UNITE® FOOT & ANKLE

Medline UNITE® DEXLOCK® KNOTLESS

Device Description
The DEXLOCK® KNOTLESS Anchor & Delivery Systems are for use in the fixation of soft tissue to bone in the shoulder, elbow, knee, hip, foot, ankle, hand & wrist. These anchors consist of cannulated anchors with integrated suture attachment or separate suture punch eyelet. The anchors are provided loaded on individual inserters with and without integrated sutures, sterile, for single use only. The DEXLOCK® KNOTLESS Suture Anchors are designed to be used by healthcare professionals (surgeons) in accordance with the indications for use in adult patients.

Contents
See primary and secondary labeling for contents.

Indications For Use
The DEXLOCK® KNOTLESS Suture Anchors are intended for use in soft tissue to bone fixation in areas such as the shoulder, elbow, knee, hip, wrist, hand, foot, and ankle.
Prior to use of the device, always verify the suitability of the device by verifying that the device is intended to be used according to the indications above and by verifying that the patient does not present any conditions listed in the Contraindications section below.

Clinical Benefits
The use of DEXLOCK® KNOTLESS suture anchors for the repair of soft tissue injuries such as ligamentous tears, tendon ruptures and labral or capsular damage can reduce significant pain and regain loss of function in patients.

Contraindications
- Anatomy 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 DEXLOCK® KNOTLESS Suture Anchor.
- Pathologic changes in the soft tissues being fixated to bone that would prevent their secure fixation by the DEXLOCK® KNOTLESS Suture Anchor.
- Comminuted bone surface that would militate against secure fixation of the DEXLOCK® KNOTLESS 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.
- DEXLOCK® KNOTLESS 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.
- Up to 3 sutures or 2 tape limbs can be fed through the eyelet using the wire loop.
- DEXLOCK® KNOTLESS 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 bone/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 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.
- 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.

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 and should be handled in accordance with accepted medical practice and applicable local and national requirements.

Packaging and Labeling
- Prior to use of the device, always verify the suitability of the device by verifying the integrity of the 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 implant is made of Zeniva® ZA-500 or ZA-600 polyetheretherketone (PEEK) from Solvay. The DEXLOCK® KNOTLESS delivery instrument is made of Lustran ABS and Stainless Steel. Sutures are made of braided Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester or polypropylene.

Manual Cleaning (Reusable Instruments)
The instruments for the DEXLOCK® KNOTLESS 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 (20-32°C, 68-90°F) large enough to fully submerge the instrument with enzymatic detergent-based cleaning solution prepared per manufacturer's instructions.
6. Place the Instrument into 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 (Instruments)
The instruments for the DEXLOCK® KNOTLESS 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	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.

For additional product information, please visit **www.medline.com** or contact customer service at **1-800-MEDLINE**

www.medline.com

Three Lakes Drive, Northfield, IL 60093 USA **1-800-MEDLINE** IFUKNOTLESS V2 RD25GHB QUAL-111358

LOT	Batch code
REF	Catalog number
	Caution
	Consult instructions for use
	Date of manufacture
	Do not reuse
	Do not use if package is damaged
	Expiration date
	Keep Dry
Rx only	Prescription use only
STERILE EO	Sterilized by Ethylene Oxide gas