

ALIGN[®] Radial Head System

INSTRUCTIONS FOR USE

R_x: For medical use only. Federal Law of the USA restricts this device to sale by or by order of a licensed physician.

Failure to follow instructions may lead to patient injury.

This package insert is designed to provide Instructions for Use of the ALIGN Radial Head System; it is not a reference, and should not be considered, as a surgical technique. Prior to use of the ALIGN Radial Head System the surgeon should become familiar with all information contained in this pamphlet and the surgical procedure.

Description:

The ALIGN Radial Head System is a radial head prosthesis and instrumentation platform which is designed to orient the Radial Head prosthesis perpendicular to the axis of forearm rotation. The fluted plasma coated Radial Stem may assist in biological fixation and is press fit into the medullary canal of the radius. Combined with its unique instrumentation, the ALIGN Radial Head offers the flexibility to adjust the orientation during implantation and restore motion at the Radial Head, then locks to form a monoblock prosthesis after the optimal implant positioning has been achieved.

The ALIGN Radial Head System is comprised of:

- Multiple sized CoCr Radial Heads with Lock Screw
- Multiple sized titanium alloy Stems, titanium plasma spray coated
- System specific instrumentation

Indications for Use:

The ALIGN Radial Head System and accessories are designed specifically for:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
 - Joint destruction and/or subluxation
 - Resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty
- The system is intended for press-fit use

Contraindications:

The ALIGN[®] Radial Head System should not be used if any of the following 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 post surgical care instructions.

⚠ Warnings:

- Radial head prosthesis cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue. Failure of the component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union or excessive loads (estimated body weight equivalent of 350 lbs or greater).
- The Head Alignment Tool must be used during the procedure to correctly align the prosthetic head and to provide the necessary counter-torque when tightening the Lock Screw.
- The Lock Screw packaged with the Radial Head must be installed and fully tightened to fix the Radial Head to the Radial Stem. If the Lock Screw is not attached and/or fully secured, the Radial Head may loosen and/or disconnect from the Radial Stem, causing soft tissue irritation and/or device failure.
- Improper selection, placement, positioning, alignment or fixation of the implanted components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.

- Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the prosthesis or anatomical structures.
- The patient must be cautioned, preferably in writing, about the use, limitations and possible adverse effects of this device including the possibility of device or treatment failure as 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.
- The patient should be informed about the importance to follow the post-surgical rehabilitation to fully understand the possible limitations in normal activities of daily living. The patient must be warned that failure to follow post-surgical care instructions may cause the prosthesis or treatment to fail.
- Potential ALIGN Radial Head System 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 result of non-compliance to post surgery rehabilitation, excessive wrist and forearm activities or construct overloading.
- DO NOT reuse any of the ALIGN Radial Head System implants or the T-20 Driver. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection which may result in patient injury.
- The Torque Handle included in the system requires calibration. DO NOT use if the calibration is overdue. Use of a Torque Handle out of calibration could result in device loosening or failure.

⚠ Precautions:

- Patient must avoid placing excessive loads on the implant.
- The Radial Head with Lock Screw and Radial Stems are supplied sterile using gamma radiation sterilization. DO NOT use if sterile barrier is damaged or if the USE BY date has expired. Any implantable components used with an expired USE BY date will void the product warranty.
- The implantable components and the T-20 Drivers are for single use only; DO NOT reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization of the implantable components and driver may:
 - Compromise the structural integrity of the construct
 - Lead to failure resulting in patient injury
 - Create a risk of contamination of the device causing patient infection or cross-contamination
 - Lead to the transmission of infectious disease(s) from one patient to another
- Protect the implants against scratching or nicking as such stress concentration may lead to construct failure.
- Before using the ALIGN Radial Head System, inspect all prosthesis 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.
- The ALIGN Radial Head System has not been evaluated for safety and compatibility in the Magnetic Resonance environment; nor has it been tested for heating or migration in the Magnetic Resonance environment.
- To maintain product traceability, record the Lot number for each of the implanted system components in the patient's medical record.
- The Skeletal Dynamics ALIGN Radial Head System is to be used only with Skeletal Dynamics instruments, implants and accessories, including the Torque Handle (calibrated to 60in/lbs).
- Dispose of contaminated implants and instruments following the established facility guidelines and protocols.
- Accuracy of Depth, Gap and Screw Gauges are within $\pm 0.25\text{mm}$.
- Caution should be taken for interference to pacemakers during use of electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.

