SURGICAL TECHNIQUE GUIDE:

PROXIMAL INTERPHALANGEAL JOINT ARTHRODESIS

PRESERVE™

HAMMERGRAFT™ SYSTEM

Exclusively foot & ankle

Paragon 28®

Acknowledgment:

Paragon 28® would like to thank Mark Myerson, M.D. and Thomas San Giovanni M.D. for their contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

The patent-pending HammerGraft™ System is part of the Paragon 28® PRESERVE™ line of biologic products, which includes minimally manipulated, aseptically processed allograft tissue. The instrumentation provided supports versatility in surgical technique, allowing for surgeon preference to dictate technique. A standard technique can be performed that allows direct drilling and placement of the implant, starting on page 4. A retrograde technique can be performed with initial K-wire placement determining toe position, starting on page 8.

CONCEPT FOR FIXATION

The implant was designed to provide the following advantages over a K-wire:

- A press fit is accomplished between the implant and bone due to a controlled, precise interference between the drill hole and the rib height on the HammerGraft™ implant
- This precise interference minimizes crushing of cancellous bone upon insertion and helps to resist pullout of the HammerGraft™ implant [1]
- The cross section of the HammerGraft™ implant helps to resist rotation
- HammerGraft™ implants are cut from tibial and femoral cortical bone
- HammerGraft™ Cancellous Spacers are harvested from areas of dense cancellous bone to allow for quicker graft incorporation while maintaining length of toe
- HammerGraft™ implants and Cancellous Spacers are processed aseptically without the use of gamma irradiation or hydrogen peroxide
- Packaged in hydration solution - no reconstitution necessary

IMPLANT OFFERING

2.3 mm Straight HammerGraft™

2.3 mm 10° Angled HammerGraft™

2.8 mm Straight HammerGraft™

2.8 mm 10° Angled HammerGraft™

HammerGraft™ Cancellous Spacer

2.3 mm x 6 mm | **2.3 mm x 8 mm** | **2.3 mm x 10 mm** | **2.8 mm x 6 mm** | **2.8 mm x 8 mm** | **2.8 mm x 10 mm**

Implant Size:	Instrument Size:
2.3 mm	1.10 mm K-wire
	1.10 mm Trocar Insert
	2.30 mm Cannulated Drill*
	1.10 mm Blunt K-wire
	2.30 mm Inserter

Implant Size:	Instrument Size:
2.8 mm	1.40 mm K-wire
	1.40 mm Trocar Insert
	2.80 mm Cannulated Drill*
	1.40 mm Blunt K-wire
	2.80 mm Inserter

* Actual drill diameter is adjusted a proprietary amount to provide interference with the ribs on the respective HammerGraft implant.

INSTRUMENTS

Planer, Ø8.0 mm

Trocar Insert, Ø1.10 mm

Trocar Insert, Ø1.40 mm

Cannulated Drill, Ø2.30 mm*

Cannulated Drill, Ø2.80 mm*

Blunt K-wire for Retrograde Technique, Ø1.10 mm

Blunt K-wire for Retrograde Technique, Ø1.40 mm

Inserter, Ø2.30 mm

Inserter, Ø2.80 mm

Double Trocar K-wire for Retrograde Technique, Ø1.10 mm

Double Trocar K-wire for Retrograde Technique, Ø1.40 mm

* Actual drill diameter is adjusted a proprietary amount to provide interference with the ribs on the respective HammerGraft implant.

