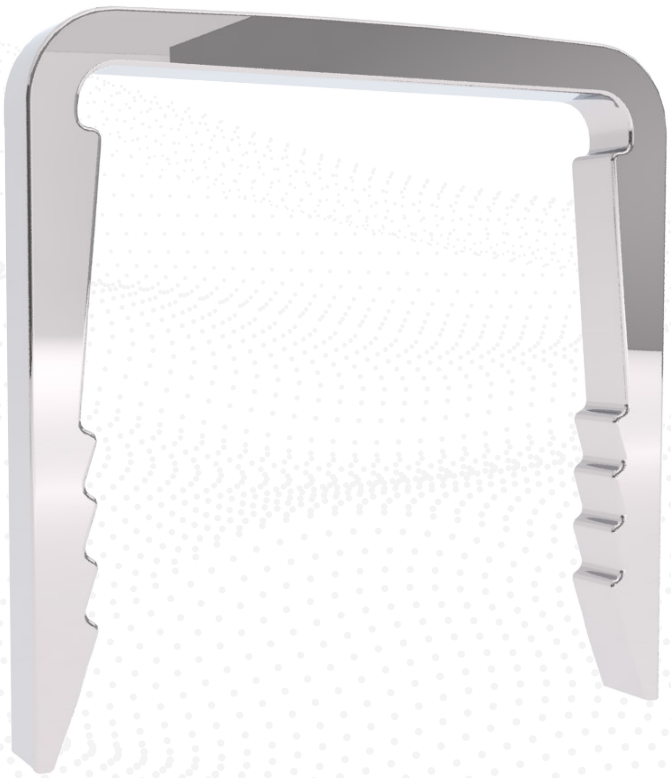
vertex®

COMPRESSION STAPLE SYSTEM

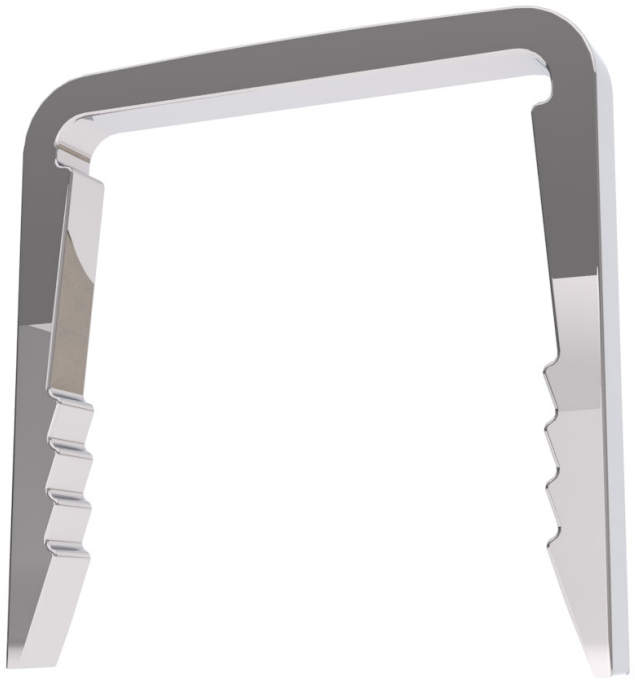
Surgical Technique Guide



NVISION™

biomedical technologies

vertex®
COMPRESSION STAPLE SYSTEM



The Vertex® Nitinol Staple is made of superlastic nitinol and is designed to provide compression to an osteotomy or bone fracture after being released from inserter.

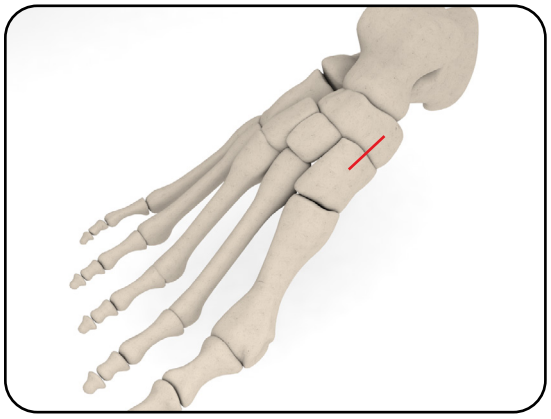
The unique design of the staple combined with the mechanical properties of the nitinol, allow the staple to have a great performance offering a 63.5% greater pullout strength than its competitors*.

