UNITE® FOOT & ANKLE

DEXTACK™ PUSH

DEVICE DESCRIPTION

The DEXTACK™ PUSH Suture Anchor Delivery Systems are for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The DEXTACK™ PUSH Suture Anchor Delivery System consists of a single anchor with integrated multiple suture attachment. The anchors are provided loaded on individual inserters with integrated sutures with needles, sterile, for single use only.

CONTENTS

1 ea. – Non-absorbable DEXTACK™ PUSH Suture Anchor made from Zeniva® ZA-500 or ZA-600 PEEK (polyetheretherketone) from Solvay.
1 ea. – Single-use disposable inserter made from ABS plastic (handle) & stainless steel (shaft).
2 ea. – Braided, uncoated, sutures made from UHMWPE (ultra-high molecular weight polyethylene) with stainless steel needles.
Refer to individual DEXTACK™ PUSH Suture Anchor delivery system product labels for material, diameter and length of anchor, size of attached sutures, and needle attachment.

INDICATIONS FOR USE

Shoulder

- Rotator Cuff Repair
- SLAP Lesion Repair
- Acromio-Clavicular Separation Repair
- Capsular Shift or Capsulolabral Reconstruction
- Bankart Repair
- Biceps Tenodesis
- Deltoid Repair

Hand and Wrist

- Scapholunate Ligament Reconstruction
- Carpal Ligament Reconstruction
- Repair/Reconstruction of Collateral Ligaments
- Repair of flexor and extensor tendons at the PIP, DIP, and MCP joints for all digits
- Digital Tendon Transfers

Elbow

- Biceps Tendon Reattachment
- Ulnar or Radial Collateral Ligament Reconstruction

Hip

- Capsular Repair
- Acetabular Labral Repair

Foot and Ankle

- Lateral stabilization
- Achilles tendon repair
- Hallux valgus reconstruction
- Mid-foot reconstuction
- Medial stabilization
- Metatarsal ligament repair
- Digital tendon transfers

Knee

- Medial collateral ligament repair
- Posterior oblique ligament repair
- Iliotibial band tenodesis reconstruction
- Lateral collateral ligament repair
- Patellar ligament/tendon repair

GENERAL SURGICAL CONTRAINDICATIONS

General contraindications for the use of these implants for joint reconstruction, osteotomy or fusion include:

- Procedures other than those listed in the Indications section.
- Pathologic conditions of bone such as cystic changes or severe osteopenia that would impair its ability to securely fix the DEXTACK™ PUSH Suture Anchor.
- Pathologic changes in the soft tissues being fixated to bone that would prevent their secure fixation by the DEXTACK™ PUSH Suture Anchor.
- Comminuted bone surface that would militate against secure fixation of the DEXTACK™ PUSH Suture Anchor.
- Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, i.e., blood supply limitation, previous infection, etc.
- Conditions which tend to limit the patient's ability to restrict activities or follow directions during the healing period.
- DEXTACK™ PUSH Suture Anchors are not designed for and should never be used to attach artificial ligaments.

ADVERSE EFFECTS

- Infections, both deep and superficial.
- Foreign body reactions.
- Adverse reactions to implant materials have sometimes necessitated the removal of the implant. Patient sensitivity to device materials must be considered prior to implantation.

WARNINGS

- No modification to the device should be made prior to implantation
- DEXTACK™ PUSH Suture Anchors are designed to anchor into cortical or cancellous bone. Bone quality must be adequate to allow proper and secure anchor placement. Incomplete insertion or poor bone quality may result in anchor pullout.
- Immediate range of motion should be avoided to allow biological bony/soft tissue healing.
- An internal fixation device must never be reused.
- Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weigh 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.
- 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. The appropriate delivery system is required for proper implantation 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.
- Detailed instructions on the use and limitations of the device should be given to the patient.
- 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.
- 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.
- Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.
- Impacting anchor off-axis of the pilot hole during insertion may result in anchor damage or premature anchor pullout

PRECAUTIONS

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

- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Detailed surgical techniques in print and electronic formats are available. Or, contact your representative for an on-site demonstration.
- Sterile Units Only: 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.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Under insertion of the device may leave the proximal end of the implant protruding beyond the cortical bone, which could potentially cause soft tissue irritation and/or pain post-operatively.
- Excessive force should not be placed on the delivery instrument.
- Careful attention should be paid to asepsis and avoidance of anatomical hazards.
- After use, this device may be a potential biohazard handled in accordance with accepted medical practice and applicable local and national requirements.

