

DEXTEN™ Tenodesis Screws

Device Description

The Medline UNITE® DEXTEN™ Tenodesis Screws are interference screws for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are provided sterile, for single use only.

Contents

See primary and secondary labeling for kit contents.

Indications

The Medline UNITE® DEXTEN™ Tenodesis Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.

The Medline UNITE® DEXTEN™ Tenodesis Screws are intended to provide soft tissue reattachment (i.e. fixation of ligament and tendon graft tissue). See below for specific indications.

Shoulder

- Deltoid Repair
- Rotator Cuff Repair
- Biceps Tenodesis

Foot and Ankle

- Hallux Valgus Reconstruction
- Medial Stabilization
- Lateral Stabilization
- Achilles Tendon Repair
- Midfoot Reconstruction
- Metatarsal Ligament Repair
- Bunionectomy
- Tendon Transfer

Knee

- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Iliotibial Band Repair
- Posterior Cruciate Ligament Repair

Elbow, Wrist, Hand

- Biceps Tendon Reattachment
- Ulnar Collateral Ligament Reconstruction
- Radial Collateral Ligament Reconstruction
- Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty)
- Carpal Ligament Reconstruction and/or repair
- Tendon transfer
- Scapholunate Ligament Reconstruction

Contraindications

- Screws that are smaller than 7mm may not be appropriate for the knee indication.
- Insufficient quantity or quality of bone.
- Blood supply limitations and previous infections which may retard healing.
- Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.
- Any active infection or blood supply limitations.
- 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.

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

- **Note:** Surgeons must apply their professional judgment when determining the appropriate screw size based on the specific indication, preferred surgical technique, and patient history.
- 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 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.
- 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.

- The 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 material should be considered prior to implantation. See Adverse Effects.

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 onsite demonstration.
- 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.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- 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 and should be handled in accordance with accepted medical practice and applicable local and national requirements.

Packaging and 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 implant materials.

The implant is made of Zeniva® ZA-500 or ZA-600 polyetheretherketone (PEEK) from Solvay. The instruments are made of Stainless Steel.

Cleaning (Reusable Instruments)

The instruments for the Medline UNITE DEXTEN Tenodesis Screws that are delivered non-sterile should be cleaned in accordance with the following cleaning instructions:

1. Wipe outer surfaces of Instrument with isopropyl alcohol (IPA), minimum concentration 70%.
2. Soak: Prepare an enzymatic detergent-based cleaning solution, per the manufacturer's instructions. Fully immerse the Instrument in the solution for a minimum of 1 minute or longer if recommended by the cleaning agent's manufacturer. After the soak, brush the components with a soft bristle brush to wash external surfaces of the Instrument with the cleaning solution.
3. Rinse: Rinse the Instrument by holding under running water for at least one minute or until cleaning solution residues are no longer visible.
4. Rinse: Prepare at least 50cc's of enzymatic detergent-based cleaning solution, per the manufacturer's instructions. Decontaminate cannulas and lumen by flushing them with a sterile syringe and using a pipe cleaner.
5. Rinse: Rinse the Instrument thoroughly under running tap water for at least one minute.
6. Ultrasound: Prepare another batch of enzymatic detergent-based cleaning solution to fill an ultrasonic cleaning tank. Place the flushed Instrument in the ultrasonic cleaner and sonicate for 10 minutes minimum.
7. Final Rinse: use distilled water, deionized water, sterilized water, or water otherwise controlled for bacterial endotoxins, to rinse the Instrument. Rinse in cool or tepid running water for at least 1 minute, or longer, if necessary, to remove visible signs of cleaning solution. Ensure that rinse water flows liberally into blind holes, recesses, and crevices.
8. Dry: Allow Instrument to air-dry.
9. Inspect: Inspect the Instrument. If any soil or fluid is visible, repeat the cleaning procedure above, with fresh batches of cleaning solution.
10. Verify mechanical function of Instrument. Do not continue to sterilization (below) if the device does not function properly, or if it is visibly damaged.

Sterilization (Instruments)

The instruments for the Medline UNITE® DEXTEN™ Tenodesis Screws that are delivered nonsterile should be disassembled and sterilized in accordance with the following steam and dry time specifications:

Cycle Type	Cycle Time	Temperature	Packaging	Dry Time
Pre-vacuum	4 minutes	132° C	Double Autoclave Wrap	40 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 onsite demonstration. If further information is needed, contact Medline Customer Service or your authorized representative.

For additional product information, please visit www.medline.com or contact customer service at 1-800-MEDLINE
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LOT	Batch code
REF	Catalog number
	Caution
	Consult instructions for use
	Do not reuse
	Do not use if package is damaged
	Expiration date
	Keep Dry
R_x only	Prescription use only
STERILE R	Sterilized using irradiation

Manufactured for:



UNITE[®]
FOOT & ANKLE

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