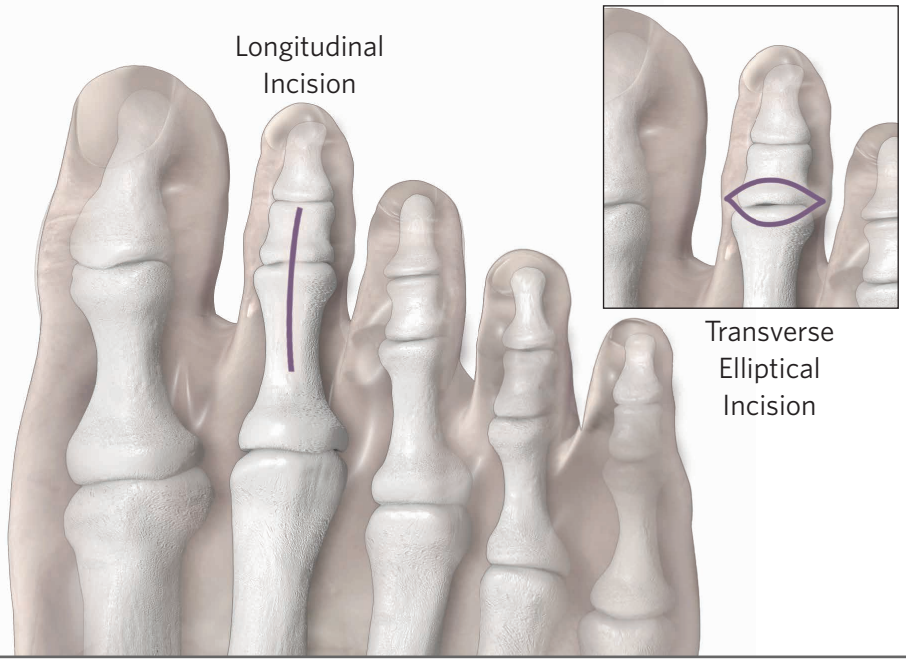
IMPLANT SELECTION

Use direct visualization intraoperatively to determine implant size. It is recommended to start with a smaller drill size and go up a drill size if there is not sufficient resistance to the drill.

INCISION/EXPOSURE

Proximal interphalangeal joint (PIPJ) arthrodesis may be performed as a sole procedure or combined with other procedures to address multiple deformities.

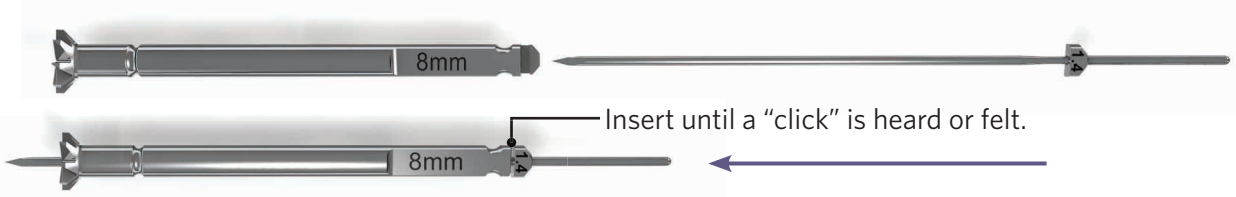
A longitudinal or transverse elliptical incision can be performed based on surgeon preference. Dissection is carried down to expose the proximal interphalangeal joint.

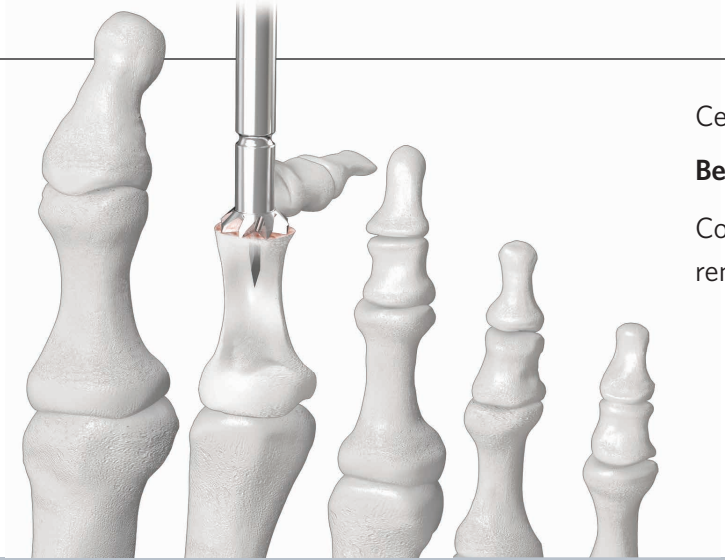


JOINT PREPARATION

A sagittal saw or hand-held bone cutter is used to resect the cartilage at the head of the proximal phalanx. It is necessary to make the cut at the level of the condyles to allow passage of the implant into the middle phalanx during insertion.

TIP: Alternatively, the planer can be used to remove cartilage from the proximal phalanx or to provide further resection after the sagittal saw cut. The trocar insert should be placed inside the planer.





Center the trocar on the proximal phalanx.

Begin movement of the planer prior to contacting bone.

Continue to engage the planer until all cartilage is removed from the head of the proximal phalanx.

