

## **SYNDEX™ with CONSTRICTOR® Technology**

### **INSTRUCTION FOR USE**

#### **A. DEVICE DESCRIPTION**

The Fixation Button device is comprised of

- Adjustable Loop Assembly (with Fixation Button)

Note: The Constrictor® device is preloaded with #5 USP UHMWPE custom Dunamis suture and a #2 USP UHMWPE suture. For optimal fixation, the device is intended to be used with custom Dunamis Medical® Fiber. Substitution or use of alternative suture may compromise the fixation.

#### **B. INDICATIONS**

The Fixation Button System is to be used for fixation of bone to bone or soft tissue to bone. The components are intended to serve as fixation posts, a distribution bridge, or for distributing suture tension over area of ligament or tendon repair.

Specifically, the Fixation Button System is intended for use in the fixation of bone and soft tissue in orthopaedic procedures requiring ligament or tendon repair/ reconstruction, including providing fixation during the healing process following acromioclavicular separations, as an adjunct to fracture repair in syndesmotic trauma, and ACL and PCL repair.

#### **C. CONTRAINDICATIONS**

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
5. Any active infection or blood supply limitations.
6. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
7. 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.
8. Do not use for surgeries other than those indicated.

#### **D. ADVERSE EFFECTS**

1. Infections, both deep and superficial.
2. Foreign body reactions.
3. Osteomyelitis surrounding the suture(s)
4. Suture(s) polyethylene wear-related painful aseptic osteolysis.

#### **E. WARNINGS**

1. The Fixation Button devices are not intended to be used as a ligament replacement.
2. Do not add additional suture to the Fixation Button devices. The extra suture may impede passage of the device through the bone.
3. Do not re-sterilize this device.
4. All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
5. Do not use this device as the sole means of reconstructing a chronic acromioclavicular joint dislocation.
6. 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.
7. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device.
8. 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.
9. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
10. Detailed instructions on the use and limitations of the device should be provided to the patient.

11. This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.
12. Once open, discard any unused suture.

#### **F. PRECAUTIONS**

1. U.S. Federal Law restricts this device to sale by or on the order of a physician.
2. Prior to use inspect the device to ensure it is not damaged. Do not use a damaged device.
3. The use of metallic surgical implants provides the orthopaedic surgeon with a means of accurate fixation and helps generally in the management of repairs and reconstructive surgery. These implants are intended as aids to normal healing, but are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.
4. Postoperative care is important. A patient should be instructed on the limitations of the implant and should be cautioned regarding weight bearing and body stresses on the appliance prior to secure bone healing.
5. Careful attention must be paid to asepsis and avoidance of anatomical hazards.
6. Disposal of passing needle may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
7. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Dunamis and Medline provides detailed surgical techniques in print. Or, contact your Medline representative for an onsite demonstration

#### **G. PACKAGING AND LABELING**

1. The devices should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

#### **H. MATERIAL SPECIFICATIONS**

Refer to the package label for the materials.

Titanium Plates: Titanium

Suture: Ultra High Molecular Weight Polyethylene (UHMWPE).

All sutures meet or exceed U.S.P. standards for non-absorbable surgical sutures.

#### **I. STORAGE CONDITIONS**

The devices must be stored in accordance to environmental conditions as specified within the labelling, in the original unopened packaging, away from moisture and should not be used after the expiration date.

#### **J. INFORMATION**

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Dunamis and Medline provide detailed surgical techniques in print. Or, contact your Medline representative for an ON-SITE DEMONSTRATION

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Distributed by:



Medline Industries Inc.  
Northfield, IL 60093 USA  
1-800-MEDLINE  
[www.medline.com](http://www.medline.com)

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Manufactured by:



Dunamis Medical, LLC  
Greenville, AL 36037 USA  
877.454.2186  
dunamismedical.com

**CONSTRICTOR**® is a registered trademark of Dunamis Medical, LLC.  
Dunamis Medical® is a registered trademark of Dunamis Medical, LLC.

**SYNDESMOSIS REPAIR IMPLANTATION SYSTEM:  
DRILL BIT 3.7mm**

**INSTRUCTIONS FOR USE**

**A. DEVICE DESCRIPTION**

The single-use surgical instruments and accessories are designed to assist in performance of surgeries. The kits, instruments and accessories are sterile single use only.

**B. INDICATIONS**

Single-use disposable instruments and accessories are intended for use in orthopedic surgical procedures.

**C. CONTRAINDICATIONS**

None Known

**D. ADVERSE EFFECTS**

None Known

**E. WARNINGS**

- Do not use if package seal is opened or damaged. Do not use if the products sterilization barrier is compromised.
- Contents are sterile unless package is opened or damaged. **DO NOT RESTERILIZE.** For single use only. Discard any open, unused product. Do not use after Expiration Date.
- It is the surgeons' responsibility to be familiar with the appropriate surgical techniques prior to use.

**F. PRECAUTIONS**

U.S. Federal law restricts this device to sale by or on the order of the physician.

- Hazards associated with reuse include, but are not limited to, patient infection, malfunction and/or instrument, accessory failure.
- Prior to use inspect, the kit packaging and seals, instruments and/or accessories to ensure no damage is visible.
- *Do not use damaged instruments and/or accessories.*
- Careful attention must be paid to asepsis and avoidance of anatomical hazards.
- With any surgical instrument or accessory, careful attention should be made to assure that excessive force is not applied. Excessive forces applied to the instrument or accessory can result in failure of device.
- Do not sharpen any instrument and/or accessory.
- After use, this device maybe potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

**G. PACKAGING AND LABELLING**

1. The devices should be accepted only if the factory packaging and labelling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

**H. MATERIAL SPECIFICATIONS**

Refer to the package label for the materials.  
Drill Bit: Stainless Steel

**I. STORAGE CONDITIONS**

The devices must be stored in accordance to environmental conditions as specified within the labelling, in the original unopened packaging, away from moisture and should not be used after the expiration date.

**J. INFORMATION**

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Dunamis and Medline provide detailed surgical techniques in print. Or, contact your Medline representative for an ON-SITE DEMONSTRATION

**K. WARRANTY**

**For single use only.** This product is warranted to be free from defects in materials and manufacturing. Do not reuse.

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