Potential Adverse Events:

The following potential risks or discomforts have been associated with radial head arthroplasty: Disassociation, loosening or migration of the prosthesis, infection, erosion of the capitellum, material sensitivity reaction, nerve injuries, undesirable shortening or lengthening of limb, stiffness of the elbow and/or forearm, dislocation or subluxation due to improper positioning, fretting and crevice corrosion can occur at interfaces between the components, wear and deformation of the articular surfaces, intraoperative and postoperative bone fracture and/or postoperative pain and infection.

Directions for Use:

The ALIGN® Radial Head System should only be used by surgeons who have experience with the system. Each surgeon must evaluate the appropriateness for the use of the ALIGN Radial Head System during radial head arthroplasty procedures based on their experience with the ALIGN Radial Head System.

Please refer to the ALIGN Radial Head Arthroplasty Surgical Technique Guide to review the surgical approach to radial head arthroplasty as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida, USA.

Cleaning

Upon receipt by the user facility, the ALIGN® Radial Head System 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, threaded nails, 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 ALIGN® Radial Head System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- The System's 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.
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.

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 different 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 ALIGN Radial Head System implantable components have been sealed then sterilized by gamma radiation. The implants are provided in an undamaged package. If any of the implants or the package appears damaged, expiration date has been exceeded, or if sterility is questionable, the implant should not be used. **DO NOT re-sterilize the implantable components.** Trial components are available in the system to avoid opening the sterile package prior to prosthesis implantation. **The implants should be removed from their sterile package only after the implant site has been prepared and properly sized.**

The Skeletal Dynamics ALIGN Radial Head System is provided nonsterile. This system is intended to be sterilized by steam sterilization at the healthcare facility.

1. Place all components and accessories into the designated areas of the sterilization tray
2. Steam sterilization may be accomplished using one of the cycles shown below:

Cycle Times for Dynamic-Air-Removal (Vacuum) Steam Sterilization Cycles

Item	Exposure time at 132°C (270° F)	Minimum Drying Times
Wrapped Sterilization Tray	4 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization **is not** recommended, but if used, should only be performed according to the requirements of ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Usage of an FDA cleared wrap is required.
- Subsequent instrument sterilization needs to be performed in the caddy provided. For reuse and sterilization, instruments should be arranged within the caddy in the manner supplied by Skeletal Dynamics.

Calibration:

The Torque Handle included in the system requires calibration. DO NOT use if calibration is overdue. Contact the Skeletal Dynamics Customer Care Department to arrange for the Torque Handle to be re-calibrated.

Handling and Storage:

When not in use, store the clean and disinfected ALIGN® Radial Head System within the Sterilization Tray. Prior to use, inspect the instrumentation for serviceability and the sterile packaged implants for signs of tampering or water contamination.

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.

ALIGN Radial Head System Ordering Information: ALN-RHS-SYS**Catalog #****Nomenclature****Implants**

