

Internal Joint Stabilizer – Elbow (IJS-E)® System

PATIENT INFORMATION LEAFLET

This leaflet has information about your implant, but does not include everything. If you have any questions, talk to your healthcare team. All implants have risks and benefits. Always follow your healthcare team's advice, even if it differs from this leaflet. Please read this leaflet carefully. Keep it in a safe place so you can refer to it in the future if needed.

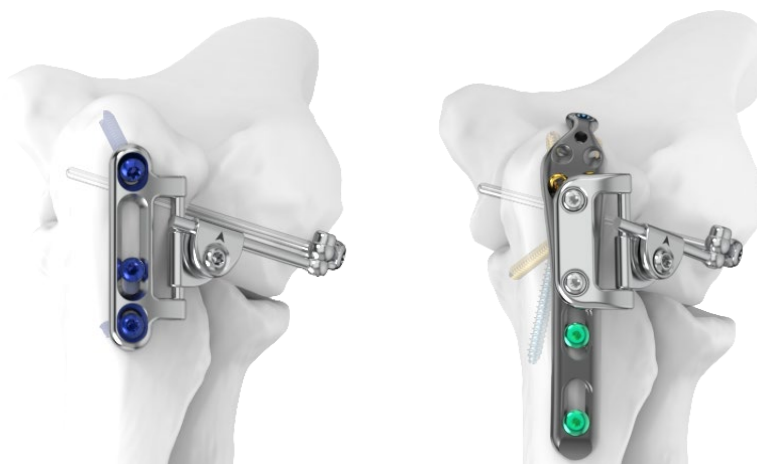
Your implant card has the name of your IJS-E® implant. If a healthcare provider asks about your implant, please show them your implant card.

Description

The IJS-E implant is placed inside your arm on the elbow bones to give stability. The implant works with the nearby bones and soft tissue to help you use your elbow again. There are two different versions:

- Single IJS-E
- PUP IJS-E

The Single IJS-E is used by itself on the elbow, while the PUP IJS-E is used with a Proximal Ulna Plate on the elbow.



Single IJS-E® (Left) and PUP IJS-E® (Right) Implants

Implant Materials

Your implant is made from the following materials:

Basic UDI Code	Basic UDI #	Device Components	Material(s)
IJS-EC-FAM	08415061048965	IJS-E Baseplate PUP IJS-E Baseplate	Titanium (Ti 6Al-4V ELI)
	N/A	Distal Connecting Rod(s) Proximal Connecting Rod(s)	Titanium (Ti 6Al-4V ELI)

Basic UDI Code	Basic UDI #	Device Components	Material(s)
	N/A	Distal Locking Screw(s) Proximal Locking Screw(s)	Cobalt Chrome
CS-FAM-CC	0841506142435X	#4-40 Screw	Cobalt Chrome
BP-FAM-CC	0841506142445Z	Axis Pins	Cobalt Chrome
SCW-FAM-TI	08415061423866	FREEFIX Compression Screws Polyaxial Non-Locking Screws	Titanium (Ti 6Al-4V ELI)

Part of your implant is made of Cobalt Chrome. Current research shows that medical devices with cobalt do not increase the risk of adverse events. Implants with Cobalt Chrome also have small amounts of Nickel. Nickel may cause sensitivity or allergic reactions in users and/or patients. Let your doctor know if you are having any reactions.

Information for Safe Use

As part of your procedure, you should have received a set of instructions on exercises, therapies, and any limits on what you can and can't do. It is very important to follow your doctor's instructions on how to recover and restart activities. Make sure you go to all your appointments. Healing takes time. Your doctor will tell you what to expect. Complications and the need for more surgery may occur if you do not follow your doctor's advice.

Images of your implant are often needed after your surgery. X-rays or CT scans are safe and will not increase risk. If you are asked to go for an MRI scan, please show your implant card or the MRI safety information below to the doctor and the MRI technician. MRI scans may affect your implant. Complications may occur if your technician does not know you have one. Sharing this information will help them manage your MRI safely.



