ALIGN® Radial Head System

INSTRUCTIONS FOR USE

Basic UDI: 00841506100753

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, 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. The Radial Head prosthesis is designed to become a monoblock following fixation of the Lock Screw. 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.

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- 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 about the use, limitations and possible adverse effects of this device including the possibility of device or treatment failure as result of 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 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 union, union, 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 is routinely verified by Skeletal Dynamics. Handles should be returned upon request to Skeletal Dynamics for verification purposes.

⇪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.
- Caution should be taken for interference to pacemakers during use of electrocautery or by uncertified drill power sources.
- 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, Sterilization, and Inspection

The ALIGN Radial Head System implantable components have been sterilized then sealed 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**.

For instructions on cleaning, disinfection, sterilization and inspection of the ALIGN instruments please refer to cleaning and sterilization instructions for use (IFU-04056-00).

Resources

The latest version of the Instructions for Use 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.

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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MD

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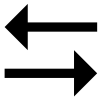
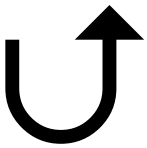
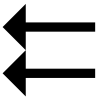
SYMBOLS GLOSSARY

Symbols that follow BS EN ISO 15223-1 / Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Symbol Reference Number and Title	Description
	5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	5.1.6 Catalogue Number	Indicates the manufacturer's catalogue number so the medical device can be identified
	5.4.3 Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	5.1.5 Batch Code	Indicates the manufacturer's batch code or lot can be identified
	5.4.2 Do Not Re-use	Indicates a medical device that is intended for one single use only
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured

	5.2.4 Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation
	5.1.1 Manufacturer	Indicates the medical device manufacturer
	5.1.2 Authorized Representative in the European Community	Indicates the authorized representative in the European union. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol
	Authorized Representative in the United Kingdom *Note not found in BS EN ISO 15223-1	Indicates the authorized representative in the United Kingdom. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol
	5.2.8 Do Not Use If Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.1.4 Use-by-date	Indicates the date after which the medical device is not to be used
	5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information