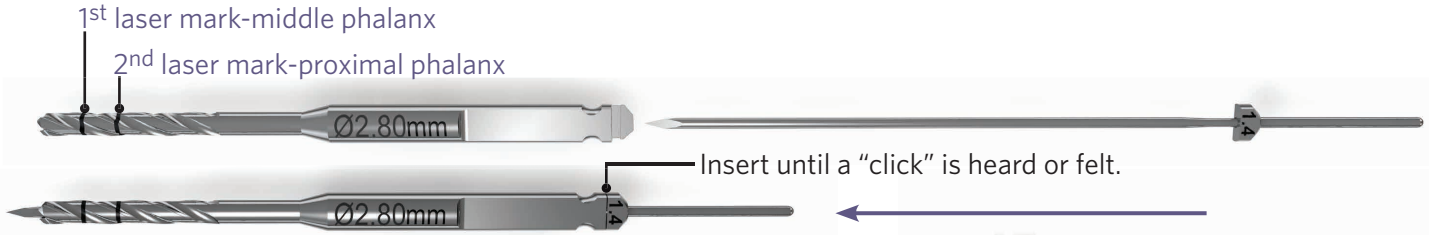
TIP: Do not attempt planer use without the trocar or a K-wire

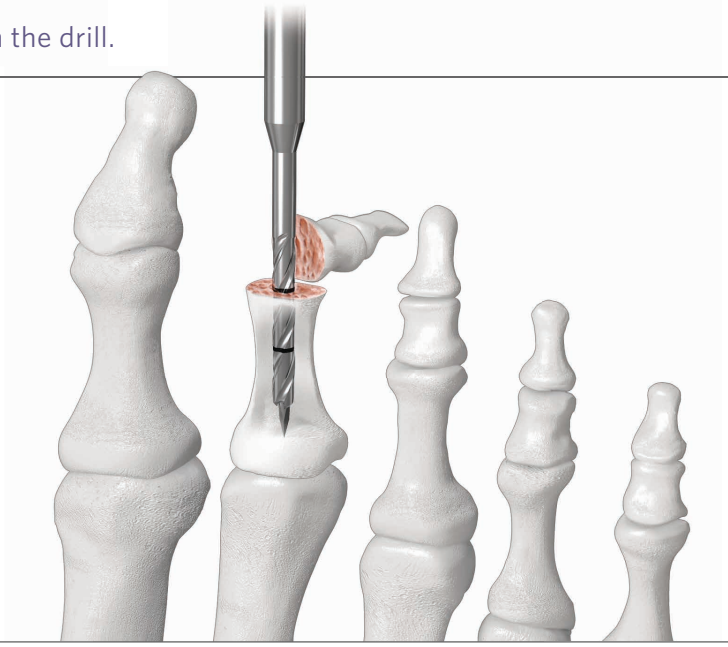
JOINT PREPARATION

The planer can be used for cartilage resection on the middle phalanx bone. Center the trocar on the middle phalanx.

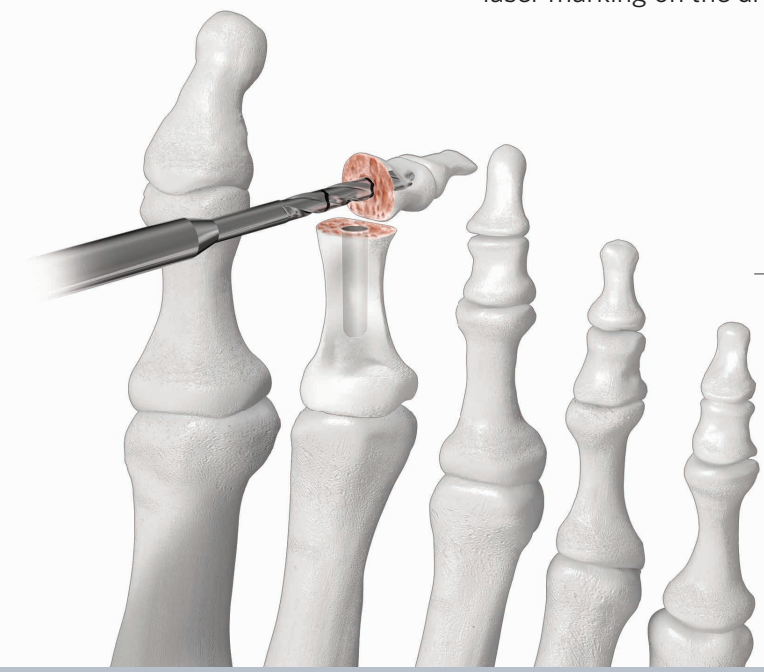
Begin movement of the planer prior to contacting bone.

