

Total Wrist Arthroplasty System

INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

Basic UDI: 00841506107523

R: 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 Total Wrist Arthroplasty System. Prior to use of the Total Wrist Arthroplasty System, the surgeon should become familiar with all information contained in this pamphlet. **Failure to follow instructions may lead to patient injury.**

Description

The Skeletal Dynamics Total Wrist Arthroplasty System consists of a cobalt chromium radial component, a cobalt chromium carpal component, two (2) titanium carpal screws, and a modular highly crosslinked vitamin E blended UHMWPE lunate component. The highly crosslinked vitamin E blended UHMWPE lunate component articulates both the radial and carpal components. The proximal aspect of the implant is designed to be inserted into the shaft of the radius bone and the distal aspect is designed to be fastened to the carpal bones of the hand. The Skeletal Dynamics Total Wrist Arthroplasty System is intended to replace the wrist. The implant is available in several size configurations with right- and left-handed options. A range of trials for each type of implant and instrumentation is provided to aid in bone preparation.

Implant Materials:

- Carpal Components (Cobalt Chrome per ASTM F75)
- Radial Components (TPS coated Cobalt Chrome per ASTM F75 and ASTM F1580)
- Lunate Components (Vitamin E Blended HXLPE per ASTM F2565 and ASTM F2695)
- Carpal Screws (Titanium per ASTM F136)

Indications for Use

The Skeletal Dynamics Total Wrist Arthroplasty System is intended for replacement of the painful wrist joint due to rheumatoid arthritis, osteoarthritis, or post-traumatic arthritis.

Contraindications

Prior to using the system, ensure that none of the following patient conditions are present: previous, active, or latent infection, insufficient quantity or quality of bone and/or soft tissue loss of wrist extensor function, material sensitivity, skeletal immaturity, or patients who are unwilling or incapable of following post-operative care instructions.

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 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.
- The patient must be cautioned 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 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 implant breakage, fixation failure, instability, delayed soft tissue healing, soft tissue irritation, delayed union, or non-union 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 implant, and associated instruments.

- The device is not designed to withstand the stress of excessive weight bearing, load bearing, or physical activity. Use of the wrist requiring lifting excessive loads is not recommended. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- Complete pre-closure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported with joint replacement implants.
- DO NOT reuse any of the system implantable components. Reuse may compromise the structural integrity of the construct.
- DO NOT reprocess or re-sterilize any of the implants. The Total Wrist Arthroplasty System implants come pre-sterile packed and do not require cleaning or sterilization. All implants are supplied sterile using ethylene oxide sterilization and are intended for single use.
- Some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include mechanical malfunction and transmission of infectious agents.
- DO NOT use if the sterile barrier is damaged or if the use by date has expired. Any product used with an expired use by date will void the product warranty.
- 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.
- Protect the final prosthesis' articular surfaces during implantation.
- DO NOT permanently implant the Skeletal Dynamics K-Wires; they are only intended to be used during provisional fixation.
- User should handle K-Wires accordingly during insertion and removal to prevent unintended K-Wire penetration or injury.
- DO NOT use screw lengths that will allow the screw tips to excessively protrude through the cortex as it may result in soft tissue irritation.
- DO NOT mix system specific instrumentation from different systems or manufacturers for metallurgical, biomechanical, and functional reasons.
- Correct selection of the implant is extremely important. The morbidity as well as patient occupation and/or degree of physical activity should be considered.
- 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 drill power sources.
- Seek medical help immediately if implant malfunctions.
- 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 implants are placed interfering with the articular surface.
- To maintain traceability of the system implantable components, record each of the respective components Lot numbers in the patient records.
- If the screws are not attached and/or fully tightened, a non-union, delayed union, soft tissue complication, or construct failure may occur.
- Use caution when drilling with K-wires or drills as it may result in vascular or nerve injury.
- Ensure sufficient space is available for proper application when used in conjunction with other implants to prevent interference. Interference with other prostheses may lead to failure of the system or postoperative complications.

- When drilling be sure to avoid drilling into the articular surfaces except as indicated in surgical technique.
- The implant construct 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.
- Protect the extraneous bony and soft tissue structures when reaming.
- Screws are not intended to be inserted under power. Do not remove or reinsert screws.
- Screws in this system are not interchangeable with screws from other Skeletal Dynamics systems.

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 range of motion, bone erosion, bone fracture, material sensitivity, stiffness, nonunion, persistent pain, loosening or migration of the implants. Undesirable shortening or lengthening of limb, implant failure, fretting and crevice corrosion damage to the articular surfaces.

MR Safety Information

The Total Wrist Arthroplasty System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or unwanted movement in the MR environment. The safety of the Total Wrist Arthroplasty System in the MR environment is unknown. Performing a MR exam on a person who has this device may result in injury or device malfunction.

Directions for Use

Use the recommended trial components for size determination, trial reduction, and range of motion evaluation. The implants should be removed from their sterile package only after the implant site has been prepared and properly sized. Trial components are available in the system to avoid opening the sterile package prior to prosthesis implantation.

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 *Total Wrist Arthroplasty System Surgical Technique Guide* (MKT-00125-00) 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, Sterilization, and Inspection

The Total Wrist Arthroplasty System implants are supplied sterile. The Total Wrist Arthroplasty System implantable components have been sealed and then sterilized by ethylene oxide (EO). The implants are provided in a sterile package. If any of the implants or the package appears damaged, or the expiration date has been exceeded then the implant should not be used. **DO NOT re-sterilize the implantable components.**

For instructions on cleaning, disinfection, sterilization and inspection of the Total Wrist Arthroplasty instruments please refer to cleaning and sterilization instructions for use (IFU-04056-00). Refer to the *Total Wrist Arthroplasty System Surgical Technique Guide* (MKT-00125-00) for proper kitted instrument tray arrangement.

Handling and Storage

When not in use, store the clean and disinfected Total Wrist Arthroplasty System within the sterilization tray. Prior to use, inspect the instrumentation for serviceability and the sterile packaged implants for signs of tampering or water contamination.

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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SYMBOLS GLOSSARY

Symbols that follow BS EN ISO 15223-1 / Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Symbol Reference Number and Title	Description
	5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	5.2.6 Do not re-sterilize	Indicates a medical device that is not to be re-sterilized
	5.1.6 Catalogue Number	Indicates the manufacturer's catalogue number so the medical device can be identified
	5.4.3 Consult Instructions for Use	Indicates the need for the user to consult the instructions for use
	5.1.5 Batch Code	Indicates the manufacturer's batch code or lot can be identified
	5.4.2 Do Not Re-use	Indicates a medical device that is intended for one single use only
	5.2.3 Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	5.1.1 Manufacturer	Indicates the medical device manufacturer
	5.2.8 Do Not Use If Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	5.1.4 Use-by-date	Indicates the date after which the medical device is not to be used
	5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	5.2.12 Double sterile barrier system	Indicates two sterile barrier systems
	5.7.7 Medical device	Indicated the item is a medical device
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured