KinematX®
Total Wrist Arthroplasty

PACKAGE INSERT

Caution: Federal law restricts this device to sale by or on the order of a Physician

DESCRIPTION OF THE MEDICAL DEVICE:
The KinematX Total Wrist Arthroplasty System is a semi-constrained implant system designed to replace the joints of the wrist to alleviate pain while restoring functionality and mobility of the wrist joints. The system consists of modular components (proximal radial and distal carpal) in various size configurations to allow for variations in patient anatomy.

Materials:

Radial Stems	CoCr (ASTM F1537)
Radial Tray	CoCr (ASTM F1537)
Radial Tray Insert	UHMWPE (ASTM F648)
Bone Screws	Ti-6Al-4V (ASTM F136)
Carpal Baseplate	Ti-6Al-4V (ASTM F136)
Radial Cap	CoCr (ASTM F1537)
Radial Stem and Carpal Baseplate Coating	CP Titanium (ASTM F1580)

INDICATIONS FOR USE
The KinematX Total Wrist Arthroplasty System is indicated for the replacement of wrist joints disabled by pain, deformity, and/or limited motion caused by:

1. Non-inflammatory degenerative wrist disease of the radiocarpal joint including osteoarthritis, post-traumatic arthritis, and Kienbock's disease
2. Revision where other devices or treatments have failed
3. Scapholunate Advanced Collapse (SLAC)
4. Rheumatoid Arthritis

The device is intended to be implanted with bone cement.

CONTRAINDICATIONS
The implant should not be used in a patient who has currently, or who has a history of:

- Local or systemic acute or chronic inflammation;
- Physiologically or psychologically inadequate patient;
- Possibility for conservative treatment;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance.
- Irreparable tendon system;
- Inadequate skin, bone, or neurovascular status
- Severe displacement, absorption, or involvement of contiguous carpal bones
- Sepsis
- Osteomyelitis
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Distant foci of infections which may spread to the implant site
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
- Absent or insufficient wrist extensor tendons.

The usage of metal sutures/wire for implant fixation is contraindicated.

WARNINGS and POTENTIAL RISKS

- The Extremity Medical implants are designed for **single patient use only and must never be reused.** As with all other orthopedic implants, the Extremity Medical components should never be re-implanted under any circumstances.
- The Extremity Medical implants can become loose, wear and/or break if subjected to increased loading. Factors such as the patient's activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity.
- Serious post-operative complications may occur from the implant in a patient who; lacks good general physical conditions; has severe osteoporosis, demonstrates physiological or anatomical anomalies; has immunological responses, sensitization or hypersensitivity to foreign materials; systemic or metabolic disorders.
- Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.
- Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
- Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue has lower adhesion strength to cement than implants handled with clean gloves.
- Do not modify implants.
- The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.
- Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. 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.
- Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred.
- The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS
The implantation of the device should be performed only by experienced surgeons with specific training in the use of this implant system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Under no circumstances should damaged components or surgically excised components be used. Implants that have already been in contact with body fluids or body tissues must not be re-sterilized.

Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of x-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity. Do not allow the implants surfaces to be damaged.

All implants and 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
- Transmission of infectious agents

Adequately instruct the patient. The physician should inform the patient about orthopedic implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature migration, damage and/or fracture of orthopedic prostheses.

IMPORTANT: The KinematX Implant 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 KinematX implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS
Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late repositioning and/or breakage of implant;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Migration of particle wear debris possible resulting in a bodily response;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Hematoma;
- Allergy;
- Thrombosis;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Pain, discomfort or wound healing complications at the surgical site;
- Misalignment of anatomical structures;
- Progressive carpal instability or collapse, and progression of disease to other carpal articulations;
- Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.

DIRECTIONS FOR USE
To implant the KinematX device, use only the specialized KinematX instrumentation. Do not use implants or instruments from any other system or manufacturer.

The KinematX instruments are provided **non-sterile** and must be cleaned and sterilized prior to use according to the procedures outlined in this document. All KinematX system components should be carefully inspected. All critical areas, including surfaces, should be checked for wear, damage or irregularities. Damaged or broken Extremity Medical devices must not be used or processed and should be returned to Extremity Medical for evaluation.

Before using the KinematX System for the first time, the surgeon should be thoroughly familiar with the

KinematX Surgical Technique as well as the functionality of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used. The implant size and side is provided on the implant package labels.

For complete instructions regarding the proper use and application of all KinematX implants and instruments, please refer to the KinematX Surgical Technique.

CARE AND HANDLING

KinematX implants should be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. Discard if open but unused. Do not use after expiration date.

KinematX instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Limitations on Processing

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage to due to use.

Point of Use

Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.

Containment and Transportation

It is recommended that instruments are reprocessed as soon as reasonably practical following use.

