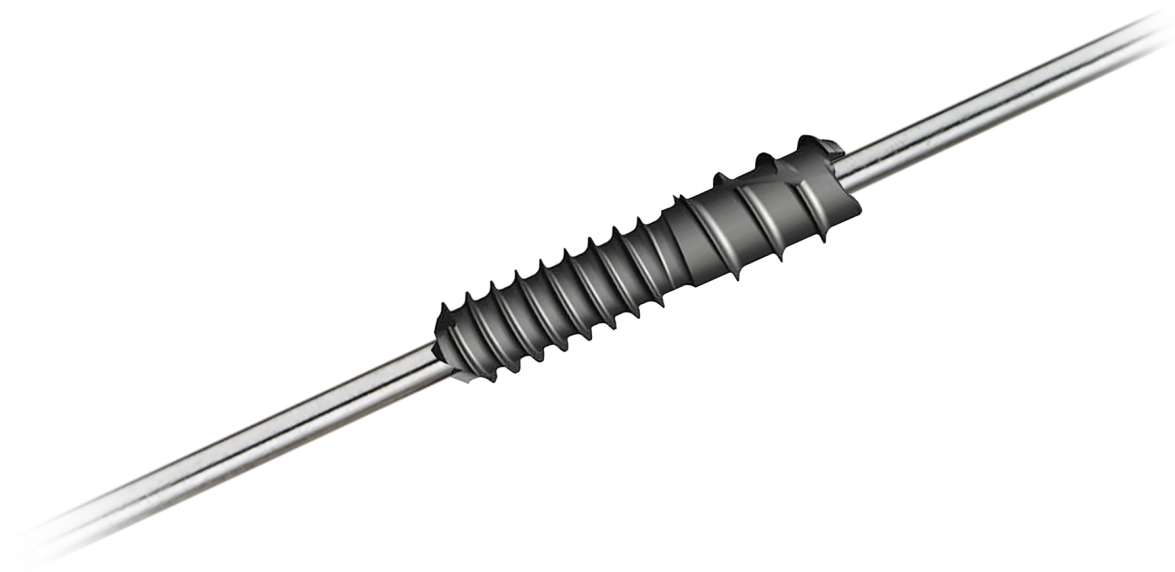


# Pro-toe<sup>®</sup> C2

## Hammertoe Fixation System

### Operative technique



# Pro-toe® C2

## Hammertoe Fixation System

### Table of contents

|  |           |
|--|-----------|
| <b>Introduction</b>                      | <b>3</b>  |
| <b>Indications and contraindications</b> | <b>4</b>  |
| <b>Operative technique</b>               | <b>5</b>  |
| <b>Ordering information</b>              | <b>12</b> |

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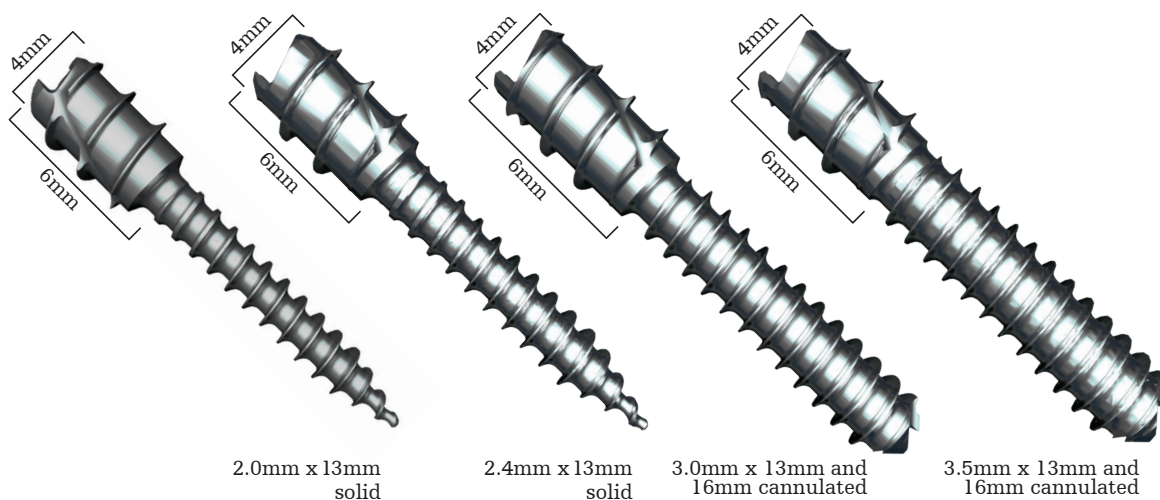
Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the package insert is available on the website listed.

