English

IJS – Elbow System

INSTRUCTIONS FOR USE (IFU) FOR THE UNITED KINGDOM AND THE EUROPEAN UNION

To ensure use of the most up-to-date revision, refer to **www.skeletaldynamics.com/resources/**

R_x: For use by physicians only. Caution: Federal Law restricts this device to sale by or on the order of a physician.

This package insert is designed to provide Instructions for Use of the Internal Joint Stabilizer – Elbow System. **Failure to follow instructions may lead to patient injury.**

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 two IJS-E Constructs.

The IJS-E construct consists of a base plate, a distal connecting rod, and a 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 appropriately sized axis pin.

The IJS-E Proximal Ulna Plate construct consists of an IJS-E proximal ulna plate base plate, a distal connecting rod, and a 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 appropriately sized axis pin.

The instrumentation includes elbow axis guides, various gauges, and other system-specific guides and drills, which enable the surgeon to identify the axis of rotation of the distal humerus, and optimally position the device depending on 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

The IJS-E System does not include medicinal substances and is provided non-sterile. It is intended for steam sterilization in the user facility.

Intended Use

The IJS-E System is intended for temporary stabilization of the elbow joint.

IJS-E Indications

The *Single IJS-E* is indicated for elbow joint instability after trauma, such as simple dislocation and complex fracture dislocations, or chronic elbow dislocation.

PUP IJS-E Indications

The *PUP IJS-E* is indicated for elbow joint instability after treatment of ulna fracture dislocations using the *Skeletal Dynamics Proximal Ulna Plate.*

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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.

Intended Patient Population

The IJS-E System is intended for skeletally mature patients with elbow instability.

Intended User

The IJS-E System should only be used by surgeons familiar with this system and by facility processing staff trained to handle, clean, and re-sterilize surgical devices. Each surgeon must evaluate the appropriateness of using the IJS-E System based on their clinical experience.

Expected Clinical Benefits

The expected clinical benefits of the IJS-E System include stabilization, early active mobilization, and improved functionality of the elbow joint when used as directed and with the recommended technique.

A summary of safety and clinical performance (IFU-00554-32) can be found at the following link: http://ec.europa.eu/tools/eudamed

Note: The EUDAMED link will only be available after the European database on medical devices, EUDAMED, is launched. The summary of safety and clinical performance is available upon request. Please refer to the resources section for further information.

Performance Characteristics of the Device

Skeletal Dynamics has established the performance and safety of the IJS-E System, and it represents the state-of-the-art medical device intended for temporary stabilization of the elbow joint after trauma or chronic elbow dislocation. Refer to the device description section of this IFU for device characteristics.

Device Lifetime

The IJS-E construct is intended to be removed once tissue healing has demonstrated sufficient joint stability. Based on the clinical data, removal is performed once complete bony and ligamentous healing is achieved, typically by 3-4 months in 98.1% of the cases. Patient factors such as weight, bone quality, activity level, and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopaedic device.

⚠ 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 must be 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.

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- The IJS-E construct is intended to be explanted when tissue healing has proved sufficient for joint stability (typically 3-4 months). Failure to remove the implant after tissue healing increases the likelihood that the device will bend, break, or disassemble, and may 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 with 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 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 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 or joint damage.
- 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 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 with pacemakers during electrocautery or by

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uncertified drills.
- Seek medical help immediately if the 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.



⚠ MR Safety Information

A person with the Skeletal Dynamics' Upper Extremity Systems may be safely scanned at 1.5 T or 3 T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Skeletal Dynamics' Upper Extremity Systems
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m (1,900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	**1.5 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 6.1$ µT) for up to one hour - Lower leg region: Normal Operating Mode for up to one hour **3 T:** - Head region: Normal Operating Mode for up to one hour - Torso, pelvis, and upper leg regions: $SAR_{WB} \leq 1.0$ W/kg (or $B_{1+RMS} \leq 3.1$ µT) for 6 minutes of scanning, followed by a minimum cooling period of 15 minutes, up to a maximum total scanning/cooling duration of one hour - Lower leg region: Normal Operating Mode for up to one hour
Scan duration	Scan duration as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Scan Regions	Landmark restrictions as detailed in the **Operating Mode** section above and in the ***MR Restricted Zone Summary***
Image Artifact	The presence of Skeletal Dynamics' Upper Extremity Systems may produce an image artifact of 5.1 cm. Some manipulation of scan parameters may be needed to compensate for the artifact
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

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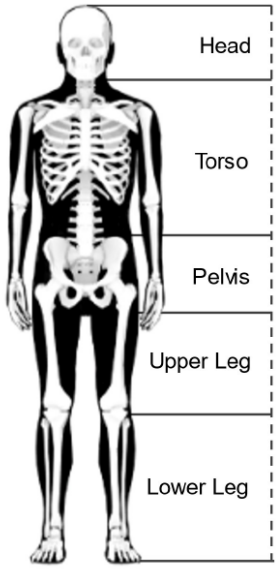
MR Restricted Zone Summary

