (01)00841506106021 (01) 00841506106021	3	Threaded Peg, Fluted, Locking, 2.3mm x 20mm, Ti TPFL-23200-TS (01)00841506104775 (01) 00841506104775
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 22mm, Ti PANL-27220-TS (01)00841506106038 (01) 00841506106038	3	Threaded Peg, Fluted, Locking, 2.3mm x 22mm, Ti TPFL-23220-TS (01)00841506104799 (01) 00841506104799
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 24mm, Ti PANL-27240-TS (01)00841506106045 (01) 00841506106045	3	Threaded Peg, Fluted, Locking, 2.3mm x 24mm, Ti TPFL-23240-TS (01)00841506104812 (01) 00841506104812
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 26mm, Ti PANL-27260-TS (01)00841506106052 (01) 00841506106052	2	Threaded Peg, Fluted, Locking, 2.3mm x 26mm, Ti TPFL-23260-TS (01)00841506104829 (01) 00841506104829

Inventory Control Sheet

2	Threaded Peg, Cortical Non-Locking, 2.7mm x 28mm, Ti PANL-27280-TS (01)00841506106069 (01) 00841506106069	1	Threaded Peg, Fluted, Locking, 2.3mm x 28mm, Ti TPFL-23280-TS (01)00841506104836 (01) 00841506104836
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 30mm, Ti PANL-27300-TS (01)00841506106076 (01) 00841506106076	1	Threaded Peg, Fluted, Locking, 2.3mm x 30mm, Ti TPFL-23300-TS (01)00841506104843 (01) 00841506104843
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 32mm, Ti PANL-27320-TS (01)00841506106083 (01) 00841506106083	1	Threaded Peg, Fluted, Locking, 2.3mm x 32mm, Ti TPFL-23320-TS (01)00841506104850 (01) 00841506104850
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 36mm, Ti PANL-27360-TS (01)00841506106106 (01) 00841506106106	1	Threaded Peg, Fluted, Locking, 2.3mm x 36mm, Ti TPFL-23360-TS (01)00841506104874 (01) 00841506104874
2	Threaded Peg, Cortical Non-Locking, 2.7mm x 40mm, Ti PANL-27400-TS (01)00841506106120 (01) 00841506106120	1	Threaded Peg, Fluted, Locking, 2.3mm x 40mm, Ti TPFL-23400-TS (01)00841506107325 (01) 00841506107325
Washer			
2	Washer, Button (Blue) WBTN-2750-T (01)00841506103730 (01) 00841506103730		
Instrumentation[1]			
4	AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870 (01) 00841506102870	3	K-Wire, 1.5mm x 127mm KWIR-DES-15127 (01)00841506107318 (01) 00841506105956
2	Drill, 2.0mm x 40mm DRLL-SSC-20040 (01)00841506101255 (01) 00841506101255	2	Driver, Peg DRVR-AOS-S20 (01)00841506101293 (01) 00841506101293
Reusable Instrumentation[2]			
1	Thread-in Drill Guide, 2.0mm TPDG-THD-DG20 (01)00841506103327 (01) 00841506103327	1	Tissue Protector / Drill Guide, Single Sided, 2.0mm TPDG-SSD-20 (01)00841506105314 (01) 00841506105314
Optional[2]			
0	Driver, Universal QC, T10, Reusable DRVR-T10R (01)00841506108827 (01) 00841506108827	0	Driver, Peg, Torque Limiting, Reusable DRVR-AOS-S20R (01)00841506108834 (01) 00841506108834
0	Driver, Peg, Reusable DRVR-S20R (01)00841506109114 (01) 00841506109114	0	Drill, Solid Side Cutting, 2.0mm x 40mm, Reusable DRLL-20040R (01)00841506108841 (01) 00841506108841

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2. CE