TRAX
Compression Screw System

Instructions for Use

Important Medical Information

CAUTION:

Federal Law restricts this device to sale by or on the order of a physician.

TRAX Compression Screw System Implants and Instrumentation are provided NON-STERILE.

DEVICE DESCRIPTION

The TRAX Compression Screw System contains cannulated Headed and Headless Screws in addition to solid Breakaway (Snap-off) Bone Screws, Washers, and Instrumentation. There is a large assortment of screws available, organized by size (length and diameter), into three kits. This allows surgeons to select the appropriate device for the patient's anatomy. The screws and washers are manufactured from 6AL-4VELI titanium and are anodized in various colors for easy size recognition.

The surgical instruments are intended to prepare the site and fixate the screws. Instrumentation includes K-wires, Drill Guides, Guide Handles, Ratcheting Drive Handles, Drill Bits, Depth Gauges, Countersinks, Hexalobe Driver Tips; all organized according to the respective kits. Colored Rings on the instruments are intended to coordinate the screws to the appropriate instrument.

The compression screw system is provided in an autoclavable instrument tray which is provided non-sterile to the end user.

INDICATIONS FOR USE

The TRAX Compression Screw System is indicated for use in adult and skeletally mature pediatric patients (aged 12-21 years), for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

Pediatric Subpopulation: Skeletally Mature Adolescents (aged 12-21 years).

MATERIAL

TRAX implants (Bone Screws and Washers) are manufactured from titanium alloy (6AL-4VELI per ASTM F136). Instruments are comprised of stainless steel.

CONTRAINDICATIONS

- Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
- Patient has sensitivity / allergies to the implant materials.
- The presence of any clinical or functional abnormalities would preclude the potential of achieving a positive result for the patient.
- There is skeletal immaturity.
- There is poor or insufficient bone stock.
- **Not** intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

TRAX SURGICAL

WARNINGS

- All implants, instruments and containers in the compression screw system are delivered **NON-STERILE** and must be cleaned, disinfected and sterilized before each use. This also applies to the first use after delivery.
- Compression Screws, Washers, K-wires, Drills, Counter Sinks and Driver Tips are single use devices and are not to be reused.
- Patient sensitivity to implant materials should be evaluated prior to implantation;
- Implant reuse could result in failure of the device and inability to perform as intended, transmission of infectious diseases, and/or harm to the patient or user.
- Implant(s) can fail due to excessive load or fatigue.
- A successful result may not be obtained in all cases. Corrective surgery may be required.
- Proper pre-operative, surgical techniques and operating procedures are important considerations for the successful use of this system.
- Selection of type and size of implant(s) is extremely important. Failure to use the appropriate size implant and instrumentation may result in loosening, fracture of the device, bone or both;
- The use of implants for purposes other than indicated may result in implant breakage, injury, reoperation and/or removal;
- Implants are intended for temporary fixation until healing is complete. Implants may not withstand weight bearing or unsupported stress.
- Cleaning and sterilization should be performed by trained personnel.

PRECAUTIONS

- It is the responsibility of the surgeon to consider the clinical status and medical standing of each patient and be knowledgeable about all aspects and potential complications of the procedure that may occur;
- Implant surgery may not meet patient expectations or the implant may deteriorate with time, necessitating revision surgery. Modification surgeries involving implants are common;
- Patient disclosure is important and they must be made aware of physical limitations derived from the implant and that physical exertion may cause premature device failure;
- Consideration of potential risks involved with implant removal and patient health derived from a secondary surgical procedure must be accounted for. Implant removal succeed by sufficient postoperative management is essential to avoid re-fracture;
- Ensure use of appropriately sized instrumentation for Bone Screw implantation;
- Damage to Driver or Screw may result from incorrectly mating Driver and Screw properly;
- Never use products that have been damaged in transport or improperly handled at the hospital. Inspect devices for defects or damage **PRIOR** to use. If you suspect an implant or instrument to be defective or damaged, **DO NOT USE**.
- Ensure Washers are inserted in the intended orientation.