# Introduction

## Device description

Pro-toe C2 Hammertoe Fixation System provides versatility, addressing two common indications of the lesser toes—hammertoe correction and MTP joint instability correction. The unique insertion method allows for compression of the proximal interphalangeal joint (PIPJ) while maintaining the integrity of the distal interphalangeal (DIP) joint. Utilizing differential thread pitches, the Pro-toe C2 provides a compression ratio of 1.75mm:1mm per revolution.

Implant options include solid or cannulated dependent on diameter. To accommodate all the lesser digits, and various patient anatomy and bone quality, the system is offered in four diameters in either 13mm and/ or 16mm lengths. Implants are offered in stainless steel.



The instrumentation is streamlined and simple. The Pro-toe C2 tray is provided non-sterile and includes implants and instruments. The tray has been designed to promote ease of use by color-coding implants to drills. A reference chart is also provided on the side of the tray.



# Indications and contraindications

## Indications

The Pro-toe Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated implants in the Pro-toe Hammertoe Fixation Systems can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g., MTP joint).

The implantable k-wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, implantable k-wires are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal (MTP) joint instability.

## Contraindications

- Active or suspected infection or in patients who are immunocompromised
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity
- Patients previously sensitized to stainless steel
- Patients with certain metabolic diseases
- Patients exhibiting disorders, which would cause the patient to ignore the limitations of internal fixation

**There are no contraindications specific to the products.** Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications, and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the package insert is available on the website listed.

## Operative technique

### Incision and proximal phalanx resection

In preparation for the implantation of the Pro-toe C2 Implant, an elliptical or longitudinal incision is created dorsally over the proximal IPJ.

#### NOTICE

The procedure for soft tissue exposure is under the discretion of the surgeon.

Resect the head of the proximal phalanx using a sagittal saw.

#### NOTICE

It is not recommended to use a sagittal saw on the middle phalanx.

### Proximal phalanx preparation

Insert the k-wire (PN45750001 or 45750003) into the center of the proximal phalanx.

#### NOTICE

Two k-wire sizes are available in the kit. Selection of k-wire size is under the discretion of the surgeon. Consideration should include, but not limited to, implant size selection and patient bone quality (Table A, page 6).

Attach the appropriate cannulated drill (PN45810003 or 45810004) to the AO cannulated handle (PN45765001) (Table A, page 6). Insert over the k-wire and drill by hand to the appropriate laser mark depending on implant length selection. The first laser mark is 13mm and the second laser mark is 16mm.

Remove drill and k-wire from proximal phalanx.

#### NOTICE

When preparing the proximal phalanx for the 2.0mm and 2.4mm solid implants, care should be taken to ensure the k-wire is driven to a minimum depth of 13mm. This may be verified under fluoroscopy.

