REDIFIX™
REDUCTION + FIXATION

Trax Redifix Anchor Instructions For Use

Important Medical Information

CAUTION:

Federal law (United States) restricts this device to sale, distribution, and use by or on the order of a physician.

DEVICE DESCRIPTION

The Trax Redifix Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. The anchors are manufactured from 6AL-4V ELI Titanium. The Trax Redifix Anchor is a 2-component anchor comprised of the Trax Redifix Screw-In and the Trax Redifix Push-In Anchor. The Trax Redifix Screw-In Anchor is designed to fixate into bone by way of threaded engagement. The Trax Redifix Push-In Anchor is designed to fixate into bone by way of press-fit engagement.

The Trax Redifix Screw-In Anchor is designed to be used alone or in conjunction with the Trax Redifix Push-In Anchor. The Trax Redifix Push-In Anchor component is designed to be used only in conjunction with the Trax Screw-In Anchor and is not sold separately.

The sutures utilized in all implants are high-strength, Ultra High Molecular Weight Polyethylene (UHMWPE). The Trax Redifix Anchor Delivery Instruments are intended to prepare the site and fixate the anchors.

All kits are intended to be sterilized by ethylene oxide (EO) and provided in a blister tray inside of a Tyvek pouch.

INDICATIONS FOR USE

The Trax Redifix Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

- Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
- Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Hand/Wrist: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

TRAX SURGICAL

MATERIAL

All Implantable Anchor Devices are manufactured from implantable grade titanium: (Ti-6Al-4V-ELI)

Suture: See package label for size and type of suture provided with device.

The Trax Redifix Anchor System is preloaded with a non-absorbable suture which is a polyblend made from ultra-high molecular weight polyethylene (UHMWPE) and polyester. UHMWPE fibers sutures are undyed (white), with trace filaments composed of polyester or nylon dyed with logwood black or blue D&C No. 6 to add visual color to the suture.

The sutures supplied meet or exceed U.S. Pharmacopeia standards for non-absorbable surgical sutures (except for diameter requirements).

CONTRAINDICATIONS

- 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.
- 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.

ADVERSE EFFECTS

- Infections, both deep and superficial.
- Foreign body reactions.

WARNINGS

- This device is intended to be used by a trained medical professional.
- An internal fixation device must never be re-used.
- Do not re-sterilize this device.
- All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
- 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.
- Preoperative 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 Trax Surgical 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.
- 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.
- Biohazard waste, such as explanted devices, needles, and contaminated surgical equipment, should be safely disposed of in accordance with the institution's policy.

PRECAUTIONS

- Surgeon should use care to avoid excessive off axis loads to prevent bending or breakage. Delivery of screw-in anchors or operation of rotary instruments should be done slowly and carefully to minimize torque loads.
- Surgeons must apply their professional judgment when determining the appropriate suture anchor size based on the specific indication, preferred surgical technique, and patient history.
- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Please contact your Trax Surgical representative for an onsite demonstration.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects may occur. The surgeon must explain these to the patient. These effects include, and are not limited to:

- Infections, both deep and superficial.
- Foreign body reactions.

MRI SAFETY INFORMATION

The Trax Redifix Anchor has not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of the Trax Redifix Anchor in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

PACKAGING AND LABELING

- Trax Surgical devices should be accepted only if the factory packaging and labeling arrive intact.
- Contact Trax Customer Service at 781-436-4350 if the package has been opened, altered or damaged.

STERILIZATION

All kits are intended to be non-pyrogenic and sterilized by ethylene oxide (EO) provided in a blister tray inside of a Tyvek pouch.

Check the package labeling for more information. Devices that are provided in a terminally sterilized configuration should never be re-sterilized under any conditions. Dispose of implants that are not used in surgery and where the sterile packaging has been opened. If either the implant or the package appears damaged the implant should not be used.

STORAGE CONDITIONS

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

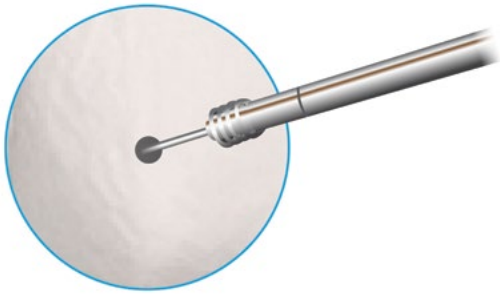
CONTACT INFORMATION

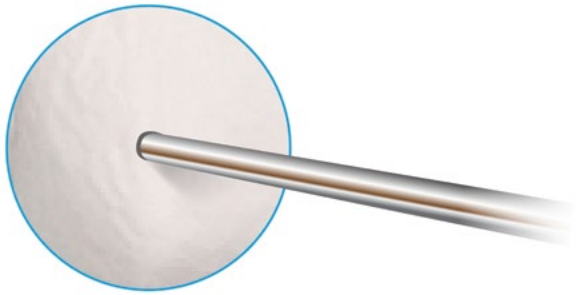
For questions, comments or to report a serious adverse event, please call Trax Customer Service at 781-436-4350.