The system consists of the staple and instrumentation such as drills and drill guides that are straightforward and ergonomic allowing for a quick and smooth staple insertion.

*Data on file.

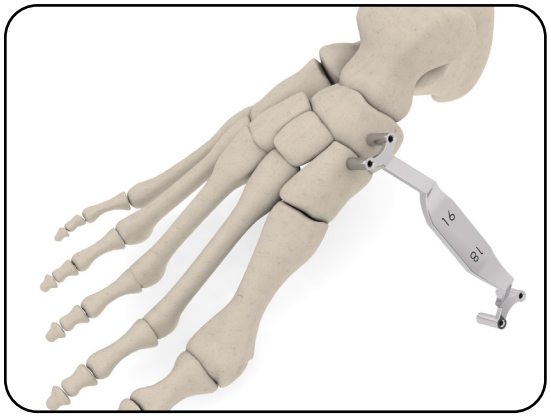
Step 1 - Site Preparation

Expose the surgical site and prepare the bone for fusion or fixation. Use temporary fixation k-wires for stabilization if needed.



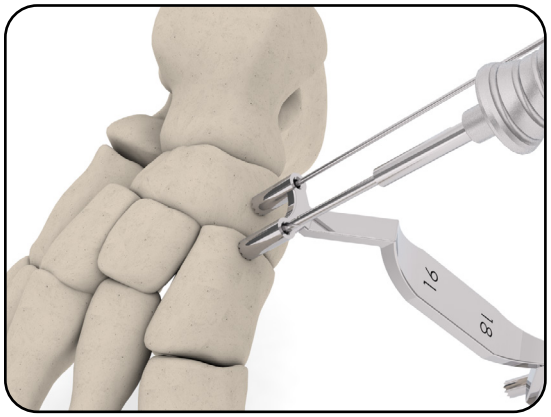
Step 2 - Implant Sizing

Use the Vertex Sizers/Drill Guides to determine the correct Vertex Staple to be used.



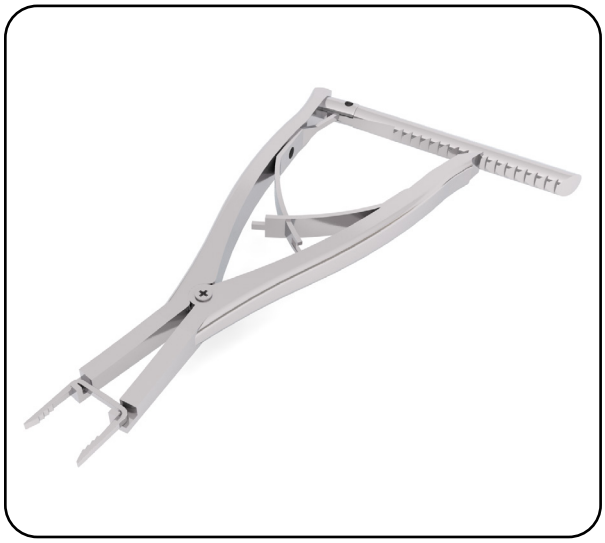
Step 3 - Drilling

Place the drill guide across the fusion or fixation site and drill to the desired depth using the laser marks as reference. Remove the drill and place a k-wire in the first hole, then drill the second hole to the desired depth.



