English

IJS™ – Elbow System

INSTRUCTIONS FOR USE

R_x: 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 Internal Joint Stabilizer – Elbow System; it does not serve as a reference to surgical technique.

Description:
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 IJS-E construct consists of a Base Plate, Connecting Arm and Boom Arm 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 Boom Arm 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 IJS-E 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)
- System specific instrumentation.

Indications:
The IJS-E System is intended to provide temporary stabilization of the elbow joint after trauma or chronic elbow dislocation.

Contraindications:
The IJS-E System should not be used if the following are present: active or latent infection, sepsis, insufficient quantity or quality of bone (bone loss greater than 30% of the total articulation or involving an entire column of the distal humerus, coronoid bone loss of 50% or more) and/or soft tissue, material sensitivity, or patients who are unwilling or incapable of following post operative care instructions. The IJS-E System should not be used in pediatric patients or patients with open growth plates.

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⚠ Warnings and Precautions:

- The Locking Screws of the construct and the Axis Pin must be installed and fully tightened to ensure that the construct will maintain the positioning and angles established intraoperatively. If the Locking Screws or the Axis Pin are not attached and/or fully tightened, the construct may loosen, shift and/or become disassembled subcutaneously.
- All 3.5mm screws must be fully tightened into the plate, and the Axis Pin fully tightened to the Boom, to maintain the integrity and strength of the finished construct. Loose or misaligned screws or the axis pin may cause soft tissue irritation, or the device or treatment may fail.
- The proximal end of the Connecting Arm must be trimmed at the level where it exits the 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.
- Improper placement, positioning, alignment or fixation of the IJS-E construct may result in unusual stress conditions which may lead to subsequent reduction in the service life of the components, construct failure, postoperative complications or ineffective treatment.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Improper insertion of the device during implantation may also increase the possibility of loosening, migration and failure of the device or the treatment.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device loosening or breakage may occur when the implant is subjected to excessive loading during soft tissue healing or delayed healing.
- The information in this document should be shared with the patient.
- Potential IJS-E construct failures such as stress fractures of the bones, loosening of the construct, instability, delayed soft tissue healing, soft tissue irritation, 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 possible adverse effects of this device including the possibility of 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.
- The patient should be informed about the importance of following the post-operative rehabilitation prescribed in order to fully understand the possible limitations in activates of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- Protect the IJS-E Systems implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the IJS-E 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 reuse any of the IJS-E System components. Reuse may compromise the structural integrity of the Base Plate Assembly's components and of the screws and/or lead to failure, which may result in patient injury.
- DO NOT permanently implant the K-Wires; they are intended to be used for proper alignment of the IJS-E System construct.
- DO NOT mix implant components from different manufacturers for metallurgical, biomechanical, and functional reasons.
- DO NOT use pin/screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.

- The IJS-E System 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 IJS-E System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- 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.
- The IJS-E System has not been evaluated in patients with instability secondary to surgical release of soft tissue.
- To maintain traceability of the IJS-E System components, you must record each of the respective components LOT numbers into the patient records post implantation.
- The Skeletal Dynamics IJS-E is to be used only with Skeletal Dynamics instruments, implants and accessories.
- The use of power tools for the installation of screws and pegs is not recommended and may lead to cross threading and damage to the screws and/or plates.
- 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 the Depth Gauges is ± 1mm.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if implant malfunctions.
- DO NOT violate the medial cortex of the distal humerus with the 1.5mm K-Wire (Guide Wire) as it may result in nerve injury.
- When drilling for the Base Plate, be sure to avoid drilling into the articular surfaces.

Potential Adverse Events:
The following are potential risks that have been associated with elbow joint stabilization surgery: Damage to nerves or vessels resulting from drilling or the insertion of screws and pins, infection, edema or swelling, joint contractures, reduced or loss of ROM, dislocation, failure to maintain the reduction of the elbow joint, loosening or migration of the implants, stiffness of the elbow, bone fracture through bone holes, material sensitivity, intraoperative bone perforation.

⚠ MRI Safety Information:
A person with the IJS-E implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	IJS-E 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.

Directions for Use:

The IJS-E System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the IJS-E System during elbow joint stabilization procedures based on their experience with the IJS-E System.

Please refer to the IJS-E Surgical Technique Guide to review the surgical approach to elbow joint instability surgery as described by Jorge L. Orbay, M.D. of the *Miami Hand & 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 IJS-E System 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 IJS-E System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

⚠ **Warnings & Precautions**

- IJS-E System 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, 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. 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.
2. 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.

