vector®

HAMMERTOE CORRECTION SYSTEM

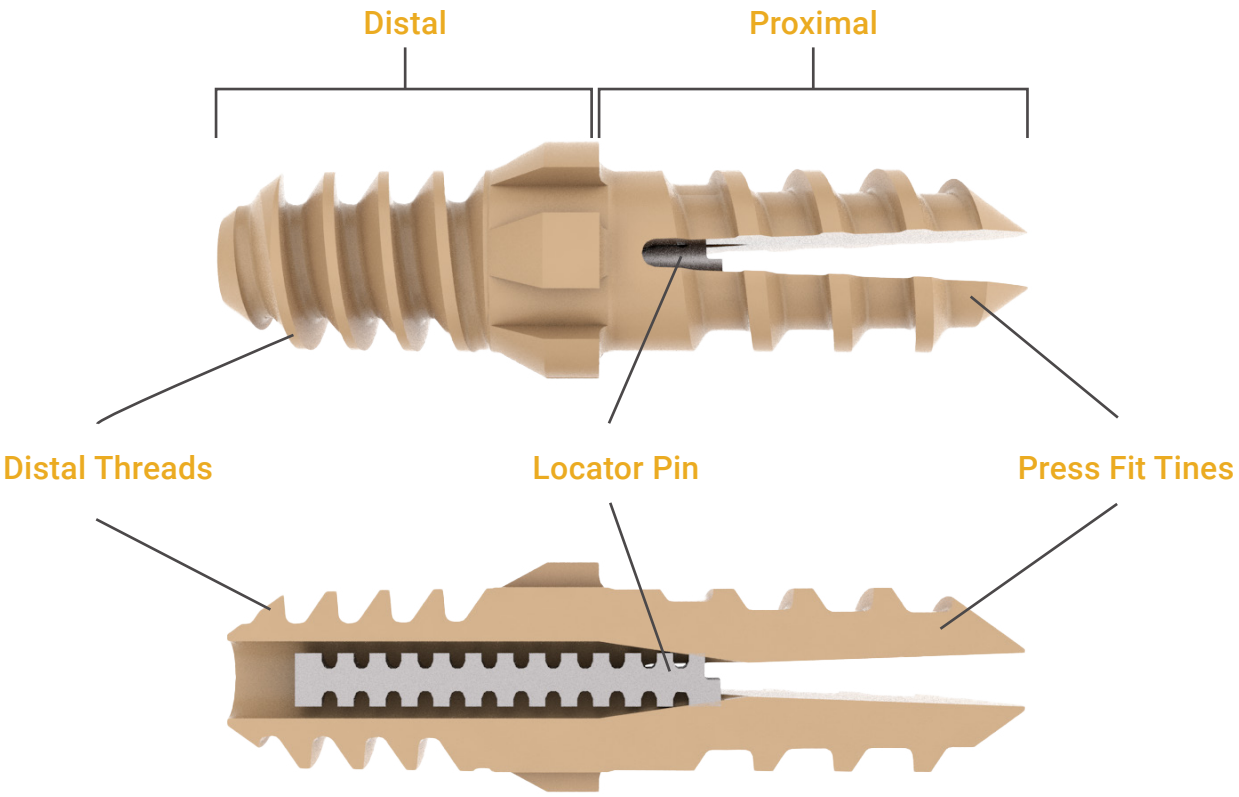
Surgical Technique Guide

NVISION™

biomedical technologies

vector®

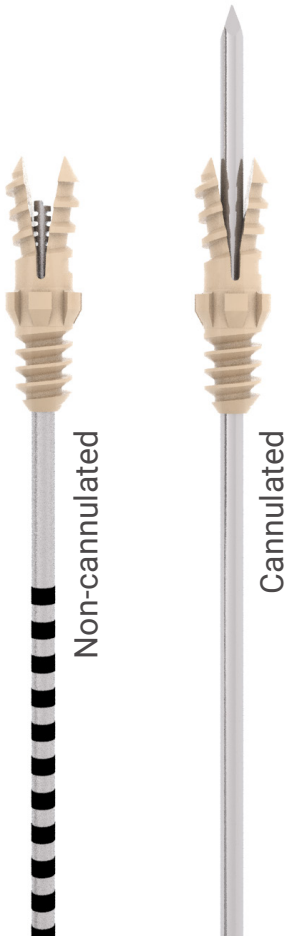
HAMMERTOE CORRECTION SYSTEM



The Vector® Hammertoe Implant is made of PEEK-Optima® HA Enhanced, where the HA is fully integrated into the PEEK (not just coated) making it available on all surfaces of the implant.

