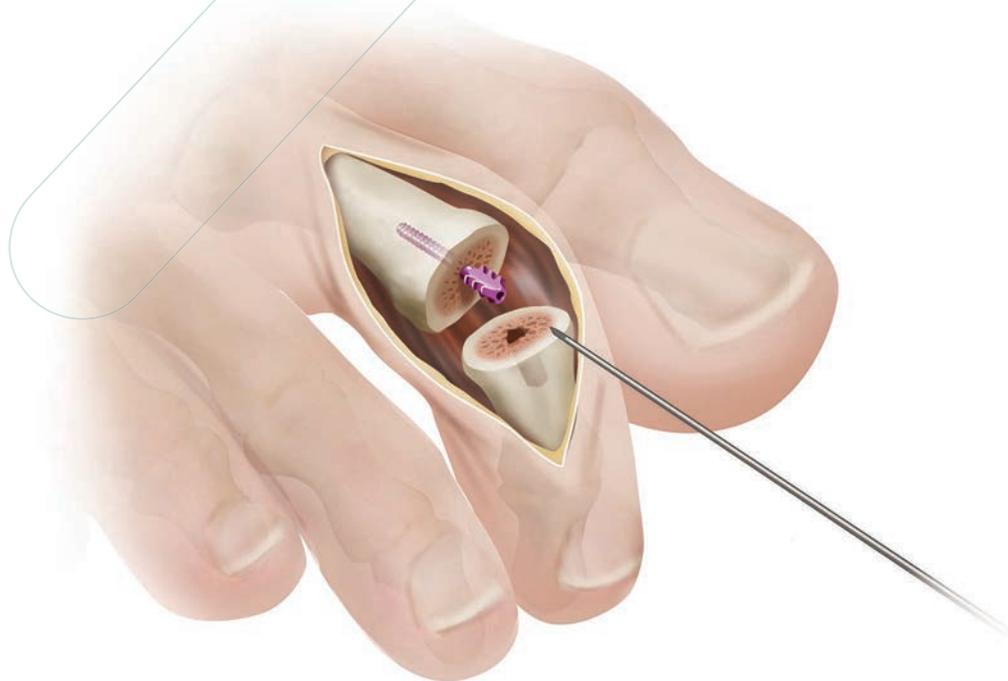


# HammerFUZE™

HAMMERTOE COMPRESSION SYSTEM



**VILEX**

SURGICAL TECHNIQUE

# HammerFUZE™

HAMMERTOE COMPRESSION SYSTEM



## Design Rationale

The HammerFUZE™ Hammertoe Compression System was designed to simplify hammertoe correction surgery by offering a user-friendly system which maximizes compression and stability of the arthrodesis. The system is completely cannulated, extending to both straight and 10° angled implants and instruments (drill, broach, and driver). Cannulation of the one-piece implants provides precise k-wire positioning into the intramedullary canal. The introduction of cannulation also allows for optional insertion of a wire into the metatarsal for additional stabilization during healing.

HammerFUZE™ implants are manufactured from Ti6Al4V titanium alloy for enhanced strength and biocompatibility. The specialized distal end of the implant includes a three-pronged, three-dimensional cutting surface. This design offers increased surface area contact for stable fixation. The distal end's barb-like appearance is designed from the helix of a screw, enabling the surgeon to achieve additional compression using the CompTWIST™ technique. The proximal end of the implant has hand-sharpened cutting tips and is self-drilling and self-tapping, similar to a cannulated Vilex screw.

### INDICATIONS FOR USE

Fixation of osteotomies and reconstruction of the lesser toes and lesser fingers following correction procedures for hammertoe, claw toe, mallet toe, and other deformities of the feet and hands.

# 1 Surgically expose the joint

Locate the dorsal surface of the proximal-intermediate-phalangeal (PIP) joint. Create an incision centrally on this dorsal surface and resect the soft tissue around the joint to expose the bone segments.

# 2 Prepare bone surfaces

Resect the head of the proximal phalanx based on the desired post-surgical joint angle:  $0^\circ$  or  $10^\circ$ , corresponding to the implant selected.