Continue to engage the planer until no cartilage remains.





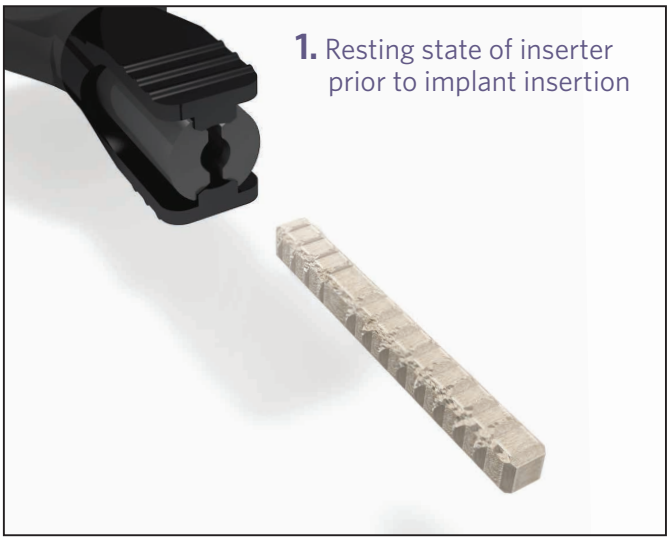
Center the trocar on the proximal phalanx and drill to the second laser marking on the drill.

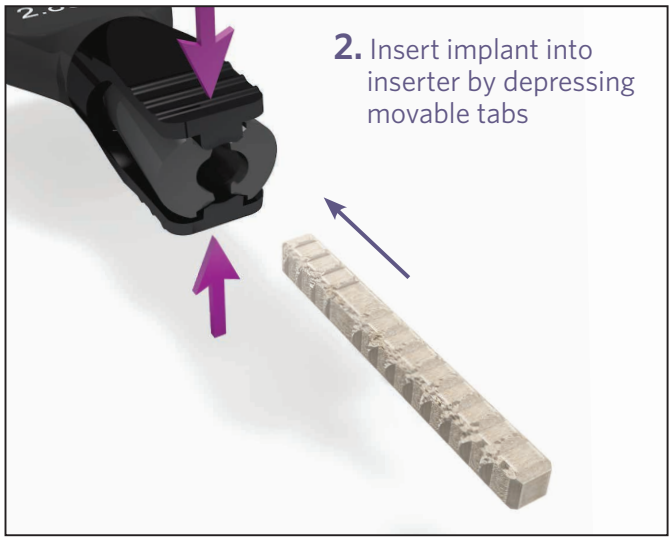


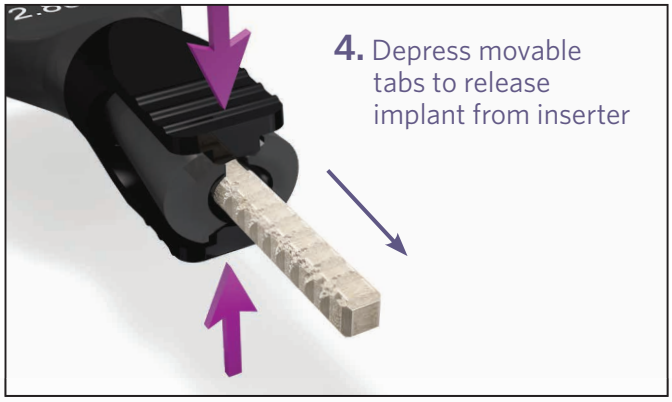
The same trocar/drill unit is then used to drill the middle phalanx. Center the trocar on the middle phalanx and drill to the first laser marking on the drill.

IMPLANT SELECTION AND INSERTION

A 0° or 10° implant can be selected at this time. During loading, depress the two movable tabs of the inserter to open up the canal for the implant. The distal aspect of the implant is loaded into the inserter such that no further advancement of the implant into the inserter can be achieved. Release the movable tabs on the inserter to secure implant.