Instructions for Use and Surgical Technique Guide are available at www.traxsurgical.com or contact Trax Customer Service at 781-436-4350 and these materials will be provided to you at no cost.

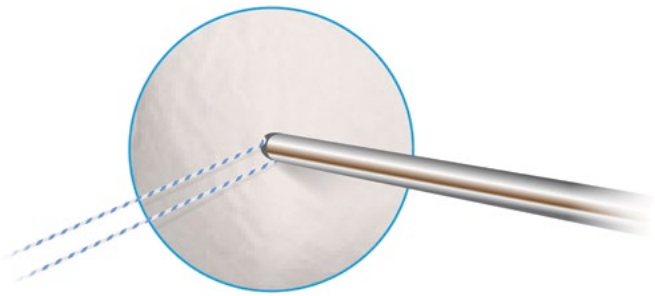
SURGICAL TECHNIQUE

1. Place 1.1mm guide wire and confirm placement.
2. Drill 2.75mm pilot hole using cannulated drill bit.
3. Drive anchor into position (note minimum depth line on driver) and confirm placement. (Sutures not shown for clarity)

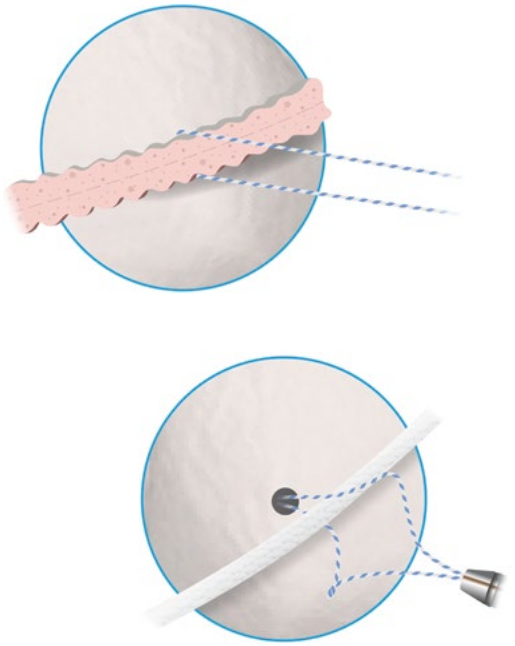




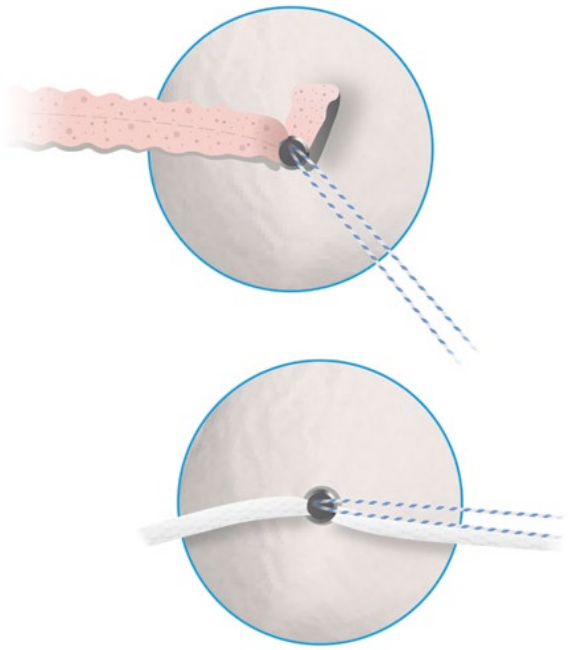
4. Release suture from driver handle and remove driver.



5. Position tissue or suture to be secured.



6. Tension mobile strand of suture (knotted end) to advance pre-tied knot or proximal anchor towards distal anchor, capturing and fixating tissue. Use the knot pusher to fully seat and tighten the pre-tied knot or proximal anchor.



Removal: Anchors can be removed by cutting suture, using the anchor driver and/or using the trephine cutter.

SYMBOLS USED IN PRODUCT LABELING					
Manufacturer	Lot Number	Catalog Number	Date of Manufacture (yyyy-mm-dd)	Prescription Device	Sterilized using Ethylene Oxide
Do not use if package is opened or damaged	Electronic IFU	Material: Titanium	Material: Stainless Steel	Do Not Reuse Single Use Only	Non-pyrogenic

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