LINKT™
COMPRESSION STAPLE

Surgical Technique Guide

LINKT™ Compression Staple System

TRAX SURGICAL

Trax Surgical recognizes that medical professionals are responsible for knowing the proper surgical procedures and techniques for orthopedic implants. The following guidelines are provided for informational purposes only. Each surgeon must evaluate the appropriateness of the procedures based on their personal medical training, experience, and patient condition. Prior to using this system, the surgeon should refer to the product Instructions For Use for a complete list of warnings, precautions, indications, contraindications and adverse effects. Instructions For Use are available at www.TraxSurgical.com and are also available by contacting the manufacturer or local representative. Contact information can be found on the back of this guide and the Instructions For Use.

Please contact your local Trax Surgical representative for product availability.

INTRODUCTION

The LINKT™ Staple System is comprised of a nitinol (shape memory alloy) implant with compressive properties, and a staple deployment kit that can be used in fixation for fractures, fusions or osteotomies of bones appropriate for the size of the device.

The LINKT™ Staple System is delivered sterile. The LINKT™ Staple is designed to compress upon release from the applicator and will provide a constant compressive force. Available in seven implant sizes of 9x9mm, 12x12mm, 15x12mm, 15x15mm, 18x14mm, 18x18mm, and 20x20mm. Each staple is individually packaged. Each deployment kit contains one disposable Inserter, Drill, Drill Guide and two disposable Locating Pins. Deployment kits are available specific to the staple width to be implanted.

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.

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.
- It is recommended to not exceed four staples in any surgical site.
- 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.

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Surgical Technique

LINKT™ Compression Staple System

Step 1

Determine the appropriately sized staple for the given procedure. Select the packaged staple and the matching size LINKT™ Staple Deployment Kit.

While maintaining the desired reduction, place the Drill Guide across the fusion site with both guides touching bone.

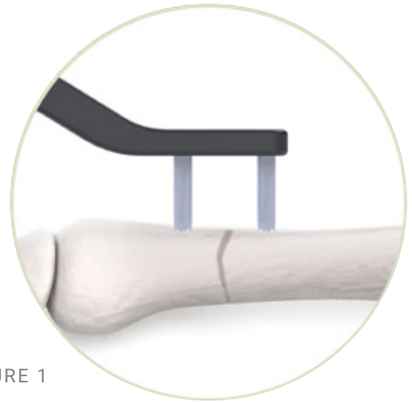

FIGURE 1

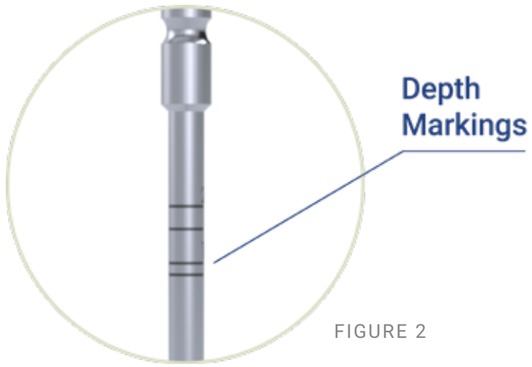

FIGURE 2

Step 2

The Drill in each Deployment Kit contains depth markings that correspond to the leg length of the staple [Figure 2]. Drill the first hole to the proper depth by referencing the depth markings on the Drill provided in the Deployment Kit [Figure 3].

NOTE: Drill until the appropriately marked reference line is aligned with dorsal aspect of the drill guide.

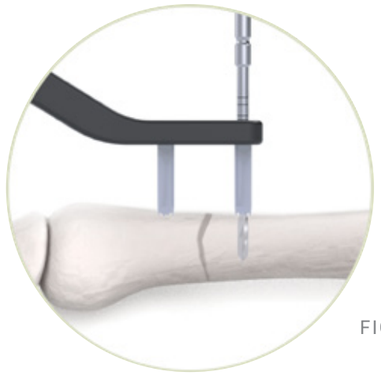

FIGURE 3

Step 3

Insert a Locating Pin into the first hole to maintain proper reduction while the second hole is drilled. While maintaining tight reduction of the fracture, drill the second hole to the proper depth by referencing the depth markings on the Drill. A second Locating Pin is provided for your convenience. Remove the Drill, Locating Pin(s) and Drill Guide.