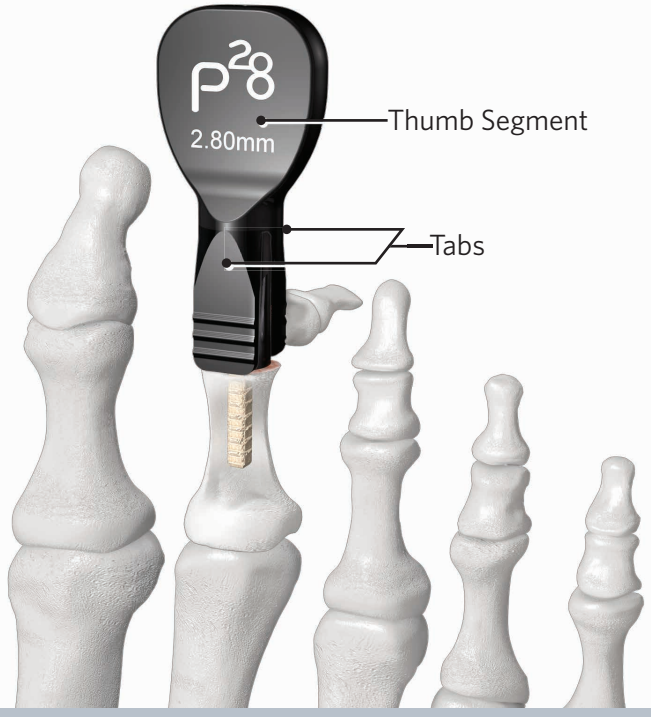






While holding the thumb segment of the inserter, insert the implant into the proximal phalanx drill hole until the inserter contacts the distal surface of the proximal phalanx, and no further advancement can be achieved. It is recommended to push the implant in fully with one motion rather than incrementally. Depress the two movable tabs of the inserter to release the implant into its seated position. Remove the inserter from the implant.

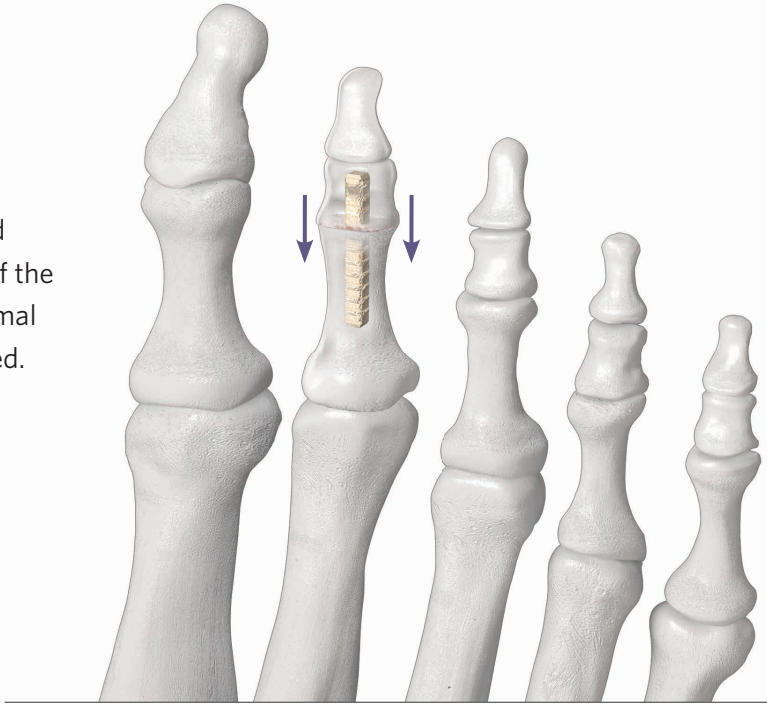
If difficulty with insertion is encountered, tap the end of inserter lightly with a mallet rather than twisting the implant to insert.



IMPLANT SELECTION AND INSERTION

The distal portion of the toe is then carefully distracted distally and translated dorsally to allow the protruding distal portion of the implant to seat within the drilled hole in the middle phalanx. If shortening of the graft is required to fit in the middle phalanx, a sagittal saw is recommended for cutting the graft to desired length.

Once seated, pressure is applied proximally to the distal aspect of the toe until apposition of the proximal and middle phalanges is achieved.



CLOSURE

Proceed to soft tissue and incision closure at this time.