PN45750001 k-wire 1.1mm

PN45750003 k-wire 1.6mm

PN45810003 drill 2.2mm

PN45810004 drill 2.6mm

PN45765001 AO cannulated handle

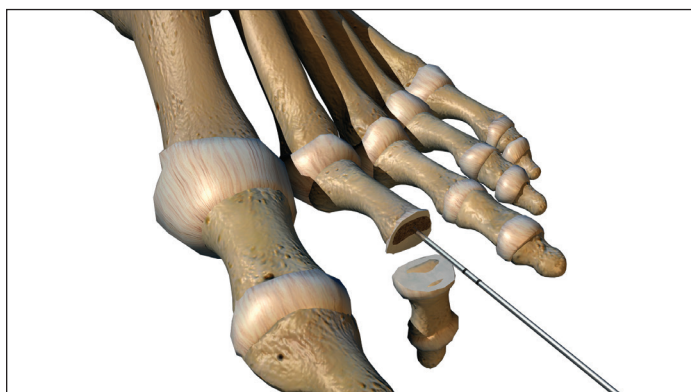


Figure 1

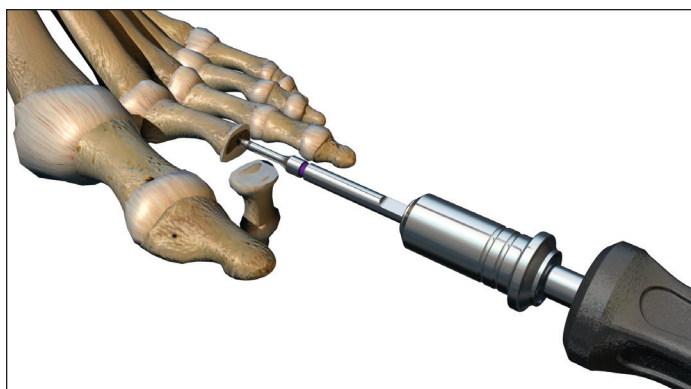


Figure 2

| Implant diameter | Accepted k-wire size |                 | Recommended drill for proximal phalanx |
|------------------|----------------------|-----------------|--|
|                  | 1.1mm (0.045in)      | 1.6mm (0.062in) |  |
| 2.0mm            | NA - solid core      | NA - solid core | No drill 1.1mm k-wire only             |
| 2.4mm            | NA - solid core      | NA - solid core | No drill 1.1mm k-wire only             |
| 3.0mm            | X                    |                 | 2.2mm                                  |
| 3.5mm            | X                    | X               | 2.6mm                                  |

Table A

### Middle phalanx preparation

Insert the 1.1mm or 1.6mm k-wire into the center of the middle phalanx. The k-wire may be advanced out of the distal end of the toe. Adequate length of k-wire must be left proximally to engage the planar.

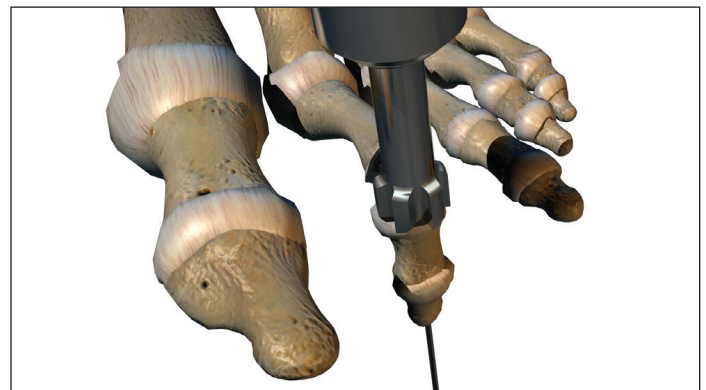


Figure 3

Use the planar (PN45765004 or 45765005) to manually prepare the joint surface. Attach the planar to the AO cannulated handle. The planar is cannulated and should be inserted over the k-wire. Rotate the planar to remove the cartilage. This technique helps minimize shortening of the digit and damage to the surrounding soft tissue.