3. 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.
4. 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.
5. 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.
6. After cleaning, visually inspect components for soil. If visible soil is found, repeat the cleaning procedure until no visible soil remains on the components.
7. Perform a final rinse on the components using RO/DI water.
8. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Sterilization:

The Skeletal Dynamics IJS-E 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
Pre-Vacuum Autoclave	270°F (132°C)	4 minutes (wrapped)	40 minutes
Pre-Vacuum Autoclave	273°F (134°C)	3 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2006 - 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.

Handling and Storage:

When not in use, store the clean and disinfected IJS-E System 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.

IJS™ - Elbow System Ordering Information: IJS-ELB-SYS

Catalog #	Nomenclature
Implants	
IJS-ELB-BPA	IJS-E, Base Plate Assembly, Ti
IJS-PUP-BPA	IJS-E Base Plate Assembly, Proximal Ulna Plate
IJS-EAP-25300	IJS-E, Axis Pin 2.5mm x 30mm, CoCr
IJS-EAP-25350	IJS-E, Axis Pin 2.5mm x 35mm, CoCr
IJS-EAP-25400	IJS-E, Axis Pin 2.5mm x 40mm, CoCr
IJS-EAP-25450	IJS-E, Axis Pin 2.5mm x 45mm, CoCr
IJS-EAP-25500	IJS-E, Axis Pin 2.5mm x 50mm, CoCr
IJS-EAP-25550	IJS-E, Axis Pin 2.5mm x 55mm, CoCr
IJS-EAP-25600	IJS-E, Axis Pin 2.5mm x 60mm, CoCr
IJS-EAP-25650	IJS-E, Axis Pin 2.5mm x 65mm, CoCr
IJS-EAP-25700	IJS-E, Axis Pin 2.5mm x 70mm, CoCr
IJS-PUP-SCRW	#4-40 Screws
Compression Screws	
PANL-35160-TS	Screw, Polyaxial Non-Locking, 3.5mm x 16mm, Ti
PANL-35180-TS	Screw, Polyaxial Non-Locking, 3.5mm x 18mm, Ti
PANL-35200-TS	Screw, Polyaxial Non-Locking, 3.5mm x 20mm, Ti
PANL-35220-TS	Screw, Polyaxial Non-Locking, 3.5mm x 22mm, Ti
PANL-35240-TS	Screw, Polyaxial Non-Locking, 3.5mm x 24mm, Ti
PANL-35260-TS	Screw, Polyaxial Non-Locking, 3.5mm x 26mm, Ti
PANL-35280-TS	Screw, Polyaxial Non-Locking, 3.5mm x 28mm, Ti
PANL-35300-TS	Screw, Polyaxial Non-Locking, 3.5mm x 30mm, Ti
PANL-35320-TS	Screw, Polyaxial Non-Locking, 3.5mm x 32mm, Ti
PANL-35340-TS	Screw, Polyaxial Non-Locking, 3.5mm x 34mm, Ti
PANL-35360-TS	Screw, Polyaxial Non-Locking, 3.5mm x 36mm, Ti
PANL-35380-TS	Screw, Polyaxial Non-Locking, 3.5mm x 38mm, Ti
PANL-35400-TS	Screw, Polyaxial Non-Locking, 3.5mm x 40mm, Ti
PANL-35420-TS	Screw, Polyaxial Non-Locking, 3.5mm x 42mm, Ti
PANL-35440-TS	Screw, Polyaxial Non-Locking, 3.5mm x 44mm, Ti
System Instrumentation	
IJS-EAG-KWG	IJS-E K-Wire Guide, Axis Guides, 1.5mm
IJS-EDG-OKW	IJS-E Depth Gauge, Over K-wire
IJS-CDC-2770	IJS-E Drill, Cannulated Distal Cutting, 2.7mm x 70mm
IJS-EAG-LAS	IJS-E Axis Guide, Lateral Approach, SM
IJS-EAG-LAM	IJS-E Axis Guide, Lateral Approach MD
IJS-EAG-LAL	IJS-E Axis Guide, Lateral Approach LG
PRT-BND-PLR	PROTEAN Plate Bending Piers
General Instrumentation	
DPGA-MDS-050	Depth Gauge, Med. Standard, 50mm
KWIR-DES-15127	K-Wire, 1.5mm x 127mm, (Guide Wire)
DRLL-SSC-25080	Drill, Solid Side Cutting, 2.5mm x 80mm
DRVR-UQC-T10	Driver, Universal QC, T-10
HNDL-UQC-FXD	Handle, Universal Quick Connect, Fixed
Sterilization Trays	
IJS-ELB-CMTI	IJS-E Caddy Module & Tray Insert
IJS-ELB-TRAY	IJS Sterilization Tray, Half DIN w/ Cover