PACKAGING & LABELING

- Implant devices should be accepted if the factory packaging and labeling arrive intact.
- Contact Customer Service if package has been opened or altered.

MATERIAL SPECIFICATIONS

Refer to the packaging label for the materials.
The device is made of polyetheretherketone (PEEK). Sutures are made of braided Ultra High Molecular Weight Polyethylene and polyester or polypropylene.

MANUAL CLEANING (REUSABLE INSTRUMENTS)

The instruments for the DEXTACK™ PUSH Suture Anchors that are delivered non-sterile should be cleaned in accordance with the following cleaning instructions:

1. Prepare a large basin with an enzymatic detergent-based cleaning solution mixed per the manufacturer's instructions. The basin should be large enough to submerge the instrument.
2. Submerge the instrument in the basin for 5 minutes, then brush throughout with a medium/soft bristle nylon brush. Pay careful attention to hard-to-reach areas to remove all visible debris. If applicable, actuate the instrument controls while submerged and brushing to loosen stuck soil and allow cleaning agents to penetrate the internal passages.
3. With the instrument pointed down, use a syringe to flush cannulas and lumens with at least 50mL of the enzymatic solution, repeating twice.
4. Rinse the instrument, including hard-to-reach areas with a water gun or under running tap water until no cleaning residues are visible.
5. Prepare an ultrasonic bath (20-32ºC 68-90ºF) large enough to fully submerge the instrument with enzymatic detergent-based cleaning solution prepared per manufacturer's instructions.
6. Place the Instrument to the enzymatic ultrasonic bath and sonicate for 10 minutes minimum, or longer per the manufacturer's instructions.
7. Use distilled, deionized, or sterile water, or water otherwise controlled for bacterial endotoxins, to rinse the instrument. Rinse in cool running water for at least 1 minute, or longer as necessary to remove all signs of cleaning solution. Ensure rinse water flows liberally into all hard-to-reach areas of the instrument, using a water gun or syringe as necessary.
8. Dry the outside of the instrument with a lint-free cloth. Dry the instrument's internal cavities using sterile compressed air, again paying specific attention to hard-to-reach areas.
9. Perform optical inspection for cleanliness. If necessary, repeat the cleaning process until the instrument is optically clean.

DISPOSAL

All disposable instruments and single use anchors should be disposed of properly and in accordance with the facility's sharps protocol.

STERILIZATION (REUSABLE INSTRUMENTS)

The instruments for the DEXTACK™ PUSH Suture Anchors that are delivered non-sterile should be sterilized in accordance with the following steam and dry time specifications:

Cycle Type	Cycle Time	Temperature	Packaging	Dry Time
Pre-vacuum	4 minutes	132º C	Double Autoclave Wrap	30 minutes

STORAGE CONDITIONS

All devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

INFORMATION

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Detailed surgical techniques are available in print and electronic formats. Or, contact your authorized representative for an on site demonstration.

If further information is needed, contact Medline Customer Service or your authorized representative.

For additional product information, please visit www.medlineunite.com or contact customer service at 877-864-8357.

Catalog number

Batch code


Consult instructions for use


Caution


Date of manufacture


Keep Dry


Do not use if package is damaged


Expiration date


Do not reuse

Sterilized by Ethylene Oxide gas


Manufacturer

Prescription use only

Additional Information:

Reporting of issues

Contact your authorized representative or our customer service department for help in reporting a problem or concern related the performance of the device or the services provided by Medline Industries, LP.

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Distributed By:

UNITE® FOOT & ANKLE

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