The Vector Hammertoe Implant is a one-piece device where the distal portion is screwed into the bone while the proximal portion is press-fitted into the bone.

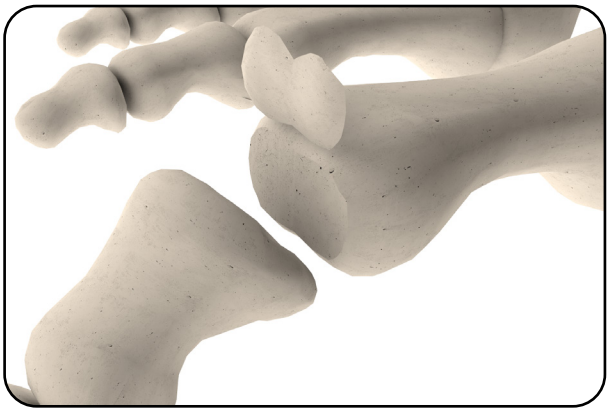
The implant contains a radiopaque locator pin to verify positioning and the radiolucent implant materials allows for fusion to be seen in post-op.

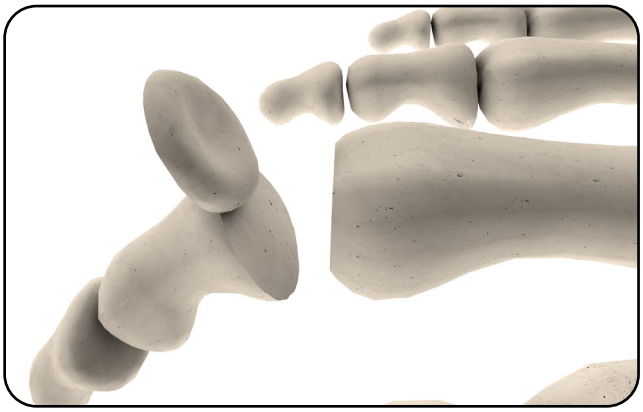


Step 1 - Joint Preparation

Create a midline incision over the dorsal aspect of the PIP joint. Perform a transverse capsulotomy and release soft tissue as necessary to allow for PIP joint exposure.

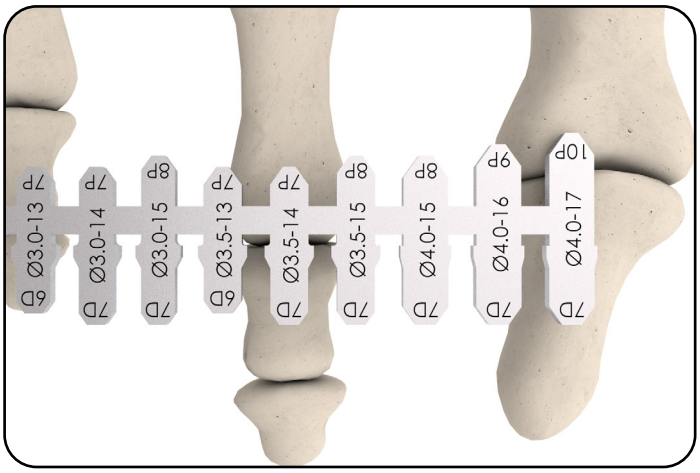
Use a sagittal saw or hand-held bone cutter to perform a transverse resection of the head of the proximal phalanx. Resect the cartilage at the base of the middle phalanx while minimizing bone loss to avoid shortening the digit.