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IJS-ELBOW™

Elbow Stabilization System

Inventory Control Sheet

Internal Joint Stabilizer Base Plate[1]	
IJS-E Base Plate Assembly IJS-ELB-BPA (01)00841506104904 (01) 00841506104904	IJS-E Base Plate Assembly, Proximal Ulna Plate IJS-PUP-BPA (01)00841506109107 (01) 00841506109107
Polyaxial Non-Locking Screw (Ti)[1]	
Screw, Polyaxial Non-Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856 (01) 00841506102856	Screw, Polyaxial Non-Locking, 3.5mm x 32mm, Ti PANL-35320-TS (01)00841506104232 (01) 00841506104232
Screw, Polyaxial Non-Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863 (01) 00841506102863	Screw, Polyaxial Non-Locking, 3.5mm x 34mm, Ti PANL-35340-TS (01)00841506104249 (01) 00841506104249
Screw, Polyaxial Non-Locking, 3.5mm x 20mm, Ti PANL-35200-TS (01)00841506104171 (01) 00841506104171	Screw, Polyaxial Non-Locking, 3.5mm x 36mm, Ti PANL-35360-TS (01)00841506104256 (01) 00841506104256
Screw, Polyaxial Non-Locking, 3.5mm x 22mm, Ti PANL-35220-TS (01)00841506104188 (01) 00841506104188	Screw, Polyaxial Non-Locking, 3.5mm x 38mm, Ti PANL-35380-TS (01)00841506104263 (01) 00841506104263
Screw, Polyaxial Non-Locking, 3.5mm x 24mm, Ti PANL-35240-TS (01)00841506104195 (01) 00841506104195	Screw, Polyaxial Non-Locking, 3.5mm x 40mm, Ti PANL-35400-TS (01)00841506104270 (01) 00841506104270
Screw, Polyaxial Non-Locking, 3.5mm x 26mm, Ti PANL-35260-TS (01)00841506104201 (01) 00841506104201	Screw, Polyaxial Non-Locking, 3.5mm x 42mm, Ti PANL-35420-TS (01)00841506104287 (01) 00841506104287
Screw, Polyaxial Non-Locking, 3.5mm x 28mm, Ti PANL-35280-TS (01)00841506104218 (01) 00841506104218	Screw, Polyaxial Non-Locking, 3.5mm x 44mm, Ti PANL-35440-TS (01)00841506104294 (01) 00841506104294
Screw, Polyaxial Non-Locking, 3.5mm x 30mm, Ti PANL-35300-TS (01)00841506104225 (01) 00841506104225	
IJS-E Axis Pin [1] and Screw	
IJS-E Axis Pin 2.5mm x 30mm IJS-EAP-25300 (01)00841506105062 (01) 00841506105062	IJS-E Axis Pin 2.5mm x 55mm IJS-EAP-25550 (01)00841506105116 (01) 00841506105116
IJS-E Axis Pin 2.5mm x 35mm IJS-EAP-25350 (01)00841506105079 (01) 00841506105079	IJS-E Axis Pin 2.5mm x 60mm IJS-EAP-25600 (01)00841506105123 (01) 00841506105123

IJS-E Axis Pin 2.5mm x 40mm IJS-EAP-25400 (01)00841506105086  (01) 00841506105086	IJS-E Axis Pin 2.5mm x 65mm IJS-EAP-25650 (01)00841506105130  (01) 00841506105130
IJS-E Axis Pin 2.5mm x 45mm IJS-EAP-25450 (01)00841506105093  (01) 00841506105093	IJS-E Axis Pin 2.5mm x 70mm IJS-EAP-25700 (01)00841506105147  (01) 00841506105147
IJS-E Axis Pin 2.5mm x 50mm IJS-EAP-25500 (01)00841506105109  (01) 00841506105109	IJS-PUP-SCRW #4-40 Screws (01)00841506107226  (01) 00841506107226
Single Use (Disposable) Instruments[1]	
K-Wire Standard Tip, 1.5mm x 127mm KWIR-STD-15127 (01)00841506102504  (01) 00841506102504	

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