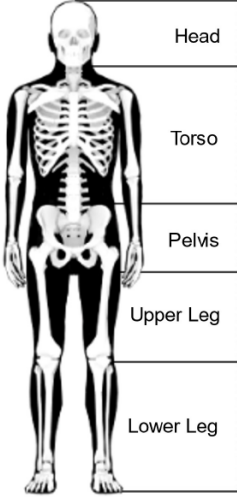
MRI Safety Information

Your implant may be safely scanned under the following conditions:

Static Magnetic Field Strength (B0)	1.5 T and 3 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	19 T/m (1,900 G/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: SARWB ≤ 1.0 W/kg 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: SARWB $\leq$ 1.0 W/kg for 6 minutes of scanning following 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 Operating Mode section above and in the <i>MRI Restricted Zone Summary</i>
Scan Regions	Landmark restrictions as detailed in Operating Mode section above and in the <i>MRI Restricted Zone Summary</i>
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

MRI Restricted Zone Summary

	Landmark Region	1.5 T Scan Restriction	3 T Scan Restriction
	Head	Normal Operating Mode*	Normal Operating Mode*
	Torso	$SAR_{wb} \leq 1.0 \text{ W/kg}$ OR $B_{1+,RMS} \leq 6.1 \mu\text{T}$	$SAR_{wb} \leq 1.0 \text{ W/kg}$ OR $B_{1+,RMS} \leq 3.1 \mu\text{T}$ 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

Possible Side Effects / Risks

Your doctor can explain any possible side effects of your procedure. All procedures have risks. The risk of a serious complication is low. However, the IJS-E® implant can wear out sooner than expected or go wrong. If you notice any changes in your elbow or arm, talk to your doctor.

Possible risks may include:

- Damage to nerves or vessels
- Infection
- Swelling (edema)
- Reduced or loss of range of motion
- Elbow dislocation
- Failure to maintain the proper anatomical position (reduction) of the elbow joint
- Loosening or migration of the implants
- Temporary or permanent stiffness of the elbow
- Abnormal bone growth (heterotopic ossification)
- Bone fracture
- Material sensitivity

These risks may require additional procedures or treatments. It may affect other parts of your body. Another procedure may not be possible for all patients. Please talk to your doctor if you have concerns.

If a serious incident happens with your IJS-E® implant, make sure to tell the manufacturer at feedback@skeletaldynamics.com and your healthcare provider.

Warnings and Precautions

- It is important to follow the care instructions given by your doctor after surgery. This will help you know what you can and can't do in your daily activities.
- Failure to follow care instructions may cause the implant or treatment to fail.
- Avoid putting too much force on your implant. It cannot be expected to handle the same level of activity and load as normal healthy bone and joint tissue. It may break or loosen if too much force is used.
- Implant failure can mean the implant becomes loose, the bones don't heal properly or fully, new bone fractures happen, or damage to nerves or soft tissues caused by the surgery or the implant itself.
- The benefits from surgery may not last or meet the patient's expectations. A second surgery may be needed to fix or replace the implant or to carry out alternative procedures.
- The IJS-E device should be removed when your elbow is stable. This usually takes 3-4 months. If it is not removed after the elbow is healed, the device may break or loosen and cause pain and discomfort.
- Seek medical help right away if your implant is not working properly.

Expected Device Lifetime

Your implant is temporary. Soft tissue healing can take 3 to 4 months after surgery. Based on clinical data, the lifetime of the IJS-E is about 98.1% for up to 4 months after surgery.

It is possible that your implant may need to be fixed or replaced at some point during this recovery time. It is hard to predict if you will have complications that may need more surgery. An implant's lifetime can be longer or (much) shorter depending on the surgery and your specific medical needs. These are some factors that could influence how long your implant lasts:

Doctor controlled factors	Patient controlled factors	Uncontrollable factors
• Selecting the proper implant for you • The technique used during surgery	• Activity level • Lifestyle choices • Your weight	• Any preexisting disease and its stage • The condition of your bone and/or tissue • Infections • Further surgeries

Resources

For the most current version of the Instructions for Use, go to www.skeletaldynamics.com/resources. The Instructions for Use should always be reviewed before using or implanting the device.

You may request the latest version of the Instructions for Use in a physical format by email

(orders@skeletaldynamics.com) or by phone (+1-877-753-5396). A copy will be sent within 7 calendar days of receiving a request from the user, or at the time of delivery of the device if requested at the time of order.



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