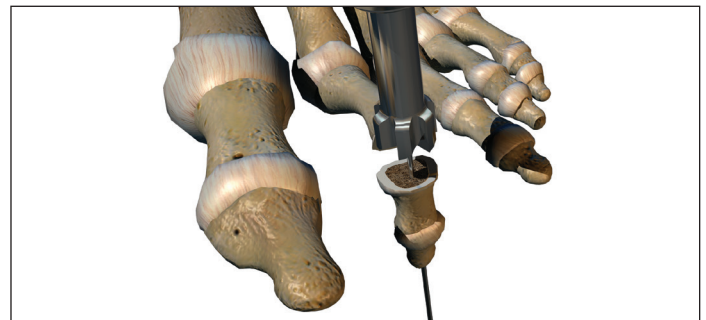


Figure 4

Using as a countersink, attach the 3.2mm drill (PN45765003) to the AO cannulated handle and insert over the k-wire. Insert to first laser mark and then remove the 3.2mm drill and the k-wire.



PN45765004 planar 6.5mm



PN45765005 planar 7.5mm



PN45765003 drill 3.2mm

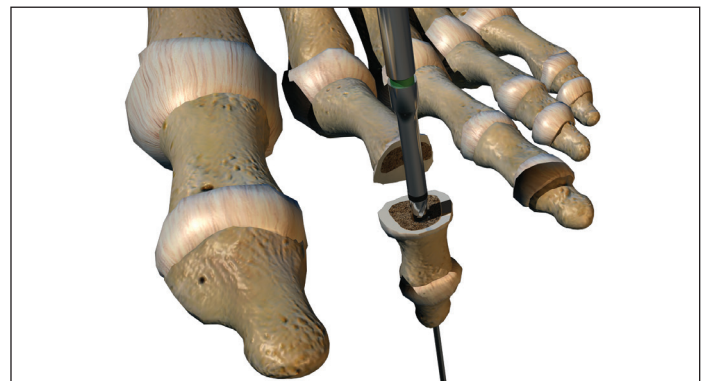


Figure 5



## Implant insertion – proximal phalanx

Attach the driver (PN45805002) to the mini QC handle (PN45805001) and select the appropriate implant size. To attach the mini QC handle to the driver, align the laser mark on the mini QC handle with the flat of the trocar end of the driver.



PN 45805002 driver



PN 45805001 mini QC handle

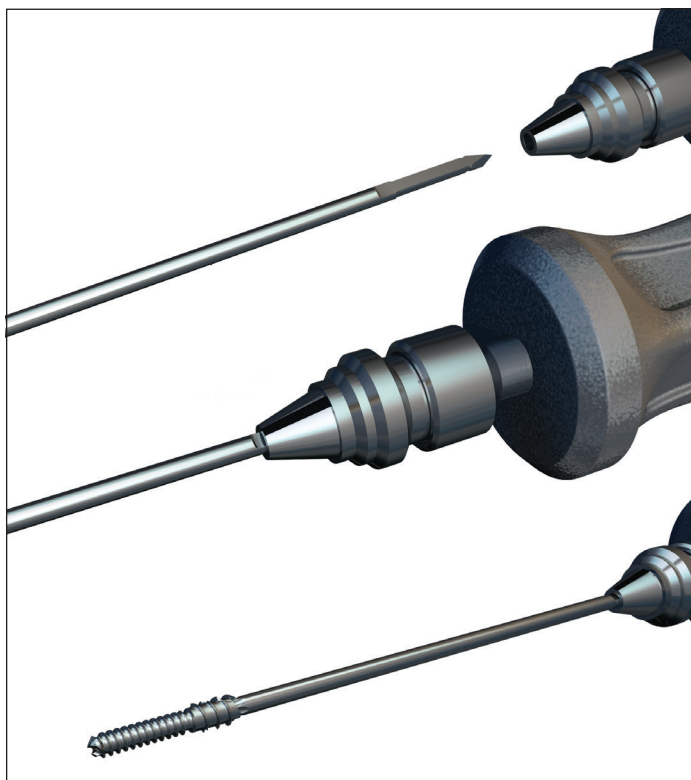


Figure 6

Fully seat the implant into the proximal phalanx. Remove the driver from the mini QC handle.

### **NOTICE**

Diameter of driver is 2.5mm.