ADVERSE EFFECTS

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

- Infection (primary or secondary);
- Pain, inflammation, discomfort, abnormal sensations due to the implant presence;
- Implant fracture, loosening, wear and tear, dislocation and/or migration requiring surgery;
- Failure or delayed correction, non-union (pseudarthrosis), malunion or malalignment;
- Decrease in bone density due to stress shielding;
- Hematoma and/or impaired wound healing;
- Loss of anatomic position with malunion or malalignment;
- Blood vessel or nerve damage; necrosis of bone;
- Allergic reaction to implant material(s);
- Histological responses;

MRI SAFETY INFORMATION

The TRAX Compression Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for temperature, migration or image artifact in the MR environment. The safety of the TRAX Compression Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING

- Thorough cleaning and disinfection are essential for effective sterilization. All implant components are intended for one single application in a single patient. Implants that were used in a patient and removed, have to be discarded following the local requirements.
- The detergents used must be suitable and compatible for use with titanium and stain less-steel products.
- The detergent manufacturers' instructions regarding concentration must be followed.

Pre-treatment Prior to Cleaning:

1. Prepare a PH neutral, enzymatic cleaning solution at the concentration and temperature specified by the detergent manufacturer.
2. Completely submerge the instruments in the cleaning solution and allow to soak for 10 minutes.
3. Submerge and thoroughly clean the tray lid, base and tool tray with a soft brush. Rinse the tray components with clean water. Visually examine the tray components for wear, damage or incomplete cleaning. Set aside these components if they are visually clean, repeat this step as required if contamination remains after cleaning.
4. Scrub instruments with lumen channel brush for a minimum of 1 minute to remove all visible soil. Pay close attention to threads, crevices, seams and any other hard to access areas. Actuate any moving mechanisms to free trapped blood and debris.
5. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
6. Prior to loading into the automated washer, place instruments into their tray. Washer cycles will be performed with trays open.

Automated Cleaning Process:

- When loading the washer / disinfector, use the loading layouts provided by the equipment manufacturer.
- Implant trays can undergo automated cleaning when loaded. Make sure the implant caddies have been properly secured with their lid prior to automated cleaning/disinfection.
- Ensure that the products have been rinsed thoroughly after pretreatment as remaining foam may have a negative impact on the cleaning result.
- Trax Surgical used "Prolystica® Ultra Concentrate HP Enzymatic Cleaner" for the automated cleaning process validation. The validation was carried out according to the table below.

Process Step	Process Description	Water Type	Minimum Temperature	Minimum Time (minutes)
1	Pre-Wash	Tap	Cold	2
2	Enzyme	Tap	Hot	4
3	Detergent	Tap	65°C	2
4	Rinse	Tap	Hot	1
5	Thermal	DI	82.2° C	1
6	Hot Air Dry	NA	Hight	6

INSPECTION

- Check all instruments after cleaning for damage and function.
- Check the instruments for damage such as corrosion, damaged surfaces, fissures, chipping, contamination and / or functionality
- Instruments that are cannulated products (e.g., cannulated drills) have to be checked for free passage without obstructions. Products without free passage or with obstructions have to be reprocessed. Damaged instruments have to be exchanged.
- Cutting instruments (e.g., drills) have to be checked for sharpness and damages. Worn or damaged instruments have to be exchanged.
- Rotating instruments (e.g., drills) have to be checked additionally for bending. This can easily be done by rolling the rotating instrument on a flat surface. Bent rotating instruments have to be exchanged.

STERILIZATION

- Trax Surgical recommends sterilizing the tray containing the implants and instruments in an FDA cleared sterilization vessel using only the vacuum cycle indicated below, wrapped with a wrap that is FDA cleared for the indicated vacuum cycle. Do Not stack trays during sterilization.

Vacuum Cycle	
Temperature	132° C (270° F)
Exposure Time	4 minutes
Drying Cycle	30 minutes

- After sterilization, the TRAX Compression Screw System must be stored in a dry and dust-free environment and kept in the wrap used for sterilization until used.

REUSABILITY
(IMPLANTS AND INSTRUMENTS)

- Compression Screws and Washers are long term implants and as such are single use devices.
- Implants that were used in a patient and removed, have to be discarded. They are not allowed to be reprocessed. Please note that any single use device which comes into contact with the patient should not be re-used and should be properly disposed of.
- K-wires, Drills, Counter Sinks and Driver Tips are intended for single use only and are to be properly disposed of after use.
- Implants that were not implanted but have come in direct contact with blood or other bodily fluids or show visual contamination must be cleaned and disinfected separately before they can be placed back into the implant tray.
- Products that have not come into direct contact with a patient may be reprocessed
- All serviceable instruments may be re-used after proper cleaning and sterilization.

DISPOSAL

Dispose of contaminated devices / materials in accordance with institutional biohazard protocol.

CONTACT TRAX SURGICAL

- For questions, comments or to report an 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.

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

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