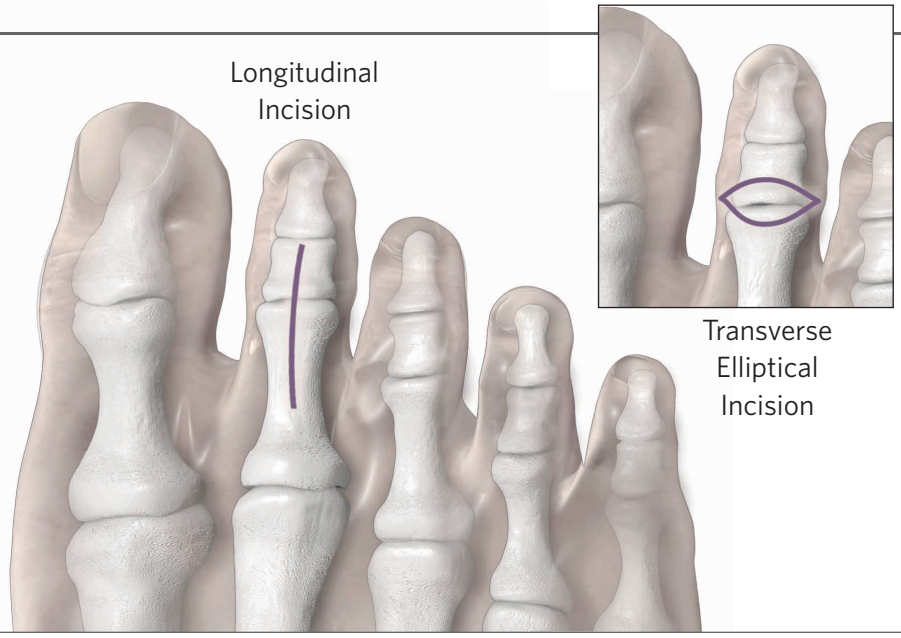
IMPLANT SELECTION

Use direct visualization intraoperatively to determine implant size. It is recommended to start with a smaller drill size and go up a drill size if there is not sufficient resistance to the drill.

INCISION/EXPOSURE

Proximal interphalangeal joint (PIPJ) arthrodesis may be performed as a sole procedure or combined with other procedures to address multiple deformities.

A longitudinal or transverse elliptical incision can be performed based on surgeon preference. Dissection is carried down to expose the proximal interphalangeal joint.



JOINT PREPARATION AND ALIGNMENT

A sagittal saw or hand-held bone cutter is used to resect the cartilage at the head of the proximal phalanx. It is necessary to make the cut at the level of the condyles to allow passage of the implant into the middle phalanx during insertion.

The retrograde technique is used to help determine final position of the toe:

- Insert the K-wire from the PIPJ into the middle phalanx, exiting the distal phalanx centrally plantar to the nail.
- The K-wire is inserted into the central medullary canal of the proximal phalanx in a retrograde fashion.
- Fluoroscopy is used to determine K-wire and toe position.
- Once optimal positioning of the K-wire is determined, pull the K-wire distally such that only 2-3 mm of wire protrudes from the base of the middle phalanx.

TIP: Alternatively, the planer can be used to remove cartilage from the proximal phalanx or to provide further resection after the sagittal saw cut.

The blunt K-wire is positioned in the canal of the proximal phalanx created by the K-wire. Slide the planer over the blunt K-wire. **Begin movement of the planer prior to contacting bone.** Continue to engage the planer until all cartilage is removed from the head of the proximal phalanx. Remove the K-wire when planing is complete.

TIP: Do not attempt planer use without the trocar or K-wire.