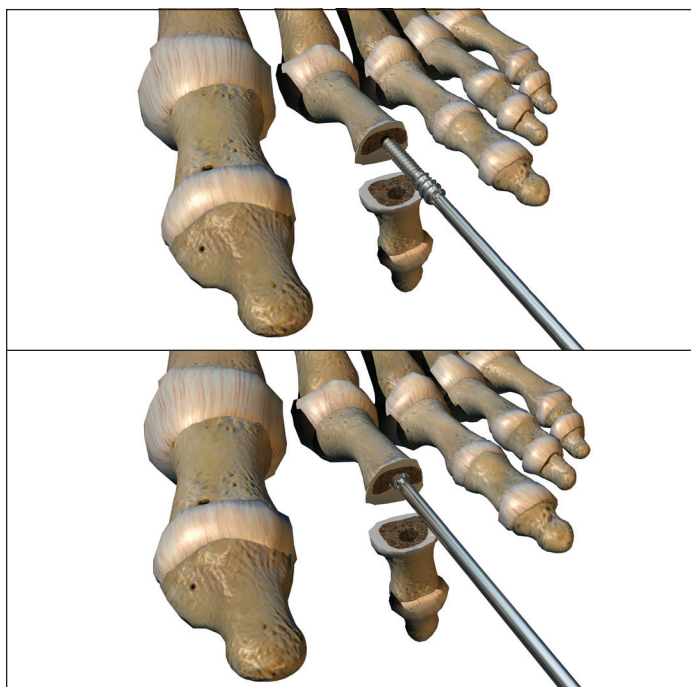


Figure 7

## Implant insertion – middle phalanx

Load the hexalobe end of the driver into the wire driver. Drive the trocar end of the driver distally into the middle phalanx until the hexalobe reaches the joint surface.

### NOTICE

An extra T8 hex driver (PN45805003) has been provided in case the implant needs to be adjusted in the proximal phalanx.

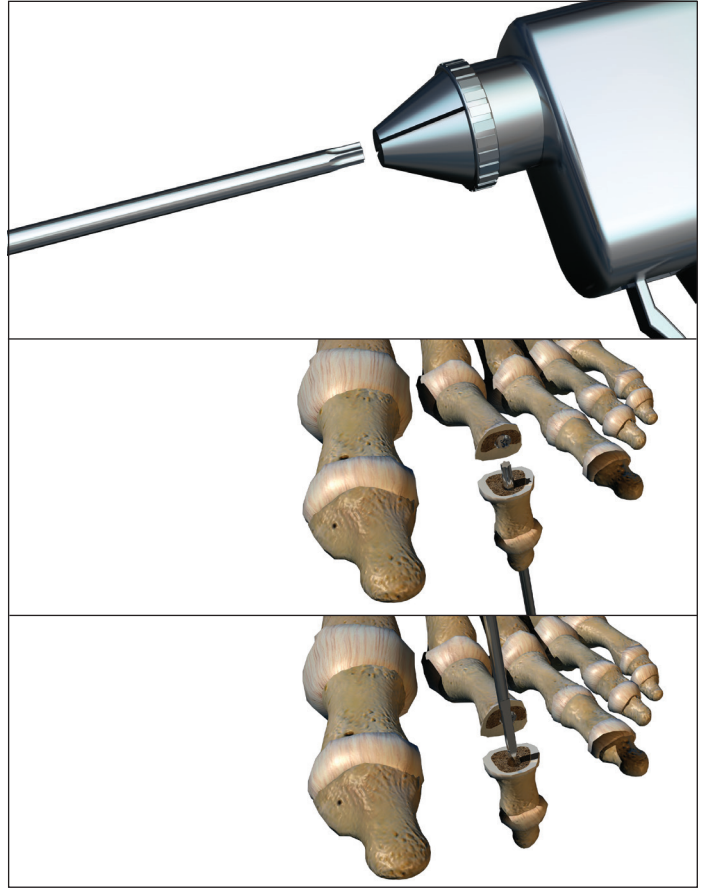


Figure 8

Reattach the driver to the mini OC handle and dock the distal portion of the implant onto the hexalobe and close the joint. While applying slight forward pressure, turn the mini OC handle three revolutions counterclockwise.

