Skeletal Dynamics Distal Elbow Set
INSTRUCTIONS FOR USE

℞ For use by physicians only. Caution: 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 Distal Elbow Set; it is not a reference to surgical techniques. Prior to use of each system in the Distal Elbow Set, the surgeon should become familiar with all information contained in this pamphlet.

SYMBOLS

MATL:	MATERIAL	**CoCr:**	COBALT CHROMIUM ALLOY
MADE IN:	MADE IN <<COUNTRY>>	**TI:**	TITANIUM ALLOY
QTY:	QUANTITY	**SS, SST:**	STAINLESS STEEL
	DO NOT REUSE (SINGLE USE)		CAUTION or ATTENTION, SEE INSTRUCTIONS FOR USE
	USE BY (EXPIRATION DATE)		CONSULT INSTRUCTIONS FOR USE
LOT	BATCH CODE		MANUFACTURER
STERILE EO	STERILIZED USING ETHYLENE OXIDE		TEMPERATURE LIMITATION
STERILE R	STERILIZED USING IRRADIATION	EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
NON STERILE	NON STERILE PRODUCT		DO NOT USE IF PACKAGE IS DAMAGED
REF	CATALOG NUMBER		

Description:

The Skeletal Dynamics Distal Elbow Set consists of the following systems:

1. Distal Elbow Plating System
    a. Proximal Ulna Plating System
    b. PROTEAN Elbow Plating System
2. REDUCT Headless Compression Screw System
3. ALIGN Radial Head System
4. Internal Joint Stabilizer- Elbow System

The ALIGN Radial Head with Lock Screw and Radial Stems are supplied sterile using gamma radiation sterilization. All other components of the system are provided non-sterile to be sterilized in the user facility.

Distal Elbow Plating System

The Skeletal Dynamics Distal Elbow Plating System consists of titanium alloy plates and screws, cobalt chrome cannulated polyaxial locking screws, k-wires, and specialized instrumentation designed for fracture fixation, fusions, osteotomies and non-unions of the radius and ulna.

The Distal Elbow Plates are available in various configurations: PROTEAN Radial Head Plates (left and right), Coronoid Plates (left and right), Y, Double Hockey Stick, and Proximal Ulna Plates (73mm, 108mm, 151mm, left and right). The titanium screws are available in locking and non-locking configurations. The cobalt chrome cannulated polyaxial locking screws are available in 2.5mm diameter for use with PROTEAN Plates and 3.0mm diameter for use with Proximal Ulna Plates.

Distal Elbow Plating System Indications for Use: The Skeletal Dynamics Distal Elbow Plating System is intended for fixation of fractures, fusions, osteotomies and non-unions of the radius and ulna, particularly in osteopenic bone.

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REDUCT Headless Compression Screw System

The REDUCT Headless Compression Screw (HCS) System consists of 2.5mm and 3.5mm cannulated titanium screws and specialized instrumentation. The 2.5mm screw is available in 11 length configurations between 10mm - 30mm, with increments of 2mm. The 3.5mm screw is available in 11 length configurations between 10mm - 30mm, with increments of 2mm.

REDUCT HCS Indications for Use: The Skeletal Dynamics HCS System is intended for fixation of osseous fragments or fractures, arthrodesis of small joints, and osteotomies, with the appropriately sized screw.

ALIGN Radial Head System

The ALIGN Radial Head System (RHS) is a radial head prosthesis and instrumentation platform that is designed to orient the Radial Head perpendicular to the axis of forearm rotation. The fluted titanium plasma coated Radial Stem is press fit into the medullary canal of the radius. Combined with its unique instrumentation, it 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. It is comprised of multiple sized CoCr Radial Heads with Lock Screw, multiple sized titanium alloy Stems with titanium plasma spray (TPS) coating, and system specific instrumentation.

ALIGN Radial Head Indications for Use: The ALIGN Radial Head System and instrumentation 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

Internal Joint Stabilizer- Elbow System

The Internal Joint Stabilizer- Elbow (IJS-E System) provides temporary subcutaneous stability between the distal humerus and proximal ulna in patients who have elbow instability allowing for early active mobilization and function of the elbow. The construct consists of a Base Plate, Distal Connecting Rod, and Proximal Connecting Rod, that are held together by adjustable locking joints and locking screws, allowing for multiple degrees of freedom. Designed for a universal application, the Base Plate can be secured to either the left or right ulna using 3.5mm Non-Locking Polyaxial Screws. The Proximal Connecting Rod is then secured to the distal humerus at the axis of rotation using the appropriate sized Axis Pin.

The instrumentation includes elbow Axis Guides in three sizes, various gauges and other system specific guides and drills which enables the surgeon to identify the axis of rotation of the distal humerus, and optimally position the device dependent of the patient's morphotype. The System is comprised of a universal titanium IJS-E construct, multiple sized CoCr humeral Axis Pins, Stainless Steel K-wires (Guide Wires) for optimal prosthesis alignment (not to be implanted), and system specific instrumentation.

Internal Joint Stabilizer- Elbow Indications for Use: The IJS-E System is intended to provide temporary stabilization of the elbow joint after trauma or chronic elbow dislocation.

Contraindications:
Prior to using the system, 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. The system should not be used in pediatric patients or patients with open growth plates.

The REDUCT Headless Compression Screw System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The IJS-E System should not be used if there insufficient quantity or quality of bone (bone loss greater than 30% of the total articulation or involving an entire column of the distal humerus, or coronoid bone loss of 50% or more).