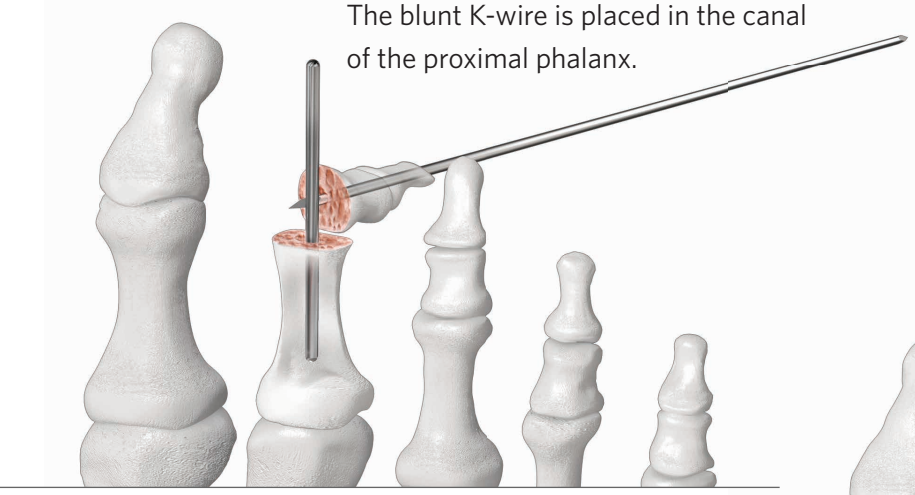
JOINT PREPARATION AND ALIGNMENT

Using the planer on its own, place the planer over the K-wire extending from the middle phalanx.

Begin motion of the planer prior to contacting bone.

Continue to engage the planer until no cartilage remains.

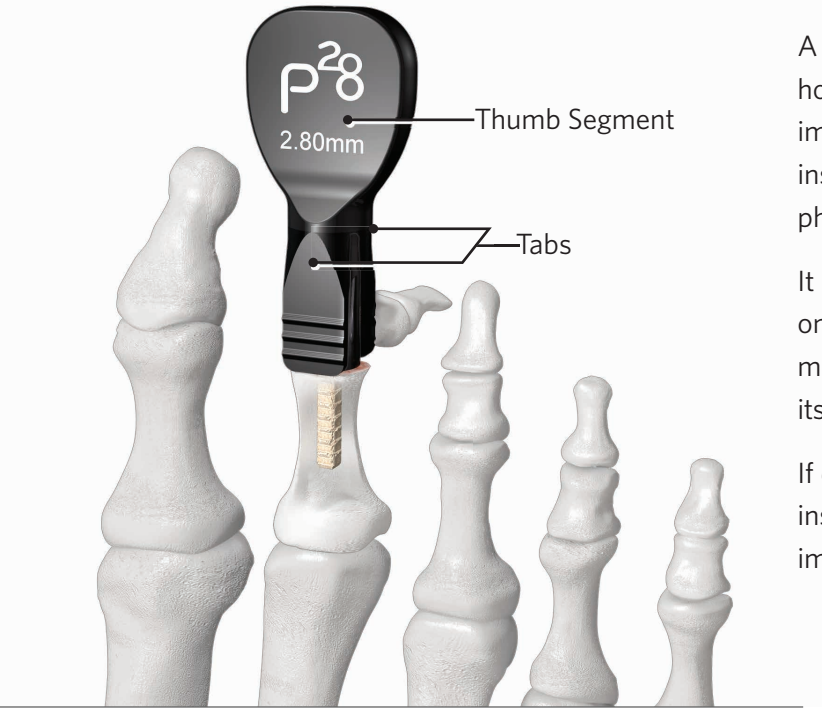
BONE PREPARATION



The blunt K-wire is placed in the canal of the proximal phalanx.

Drill over the blunt K-wire to the second laser marking on the drill.

The blunt K-wire is removed. The same drill is then used to drill the middle phalanx. Insert the K-wire into the cannula of the drill. Drill to the first laser marking on the drill.

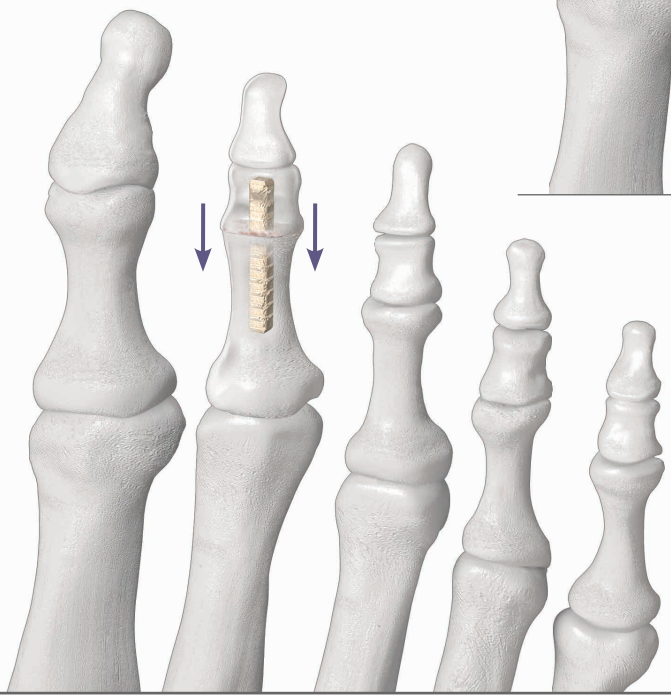


A 0° or 10° implant can be selected at this time. While holding the thumb segment of the inserter, insert the implant into the proximal phalanx drill hole until the inserter contacts the distal surface of the proximal phalanx, and no further advancement can be achieved.