Step 2 - Implant Sizing

Determine the optimal implant size intra-operatively using the implant sizer. The length and width of the sizer footprints match the length and major diameter of the correspondent implant. The sizing template is radiopaque and can be used under fluoroscopy.

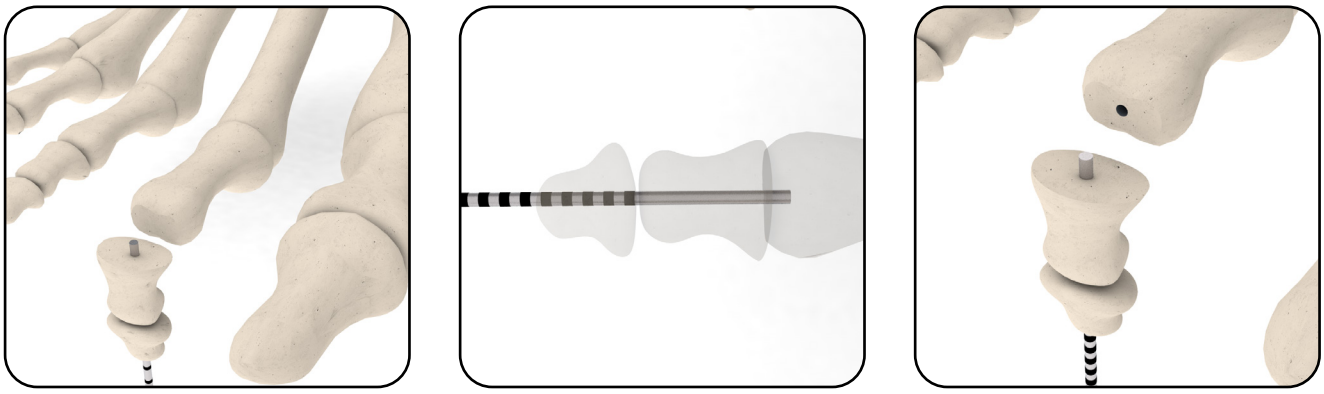


Step 3 - Middle Phalanx Preparation

A. Insert K-Wire

Non-cannulated:

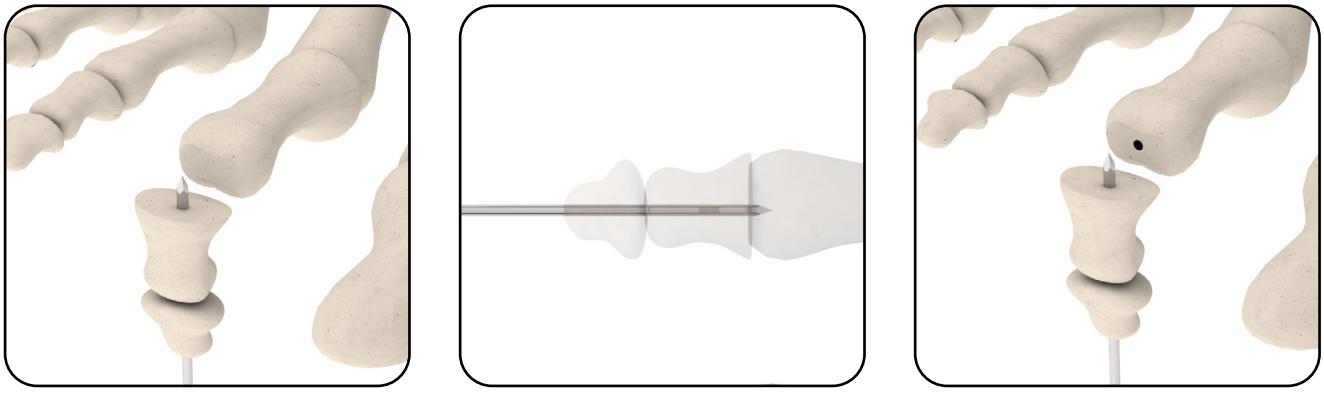
Insert the trocar tip of the K-wire into the middle phalanx antegrade along its central axis, exiting the distal end of the toe. The K-wire should be protruding 1-2mm from the base of the middle phalanx. Indent the central axis of the proximal phalanx with the blunt end of the K-wire for proximal drilling reference.