NOTE: Drill until the appropriately marked reference line is aligned with dorsal aspect of the drill guide.

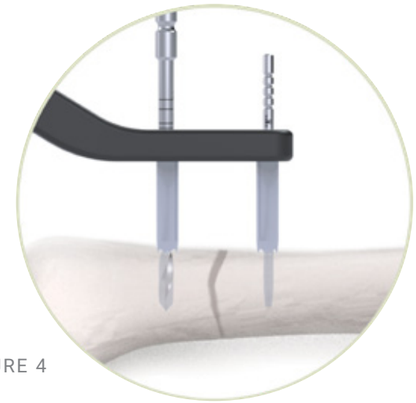

FIGURE 4

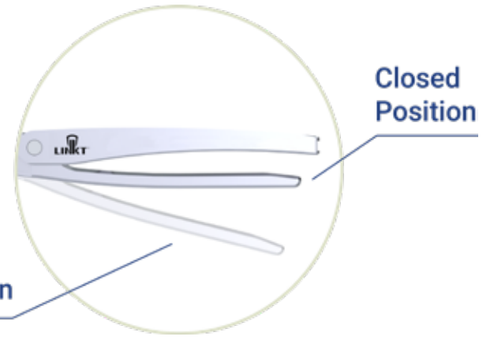

FIGURE 5

Step 4

Move the handle of the staple inserter to the open position [Figure 5]. Place the staple onto the distal end of the staple inserter and close the handle to secure it. Squeeze the handle to open the staple legs so they are parallel [Figure6].

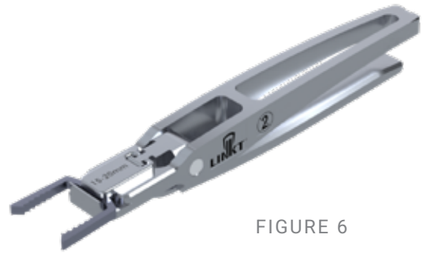

FIGURE 6

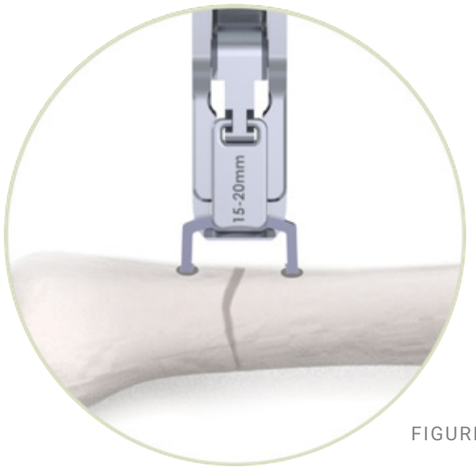

FIGURE 7

Step 5

While maintaining reduction, align and insert the tips of the LINKT™ Staple into the drilled holes.

