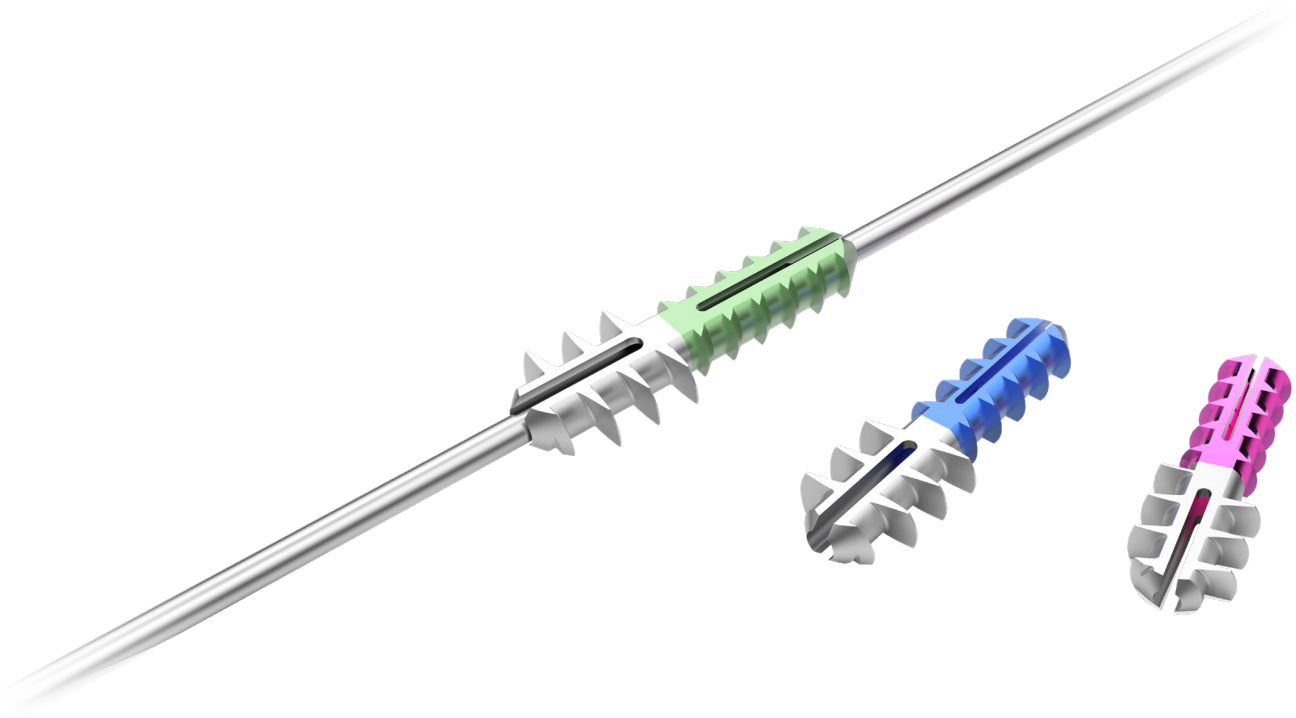
stryker

Phalinx™

Hammertoe Fixation Sterile Offering

Operative technique



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Phalinx™
Hammertoe Fixation Sterile Offering

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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 surgical technique and the package insert is available on the website listed.

Contact the sales representative/distributor for product availability.

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, 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.

Important

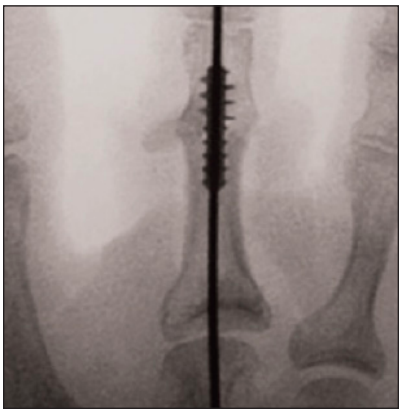
- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future.
- Cleaning and sterilization information is provided in the applicable instructions for use.
- Non-sterile devices, including implants and instruments, must be cleaned and sterilized prior to use, in accordance with validated methods.
- Devices that are able to be disassembled should be disassembled prior to point-of-use processing. Additionally, devices with movable components that do not facilitate disassembly should be manually articulated during the point-of-use processing step in order to evacuate additional soils.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.wright.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant

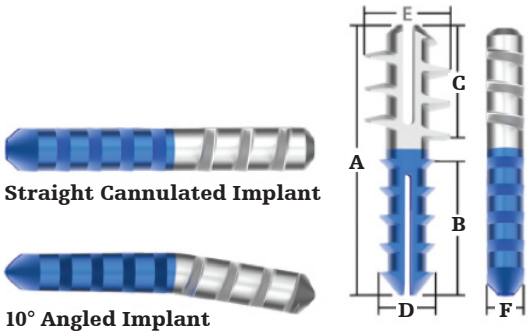
Introduction

Device Description

Phalinx Hammertoe System provides a simple and effective method for hammertoe correction. The implants are manufactured out of implant grade titanium and available in four sizes. The range of sizes accommodate varying anatomical and bone quality needs. Implants are available in 0° cannulated and 10° solid.

Phalinx Hammertoe System is available in sterile, ready-for-surgery procedure packs that include an implant and all instruments required for surgery. A separately packed, sterile sizer is also available to determine the correct implant size, if desired.

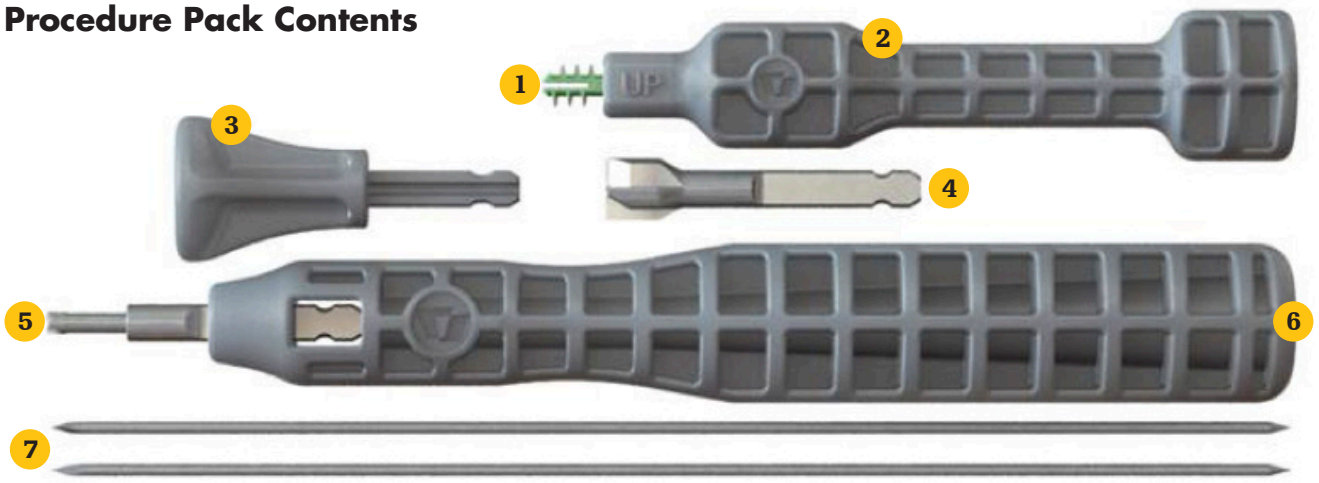




Phalinx Implant Dimensions

Implant description/size	Length (mm)			Length (mm)		
	A Overall	B Proximal	C Distal	D Proximal	E Distal	F Thickness
Extra Small Cannulated/Angled	11.2	6	4.2	2.5	3.2	1.8
Small Cannulated/Angled	13.0	7	5.5	2.8	4.0	1.9
Medium Cannulated/Angled	14.1	7	6.0	3.0	4.5	2.0
Large Cannulated/Angled	15.2	8	6.2	3.3	5.0	2.0

Procedure Pack Contents



1	Implant
2	Implant Inserter
3	Impactor (not included
4	Planar/Reamer
5	Drill
6	AO Handle
7	K-wires

Intended Use

Indications

The Phalinx Hammertoe System in indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoes, claw toe, and mallet toe.