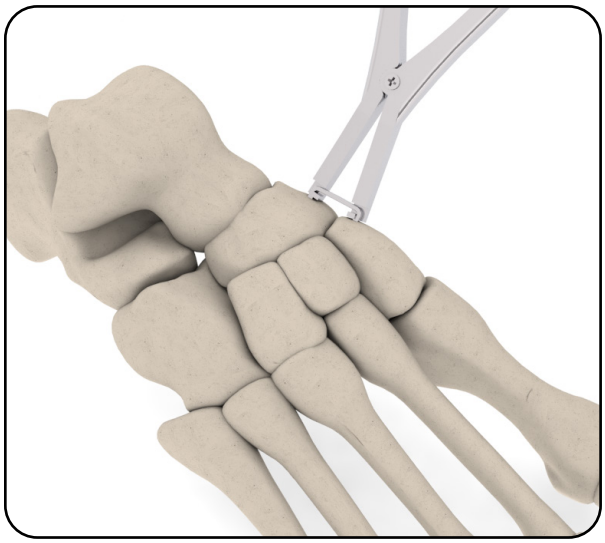
Step 4 - Load Staple Spreader

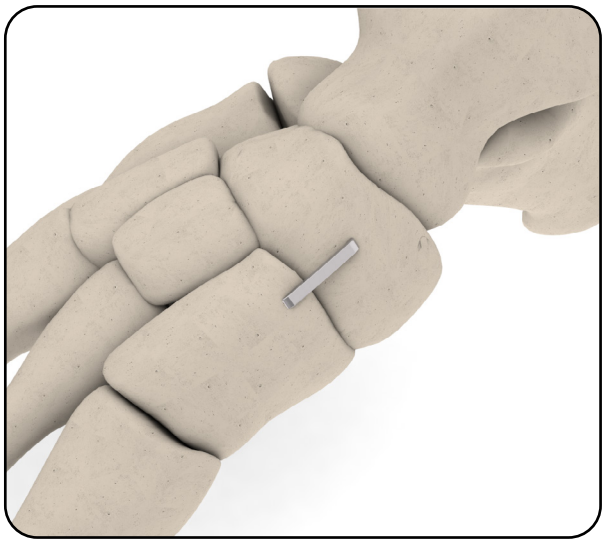
Place staple on the staple spreader and distract the staple legs until they are parallel. Verify the staple legs are parallel by placing the staple legs into the implant caddy sizing holes.



Step 5 - Insert Staple

Insert staple legs into drilled holes, tamping the spreader if necessary. Disengage and remove the staple spreader. Tamp the staple flush to bone.





Indications For Use

The Vertex® Nitinol Staple System is indicated for bone fragments and osteotomy fixation and joint arthrodesis of the hand or foot.

Contraindications

Use of the Vertex® Nitinol Staple System is contraindicated in the following instances:

- Active or suspected infection or osteomyelitis
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- Poor bone quality, i.e. osteoporotic bone that is susceptible to fracture
- Known or suspected sensitivity to metal or foreign bodies
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Physical conditions that may hinder the healing process
- Conditions that limit the patient's ability or willingness to follow postoperative instructions
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Warnings and Precautions

- For safe and effective use of the Vertex Nitinol Staple System, the surgeon should be familiar with the procedure and devices and must exercise reasonable judgment in use of the device. Improper selection, placement or positioning may result in reduced lifetime of the implant(s).
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Do not resterilize the Vertex Nitinol Staple System implants or instruments. The implants and instruments are intended for single use only.
- Instruments are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Vertex Nitinol Staple System. Failure to use the provided, unique Vertex Nitinol Staple System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants, instruments and packaging prior to use to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Do not modify the design of the implants.
- Never use the implants for a use other than that specified in the section "Indications"
- Do not modify the form of the implant except when required for normal use
- Immobilize the patient during implantation of the device. Any movement of the patient could impair optimal use of the device.
- Inform the patient of the precautions necessary to ensure the success of the implantation.
- The device does not permit immediate resumption of the patient's activities and is not designed to withstand a load immediately after the operation. Immobilization is necessary during osteosynthesis.
- The clinical results depend on the appropriate choice of device in relation to the indication and the quality of the surgical procedure.
- Factors likely to compromise the success of the implantation are:
    - Metabolic disease reducing the patient's resistance or leading to progressive bone degradation
    - Localized bone tumors
    - Severe bone deformity causing incorrect positioning of the implants or a weakened attachment
    - Severe osteoporosis
    - The practice of high-risk sports or activities exposing the implant to excessive or repeated stress.
    - Bone disease, systemic or metabolic disorders and infectious diseases
    - Senility, mental disease, addictive behavior
    - Overweight
    - Risk of incompatibility with other implants
    - Risk of articular conflict

Potential Adverse Events

In any surgical procedure, the potential for complications and adverse reactions exist. These do not include all adverse effects which can occur with surgery, but are important considerations particular to metallic internal stabilization devices.

