English

IJS – Elbow System

INSTRUCTIONS FOR USE FOR UNITED KINGDOM AND EUROPEAN UNION

Basic UDI: 00841506104898

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.

There are three IJS-E Constructs.

The IJS-E construct consists of a base plate, distal connecting rod and proximal connecting rod. These components are connected using 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 compression screws. The proximal connecting rod is then secured to the distal humerus at the axis of rotation using the appropriate sized axis pin.

The Double IJS-E construct consists of a Double IJS-E base plate, two distal connecting rods and two proximal connecting rods, one at each side of the base plate. These components are connected using 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 compression screws. The proximal connecting rods from each side of the Double IJS-E base plate, are secured to the distal humerus at the axis of rotation using the cobalt chrome male axis pin from one side and the cobalt chrome female axis pin from the other side. The male axis pin telescopes within the female axis pin within the distal humerus.

The IJS-E Proximal Ulna Plate construct consists of an IJS-E proximal ulna plate base plate, distal connecting rod and proximal connecting rod. These components are connected using adjustable locking joints and locking screws allowing for multiple degrees of freedom. The base plate can be secured to the proximal ulna plates by means of two #4-40 cobalt chrome screws of 5.5mm in length. 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, 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:

- Titanium plates and rods (Titanium per ASTM F136 and ASTM F67)
- Multiple sized CoCr humeral axis pin(s) and screws (Cobalt Chrome per ASTM F1537 and ASTM F75)
- Stainless Steel K-Wires (Guide Wires) for optimal prosthesis alignment (not to be implanted)
- System specific instrumentation.

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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, 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.

⇪ 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.
- The IJS-E construct Connecting Rod splines must be fully seated prior to tightening. Improper positioning may result in loosening of the construct.
- 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. Failure to remove the implant after tissue healing, increases likelihood of the device to bend, break, disassemble, cause localized tissue reactions, pain, or discomfort.
- 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, 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 implant breakage, loosening, 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 about the use, limitations and possible adverse effects of this device including the possibility of device or treatment failure as a result 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 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.
- 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 system specific instrumentation from different systems or 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 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 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.
- 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 of 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 range of motion, dislocation, failure to maintain the reduction of the elbow joint, loosening or migration of the implants, stiffness of the elbow, bone fracture, material sensitivity. Serious incidents should be reported to Skeletal Dynamics Inc., or an in-country representative, and to the health authority where the incident occurred.

⇪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, Sterilization, and Inspection

For instructions on cleaning, disinfection, sterilization and inspection of the IJS-E products please refer to cleaning and sterilization instructions for use (IFU-04056-07). Refer to the IJS-E Surgical Technique Guide (MKT-00455-00) for proper kitted tray arrangement. **Do not disassemble the construct prior to cleaning**.

Safety and Clinical Performance

The IJS-E System has information on safety and clinical performance in the *Summary of Safety and Clinical Performance* (IFU-00554-32) document.

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:

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CE
2797

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NON STERILE

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IJS-ELBOW

Elbow Stabilization System

Inventory Control Sheet

Internal Joint Stabilizer Base Plate	
IJS-E Base Plate Assembly, Ti/CoCr IJS-ELB-BPA (01)00841506104904 (01) 00841506104904	IJS-E Base Plate Assembly, Proximal Ulna Plate, Ti/CoCr IJS-PUP-BPA (01)00841506109107 (01) 00841506109107
Double IJS-E, Assembly, Ti/CoCr IJS-DBL-BPA (01)00841506109138 (01) 00841506109138	
Polyaxial Non-Locking Screw (Ti)	
Screw, Polyaxial Non-Locking, 3.5mm x 8mm, Ti PANL-35080-TS (01)00841506102771 (01) 00841506102771	Screw, Polyaxial Non-Locking, 3.5mm x 28mm. Ti PANL-35280-TS (01)00841506104218 (01) 00841506104218
Screw, Polyaxial Non-Locking, 3.5mm x 10mm, Ti PANL-35100-TS (01)00841506102795 (01) 00841506102795	Screw, Polyaxial Non-Locking, 3.5mm x 30mm, Ti PANL-35300-TS (01)00841506104225 (01) 00841506104225
Screw, Polyaxial Non-Locking, 3.5mm x 12mm, Ti PANL-35120-TS (01)00841506102818 (01) 00841506102818	Screw, Polyaxial Non-Locking, 3.5mm x 32mm, Ti PANL-35320-TS (01)00841506104232 (01) 00841506104232
Screw, Polyaxial Non-Locking, 3.5mm x 14mm, Ti PANL-35140-TS (01)00841506102832 (01) 00841506102832	Screw, Polyaxial Non-Locking, 3.5mm x 34mm, Ti PANL-35340-TS (01)00841506104249 (01) 00841506104249
Screw, Polyaxial Non-Locking, 3.5mm x 16mm, Ti PANL-35160-TS (01)00841506102856 (01) 00841506102856	Screw, Polyaxial Non-Locking, 3.5mm x 36mm, Ti PANL-35360-TS (01)00841506104256 (01) 00841506104256
Screw, Polyaxial Non-Locking, 3.5mm x 18mm, Ti PANL-35180-TS (01)00841506102863 (01) 00841506102863	Screw, Polyaxial Non-Locking, 3.5mm x 38mm, Ti PANL-35380-TS (01)00841506104263 (01) 00841506104263
Screw, Polyaxial Non-Locking, 3.5mm x 20mm, Ti PANL-35200-TS (01)00841506104171 (01) 00841506104171	Screw, Polyaxial Non-Locking, 3.5mm x 40mm, Ti PANL-35400-TS (01)00841506104270 (01) 00841506104270

