helix®

COMPRESSION SCREW SYSTEM

Surgical Technique Guide

NVision™

biomedical technologies

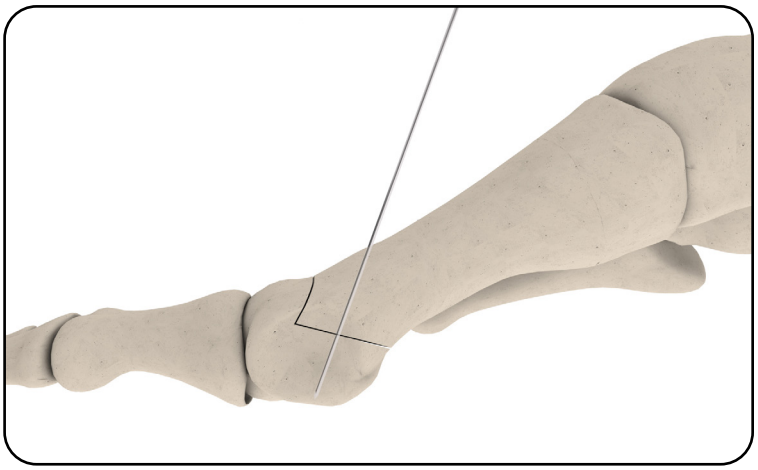
healix®
COMPRESSION SCREW SYSTEM

The Healix® Compression Screw System offers titanium alloy screws and stainless-steel instrumentation to be used for bone fractures, arthrodesis, osteochondritis and tendon reattachment, among other, forefoot, midfoot and hindfoot applications.

The self-drilling and self-tapping screws are offered in headed and headless versions. Special features of the Healix Compression Screws include Stay-Drive™ Technology and Multi-Drive™ Technology.

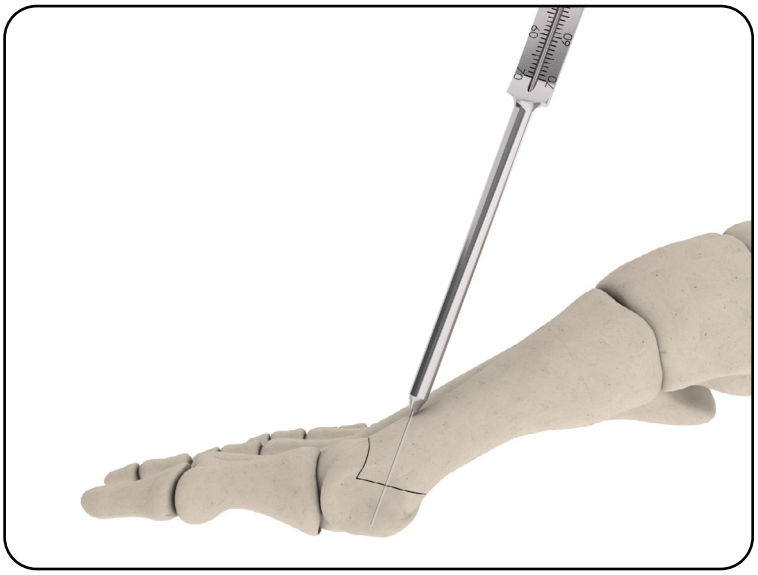
Step 1 - Insert K-wire

Insert the k-wire across fracture/osteotomy site until the distal trocar tip of the k-wire penetrates the far cortex or until desired depth. Verify correct placement using fluoroscopy.



Step 2 - Measure

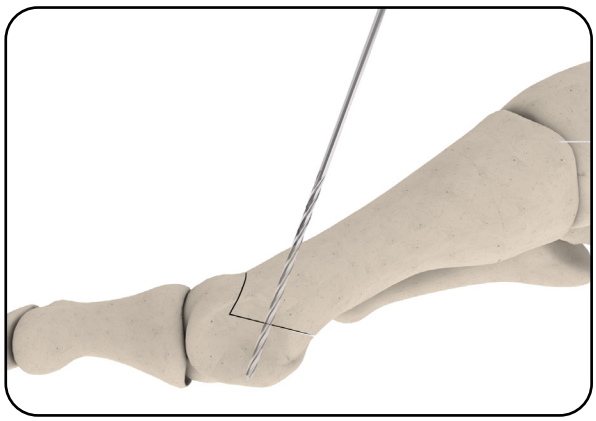
Slide the depth gauge onto the k-wire and slide forward until it reaches the near cortex to determine appropriate screw length.