- Infection
- Loosening, deformation, migration or fracture of the implant
- Fractures resulting from unilateral joint loading
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

Disclaimers

This publication details recommended procedures for using Nvision Biomedical Technologies' devices and instruments. It offers guidance but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to the first surgery. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. For additional information please refer to the instructions for use (IFU) delivered with each implant. The surgeon must discuss all relevant risks, including the finite lifetime.

All possible complications listed are not typical of Nvision Biomedical Technologies products but are in principle observed with any implant. Promptly inform Nvision Biomedical Technologies as soon as complications occur in connection with implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality, or mechanical stability is suspected, please provide Nvision Biomedical Technologies with explant(s) in a cleaned, disinfected, and sterile condition. Nvision cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of osseous implant bed in the case of implants, incorrect indication or surgical technique, or with any incorrect patient information and consequent incorrect patient behavior.

Additional Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Nvision Biomedical Technologies development surgeons. As the manufacturer of this device, Nvision Biomedical Technologies does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

NVISION BIOMEDICAL TECHNOLOGIES
4590 Lockhill Selma Rd
San Antonio, TX 78249

Notes

Notes

ORDERING INFORMATION

Vertex®
COMPRESSION STAPLE SYSTEM

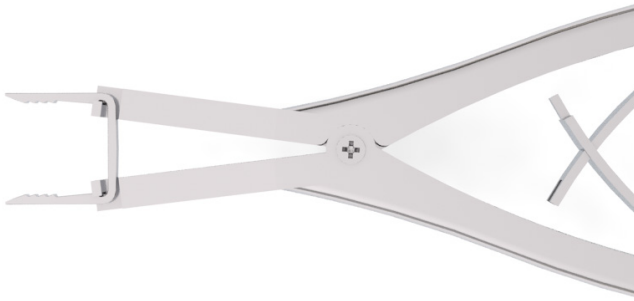
Symmetrical Leg Staples

Part Number	Description
STK-08-08-08	8mm bridge staple, 8mm x 8mm legs
STK-10-10-10	10mm bridge staple, 10mm x 10mm legs
STK-12-12-12	12mm bridge staple, 12mm x 12mm legs
STK-14-14-14	14mm bridge staple, 14mm x 14mm legs
STK-16-14-14	16mm bridge staple, 14mm x 14mm legs
STK-16-16-16	16mm bridge staple, 16mm x 16mm legs
STK-18-14-14	18mm bridge staple, 14mm x 14mm legs
STK-18-18-18	18mm bridge staple, 18mm x 18mm legs
STK-20-14-14	20mm bridge staple, 14mm x14mm legs
STK-20-18-18	20mm bridge staple, 18mm x 18mm legs
STK-20-20-20	20mm bridge staple, 20mm x 20mm legs

Asymmetrical Leg Staples*

Part Number	Description
STK-10-12-14	10mm bridge staple, 12mm x 14mm legs
STK-10-14-16	10mm bridge staple, 14mm x 16mm legs
STK-10-16-18	10mm bridge staple, 16mm x 18mm legs
STK-18-14-16	18mm bridge staple, 14mm x 16mm legs
STK-18-16-18	18mm bridge staple, 16mm x 18mm legs

*Special order. Please allow 12 weeks.



Instruments

Part Number	Description
STK-1000C-001	Vertex Reusable Tray Base
STK-1000C-002	Vertex Reusable Tray Lid
STK-1000C-003	Vertex Reusable Tray Caddy Base
STK-1000C-004	Vertex Reusable Tray Caddy Lid
STK-1000T-001	Sizing Guide Body 08-10
STK-1000T-002	Sizing Guide Body 12-14
STK-1000T-003	Sizing Guide Body 16-18
STK-1000T-004	Sizing Guide Body 20-25
STK-1000T-007	1.7mm Drill
STK-1000T-008	1.9mm Drill
STK-1000T-009	2.1mm Drill
STK-1000T-010	2.3mm Drill
STK-1000T-011	2.5mm Drill
STK-1000T-DIS1	Staple Distractor
CSRW-1000T-330	1.30mm x 150mm K-Wire

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Scan to visit our website.

Scan to view Vertex in augmented reality.

STK-1000L-102 REV B
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