

English

Suture-Button Repair System INSTRUCTIONS FOR USE

R: For use by physicians only. Federal Law (USA) restricts this device to sale by or on 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 Suture-Button Repair System; it is not a reference to surgical techniques. Prior to use of the Suture-Button Repair System, the surgeon should become familiar with all information contained in this pamphlet.

Description:

The Skeletal Dynamics Suture-Button Repair System is composed of the following subsystems:

- Distal Biceps Repair
- IOL Reconstruction
- CMC Suspension Arthroplasty

The Suture-Button Repair System consists of a combination of Titanium Alloy buttons, UHMWPE non-absorbable, sutures, and specialized instrumentation.

Indications:

The Suture Button Repair System is intended for fixation of bone and soft tissue in upper extremity orthopedic procedures requiring ligament or tendon reconstruction in the hand, wrist, forearm, elbow and shoulder.

Contraindications:

Prior to using the system, ensure that none of the following patient conditions are present:

- Insufficient quantity or quality of bone.
- Previous, active, or latent infection or blood supply limitations.
- Local or systemic acute or chronic inflammation.
- Blood supply limitations and previous infections, which may retard healing.
- Metabolic disorders which may impair bone formation.
- Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made, and sensitivity ruled out prior to implantation.
- Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
- Do not use for surgeries other than those indicated.

Warnings & Precautions

- This device is intended to be used by a trained medical professional.
- #2 UHMWPE Sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. #2 UHMWPE Sutures are not absorbed, nor is there any significant change in tensile strength retention known to occur in vivo.
- As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation. Discard opened or unused sutures. Do not resterilize.
- This device should be used by or on the order of a physician. User should be familiar with surgical procedure, techniques, proper implant sizing, and instructions for use prior to use. Appropriate instrumentation should be used for device implantation.
- Do not add additional sutures to the Skeletal Dynamics Buttons. The additional sutures may impede passage of the device through the bone tunnels.

- The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this device including the possibility of device or treatment failure as a result of loose fixation and/or 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.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
- The patient implant card provided should be given to the patient.
- Implants and instrumentation identified as single use are not to be reused. Reuse of these devices could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
- DO NOT reprocess or re-sterilize any of the implants. All implants are supplied sterile using ethylene oxide sterilization and are intended for single use and do not require additional cleaning or sterilization.
- 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.
- Properly dispose of any unused suture.
- Dispose of contaminated implants and instruments per established facility guidelines and protocols.
- 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.
- The suture system is not intended to be used as a ligament replacement.
- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Skeletal Dynamics provides detailed surgical techniques in print and electronic formats.
- In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to the application of surgical instruments such as forceps or needle holders. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be appropriate when knotting monofilaments.
- The loop length must be adequate for the button to exit the cortex.
- Loop and button should be properly oriented during passing and fixation, per technique guide, in order to function properly.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device and bone

Potential Adverse Events:

Adverse effects associated with the use of this device include wound dehiscence, calculi formation when prolonged contact with salt solution occur, enhanced bacterial infectivity, minimal acute inflammatory reaction, transitory local irritation, and other reactions to device materials. Serious incidents should be reported to Skeletal Dynamics, Inc., at feedback@skeletaldynamics.com.

MRI Safety Information:

The Suture-Button Repair 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 Suture-Button Repair System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Directions for Use:

The Suture-Button Repair System should only be used by surgeons who have experience with this system. Each surgeon must evaluate the appropriateness for the use of the Suture-Button Repair Systems based on their clinical experiences. Please refer to each Suture-Button Repair System's Surgical Technique Guide 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, USA.

Cleaning

Upon receipt by the user facility, the Suture-Button Repair System instrumentation should be cleaned prior to sterilization. The recommended manual cleaning instructions are set forth below. Other cleaning methods must be validated by the user.

Instrument Cleaning

The Suture-Button Repair System instrumentation must be cleaned thoroughly before re-use to achieve sterilization.

Warnings & Precautions

- The System's reusable instruments and accessories, including sterilization tray and tray components, 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, and 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.

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.

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.
2. Rinse all components, including instruments, sterilization tray and tray 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 all 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 whenever longer exposure times are recommended.
4. Thoroughly rinse all 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 all 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.
6. Rinse all components thoroughly under reverse osmosis/deionized (RO/DI) 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 all components for soil. Repeat the cleaning procedure until no visible soil remains on the components.
8. Perform a final rinse on all components using running critical water.
9. Dry the clean components using compressed air or a soft, lint free, clean cloth.

Sterilization:

The following components from the Skeletal Dynamics Suture-Button Repair System have been sealed then sterilized via ethylene oxide.

- #2 Suture Loop with ST Needle
- Button Threader Assembly
 - Circular Button
 - Suture Threader Holder
 - Suture Threader Handle
- 2-0 Suture Passing Needle Assembly
- #2 Suture Button Assembly, IOL
- #2 Suture Button Assembly, CMC
- Suture Passing K-Wire

The components are provided in an undamaged package. If any of the components or the package appears damaged, expiration date has been exceeded, or if sterility is questionable, the component should not be used. DO NOT re-sterilize these components. The components should be removed from their sterile package only after the implant site has been prepared and properly sized.

The Skeletal Dynamics Suture-Button Repair System Instruments are provided non-sterile. This system is intended for steam sterilization at the healthcare facility.

1. Place all components and accessories into the designated areas of the sterilization tray. Do not stack trays during sterilization.
2. Steam sterilization may be accomplished using one of the cycles shown below:

Cycle Times for Dynamic-Air-Removal (Vacuum) Steam Sterilization Cycles		
Item	Exposure time at 132°C (270° F)	Minimum Drying Times
Wrapped Sterilization Tray	4 minutes (wrapped)	40 minutes

- Follow ANSI/AAMI ST79:2017 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Usage of an FDA cleared 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 Suture-Button Repair System instruments within the Sterilization Tray. Prior to use, inspect the instrumentation for serviceability. Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

Disclaimer of Warranty and Limited Remedies:

Skeletal Dynamics, Inc. 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, Inc. 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, Inc. to any representation or warranty except as specifically set forth in this publication. Descriptions or specifications provided by Skeletal Dynamics, Inc. in any publication are only included to generally describe the product when manufactured and do not constitute any express warranties


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SYMBOLS GLOSSARY

Symbols that follow 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
	5.2.3 / Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	5.2.7 / non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	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
	5.1.3 / Date of Manufacture	Indicates the date when the medical device was manufactured
	5.1.1 / Manufacturer	Indicates the medical device manufacturer
	5.1.2 / Authorized representative in the European Community	Indicates the authorized representative in the European union. Symbol is accompanied by the name and address of the authorized representative adjacent to the symbol
	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
	7.7 / Medical device	Indicated the item is a medical device
	5.7.10 / Unique device identifier	Indicates a carrier that contains unique device identifier information