Preparation for Cleaning

- If possible, it is recommended that devices be reprocessed promptly after use.
- Where instruments interface with other devices, disassemble prior to cleaning.
- Remove gross soil with a clean, disposable, absorbent Kimwipe or equivalent.
- Soak and/or rinse cannulated and multi-component assemblies with neutral or mild alkaline cleaning agent solution. Follow the cleaning agent manufacturer's instructions for correct exposure time, temperature, water quality, and concentration.
- Ensure debris are cleared from cannulations/lumens via cleaning brush or equivalent, where applicable.
- Repeat soak/rinse step followed by cleaning via cleaning brush or equivalent until visibly clean
- Extremity Medical devices must be cleaned separately from Extremity Medical instrument trays/cases.
- Instruments must be thoroughly cleaned.

Cleaning (Automated)

- Ensure all gross soil is removed from the device and that all preparation for cleaning steps are complete.
- For devices that have cannulations/lumens or present complexity, a preliminary manual cleaning may be required.
- Use a validated, properly maintained, and calibrated washer disinfector.
    - Equipment: Washer Disinfectant/ Decontaminator (Hydrim L110W) and detergent (HIP Cleaning Solution L110W) or equivalent.
- Place the device(s) in a washer basket or equivalent for loading into washer disinfector
    - Ensure that the devices are oriented in a way that allows devices to drain
    - Ensure device orientation aligns with manufacturer's orientation recommendations.
- It is recommended that a pH-neutral enzymatic solution is used. If using an alkaline solution, a neutralizer must be added. Please follow manufacturer's datasheet for concentration of solution, time of use, and temperature.
- Rinse devices using sterile or freshly prepared purified water
- Use automated drying cycle to dry devices or hand dry using absorbent, non-shedding cloth.
- The following cycle will be selected (at a minimum):

Prewash	Cold Water + Hot Water for 2 minutes (tap water)
Pulsed Enzyme	Hot water for 11 minutes (tap water) with Prolystica 2x Concentrate Enzymatic Pre-Soak and Cleaner (1/8oz of detergent/gallon of water)
Rinse	Purified water for 2 minutes
Thermal Disinfection	90°C for 5 minutes
Dry	High Temperature for 30 minutes

- Inspection: When unloading, visually inspect the devices for complete removal of any debris. If the device is not visually clean, repeat the automated cleaning cycle or use manual cleaning.
- Remove instruments from the Washer/Disinfector and wrap devices with sterilization wrap or place instrument in a sterilization pouch.

Cleaning (Manual)

All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

Manual Cleaning Instructions:

- Alcohol wipe the instruments.
- Bathe the instruments in an enzymatic solution for 20 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution.
- Scrub the instruments with a soft brush.
- Rinse the instruments in cold water.
- Submerge the samples in cleaning/disinfection solution and sonicate for 15 min at 40˚C (104˚F).
- Scrub the instruments with a soft brush.
- Rinse the instruments in deionized water until all traces of cleaning solution are removed.
- Pat dry the instruments with a clean, disposable, absorbent Kimwipe or equivalent.
- If necessary, repeat manual cleaning cycle.

Disinfection

Disinfection solution may be used in accordance with the label instructions.

If automated cleaning is employed, a final rinse at 60 ˚C for 20 minutes may be used to affect thermal disinfection.

Maintenance and Repair

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Warning: Do not attempt to repair any Extremity Medical instrument.

If your Extremity Medical instrument requires repair or maintenance, return the instrument in the Extremity Medical box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:

Extremity Medical, LLC
300 Interpace Parkway
Building A, 2nd Floor
Parsippany, NJ 0705
Attn: Extremity Medical Technical Services

Note: Instruments returned to Extremity Medical must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Inspection and Function Testing

All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Packaging

Instruments may be loaded into dedicated instrument trays, or in general-purpose trays. Wrap the trays using an appropriate method.

Storage

Extremity Medical instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

Sterilization

KinematX Stems, Radial Bodies, Baseplates and Carpal Caps are provided sterile by gamma irradiation.

Do not resterilize.

Instruments and Locking Screws

Warning: Extremity Medical does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10^{-6}, Extremity Medical recommends the following parameters for the instruments and Locking Screws:

Cycle: pre-vacuumed autoclave (Use an FDA cleared wrap for sterilization)

- Temperature : 132 °C
- Time : 4 minutes exposure
- Drying : 20 minutes

Extremity Medical recommends following the recommendations of AAMI Guideline for Steam Sterilization ST79 which includes: physical monitoring of the cycle, including a chemical indicator external and internal of the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

CUSTOMER SERVICE

For further information regarding the KinematX System or a copy of the KinematX System Surgical Technique, please contact Extremity Medical, LLC or your local Extremity Medical Distributor.

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