*For headed screw, complete countersinking before measuring.

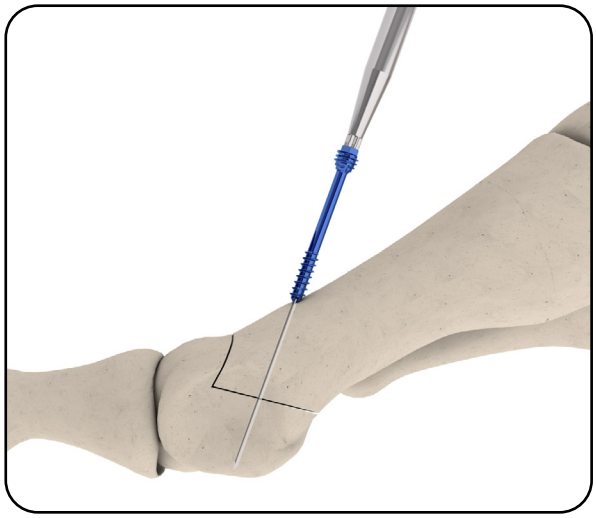
Step 3 - Drill Optional

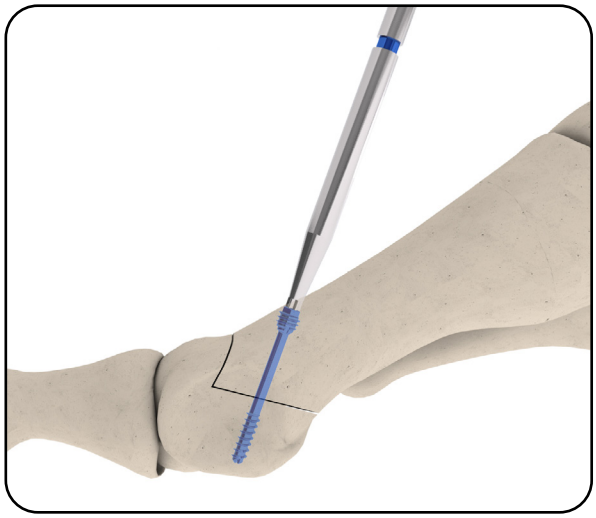
Slide appropriate color-coded cannulated drill over the k-wire based on the screw diameter to be used. Drill to the desired depth or to the far cortex surface to facilitate bi-cortical fixation. Fluoroscopy may be used to aid in drilling depth identification.



Step 4 - Insert Screw

Insert the indicated screw over the k-wire with its corresponding driver. Drive the screw clockwise into the bone until the desired depth and compression is achieved. Confirm placement of screw with fluoroscopy.



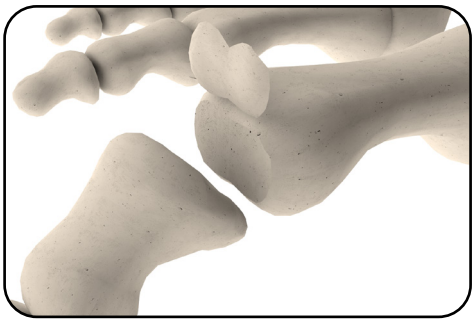


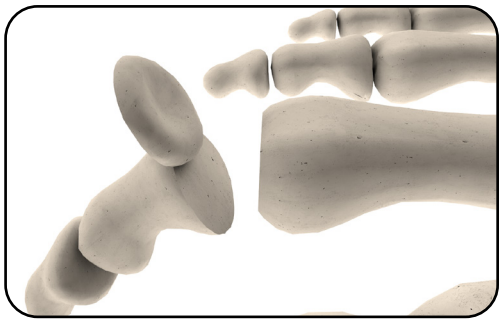
*For headless screws: bury the multidrive feature until it is flush with the bone.

