Trax Surgical

LINKT™ Compression Staple System 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.

DESCRIPTION

The Linkt™ Compression Staple System Implants and Instrumentation are provided STERILE. The compression Staple is a one-piece device made of Nickel-Titanium Alloy intended to facilitate bone fusion. The implant is available in a range of sizes and is individually packed in a sterile package.

The Linkt™ Staple Deployment Kit is provided sterile and contains:

- One each
  - staple inserter
  - drill guide
  - drill
- Two each
  - Locating pins

The staple implant and deployment kit instruments are for single use. All associated instruments are disposable.

INDICATIONS FOR USE

The Linkt™ Compression Staple System is intended to be used for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

MATERIAL

Linkt™ Staple implants are manufactured from Nitinol (Nickel-Titanium Alloy ASTM F 2063). Instruments are comprised of stainless steel and Polyphenylsulfone (PPSU).

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.

WARNINGS

- 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 proper 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.
- The expected life of an implant is difficult to estimate but it is limited. Staple implants are made of foreign materials, which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time.

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.
- Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device.

- This implantable product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.
- Ensure use of appropriately sized instrumentation for Staple implantation.
- 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**.

POTENTIAL ADVERSE EFFECTS

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

- pain, discomfort, or abnormal sensation due to the presence of the implant
- metal sensitivity or allergic reaction to a foreign body
- bleeding
- infection
- delayed correction in alignment
- decrease in bone density due to stress shielding
- bursitis
- loss of use of the foot or hand
- permanent disability

MRI SAFETY INFORMATION

A patient with the Linkt™ Compression Staple may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient. The implant system is MR Conditional.

Name/identification of device	Linkt™ Compression Staple
Nominal values(s) of Static Magnetic Field [T]	1.5 T or 3T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3,000 gauss/cm)
RF Transmit Coil Type	Whole Body / Local
Maximum Whole Body SAR [W/kg]	2 W/kg
Highest Temperature Change	2.9C at 1.5T and 3.7C at 3T (based on electromagnetic simulation model)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

STERILIZATION

The Linkt™ Compression Staple implant and Deployment Kit have been sterilized by gamma irradiation.

Do not re-sterilize. 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.

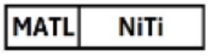
SURGICAL PROCEDURES

A manual is available describing surgical procedures for use of the Linkt™ system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be up to date with clinical application of bone compression devices and consult with experienced associates regarding the implant procedures before use.

POST-OPERATIVE PROTOCOL

Protected weight bearing with below the knee walking cast or walking boot is recommended. A gradual return to limited activity in 4 to 6 weeks is allowed as tolerated. Patient specific post-operative care is the responsibility of the surgeon.

SYMBOLS

Symbol	Definition
	Catalog number
	Lot code
	Do not re-use
	Do not re-sterilize
	Manufactured using Nitinol
	Manufactured using Stainless Steel
	Consult operating instructions
	Use by
	Date of manufacture
	Manufacturer
	Sterilized using radiation
	Do not use if package is damaged
	For prescription use only
	MR Conditional

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.

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