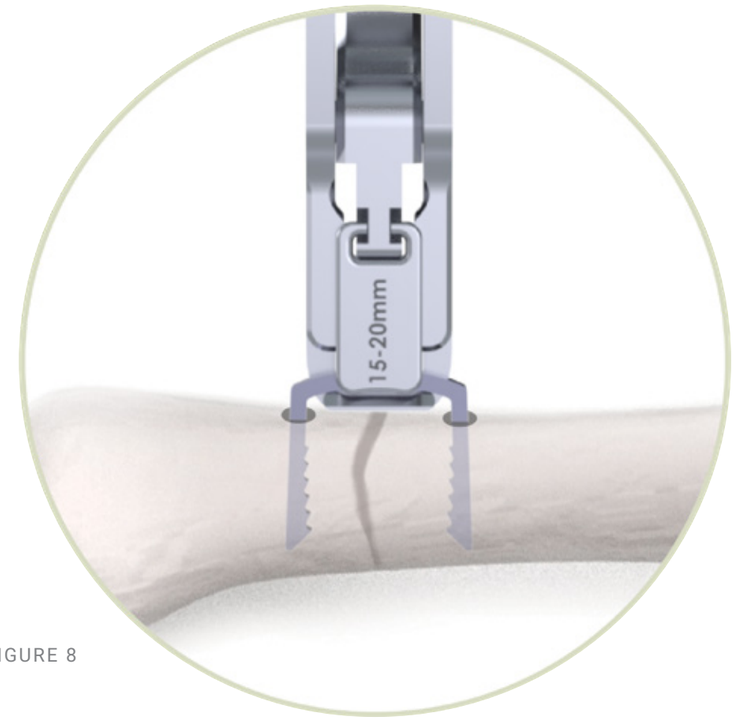

FIGURE 8

Step 6

Seat the LINKT™ Staple implant as flush to the bone as possible. Implant positioning may be evaluated radiographically.

Step 7

Move the Staple Inserter lever to the open position to release the Implant.

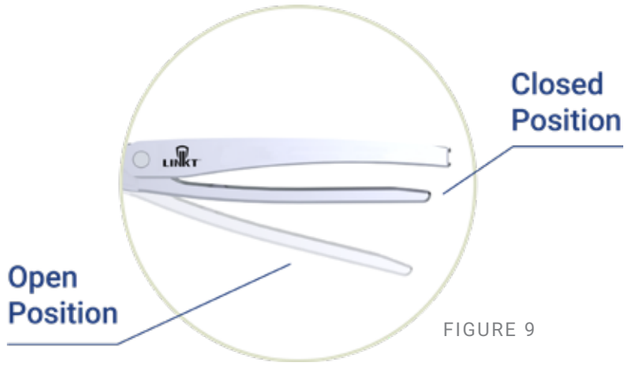

FIGURE 9

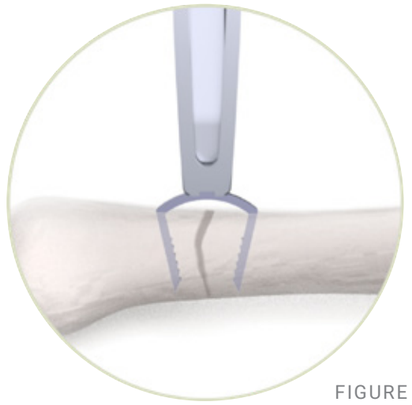

FIGURE 10

Place the end of the Inserter on the implant and apply pressure, manually or using a mallet, to fully seat the LINKT™ Staple Implant.

Apply additional LINKT™ Implants as deemed appropriate for optimum stability.

EXPLANT INFORMATION

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering Information

LINKT™ Compression Staple System

Order Number	Description	Bridge Width	Leg Length
STP0909	LINKT™ COMPRESSION STAPLE 9X9	9	9
STP1212	LINKT™ COMPRESSION STAPLE 12X12	12	12
STP1512	LINKT™ COMPRESSION STAPLE 15X12	15	12
STP1515	LINKT™ COMPRESSION STAPLE 15X15	15	15
STP1814	LINKT™ COMPRESSION STAPLE 18X14	18	14
STP1818	LINKT™ COMPRESSION STAPLE 18X18	18	18
STP2020	LINKT™ COMPRESSION STAPLE 20X20	20	20
SK09	LINKT™ STAPLE DEPLOYMENT KIT 9MM	9	9
SK12	LINKT™ STAPLE DEPLOYMENT KIT 12MM	12	12
SK15	LINKT™ STAPLE DEPLOYMENT KIT 15MM	15	12/15
SK18	LINKT™ STAPLE DEPLOYMENT KIT 18MM	18	14/18
SK20	LINKT™ STAPLE DEPLOYMENT KIT 20MM	20	20

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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