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Screw, Polyaxial Non-Locking, 3.5mm x 22mm, Ti PANL-35220-TS (01)00841506104188 (01) 00841506104188	Screw, Polyaxial Non-Locking, 3.5mm x 42mm, Ti PANL-35420-TS (01)00841506104287 (01) 00841506104287
Screw, Polyaxial Non-Locking, 3.5mm x 24mm, Ti PANL-35240-TS (01)00841506104195 (01) 00841506104195	Screw, Polyaxial Non-Locking, 3.5mm x 44mm, Ti PANL-35440-TS (01)00841506104294 (01) 00841506104294
Screw, Polyaxial Non-Locking, 3.5mm x 26mm, Ti PANL-35260-TS (01)00841506104201 (01) 00841506104201	
FreeFix Compression Screw (Ti)	
Screw, FreeFix Compression, 3.5mm x 8mm, Ti FFC-35080-TS (01)00841506130224 (01) 00841506130224	Screw, FreeFix Compression, 3.5mm x 28mm, Ti FFC-35280-TS (01)00841506130361 (01) 00841506130361
Screw, FreeFix Compression, 3.5mm x 10mm, Ti FFC-35100-TS (01)00841506130248 (01) 00841506130248	Screw, FreeFix Compression, 3.5mm x 30mm, Ti FFC-35300-TS (01)00841506130378 (01) 00841506130378
Screw, FreeFix Compression, 3.5mm x 12mm, Ti FFC-35120-TS (01)00841506130262 (01) 00841506130262	Screw, FreeFix Compression, 3.5mm x 32mm, Ti FFC-35320-TS (01)00841506130385 (01) 00841506130385
Screw, FreeFix Compression, 3.5mm x 14mm, Ti FFC-35140-TS (01)00841506129976 (01) 00841506129976	Screw, FreeFix Compression, 3.5mm x 34mm, Ti FFC-35340-TS (01)00841506130392 (01) 00841506130392
Screw, FreeFix Compression, 3.5mm x 16mm, Ti FFC-35160-TS (01)00841506130293 (01) 00841506130293	Screw, FreeFix Compression, 3.5mm x 36mm, Ti FFC-35360-TS (01)00841506130408 (01) 00841506130408
Screw, FreeFix Compression, 3.5mm x 18mm, Ti FFC-35180-TS (01)00841506130316 (01) 00841506130316	Screw, FreeFix Compression, 3.5mm x 38mm, Ti FFC-35380-TS (01)00841506130415 (01) 00841506130415
Screw, FreeFix Compression, 3.5mm x 20mm, Ti FFC-35200-TS (01)00841506130323 (01) 00841506130323	Screw, FreeFix Compression, 3.5mm x 40mm, Ti FFC-35400-TS (01)00841506130422 (01) 00841506130422
Screw, FreeFix Compression, 3.5mm x 22mm, Ti FFC-35220-TS (01)00841506130330 (01) 00841506130330	Screw, FreeFix Compression, 3.5mm x 42mm, Ti FFC-35420-TS (01)00841506130439 (01) 00841506130439

Screw, FreeFix Compression, 3.5mm x 24mm, Ti FFC-35240-TS (01)00841506130347 (01) 00841506130347	Screw, FreeFix Compression, 3.5mm x 44mm, Ti FFC-35440-TS (01)00841506130446 (01) 00841506130446
Screw, FreeFix Compression, 3.5mm x 26mm, Ti FFC-35260-TS (01)00841506130354 (01) 00841506130354	
IJS-E Axis Pin 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
IJS-E Axis Pin Female, 30mm IJS-EAP-F30 (01)00841506114019 (01) 00841506114019	
Single Use (Disposable) Instruments	
K-Wire Standard Tip, 1.5mm x 127mm KWIR-STD-15127 (01)00841506102504 (01) 00841506102504	