

PROTEAN® Radial Head Plate Module

INSTRUCTIONS FOR USE

R: 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 to 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 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 $\pm .5$ 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.



MR 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 may produce an image artifact.

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 (MKT-00082-00) to review the surgical approach as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of PROTEAN® Radial Head 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-00082-00) 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.

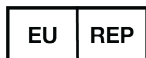
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PROTEAN®

Radial Head Plate

Inventory Control Sheet

Quantity

Plates ¹			
Radial Head Plate, Right PRT-RHP-RT (01)00841506104669		Radial Head Plate, Left PRT-RHP-LT (01)00841506104652	
2.3 mm Threaded Peg, Fluted, Locking (Green) ¹		2.7 mm Threaded Peg, Non-Locking (Blue) ¹	
Threaded Peg, Fluted, Locking, 2.3mm x 10mm, Ti TPFL-23100-TS (01)00841506104713		Threaded Peg, Non-Locking, 2.7mm x 10mm, Ti TPNL-27100-TS (01)00841506103518	
Threaded Peg, Fluted, Locking, 2.3mm x 12mm, Ti TPFL-23120-TS (01)00841506104720		Threaded Peg, Non-Locking, 2.7mm x 12mm, Ti TPNL-27120-TS (01)00841506103525	
Threaded Peg, Fluted, Locking, 2.3mm x 14mm, Ti TPFL-23140-TS (01)00841506104737		Threaded Peg, Non-Locking, 2.7mm x 14mm, Ti TPNL-27140-TS (01)00841506103532	
Threaded Peg, Fluted, Locking, 2.3mm x 16mm, Ti TPFL-23160-TS (01)00841506104744		Threaded Peg, Non-Locking, 2.7mm x 16mm, Ti TPNL-27160-TS (01)00841506103549	
Threaded Peg, Fluted, Locking, 2.3mm x 18mm, Ti TPFL-23180-TS (01)00841506104751		Threaded Peg, Non-Locking, 2.7mm x 18mm, Ti TPNL-27180-TS (01)00841506103556	
Threaded Peg, Fluted, Locking, 2.3mm x 20mm, Ti TPFL-23200-TS (01)00841506104775		Threaded Peg, Non-Locking, 2.7mm x 20mm, Ti TPNL-27200-TS (01)00841506103563	
Threaded Peg, Fluted, Locking, 2.3mm x 22mm, Ti TPFL-23220-TS (01)00841506104799		Threaded Peg, Non-Locking, 2.7mm x 22mm, Ti TPNL-27220-TS (01)00841506103570	
Threaded Peg, Fluted, Locking, 2.3mm x 24mm, Ti TPFL-23240-TS (01)00841506104812		Threaded Peg, Non-Locking, 2.7mm x 24mm, Ti TPNL-27240-TS (01)00841506103587	
Threaded Peg, Fluted, Locking, 2.3mm x 26mm, Ti TPFL-23260-TS (01)00841506104829		Threaded Peg, Non-Locking, 2.7mm x 26mm, Ti TPNL-27260-TS (01)00841506103594	
Threaded Peg, Fluted, Locking, 2.3mm x 28mm, Ti TPFL-23280-TS (01)00841506104836		Threaded Peg, Non-Locking, 2.7mm x 28mm, Ti TPNL-27280-TS (01)00841506103600	
Threaded Peg, Fluted, Locking, 2.3mm x 30mm, Ti TPFL-23300-TS (01)00841506104843		Threaded Peg, Non-Locking, 2.7mm x 30mm, Ti TPNL-27300-TS (01)00841506103617	
Threaded Peg, Fluted, Locking, 2.3mm x 32mm, Ti TPFL-23320-TS (01)00841506104850		Threaded Peg, Non-Locking, 2.7mm x 32mm, Ti TPNL-27320-TS (01)00841506103624	
Threaded Peg, Fluted, Locking, 2.3mm x 36mm, Ti TPFL-23360-TS (01)00841506104874		Threaded Peg, Non-Locking, 2.7mm x 36mm, Ti TPNL-27360-TS (01)00841506103914	
Threaded Peg, Fluted, Locking, 2.3mm x 40mm, Ti TPFL-23400-TS (01)00841506104881		Threaded Peg, Non-Locking, 2.7mm x 40mm, Ti TPNL-27400-TS (01)00841506103938	
Instruments ¹			
Drill, Solid Side Cutting, 2.0mm x 40mm DRLL-SSC-20040 (01)00841506101255		Driver, AO Connection, Square Tip 2.0mm DRV-R-AOS-S20 (01)00841506101293	
K-Wire, 1.5mm x 127mm KWIR-STD-15127 (01)00841506102504		AIMing Guides, 1.5mm PDG-AIM-015 (01)00841506102870	
Washer, Button, Inside 2.7mm, Outside 5.0mm WBTN-2750-T (01)00841506103730			