ALN-RHI-180	ALIGN Radial Head Implant & Lock Screw, 18mm, CoCr
ALN-RHI-200	ALIGN Radial Head Implant & Lock screw, 20mm, CoCr
ALN-RHI-220	ALIGN Radial Head Implant & Lock screw, 22mm, CoCr
ALN-RHI-240	ALIGN Radial Head Implant & Lock screw, 24mm, CoCr
ALN-RHI-260	ALIGN Radial Head Implant & Lock screw, 26mm, CoCr
ALN-RHI-280	ALIGN Radial Head Implant & Lock screw, 28mm, CoCr
ALN-RST-0600	ALIGN Radial Stem Implant, 6mm x 0mm, Ti
ALN-RST-0602	ALIGN Radial Stem Implant, 6mm x 2mm, Ti
ALN-RST-0604	ALIGN Radial Stem Implant, 6mm x 4mm, Ti
ALN-RST-0606	ALIGN Radial Stem Implant, 6mm x 6mm, Ti
ALN-RST-0608	ALIGN Radial Stem Implant, 6mm x 8mm, Ti
ALN-RST-0700	ALIGN Radial Stem Implant, 7mm x 0mm, Ti
ALN-RST-0702	ALIGN Radial Stem Implant, 7mm x 2mm, Ti
ALN-RST-0704	ALIGN Radial Stem Implant, 7mm x 4mm, Ti
ALN-RST-0706	ALIGN Radial Stem Implant, 7mm x 6mm, Ti
ALN-RST-0708	ALIGN Radial Stem Implant, 7mm x 8mm, Ti
ALN-RST-0800	ALIGN Radial Stem Implant, 8mm x 0mm, Ti
ALN-RST-0802	ALIGN Radial Stem Implant, 8mm x 2mm, Ti
ALN-RST-0804	ALIGN Radial Stem Implant, 8mm x 4mm, Ti
ALN-RST-0806	ALIGN Radial Stem Implant, 8mm x 6mm, Ti
ALN-RST-0808	ALIGN Radial Stem Implant, 8mm x 8mm, Ti
ALN-RST-0900	ALIGN Radial Stem Implant, 9mm x 0mm, Ti
ALN-RST-0902	ALIGN Radial Stem Implant, 9mm x 2mm, Ti
ALN-RST-0904	ALIGN Radial Stem Implant, 9mm x 4mm, Ti
ALN-RST-0906	ALIGN Radial Stem Implant, 9mm x 6mm, Ti
ALN-RST-0908	ALIGN Radial Stem Implant, 9mm x 8mm, Ti
ALN-RST-1000	ALIGN Radial Stem Implant, 10mm x 0mm, Ti
ALN-RST-1002	ALIGN Radial Stem Implant, 10mm x 2mm, Ti
ALN-RST-1004	ALIGN Radial Stem Implant, 10mm x 4mm, Ti
ALN-RST-1006	ALIGN Radial Stem Implant, 10mm x 6mm, Ti
ALN-RST-1008	ALIGN Radial Stem Implant, 10mm x 8mm, Ti
ALN-RST-1100	ALIGN Radial Stem Implant, 11mm x 0mm, Ti
ALN-RST-1102	ALIGN Radial Stem Implant, 11mm x 2mm, Ti
ALN-RST-1104	ALIGN Radial Stem Implant, 11mm x 4mm, Ti
ALN-RST-1106	ALIGN Radial Stem Implant, 11mm x 6mm, Ti
ALN-RST-1108	ALIGN Radial Stem Implant, 11mm x 8mm, Ti
ALN-RST-1200	ALIGN Radial Stem Implant, 12mm x 0mm, Ti
ALN-RST-1202	ALIGN Radial Stem Implant, 12mm x 2mm, Ti
ALN-RST-1204	ALIGN Radial Stem Implant, 12mm x 4mm, Ti
ALN-RST-1206	ALIGN Radial Stem Implant, 12mm x 6mm, Ti
ALN-RST-1208	ALIGN Radial Stem Implant, 12mm x 8mm, Ti

Trial Heads

ALN-RHT-180	ALIGN Radial Head Trial, 18mm
ALN-RHT-200	ALIGN Radial Head Trial, 20mm

ALN-RHT-220	ALIGN Radial Head Trial, 22mm
ALN-RHT-240	ALIGN Radial Head Trial, 24mm
ALN-RHT-260	ALIGN Radial Head Trial, 26mm
ALN-RHT-280	ALIGN Radial Head Trial, 28mm