Skeletal Dynamics' Upper Extremity Systems



Landmark Region	1.5 T Scan Restriction	3 T Scan Restriction
Head	Normal Operating Mode*	Normal Operating Mode*
Torso	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 6.1$ µT	$SAR_{wb} \leq 1.0$ W/kg OR $B_{1+,RMS} \leq 3.1$ µT for 6 minutes of scanning followed by a minimum cooling period of 15 minutes
Pelvis		
Upper Leg		
Lower Leg	Normal Operating Mode*	Normal Operating Mode*

Under these conditions, total scanning duration for up to one hour is permitted unless otherwise specified. When a cooling period is recommended, repeated scan/cool sequences are permitted for a total duration of up to one hour. Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
SAR_{wb}: Whole body averaged specific absorption rate
SAR_{head}: Head averaged specific absorption rate
$B_{1+,RMS}$: RMS RF magnetic field (B_{1+})

**Normal Operating Mode limits defined by IEC 60601-2-33 Table 201.104:*
- *SAR_{wb}: 2 W/kg*
- *SAR_{head}: 3.2 W/kg*

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, heterotopic ossification, 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.

Directions for Use

The IJS-E System should be used only by surgeons familiar with the 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* (MKT-00455-00) 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.

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Cleaning, Sterilization, and Inspection

Instructions for cleaning, disinfection, sterilization, and inspection of IJS-E products are provided in the Reprocessing IFU, ***Instructions for Reprocessing (Cleaning, Disinfection, and Sterilization) of Skeletal Dynamics Products*** (IFU-04056-00), available at **www.skeletaldynamics.com/resources**. Proper kitted tray arrangement is described in **the *IJS-E Surgical Technique Guide*** (MKT-00455-00). The construct must not be disassembled prior to cleaning.

Resources

The latest version of the Instructions for Use, Summary of Safety and Clinical Performance, and/or Patient Pamphlet 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.

Implant Materials

Basic UDI Codes	Basic UDI #s	Device Components	Materials(s)	Standard(s)
IJS-EC-FAM	08415061048965	IJS-E Baseplate PUP IJS-E Baseplate	Ti 6Al-4V ELI	ASTM F136
		Distal Connecting Rod(s) Proximal Connecting Rod(s)	Ti 6Al-4V ELI	ASTM F136
		Distal Locking Screw(s) Proximal Locking Screw(s)	CoCrMo	ASTM F1537
CS-FAM-CC	0841506142435X	#4-40 Screw	CoCrMo	ASTM F1537
BP-FAM-CC	0841506142445Z	Axis Pins	CoCrMo	ASTM F75
SCW-FAM-TI	08415061423866	FreeFix Compression Screws Polyaxial Non-Locking Screws	Ti 6Al-4V ELI	ASTM F136

The titanium implants and implant components conform to ASTM F136, which provides the following tolerances for the material:

ASTM F136 Chemical Composition

Element	Composition % (mass)
Nitrogen, Ni	≤ .05%
Carbon	≤ .08%
Hydrogen	≤ .015%
Iron	≤ .25%
Oxygen	≤ .13%
Aluminum	≤ 6.5%
Vanadium	≤ 4.5%
Titanium	balance*

*the percentage of Titanium is determined by the difference and is not determined or certified.

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Cobalt Chrome screws and axis pins conform to ASTM F1537, which provides the following tolerances for the material:

ASTM F1537 Chemical Composition

Element	Composition % (mass)
Carbon	≤ 0.14%
Chromium	≤ 30%
Molybdenum	≤ 7.0%
Nickel*	≤ 1.0%
Iron	≤ 0.75%
Silicon	≤ 1.0%
Manganese	≤ 1.0%
Nitrogen	≤ 0.25%
Cobalt	balance**

*Nickel, classified as skin sensitizer 1: sensitization or allergic reactions to users and/or patients. Classification based on EU CLP Regulation (EC No 1272/2008) for chemical substances

** The percentage of Cobalt is determined by the difference and is not determined or certified.

Cobalt	Cobalt Chrome ASTM 1537	This device contains Cobalt in a concentration above 0.1% weight by weight. Current scientific evidence supports medical devices manufactured do not show any significant incidence of adverse events due to the presence of Cobalt.

The IJS-E assembly, interplate screws, and axis pins will contain nickel and should not be used on any patient with a known allergy.

Disclaimer of Warranty and Limited Remedies

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Skeletal Dynamics, Inc.
7300 N. Kendall Dr. / Suite 800
Unites States of America, Miami, FL 33156
1-877-753-5396

EU REP
European Representative
Emergo Europe.
Westervoortsedijk 60
6827 AT Arnhem,
The Netherlands

UK REP
UK Representative
Emergo Consulting (UK) Limited
c/o Cr 360 - UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

MD NON STERILE CE 2797

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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
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
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

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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	

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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
Single Use (Disposable) Instruments	
K-Wire Standard Tip, 1.5mm x 127mm KWIR-STD-15127 (01)00841506102504	(01) 00841506102504

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