Hammertoe Surgical Technique

Step 1 - Incision

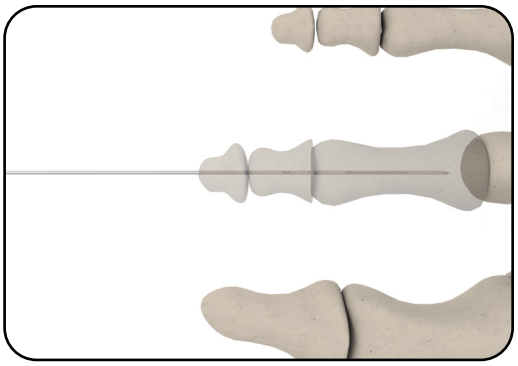
Make an incision dorsally over the PIP joint and retract soft tissue to expose the joint. Using a sagittal saw, remove the articular cartilage from the head of the proximal phalanx and base of intermediate phalanx with a transverse cut.





Step 2 - Insert K-wire

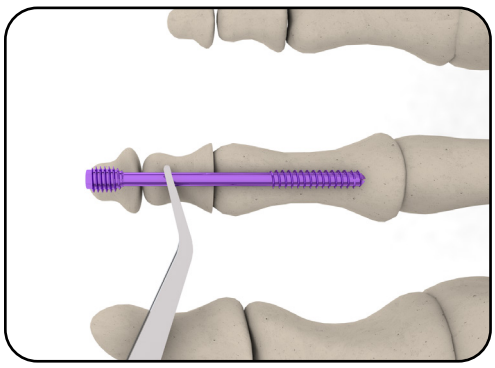
Insert the k-wire into the intermediate phalanx, proximal to distal, and continue through the distal tip of the toe. Retrograde the k-wire and drive into the proximal phalanx.

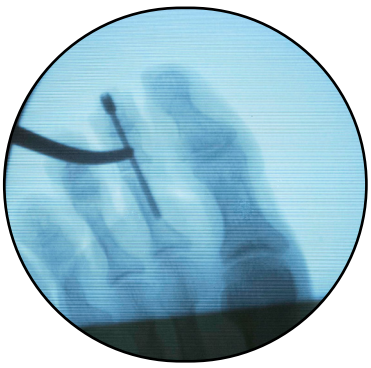


*Verify placement of k-wire with fluoroscopy.

Step 3 - Measure

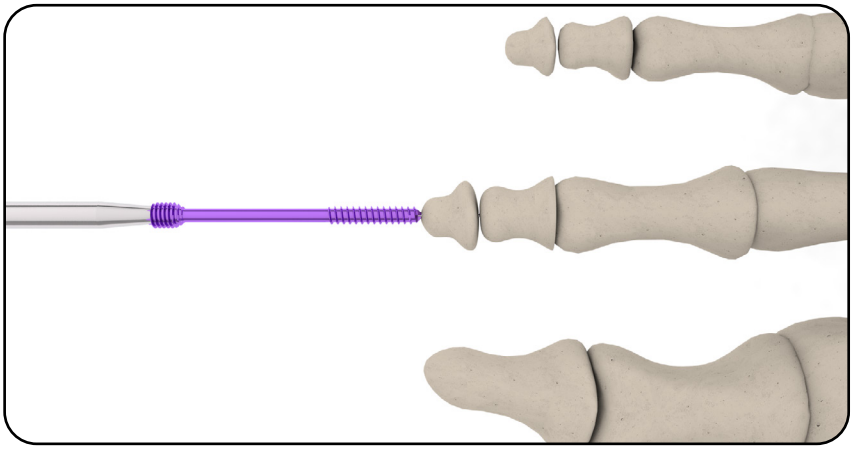
Under fluoroscopy, hold screws over joint to determine appropriate diameter and length.