Manually remove driver out distal end of toe.



PN45805003 T8 hex driver

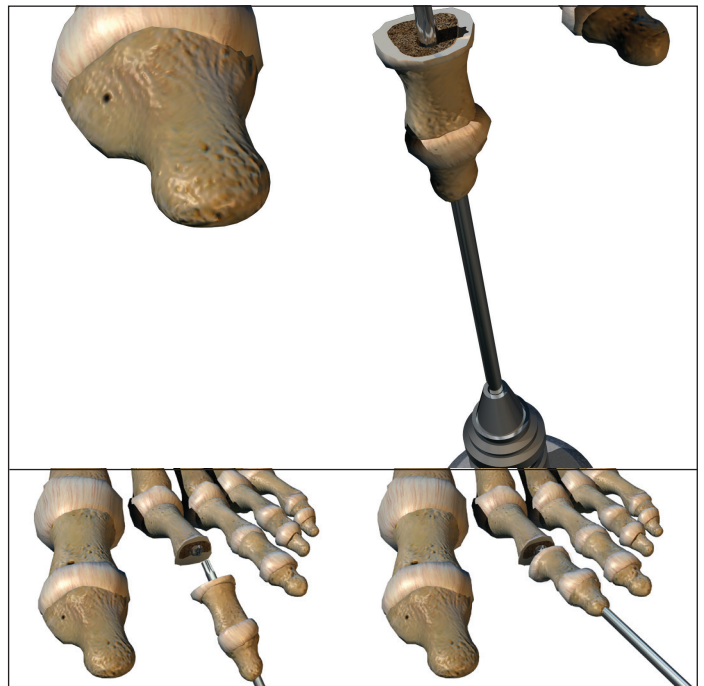


Figure 9



**NOTICE**

It is recommended to view under fluoroscopy after three revolutions while the driver is engaged.

**NOTICE**

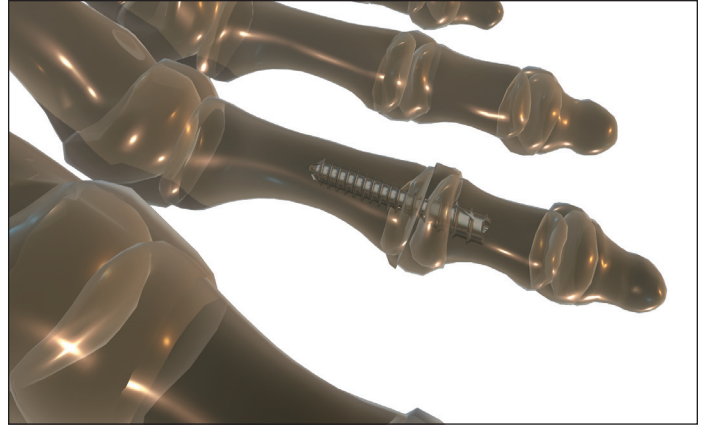
One or two additional turns may be required to help dock the middle phalanx onto the distal end of the implant.

**⚠ CAUTION**

After the distal portion of the implant is in the middle phalanx, the joint can only be compressed by driving the implant distally (i.e., counterclockwise). Once the distal threads are engaged in the middle phalanx, distraction of the joint may occur if the implant is driven proximally (i.e., clockwise).

**NOTICE**

The procedure for soft tissue repair is under the discretion of the surgeon.



**Figure 10**

## Hammertoe correction and MTP joint instability correction (3.0mm and 3.5mm implants only)

After implant insertion, manually insert and align the k-wire through the distal end of the toe. To maintain appropriate trajectory, follow the path created by the driver to insert k-wire into the cannulated implant. Using power, drive the k-wire proximally through the implant and across the MTP joint.

Selection of the k-wire size is dependent on implant size and surgeon discretion (Table B).

