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CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

DEVICE DESCRIPTION

The SpeedButton Suture Anchor is intended to be used for fixation of suture to bone in foot and ankle, applications.

Contents
SpeedButton Suture Anchor (Titanium)
Suture (#2-0, Braided, uncoated UHMWPE, non-absorbable)
Refer to individual product labels for implant size and suture type & quantity
(2) CT-2 Needles (Stainless steel)
(1) K-Wire (Stainless steel)
(1) SpeedButton Inserter (Stainless steel, ABS)

Implants
The SpeedButton™ Anchor System is a device which is preloaded with suture and is designed to attach soft tissues to bone. The device is deployed through a bicortical drill hole and secured on the far cortex. The SpeedButton™ Anchor System includes an anchor implant assembled with suture and the related instruments needed for the procedure. The SPEEDBUTTON™ implants are made of biocompatible titanium secured with ultra-high molecular weight polyethylene suture. The SPEEDBUTTON™ Anchor System Kit components will be provided sterile and are intended for single use only.

Instrument System
Instruments used with the SPEEDBUTTON™ System include the following: Implant Inserter and Kirschner wire. Instruments are provided sterile as a part of the kit.

INDICATIONS FOR USE
The SPEEDBUTTON™ Suture Anchor is intended to be used for suture or tissue fixation in the foot and ankle. Specific indications are listed below:

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction

CONTRAINDICATIONS
Contraindications for the SPEEDBUTTON™ System are as follows:

- Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be performed and sensitivity ruled out prior to implantation.
- Surgical procedures other than those listed Indicated for Use section.
- Pathological conditions of bone, such as cystic changes or severe osteopenia, which would compromise secure construct fixation.
- Pathological conditions in the soft tissues to be attached which would impair secure fixation by suture.
- Comminuted bone surface, which would compromise secure construct fixation.
- Physical conditions which would eliminate, or tend to eliminate, adequate construct support or impair healing, i.e., limitation of blood supply, infection, etc.

Contraindications may be relative or absolute and are left to the discretion of the surgeon.

WARNINGS
- Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging 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 the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of the device.
- Read these instructions completely prior to use.
- Product must be stored in the original sealed packaging.
- Incomplete SpeedButton Suture Anchor insertion may result in poor performance.
- Only use the appropriate SpeedButton procedure specific instruments intended for use with the SpeedButton Suture Anchor or the implant may not function properly.
- Do not resterilize or reuse SpeedButton Suture Anchors, sutures, inserter, drill, or drill guide devices packaged with the SpeedButton Suture Anchor.
- Do not attempt to implant this device within cartilage epiphyseal growth plates or nonosseous tissue.
- The SpeedButton Suture Anchor has not been evaluated for safety and compatibility in the MR environment. The SPEEDBUTTON™ Anchor System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SpeedButton Suture Anchor in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- **A single use device (SUD) that comes into contact with human blood or tissue should not be re-used and should be properly disposed.**

Dispose of used device in accordance with healthcare facility policy and local regulations.

CONCERNING MAGNETIC RESONANCE ENVIRONMENT
The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The SPEEDBUTTON™ Anchor System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SpeedButton Suture Anchor in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
In any surgical procedure, the potential for complications exist. Surgical procedures involving these devices should not be attempted by physicians unfamiliar with possible adverse clinical events which may occur during or after the procedure and could require additional surgery for implant revision. The risks and complications with this system include:

- Loosening or breakage of the suture and/or implant potentially leading to revision surgery
- Loss of fixation or pullout of suture anchors can occur
- Mild inflammatory reaction
- Foreign body reaction
- Infection, both deep and superficial
- Allergic reaction
- Damage to nerves and vessels
- Edema
- Muscle tendon impalement and excessive operative bleeding
- Venous thrombosis, pulmonary embolism, cardiovascular problems

The anticipated adverse device effects are the same as those associated with the currently available fixation procedures.

No additional risks are associated with the SPEEDBUTTON™ System

PATIENT SELECTION
Use of surgical fusion hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant
- Availability of post-operative therapy
- Cooperative patient

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

PRECAUTIONS

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

- Hazards associated with reuse of this device include, but are not limited to, patient infection and/or device malfunction.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- 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 tissue healing.
- Do not use sharp instruments to manage or control the suture.
- Breakage of the suture can occur if there is damage caused by sharp instruments.
- Use of excessive force during insertion can cause failure of the SpeedButton Suture Anchor.
- The SpeedButton Suture Anchor and suture are not intended to provide indefinite biomechanical integrity. As with all suturing techniques, the fixation given should be considered as only temporary, until biological attachment of tissue to bone is completed. The fixation may not withstand weight or other unsupported stresses.
- Bone quality must be adequate to allow proper placement of the SpeedButton Suture Anchor.
- Inadequate bone quality could result in loss of fixation.
- Do not alter the implant or instrumentation or performance may be compromised.
- Postoperative range of motion is to be determined by the physician.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

HOW SUPPLIED, CLEANING AND STERILIZATION

Implants and Instruments

The SPEEDBUTTON™ implants and instruments are provided sterile to the end user.

Sterile packaging and components should be inspected to ensure there is no damage. If the packaging or implants' integrity has been compromised use an alternate item and contact the manufacturer for further instructions.

Implants are for single use only. A single use device (SUD) that comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.

CARE AND CAUTION

- All components of the SPEEDBUTTON™ System are provided sterile for single use only.
- Inspect the sterile packaging used for the implants and instruments prior to use. If the packaging and/or seal is damaged, sterilization may be compromised, and the implant and/or instrument should not be used.
- SPEEDBUTTON™ System implants and instruments may be stored at room temperature.

OTHER SUPPLIES AND EQUIPMENT NEEDED

- Standard OR equipment used in patient preparation and surgical exposure.

INSTRUCTIONS FOR USE

1. Create a bicortical bone tunnel in the desired location using the K-wire.
2. Place the SpeedButton Inserter into the bone tunnel such that the tip is beyond the far cortex of the bone. (***CAUTION:*** Use of excessive force during insertion can cause failure of the SpeedButton Suture Anchor.)
3. Flip open the Inserter cap and press the Inserter button deploying the anchor outside of the far cortex of the bone.
4. Remove the Inserter from the bone tunnel and secure tissues with the sutures and needles.
5. Trim the remaining suture limbs to complete the repair.

SYMBOLS

Refer to package labels to determine which symbols are relevant to the device in the package.

	Caution consult accompanying documents
	Catalogue number
	Consult instructions for use
	Do not reuse
	Lot number
	Manufacturer
	Sterilized using ethylene oxide
	Prescription only - device restricted to use by or on the order of a physician
	Use By: YYYY-MM-DD (YYYY is year; MM is month; DD is the day)

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