Note: **In cannulated surgeries, the double trocar K-wire will be used.**

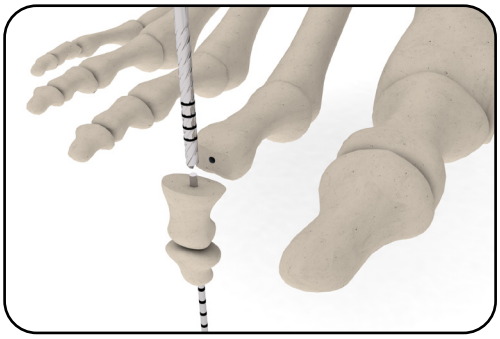
Cannulated:

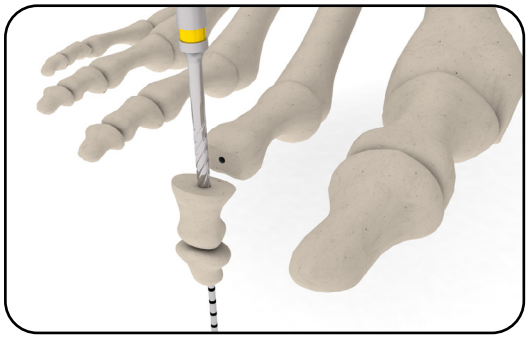
Insert the double trocar K-wire into the middle phalanx antegrade along its central axis, exiting the distal end of the toe. The K-wire should be protruding 1-2mm from the base of the middle phalanx. Indent the central axis of the proximal phalanx with the proximal end of the K-wire for proximal drilling reference.



B. Drill

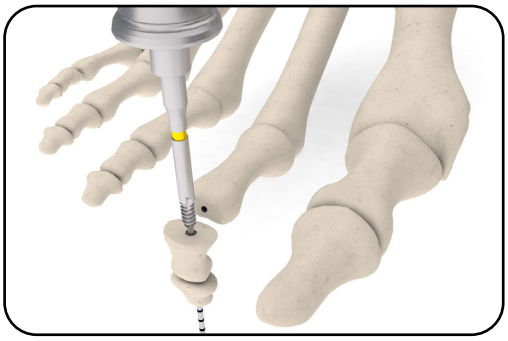
Slide the appropriate diameter cannulated drill over the K-wire and hand drill to the last laser line or stop when reaching inner cortical wall.

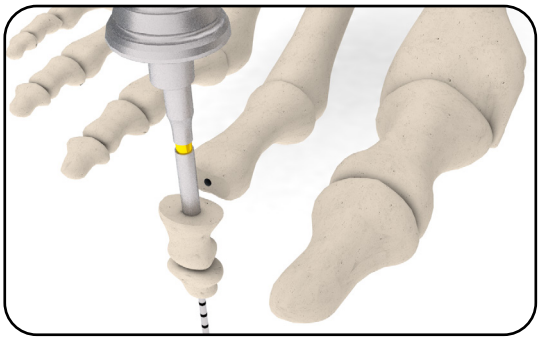




C. Tap

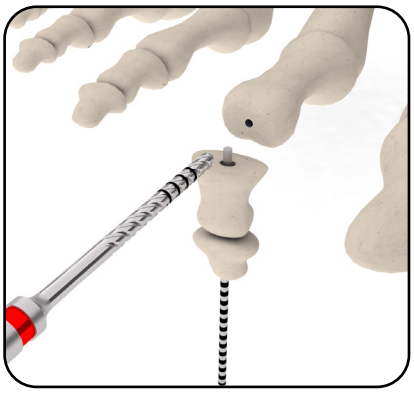
Slide the appropriate tap over the K-wire and advance until the shoulder is flush with the joint surface.