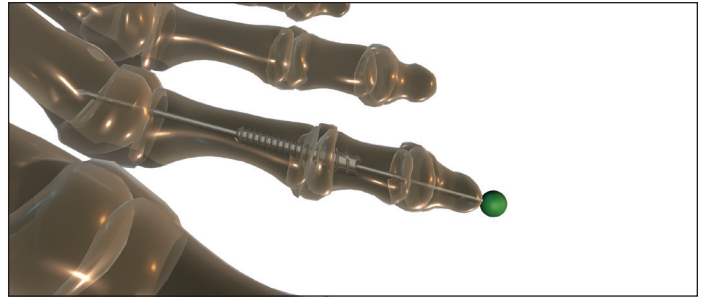


Figure 11

| Implant diameter | Accepted k-wire size |                 |
|------------------|----------------------|-----------------|
|                  | 1.1mm (0.045in)      | 1.6mm (0.062in) |
| 2.0mm            | NA - solid core      | NA - solid core |
| 2.4mm            | NA - solid core      | NA - solid core |
| 3.0mm            | X                    |                 |
| 3.5mm            | X                    | X               |

Table B

If the k-wire is intended to be left implanted, cut and cap the end of the k-wire external to the toe per standard protocol.

### NOTICE

Fluoroscopy may be used to verify alignment of the k-wire with the implant.

### NOTICE

The procedure for soft tissue repair is under the discretion of the surgeon.

## Postoperative protocol

Postoperative protocol is under the discretion of the surgeon and may be dictated by adjunct procedures. Typical protocols recommend protected weight-bearing in a postoperative shoe or fracture boot for approximately four to six weeks. This applies to procedures performed in isolation.

## Explant information

The need for implant removal should be exceedingly rare, but there may be instances when it is necessary or desired (e.g., deep infection). In these cases, the dorsal incision is recreated to allow access to the PIPJ. If the implant is loose, it may be possible to distract the toe and dislocate the PIPJ, exposing the distal end of the implant. The implant can then be backed out using the driver.

In the event there is solid arthrodesis and it is necessary to remove the implant, a corticotomy will be needed at the level of the original PIPJ. The corticotomy is carried down to the implant and a small section of bone is removed, exposing the implant. This technique requires re-insertion of the hexalobe end of the driver through the distal end of the toe. Once engaged with the implant, turn the handle clockwise to distract the joint.

Another option is to use a Steinmann pin cutter through the resected joint line, cutting the implant into two halves. At this point, manually back out each half of the implant.

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 operative technique, to receive instructions for returning the explanted device to the manufacturer for investigation.

### **NOTICE**

Removal of the implant is under the discretion of the surgeon.

# Ordering information

## Implants

| Non-sterile, stainless steel | Part number |
|------------------------------|-------------|
| 2.0mm x 13mm                 | 45802013    |
| 2.4mm x 13mm                 | 45802413    |
| 3.0mm x 13mm                 | 45803013    |
| 3.0mm x 16mm                 | 45803016    |
| 3.5mm x 13mm                 | 45803513    |
| 3.5mm x 16mm                 | 45803516    |

## Implantable k-wire

| Non-sterile, stainless steel | Part number |
|------------------------------|-------------|
| 1.1mm x 150mm                | 45750001    |
| 1.6mm x 150mm                | 45750003    |

## Instruments

| Description                     | Part number |
|---------------------------------|-------------|
| Mini OC handle                  | 45805001    |
| Driver (with trocar)            | 45805002    |
| T8 hex driver                   | 45805003    |
| Driver handle AO (cannulated)   | 45765001    |
| Drill 2.2mm                     | 45810003    |
| Drill 2.6mm                     | 45810004    |
| Drill 3.2mm                     | 45765003    |
| Planar 6.5mm (cannulated 1.6mm) | 45765004    |
| Planar 7.5mm (cannulated 1.6mm) | 45765005    |

## Foot & Ankle

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