

Suture-Button Repair System

INSTRUCTIONS FOR USE FOR THE UNITED STATES OF AMERICA

R: For use by physicians only. Federal Law (USA) restricts this device to sale by or on order of a physician.

This package insert is designed to provide Instructions for Use of the Suture-Button Repair System. Prior to use of the Suture-Button Repair 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 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. The user should be familiar with

the 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 the 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's 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 the 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 solutions occurs, 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.

MR 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. Scanning a patient who has this system implanted may result in patient injury.

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 (MKT-00445-00 and MKT-00446-00) 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, USA.

Cleaning, Sterilization, and Inspection

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.

For instructions on cleaning, disinfection, sterilization, and inspection of the Suture-Button Repair System instrumentation, please refer to cleaning and sterilization instructions for use (IFU-04056-00). Other cleaning methods must be validated by the user. Refer to the appropriate Surgical Techniques (MKT-00445-00 or MKT-00446-00) for the proper arrangement of the instrument tray.

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.

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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
	5.1.1 Manufacturer	Indicates the medical device manufacturer
	5.1.3 Date of Manufacture	Indicates the date when the medical device was manufactured
	5.1.4 Use-by-date	Indicates the date after which the medical device is not to be used
	5.1.5 Batch code	Indicates the manufacturer's batch code or lot can be identified
	5.1.6 Catalogue number	Indicates the manufacturer's catalogue number so the medical device can be identified
	5.2.3 Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	5.2.6 Do not re-sterilize	Indicates a medical device that is not to be re-sterilized
	5.2.7 non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	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
	5.2.12 Double sterile barrier system	Indicates two sterile barrier systems
	5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only
	5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use
	5.7.7 Medical device	Indicated the item is a medical device
	5.7.10 Unique device identifier	Indicates a carrier that contains unique device identifier information