English

STABLYX™ CMC Arthroplasty System

INSTRUCTIONS FOR USE

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 STABLYX CMC Arthroplasty System; it is not a reference to surgical techniques. Prior to use of the STABLYX CMC Arthroplasty System the surgeon should become familiar with all information contained in this pamphlet.

Description:
The STABLYX CMC Arthroplasty System is a hemi joint replacement for the base of the first metacarpal of the first Carpometacarpal (CMC) joint. The monoblock prosthesis is a single piece prosthesis having a highly polished, saddle shaped (toroidal) articular surface designed to mirror the normal anatomy of the base of the first metacarpal. The STABLYX prosthesis bears against the mating saddle articular surface of the trapezium. The saddle design of the STABLYX CMC prosthesis allows for flexion-extension, abduction-adduction and opposition motions. It is comprised of Cobalt Chrome (CoCr) with a Titanium Plasma Sprayed (TPS) stem, which is press fit into the medullary canal. Each prosthesis is packaged and provided sterile.

The STABLYX CMC Arthroplasty System is comprised of:

- Multiple sized hemi joint prosthesis
- System specific instrumentation

Indications for Use:
The STABLYX CMC Arthroplasty System is intended to replace the base (proximal end) of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation of bone loss that present as either a painful, unstable thumb, or a thumb with limited range of motion. This implant is intended for non-cemented, press fit use.

Contraindications:
The STABLYX CMC Arthroplasty System should not be used if any of the following are present: active or latent infection, sepsis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity, or patients who are unwilling or incapable of following post operative care instructions.

⚠ Warnings and Precautions:

- Do not use the STABLYX CMC where the trapezium is severely compromised and the implant cannot be supported. The saddle shape of the implant requires a normal or near normal share of the distal surface of the trapezium.
- Avoid injury to the Flexor Carpi Radialis and Flexor Policis Longus tendons while exposing the palmer aspect of the CMC joint, resecting bone and removing osteophytes.
- Avoid a longitudinal capsulotomy, as it is more likely to devascularize the trapezium.
- Excise suffient bone and osteophytes from the trapazium to allow proper seating of the prosthesis.
- When reducing the CMC joint, be sure to avoid injury to the articular surface of the trapezium.
- Assure the CMC joint is congruent throughout its full arc of motion, and that adequate soft tissue tensioning has been achieved.
- Improper selection, placement, positioning, alignment or fixation of the implants may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components, postoperative complications, or ineffective treatment.
- Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the prosthesis or anatomical structures.
- When using the optional suture attachment point, keep the suture line taut during impaction of the prosthesis so that the suture is not kinked or damaged.

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- For safe and effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, 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, bone or soft tissue injury may occur when the implant is subjected to excessive loading.
- The information in this document should be shared with the patient.
- Potential STABLYX CMC Arthroplasty System construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, subsidence, soft tissue irritation, or incomplete healing may occur as a result of non compliance to post operative rehabilitation, excessive activities or construct overloading.
- The patient must be cautioned, preferably in writing, about the use, limitations and possible adverse effects of this device including the possibility of device or treatment failure as a result of loose fixation, loosening, stress, excess 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 postoperative rehabilitation prescribed in order to fully understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the prosthesis or treatment to fail.
- DO NOT reuse any of the STABLYX CMC Arthroplasty System implants. Reuse may compromise the structural integrity of the construct and/or lead to failure, which may result in patient injury.
- The STABLYX CMC implant is supplied sterile using gamma radiation sterilization. DO NOT use if sterile barrier is damaged or if the USE BY date has expired. Any implantable components used with an expired USE BY date will void the product warranty.
- The implantable components are for single use only; DO NOT reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization of the implantable components may:
    - Compromise the structural integrity of the construct
    - Lead to failure resulting in patient injury
    - Create a risk of contamination of the device causing patient infection or cross-contamination
    - Lead to the transmission of infectious disease(s) from one patient to another
- Protect the implants against scratching or nicking as such stress concentration may lead to construct failure.
- Before using the STABLYX CMC Arthroplasty System, inspect all prosthesis 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.
- The STABLYX CMC Arthroplasty System 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 device in the MR environment in unknown. Scanning a patient who has this device may result in patient injury.
- To maintain product traceability, record the Lot number for each of the implanted system components.
- DO NOT mix implant components from different manufacturers for metallurgical, biomechanical, and functional reasons.
- 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 STABLYX CMC Arthroplasty System is to be used only with Skeletal Dynamics instruments, implants and accessories.
- Dispose of contaminated implants and instruments per established facilities guidelines and protocols.
- Caution should be taken for interference to pacemakers during electrocautery or by uncertified drills.
- Seek medical help immediately if the implant malfunctions.