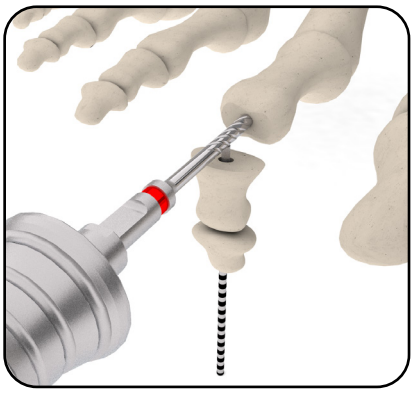


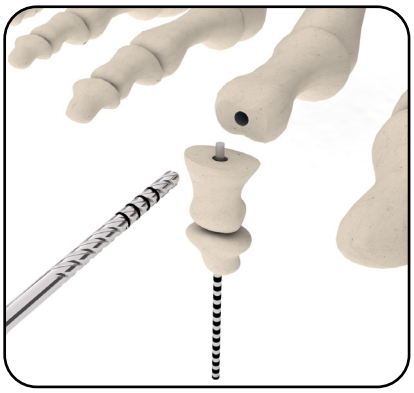


Step 4 - Proximal Phalanx Preparation

Use the indentation performed in **Step 3** as a pilot hole to hand drill the proximal phalanx with the red drill to the last laser mark or stop when reaching the inner cortical wall. If needed, insert a separate K-wire along the central axis of the proximal phalanx to aid with drill alignment.





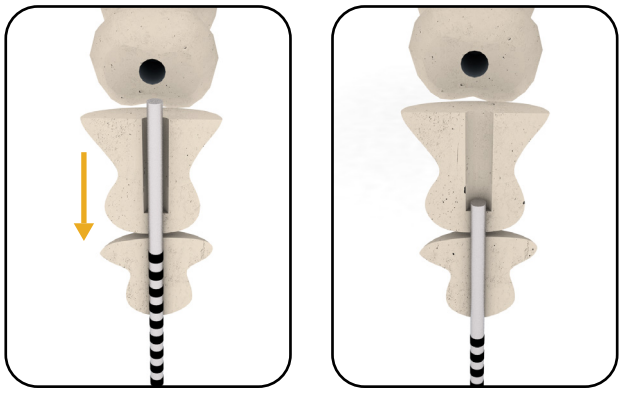


Step 5 - Middle Phalanx Implant Insertion

A. Position K-Wire

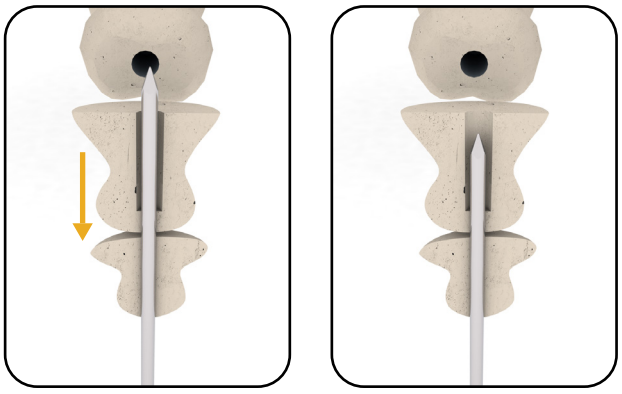
Non-cannulated:

Slowly pull the K-wire distally until the blunt end of the k-wire comes flush with the bottom of the distal pilot hole.