## **$0^\circ$ IMPLANT**

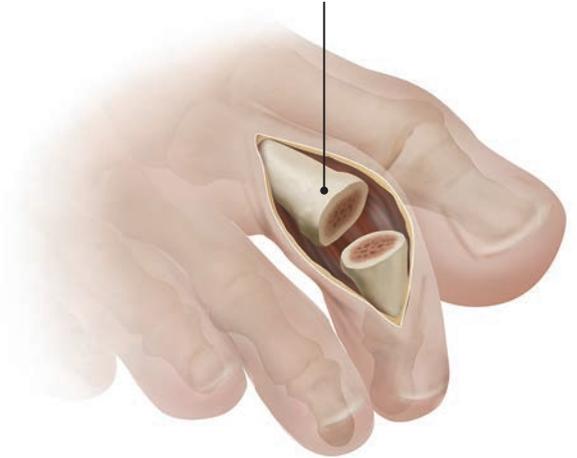
Perpendicular to the medullary canal for a neutral position

## **$10^\circ$ IMPLANT**

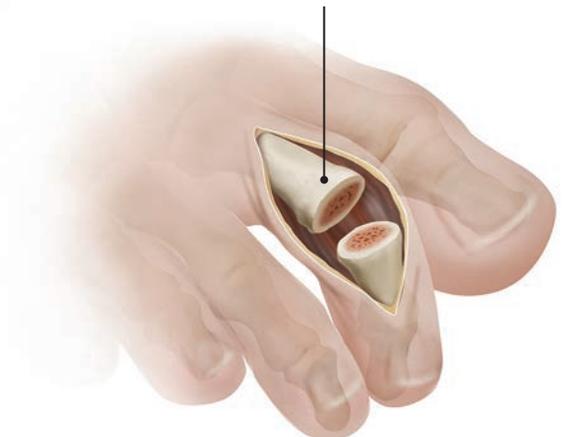
Angled  $\sim 10^\circ$  plantar from the medullary canal for a plantar-biased position

Resect the base of the intermediate phalanx perpendicular to the medullary canal.

RESECTED FOR  $0^\circ$  JOINT ANGLE



RESECTED FOR  $10^\circ$  JOINT ANGLE



### 3 Place the intermediate guide wire

Insert the appropriate guide wire for the selected implant into the medullary canal of the intermediate phalanx:

#### 0.9MM WIRE

For use with 2.2mm implants.

#### 1.1MM WIRE

For use with 2.5mm/3.0mm implants.

Bi-planar fluoroscopy (medial/lateral and dorsal/plantar) is recommended to ensure that the guide wire is located centrally within the canal of the proximal phalanx. If wire placement is not as desired, reposition the wire until a satisfactory position is achieved.

### 4 Drill the medullary canal

Drill the intermediate phalanx using the cannulated 2.0mm stop drill over the installed guide wire.

Ensure the drill advances until the stop on the drill bit makes firm contact with the bone.



#### INSTRUMENTATION USED

- |            |                        |               |
|------------|------------------------|---------------|
| • K100-11D | Wire, Double Trocar    | 1.1mm X 100mm |
| • ZTH-DDRL | Stop Drill, Cannulated | 2.0mm         |

# 5 Broach the medullary canal



## Non-CompTWIST™ TECHNIQUE:

Place the broach over the installed guide wire and align the broach appropriately for the final implant position. The dorsal side of the broach is clearly indicated on the instrument – this side must be aligned dorsally prior to applying pressure on the broach.

Once alignment is verified, advance the broach into the intermediate phalanx until the stop makes firm contact with the bone.



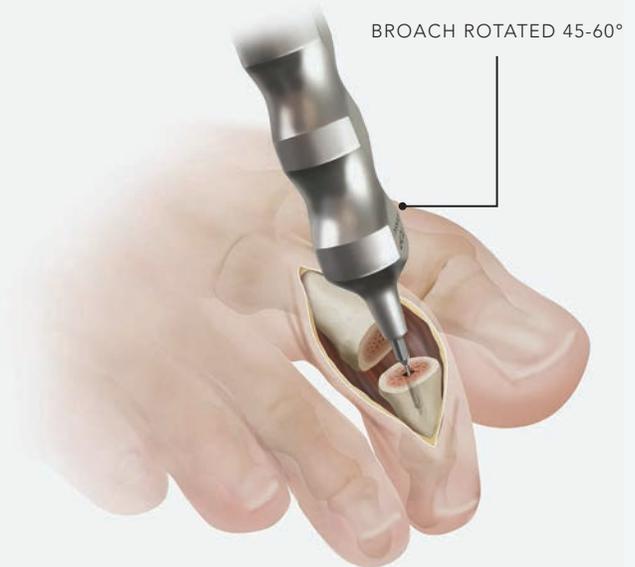
## CompTWIST™ TECHNIQUE:

Place the broach over the installed guide wire and align the broach appropriately for the final implant position.

The dorsal side of the broach is clearly indicated – align this side dorsally to the intermediate phalanx, and then rotate the broach ~45-60° counter-clockwise about the wire (facing distally) prior to applying pressure on the broach.

**NOTE:** Broaching the intermediate phalanx using this orientation will allow use of the CompTWIST™ feature in subsequent steps.

Once alignment is verified, advance the broach into the intermediate phalanx until the stop makes firm contact with the bone.