General Warnings and Precautions

- 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.
- 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.
- Potential construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, instability, delayed soft tissue healing, soft tissue irritation, delayed fusion, non-fusion, or incomplete healing may occur as a result of noncompliance to post-operative rehabilitation, excessive activities, or construct overloading.
- 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 system may include delayed union, non-union, loosening of fixation, migration or failure of the device, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance 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, nonunion, or soft tissue healing. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- DO NOT reuse any of the system implantable components. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.
- Protect the system's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the 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 only intended to be used during provisional fixation.
- Some K-Wires are double trocar. User should handle K-Wires accordingly during insertion and removal to prevent unintended K-Wire penetration or injury.
- DO NOT permanently implant the pre-loaded Drill Guides or A.I.M.ing Guides; they are intended to be removed prior to screw insertion.
- DO NOT use pin/peg/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- DO NOT mix implant components or system specific instrumentation from different systems or manufacturers for metallurgical, biomechanical and functional reasons.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- Accuracy of Depth, Gap and Screw Gauges are within ± 0.25mm, 0.50mm, or 1.0mm, depending on the system.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.
- To maintain traceability of the Distal Elbow Plating System implantable components, you must record each of the respective components LOT numbers into the patient records post implantation.
- 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.
- Care should be taken that no screws are placed in the joint.
- To maintain traceability of the system implantable components, record each of the respective components Lot numbers in the patient records post implantation.
- The system is to be used only with Skeletal Dynamics instruments, implants and accessories.

Internal Joint Stabilizer- Elbow System Warnings and Precautions

- All screws and axis pins must be implanted and fully tightened to maintain the integrity and strength of the finished construct, and the positioning and angles established intraoperatively. If the screws or axis pins are not attached and/or fully tightened, a non-union, delayed union, soft tissue complication, or construct failure may occur.
- DO NOT violate the medial cortex of the distal humerus with the 1.6mm K-wire (Guide Wire) as it may result in nerve injury.
- The proximal end of the IJS-E System Connecting Arm must be trimmed at the level where it exits the Purple Locking Joint if protruding. Failure to cut to the proper length may cause soft tissue irritation.
- Wear eye protection when cutting the Connecting Arm to avoid injury.
- Ensure sufficient space is available for proper application of the IJS-E System when used in conjunction with other implants to prevent interference. Interference with other prostheses may lead to failure of the IJS-E System or postoperative complications.
- The IJS-E construct is intended to be explanted when tissue healing has proved sufficient for joint stability.
- The IJS-E System has not been evaluated in patients with instability secondary to surgical release of soft tissue.
- When drilling for the IJS-E System Base Plate, be sure to avoid drilling into the articular surfaces.

Distal Elbow Plating System Warnings and Precautions

- Caution should be taken when contouring plates. Bending the plates may weaken or break the plates.
- The maximum angulation of the PLS should not exceed 10° from the trajectory of the respective hole.
- The PLS is not intended for placement in the proximal end of the PROTEAN Radial Head Plate as the head of the screw could sit prominent and cause 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 partially or fully threaded pegs cannot be used.

ALIGN Radial Head System Warnings and Precautions

- The ALIGN 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 ALIGN 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 T20 Drivers are single use and are to be used with the Skeletal Dynamics Torque Handle (calibrated at 60 in-lbs); DO NOT reuse, reprocess or re-sterilize. Reuse may compromise the structural integrity of the construct and/or lead to failure or infection, which may result in patient injury.
- The Lock Screw packaged with the ALIGN 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.
- The ALIGN 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.

Potential Adverse Events:
The following are potential risks that have been associated with surgery: discomfort, or abnormal sensations, damage to nerves, vessels, or soft tissue, infection, edema or swelling, joint contractures, reduced or loss of ROM, bone erosion, bone fracture through bone holes, material sensitivity, intraoperative bone perforation, stiffness, nonunion, persistent pain, stiffness, disassociation, loosening or migration of the implants resulting in mal-alignment. Undesirable shortening or lengthening of limb, dislocation or subluxation due to improper positioning, implant failure, fretting and crevice corrosion may occur at interfaces between components, wear and deformation of the articular surfaces. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur.

MRI Safety Information:
The Distal Elbow Set has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Distal Elbow Set in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

The surgeon should select the type and size implant to best meet the patient's needs. Although the surgeon is the medical intermediary between the company and the patient, this document contains important medical information that should be shared with the patient.

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 Surgical Technique Guide(s) 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.

Cleaning:
The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

Implant Cleaning:
The Distal Elbow Plating System implants must be cleaned thoroughly to achieve 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. Implanted plates, screws, or associated components should never be re-used. Any implant that has not been used, but has become soiled, must be cleaned.

Warnings & Precautions
- Any implant contaminated with blood, tissue, and/or bodily fluids/matter should be processed according to healthcare facility protocol.
- Do not use an implant if the surface has been damaged. Damaged implants should be 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 Distal Elbow Plating System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions
- Distal Elbow Plating System reusable instruments and accessories 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

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 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 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 exposure time.
4. Thoroughly rinse the 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 the 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 components thoroughly with deionized or purified 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 components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on the components using deionized water or purified water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

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 Distal Elbow Plating System 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
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 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 approved wrap or sterilization container 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.

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 recalibrated.

Handling and Storage:
When not in use, store the clean and disinfected Distal Elbow Plating System within the Sterilization Tray. Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect the instrumentation for serviceability.

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 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.

Disclaimer of Warranty and Limited Remedies:

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