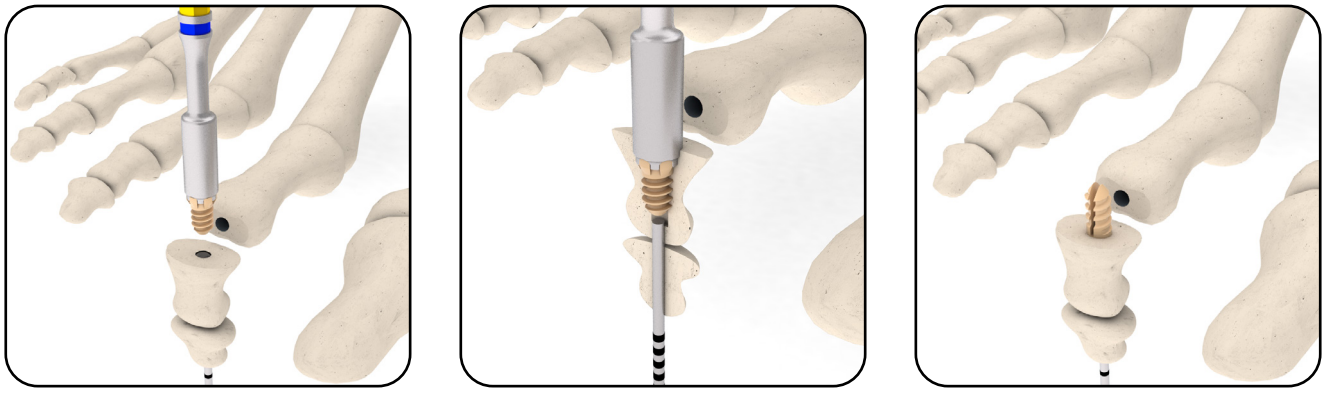
Cannulated:

Slowly pull the K-wire distally until the proximal end of the k-wire is 3-5mm subflush.



B. Insert Implant

Use the inserter to thread the distal portion of the implant into the middle phalanx until the shoulder of the inserter is 0.5mm subflush with the surface of the middle phalanx.

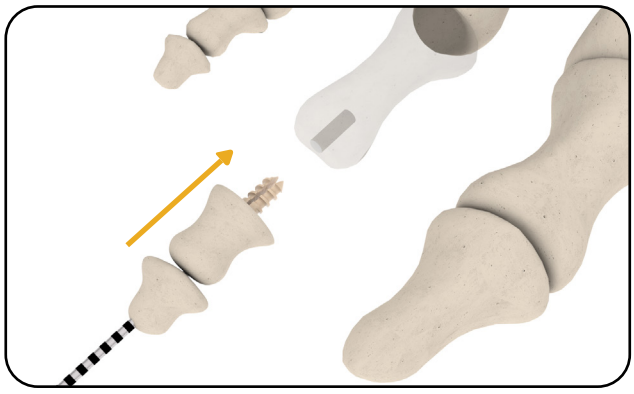


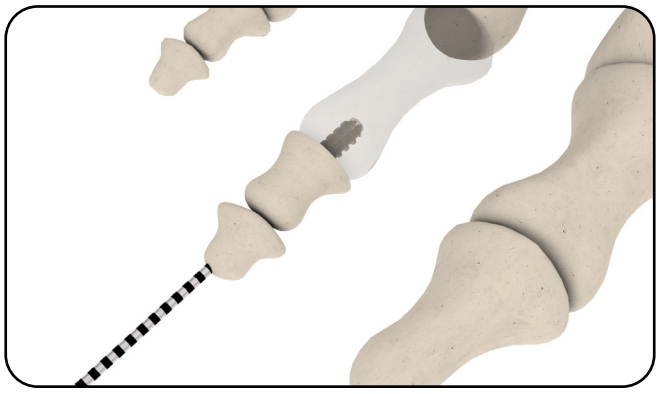
*Position the implant's tines mediolaterally to ease proximal insertion, further advancing the implant if needed.

Step 6 - Proximal Phalanx Implant Insertion

A. Insert Implant

Press fit the implant into the pre-drilled canal of the proximal phalanx.