### INSTRUMENTATION USED

- K100-11D Wire, Double Trocar 1.1mm X 100mm
- ZTH-BRCH Broach

## 6 Wire removal

After drilling and broaching, remove the guide wire from the intermediate phalanx.



## 7 Place the proximal guide wire

Insert the appropriate guide wire for the selected implant into the medullary canal of the proximal phalanx:

### 0.9MM WIRE

For use with 2.2mm implants.

### 1.1MM WIRE

For use with 2.5mm/3.0mm implants.

Bi-planar fluoroscopy (medial/lateral and dorsal/plantar) is recommended to ensure the guide wire is central within the canal. If placement is not as desired, reposition the wire until a satisfactory position is achieved.



#### INSTRUMENTATION USED

- K100-11D Wire, Double Trocar 1.1mm X 100mm

# 8 Prepare implant for driving

Place the selected implant into the driver by inserting the barbed end of the implant into the appropriate cavity on the end of the driver instrument:

## USE OF THE CORRECT DRIVER END

Ensure the correct end of the driver is used based on the selected implant angle (0° or 10°). Markings indicate one end of the driver is used exclusively with 0° implants and the opposite end is used exclusively with 10° implants. Ensure the orientation of the implant within the driver is correct:

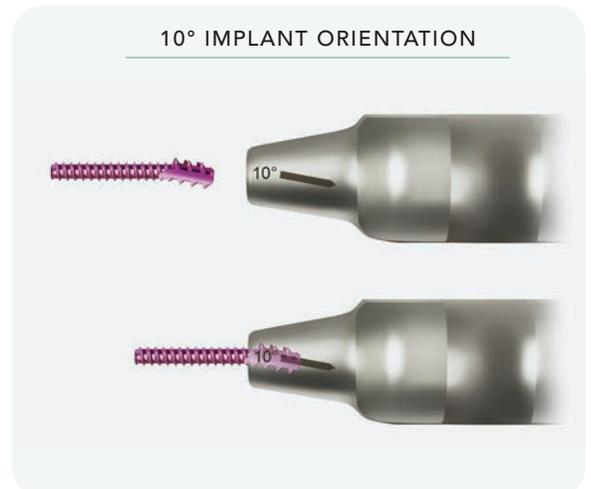
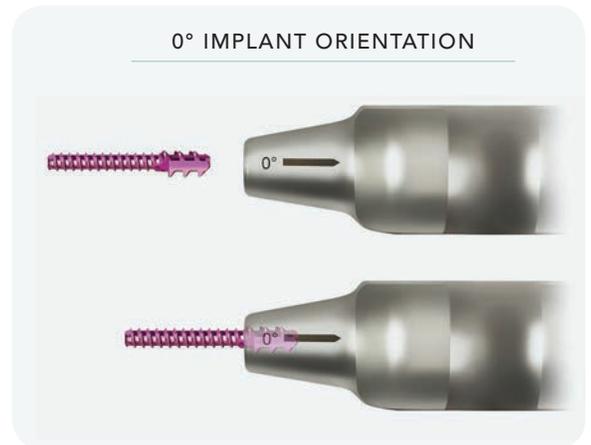
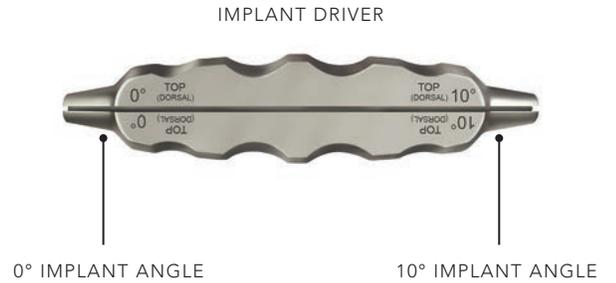
## 0° IMPLANT ORIENTATION

The 0° implant may be placed in any orientation within the driver.

## 10° IMPLANT ORIENTATION

The 10° implant must be inserted in the direction shown on the side of the driver – when placed correctly, the proximal side of the implant will be aligned with the body of the driver.

If the implant is not fully inserted into the driver, the guide wire may not thread through the apparatus in the following step; ensure the implant is fully-seated within the driver cavity.



### INSTRUMENTATION USED

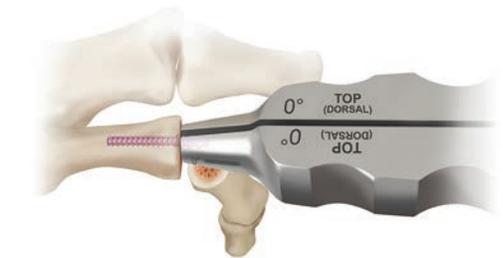
- ZTH-DRVR Driver, Double-Sided
- Implants shown: TH30-25T-1100 and TH30-25T-1110

## 9 Implantation (proximal phalanx)

Place the implant/driver over the installed guide wire. Ensure that the wire can advance through the implant and into the body of the driver – if not, revisit the previous step to ensure the implant is seated fully within the driver.