Potential Adverse Events:
The following potential risks or discomforts have been associated with carpometacarpal arthroplasty: Disassociation, loosening or migration of the prosthesis, infection, erosion and desvascularization of the trapezium, material sensitivity reaction, tendon and nerve injuries, undesirable shortening or lengthening of thumb, stiffness of the CMC joint, dislocation or subluxation due to improper positioning, wear and deformation of the articular surfaces, intraoperative and postoperative bone fracture and/or postoperative pain and infection.

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⚠ **MRI Safety Information.**

The STABLYX CMC Arthroplasty System 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 STABLYX CMC Arthroplasty System in the MR environment is unknown. Scanning a patient who has this device implanted may result in patient injury.

Directions for Use:
CMC arthroplasty requires skill and training by the medical professional. The STABLYX CMC Arthroplasty System should only be used by surgeons who have experience with the system. Each surgeon must evaluate the appropriateness for the use of the STABLYX CMC Arthroplasty System during CMC arthroplasty procedures based on their experience with the STABLYX CMC Arthroplasty System.

Please refer to the STABLYX CMC Arthroplasty Surgical Technique Guide (MKT-00117-00) to review the surgical approach to CMC arthroplasty as described by Jorge L. Orbay, M.D. of the *Miami Hand Institute* located in Miami, Florida.

Cleaning:
Upon receipt by the user facility, the STABLYX CMC Arthroplasty System should be cleaned prior to sterilization. The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

Implant Cleaning:
Implanted plates, screws, or associated components should never be re-used. After each use, unused implants must be cleaned separately from contaminated instruments to prevent cross-contamination utilizing the cleaning instructions provided below.

Warnings & Precautions
- If the implant has been in contact with the patient, body fluids or tissues or is damaged, it may NOT be reprocessed and MUST be properly discarded.
- Users should wear appropriate personal protective equipment (PPE).
- Users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.

Instrument Cleaning
The STABLYX CMC Arthroplasty System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

⚠ Warnings & Precautions
- System instruments and accessories should be decontaminated immediately after completion of the surgical procedure. Contaminated instruments should not be allowed to dry prior to cleaning/reprocessing. Excess blood or debris should be wiped off to prevent it from drying.
- Only qualified personnel with documented evidence of training and competency should clean the instruments. Training should be inclusive of current applicable guidelines and standards and healthcare facility policies.
- Avoid the use of metal brushes or scouring pads during the cleaning process.
- Instruments should be rinsed of cleaning agents to prevent residue.
- Do not use mineral oil or silicone lubricants on instruments.
- Neutral pH enzymatic and cleaning agents are recommended for cleaning instruments. It is important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
- Prior to sterilization, instruments should be inspected for cleanliness of surfaces, joints, lumens, proper function, and wear and tear. If the product cannot be cleaned after repeated washing or 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.

Cleaning Instructions

Cleaning should begin at the point of use prior to processing. Keep instruments moist after use to prevent soil from drying on them. An enzymatic detergent (Enzol) was used to validate the cleaning process.
1. Disassemble instrumentation, if applicable.

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2. Rinse components thoroughly under running cool tap water. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components.
3. Soak components in a neutral enzymatic cleaner for a minimum of ten (10) minutes. Components must be fully immersed in the cleaner. Follow the cleaner manufacturer's instructions for cleaner preparation and exposure time.
4. Thoroughly rinse the components with cool water. While rinsing, use soft bristle brushes, pipettes or a water jet to clean out lumens, holes, and other challenging features.
5. Manually scrub the components thoroughly in newly made, clean, neutral pH enzymatic cleaner using soft bristle brushes or pipettes. All lumens, holes, hinged components, mating surfaces, and crevices, and challenging components should be thoroughly scrubbed. Actuate all moveable features and expose all areas to cleaner and to the brush or pipette.
   Note: When scrubbing rasps, a stiff bristle brush will be required.
6. Rinse components thoroughly with deionized or purified water; using pipettes or a water jet to clean out lumens, holes, and other hard to reach or challenging features. Actuate all movable features to fully irrigate all areas.
7. Visually inspect components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on the components using deionized water or purified water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Sterilization:
The STABLYX CMC Arthroplasty System implantable components have been sealed then sterilized by gamma radiation. The implants are provided in an undamaged package. If any of the implants or the package appears damaged, expiration date has been exceeded, or if sterility is questionable, the implant should not be used. **DO NOT re-sterilize the implantable components**. Trial components are available in the system to avoid opening the sterile package prior to prosthesis implantation. The implants should be removed from their sterile package only after the implant site has been prepared and properly sized.

The accessories and instruments of the STABLYX CMC Arthroplasty Implant Set are provided non sterile. They are intended for steam sterilization at the healthcare facility. Steam sterilization may be accomplished using one of the cycles shown below.