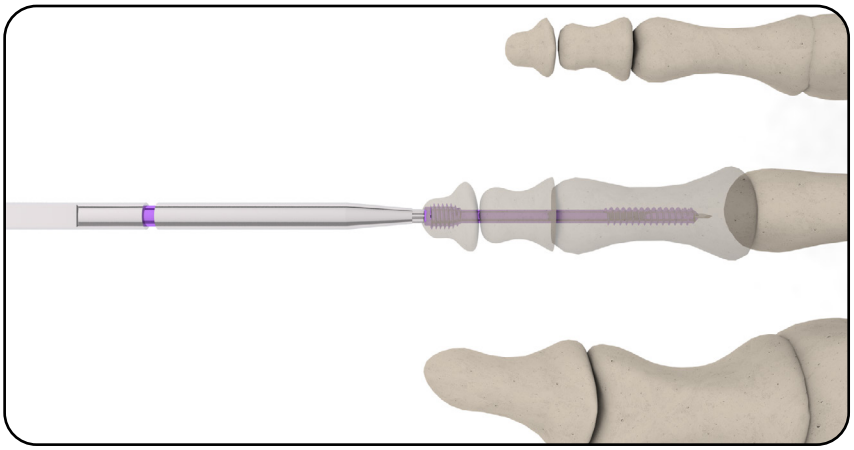




Step 4 - Insert Screw

Make a 3mm horizontal incision at the distal aspect of the toe surrounding the k-wire exit site. Insert the indicated screw over the k-wire with its corresponding driver and advance the screw by rotating it clockwise. Confirm placement using fluoroscopy, remove the k-wire if desired.





Indications for Use
The HEALIX Compression Screw (HCS) System is indicated for Bone Fractures, Osteotomies, Arthrodesis, Osteochondritis, and Tendon Reattachment. It is intended for, but not limited to, Hand Surgery, Orthopedic Surgery, and Podiatric Surgery but is not intended for attachment or fixation to the posterior elements (pedicles) of the spine.

Contraindications
Prior to using the HCS System, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions. These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Warnings and Precautions
- Nvision compression screw systems have not been evaluated for safety and use in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling or respective operative technique.
- Detailed information is included in the instructions for use being attached to every implant. Possible side effects during the implantation of osteosynthesis devices are, delay in consolidation, pseudarthrosis, the implant pulling free, rupture or deformation of all or part of the implant, infection, hematoma, venous thrombosis, pulmonary embolism and cardiovascular problems. Factors capable of compromising implantation success are bone pathology, osteoporosis, bone tumors, systemic or metabolic problems and infectious diseases, senility, mental illness, abuse of illegal drugs, prescription drugs or alcohol, excess weight, intense professional or sporting physical activity that exposes the implant to excessive or repeated loads, risk of conflict with other implants, risk of articular conflict.
- See package insert for warnings, precautions, adverse effects and other essential product information.

Potential Adverse Effects
Possible adverse effects associated with compression screws are infection, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant my break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

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

ORDERING INFORMATION

healix®
COMPRESSION SCREW SYSTEM

Forefoot Compression Screw System

Diameter	Length (2mm increments)
2.0mm	10-30mm *32-50mm
2.5mm	10-30mm *32-50mm
3.0mm	10-40mm *42-50mm

Midfoot Compression Screw System

Diameter	Length (2mm increments)
*3.5mm	16-40mm 42-54mm
*4.0mm	18-50mm 52-60mm
*4.5mm	20-60mm 62-70mm

Hindfoot Compression Screw System

Diameter	Length
*5.0mm	22-60mm (2mm increments)
*5.5mm	24-60mm (2mm increments) 65-75mm (5mm increments)
*6.0mm	26-60mm (2mm increments) 65-90mm (5mm increments)
*6.5mm	42-60mm (2mm increments) 65-100mm (5mm increments)
*7.0mm	30-60mm (2mm increments) 65-130mm (5mm increments)
*7.5mm	30-60mm (2mm increments) 65-130mm (5mm increments)
*8.0mm	30-60mm (2mm increments) 65-120mm (5mm increments)
*8.5mm	30-60mm (2mm increments) 65-140mm (5mm increments)

*Cleared, inquire about availability.

Headless Cannulated Hammertoe Compression Screws with Multi-Drive Technology

Diameter	Length
2.0mm	35mm, 40mm
2.5mm	40mm, 45mm

Nvision™ biomedical technologies

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View Healix in augmented reality.

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