Thread the implant into the proximal phalanx using the driver. Drive the implant until the barb region is against the proximal phalanx bone.

Once the barb region makes contact with the phalanx, advance the implant further until the driver is positioned anatomically with the dorsal side (labeled on the driver) aligned dorsally to the phalanx. This positions the implant correctly with regard to orientation and depth.



## 10 Wire removal (proximal phalanx)

After installing the implant into the proximal phalanx, remove the driver from the implant and the wire from the phalanx.

### INSTRUMENTATION USED

- K100-11D Wire, Double Trocar 1.1mm X 100mm
- ZTH-DRVR Driver, Double-Sided
- Implant shown: TH30-25T-1100

# 11 Install the implant into the intermediate phalanx

## Non-CompTWIST™ TECHNIQUE:

Place the barbed region of the implant into the broached hole within the intermediate phalanx, ensuring that the two phalanges are aligned. Compress the joint by applying pressure on each segment – this will advance the barbed region into the intermediate phalanx. Pressure should be applied until the proximal and intermediate phalanges are fully in contact with one another across the resection line.

If the implant does not fully seat and a gap is present, separate the intermediate phalanx from the implant and repeat the drilling/broaching process (Steps 4-5) prior to re-attempting this step. Alternatively, the implant may be driven further into the proximal phalanx using the driver (Step 9) in order to allow complete bridging of the bone anatomy across the space.



## CompTWIST™ TECHNIQUE:

Rotate the intermediate phalanx clockwise (facing distally) by  $\sim 45-60^\circ$  to align the previously-broached phalanx with the implant barbed region. Place the barbed region of the implant into the broached hole within the intermediate phalanx. Compress the joint by applying pressure on each segment – this will advance the barbed region into the intermediate phalanx. Pressure should be applied until the proximal and intermediate phalanges are fully in contact with one another across the resection line.

Firmly grasp the proximal and intermediate phalanges and twist the intermediate phalanx counter-clockwise (facing distally) by  $\sim 45-60^\circ$  until it is aligned anatomically to the proximal phalanx. Apply axial pressure during this twist motion to facilitate compression.



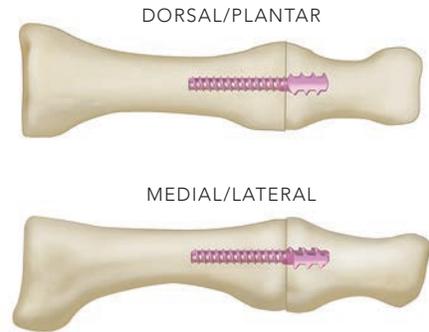
### INSTRUMENTATION USED

- Implant shown: TH30-25T-1100

# 12 Ensure correct installation

Use bi-planar fluoroscopy (dorsal/plantar and medial/lateral) to verify that the implant is fully-seated within each bone segment and that the two phalanges are in bone-to-bone contact across the resected regions.

Implant resides centrally in both medial/lateral and dorsal/plantar directions, with bone in contact around implant and no gapping.



## Item Listing

VILEX P/N	DESC	CASE QTY	TYPE
TH22-18T-0900	HammerFuze Fusion Device - Titanium, 0° Angle, 2.2mm X 18mm	8	Implant
TH22-18T-0910	HammerFuze Fusion Device - Titanium, 10° Angle, 2.2mm X 18mm	4	Implant
TH25-20T-1100	HammerFuze Fusion Device - Titanium, 0° Angle, 2.5mm X 20mm	8	Implant
TH25-20T-1110	HammerFuze Fusion Device - Titanium, 10° Angle, 2.5mm X 20mm	4	Implant
TH30-25T-1100	HammerFuze Fusion Device - Titanium, 0° Angle, 3.0mm X 25mm	8	Implant
TH30-25T-1110	HammerFuze Fusion Device - Titanium, 10° Angle, 3.0mm X 25mm	4	Implant
ZTH-DDRL	Stop Drill, Cannulated, AO Connect	2	Instrument
ZTH-BRCH	Broach	1	Instrument
ZTH-DRVR	Driver, Double-Sided Instrument	1	Instrument
Z255	Screw Handling Forceps	1	Instrument
K100-09D	Wire, Double Trocar, 0.9mm X 100mm	6	Instrument
K100-11D	Wire, Double Trocar, 1.1mm X 100mm	6	Instrument



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