Cycle Type	Temperature	Duration	Drying Time
Pre-Vacuum Autoclave	270°F (132°C)	4-5 minutes (wrapped)	40 minutes
Pre-Vacuum Autoclave	273°F (134°C)	3-5 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Immediate-Use Steam Sterilization (IUSS) not recommended.
- Usage of an FDA approved wrap is required.
- Subsequent instrument sterilization needs to be performed in the tray system provided. For reuse and sterilization, instruments should be arranged within the tray system in the manner supplied by the company.

Handling and Storage:
When not in use, store the clean and disinfected STABLYX CMC Arthroplasty Set within the Sterilization Tray. Prior to use, inspect the instrumentation for serviceability and the sterile packaged implants for signs of tampering or water contamination.

Functional Checks should be performed where possible:
1. Mating devices should be checked for proper assembly.
2. Reusable devices with moving parts should be operated to check correct operation (medical grade lubricant suitable for steam sterilization can be applied as required).
3. Rotating instruments (e.g. drill bits, reamers) should be checked for straightness. This can be achieved by rolling the instrument on a flat surface.

Note: The useful life of these devices is dependent on many factors including, but not limited to the method and duration of each use and the handling of the devices between uses. Routine and careful inspection and functional testing of the device is the best method of determining the serviceable life span for the medical device.

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Disclaimer of Warranty and Limited Remedies:

Skeletal Dynamics makes no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on the product(s) described in this publication. Skeletal Dynamics shall not be liable under any circumstances for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has authority to bind Skeletal Dynamics to any representation or warranty except as specifically set forth in this publication. Descriptions or specifications provided by Skeletal Dynamics in any publication are only included to generally describe the product when manufactured and do not constitute any express warranties.

STABLYX CMC Arthroplasty Set - Cat.# STX-SYS

Catalog #	Nomenclature
Implants[1]	
STX-IS1	STABLYX, CMC Arthroplasty Implant, Sz. 1
STX-IS2	STABLYX, CMC Arthroplasty Implant, Sz. 2
STX-IS3	STABLYX, CMC Arthroplasty Implant, Sz. 3
STX-IS4	STABLYX, CMC Arthroplasty Implant, Sz. 4
STX-IS5	STABLYX, CMC Arthroplasty Implant, Sz. 5
Trials[2]	
STX-TS1	STABLYX, CMC Arthroplasty Trial, Sz. 1
STX-TS2	STABLYX, CMC Arthroplasty Trial, Sz. 2
STX-TS3	STABLYX, CMC Arthroplasty Trial, Sz. 3
STX-TS4	STABLYX, CMC Arthroplasty Trial, Sz. 4
STX-TS5	STABLYX, CMC Arthroplasty Trial, Sz. 5
System Instrumentation[2]	
HNDL-UQC-FXD	Handle, Universal Quick Connect, Fixed
FRCP-BHS-RTC	Forceps, Bone Holding Small, Ratcheting
STX-VCE	STABLYX, Capsule Elevator
STX-VOR	STABLYX, Volar Osteophyte Rasp
STX-MR1	STABLYX, Metacarpal Rasp, Sz. 1
STX-MR2	STABLYX, Metacarpal Rasp, Sz. 2
STX-MR3	STABLYX, Metacarpal Rasp, Sz. 3
STX-MR4	STABLYX, Metacarpal Rasp, Sz. 4
STX-MR5	STABLYX, Metacarpal Rasp, Sz. 5
STX-MP1	STABLYX, Metacarpal Planar, Sz. 1
STX-SZ1	STABLYX, Trapezial Sizer, Sz. 1
STX-SZ2	STABLYX, Trapezial Sizer, Sz. 2
STX-SZ3	STABLYX, Trapezial Sizer, Sz. 3
STX-SZ4	STABLYX, Trapezial Sizer, Sz. 4
STX-SZ5	STABLYX, Trapezial Sizer, Sz. 5
STX-TP1	STABLYX, Trapezial Punch, Sz. 1
STX-TP2	STABLYX, Trapezial Punch, Sz. 2
STX-TP3	STABLYX, Trapezial Punch, Sz. 3
STX-TP4	STABLYX, Trapezial Punch, Sz. 4
STX-TP5	STABLYX, Trapezial Punch, Sz. 5
STX-TC1	STABLYX, Trapezial Contouring Tool
STX-CMA-IMP	STABLYX, CMC Impactor
OST-CRV	Osteotome, Curved
STX-CMA-STP	STABLYX, Norman Suture Passer
AWL-STR-020	Awl, Straight, 2.0mm
Sterilization Trays[2]	
STX-TRAY	STABLYX CMC Arthroplasty System Sterilization Tray

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2 CE

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