It is recommended to push the implant in fully with one motion rather than incrementally. Depress the two movable tabs of the inserter to release the implant into its seated position. Remove the inserter from the implant.

If difficulty with insertion is encountered, tap the end of inserter lightly with a mallet rather than twisting the implant to insert.

The distal portion of the toe is then carefully distracted distally and translated dorsally to allow the protruding distal portion of the implant to seat within the drilled hole in the middle phalanx.



Once seated, pressure is applied proximally to the distal aspect of the toe until apposition of the proximal and middle phalanges is achieved.

CLOSURE

Proceed to soft tissue and incision closure at this time.

HAMMERGRAFT CANCELLOUS SPACER

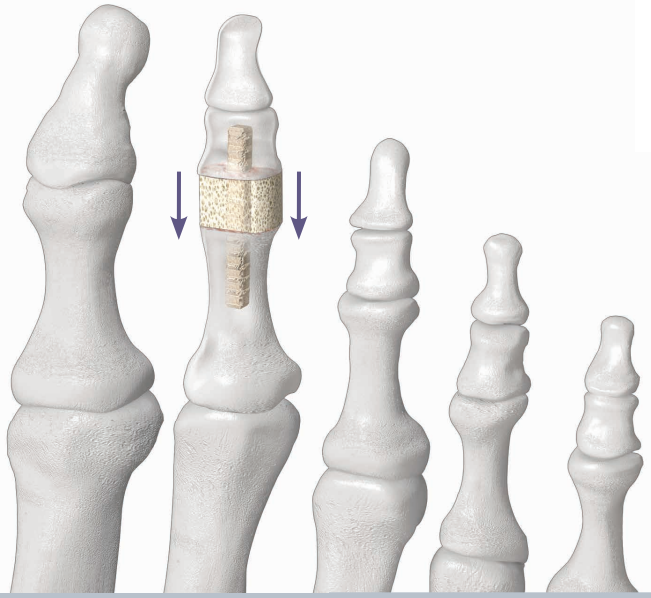
If overshortening of the phalanges is encountered during a primary or revision hammertoe procedure, a cancellous spacer is available to allow for restoration of the length of the toe. The Cancellous Spacers are available in 3 lengths: 6 mm, 8 mm and 10 mm and are intended to be used with the 2.3 mm or 2.8 mm HammerGraft implants, respectively.

Perform joint and bone preparation as previously described. Following selection of HammerGraft implant, select the corresponding Cancellous Spacer size, such that the HammerGraft implant diameter (2.3 mm or 2.8 mm) matches the hole diameter listed on the packaging for the Cancellous Spacer and the length of the Cancellous Spacer restores appropriate toe length. The Cancellous Spacer must be reconstituted in saline for a minimum of 5 minutes prior to implantation.

Insert the selected Cancellous Spacer over the HammerGraft Implant until it is centered on the HammerGraft Implant.

TIP: If using an angled HammerGraft Implant, insert the Cancellous Spacer from the proximal portion of the implant distally to the bend in the implant.

Insert the proximal portion of the HammerGraft implant into the proximal phalanx. The distal portion of the toe is then carefully distracted distally and translated dorsally to allow the protruding distal portion of the implant to seat within the drilled hole in the middle phalanx.



Once seated, pressure is applied proximally to the distal aspect of the toe until apposition of the proximal and middle phalanges is achieved.

PRESERVE™

HAMMERGRAFT™ SYSTEM

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Exclusively foot & ankle Paragon 28®

www.PARAGON28.com

Endnotes:

1 Test Report 17011701.

P01-STG-0002 RevC

Patents: www.paragon28.com/index.php/patents

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DISCLAIMER

The purpose of the HammerGraft™ Surgical Technique Guide is to demonstrate the optionality and functionality of the PRESERVE™ HammerGraft™ Hammertoe Implant System.
Although variations in placement and use of the HammerGraft™ Implant can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the HammerGraft™ can be employed for bone replacement, appropriate for the size of the device.