Trial Necks

ALN-RNT-000	ALIGN Radial Neck Trial, 0.0mm
ALN-RNT-020	ALIGN Radial Neck Trial, 2.0mm
ALN-RNT-040	ALIGN Radial Neck Trial, 4.0mm
ALN-RNT-060	ALIGN Radial Neck Trial, 6.0mm
ALN-RNT-080	ALIGN Radial Neck Trial, 8.0mm

Trial Stems

ALN-STT-070	ALIGN Radial Stem Trial, 7.0mm
ALN-STT-080	ALIGN Radial Stem Trial, 8.0mm
ALN-STT-090	ALIGN Radial Stem Trial, 9.0mm
ALN-STT-100	ALIGN Radial Stem Trial, 10.0mm
ALN-STT-110	ALIGN Radial Stem Trial, 11.0mm

Long Trial Stem

ALN-STL-060	ALIGN Radial Stem Trial, 6.0mm
ALN-STL-070	ALIGN Radial Stem Trial, 7.0mm
ALN-STL-080	ALIGN Radial Stem Trial, 8.0mm
ALN-STL-090	ALIGN Radial Stem Trial, 9.0mm
ALN-STL-100	ALIGN Radial Stem Trial, 10.0mm
ALN-STL-110	ALIGN Radial Stem Trial, 11.0mm
ALN-STL-120	ALIGN Radial Stem Trial, 12.0mm

System Instrumentation

ALN-RHG-PFA	ALIGN Percutaneous Forearm Axis Jig, Radial Head Guide
ALN-RHG-CRL	ALIGN Captive Rail, Radial Head Guide
ALN-RHG-BHF	ALIGN Bone Holding Forceps, Radial Head Guide
ALN-RHG-HAT	ALIGN Head Alignment Tool, Radial Head Guide
ALN-RRA-060	ALIGN Radial Rasp, 6.0mm
ALN-RRA-070	ALIGN Radial Rasp, 7.0mm
ALN-RRA-080	ALIGN Radial Rasp, 8.0mm
ALN-RRA-090	ALIGN Radial Rasp, 9.0mm
ALN-RRA-100	ALIGN Radial Rasp, 10.0mm
ALN-RRA-110	ALIGN Radial Rasp, 11.0mm
ALN-RRA-120	ALIGN Radial Rasp, 12.0mm
ALN-RPL-070	ALIGN Radial Planer, 7.0mm
ALN-RPL-080	ALIGN Radial Planer, 8.0mm
ALN-RPL-090	ALIGN Radial Planer, 9.0mm
ALN-RPL-100	ALIGN Radial Planer, 10.0mm
ALN-RPL-110	ALIGN Radial Planer, 11.0mm
ALN-RPL-UNI	ALIGN, Radial Planer, Stem, Universal
ALN-RHS-SZR	ALIGN Sizer, Radial Head Implant
ALN-NGI-000	ALIGN Neck Gauge & Head Inserter, 0mm
ALN-NGI-020	ALIGN Neck Gauge & Head Inserter, 2mm
ALN-NGI-040	ALIGN Neck Gauge & Head Inserter, 4mm
ALN-NGI-060	ALIGN Neck Gauge & Head Inserter, 6mm

ALN-NGI-080	ALIGN Neck Gauge & Head Inserter, 8mm
	ALIGN Impactor, Radial Stem ALIGN Torque Handle,
ALN-RST-IMP	Radial Head
ALN-RHA-TQH	ALIGN Torque Handle, Radial Head

General Instrumentation

DRV-UR-UQC-T20 Driver, Universal QC, T-20
HNDL-UQC-FXD Handle, Universal Quick Connect, Fixed
HNDL-UQC-DXT Driver Extraction Tool

Sterilization Trays

ALN-RHA-TRAY ALIGN Sterilization Tray System



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