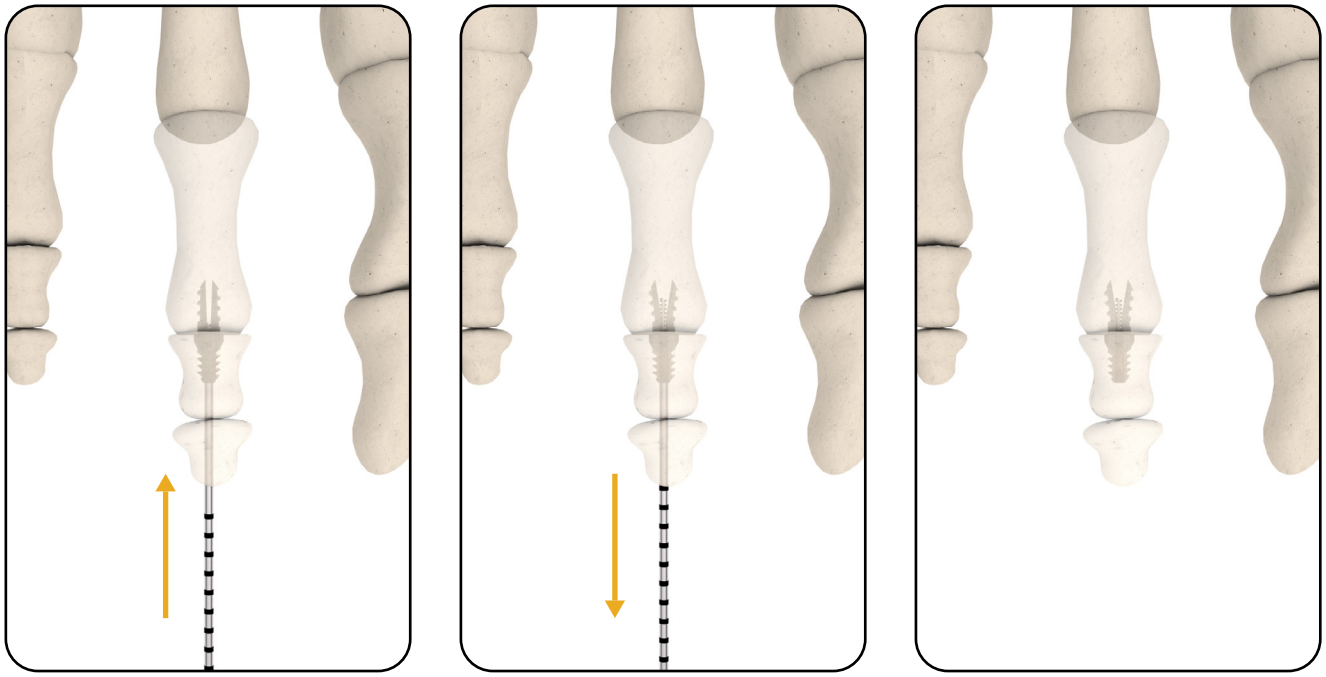
*Do not twist the implant when press fitting into the proximal phalanx to avoid breaking the tines.

Step 6 Continued - Proximal Phalanx Implant Insertion

B. Advance Locator Pin

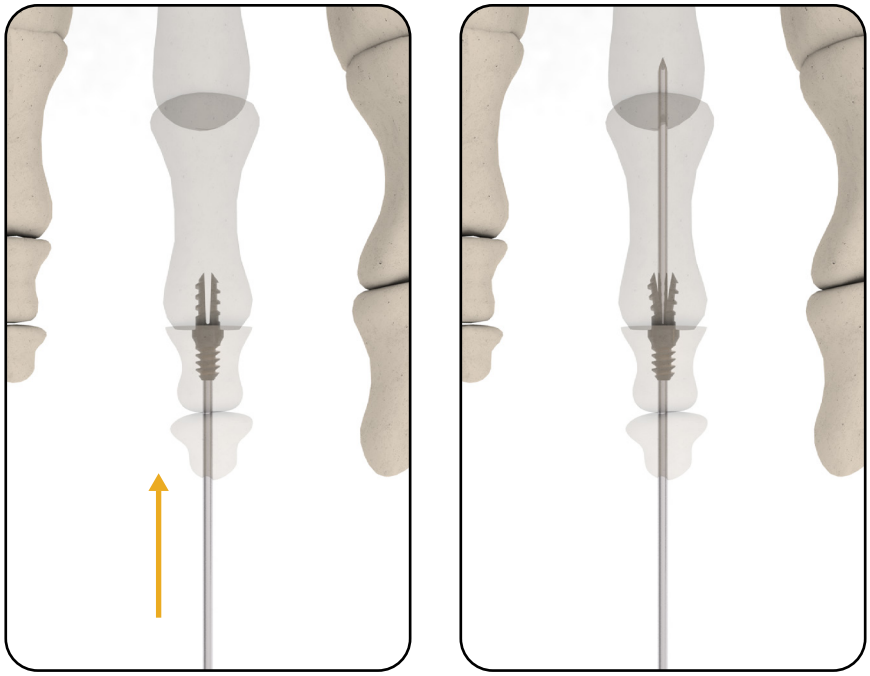
Non-cannulated:

Advance the K-wire to the next laser mark to push the locator pins proximally splaying the proximal legs of the implant, then remove K-wire.



Cannulated:

Advance the K-wire retrograde throught the PIP joint and stop at surgeon desired location.



Indications for Use

The Vector® System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures. The Vector implants may be used without any other additional device. The cannulated implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophalangeal joint.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the Vector System.

Contraindications

Use of the Vector Hammertoe Correction System is contraindicated in the following instances:

- Active or suspected infection
- Patients who are physiologically or psychologically inadequate
- Patients with insufficient quantity or quality of bone to permit stabilization of the bony segments
- Patients with high level of activity where there is a possibility for conservative treatment

Warnings and Precautions

- 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
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site
- The implants and guide wires are intended for single use only
- Instruments and K-wires are to be treated as sharps
- Do not use other manufacturers' instruments or implants in conjunction with the Vector System
- Do not re-sterilize the Vector System implants

Potential Adverse Effects

Potential Complications and Adverse Effects 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 internal stabilization devices.

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized 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 San Antonio, TX 78249

Notes

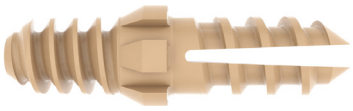
Notes

ORDERING INFORMATION

Vector®
HAMMERTOE CORRECTION SYSTEM

Non-cannulated Hammertoe Implant

Part Number	Description
HAM-13-35	13mm long, 3.5mm Diameter
HAM-14-35	14mm long, 3.5mm Diameter
HAM-15-35	15mm long, 3.5mm Diameter
HAM-15-40	15mm long, 4.0mm Diameter
HAM-16-40	16mm long, 4.0mm Diameter
HAM-17-40	17mm long, 4.0mm Diameter



Cannulated Hammertoe Implant

Part Number	Description
HAM-12-30C	12mm long, 3.0mm Diameter
HAM-13-30C	13mm long, 3.0mm Diameter
HAM-14-30C	14mm long, 3.0mm Diameter
HAM-15-30C	15mm long, 3.0mm Diameter
HAM-13-35C	13mm long, 3.5mm Diameter
HAM-14-35C	14mm long, 3.5mm Diameter
HAM-15-35C	15mm long, 3.5mm Diameter
HAM-15-40C	15mm long, 4.0mm Diameter
HAM-16-40C	16mm long, 4.0mm Diameter
HAM-17-40C	17mm long, 4.0mm Diameter

Instruments

Part Number	Description
HAM-1001T-K11	K-wire (with laser marking)
HAM-1002T-K12	Double Trocar K-wire
HAM-1001T-TP30	Cannulated Tap 3.0mm diameter
HAM-1001T-TP35	Cannulated Tap 3.5mm diameter
HAM-1001T-TP40	Cannulated Tap 4.0mm diameter
HAM-1001T-DR30	Drill, 3.0mm
HAM-1001T-DR35	Drill, 3.5mm
HAM-1001T-DR40	Drill, 4.0mm
HAM-1001T-DR45	Drill, 4.5mm
HAM-1001T-ISRT	Implant Inserter
HAM-1001T-IS30	Implant Inserter, 3.0
HAM-1001T-SIZE	Implant Sizer
CSRW-1000T-500	Handle, Small

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Scan to view Vector® in augmented reality.

HAM-1000L-101 REV B
01/25/2021