Cannulated implants in the Phalinx Hammertoe Fixation System can be used with k-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

Contraindications

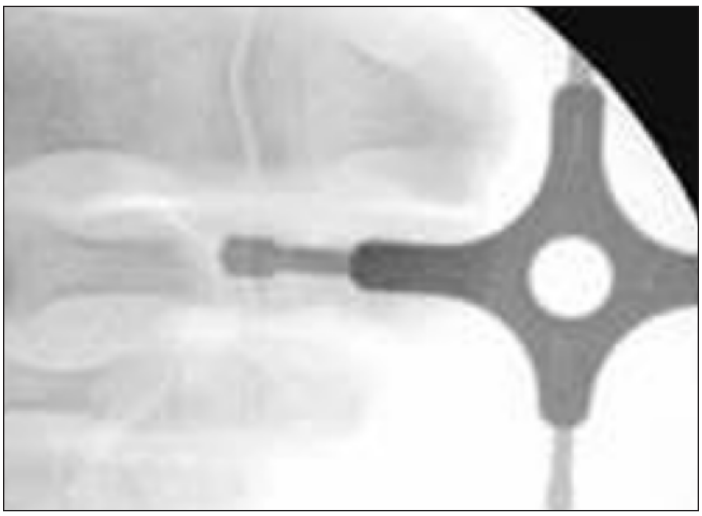
The Phalinx Hammertoe System does not have product specific contraindications.

Implant Selection

Use the Phalinx Sterile Sizer to determine the correct implant size.

Sterile Sizer

The Phalinx Sterile Sizer is separately sterile packed with representative sizers for all four implant sizes and can be used to determine the correct implant size for both cannulated and angled implants.



Place the Phalinx Sterile Sizer over the toe, outside the skin, and view under fluoroscopy.

Measure off the proximal phalanx to determine the correct size implant to use. Always size down if in between sizes.

Surgical technique

Joint preparation

After site preparation, the head of the proximal phalanx is removed with a sagittal saw or bone cutting tool. Ensure the cut is perpendicular to the long axis of the proximal phalanx. (Figure 1)

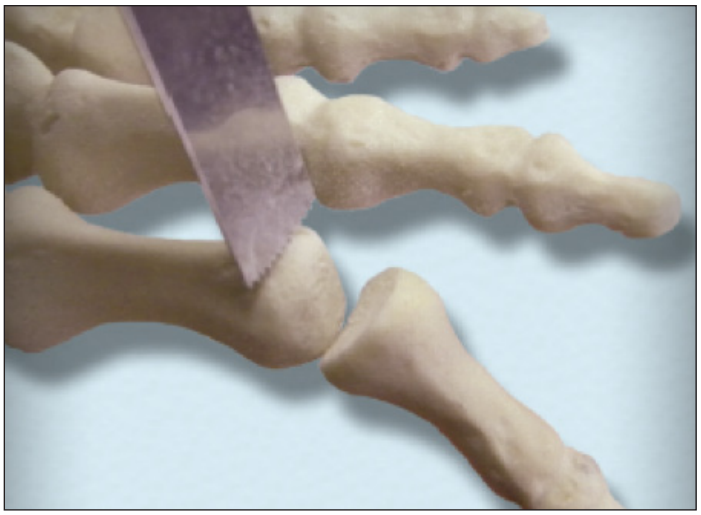


Figure 1

Identify the laser mark on the K-wire included in the procedure pack. Keeping the laser mark proximal, drive the K-wire distally, under power, through the intermediate and distal phalanges and out the distal tip of the toe. Then antegrade the K-wire distally until the laser mark is flush with the base of the intermediate phalanx.

Attach cannulated planar to the drill handle included in the procedure pack. Insert the planar over the k-wire, positioned in the middle phalanx, and rotate to remove the cartilage. (Figure 2)

Figure 2

Using the tip of the K-wire, create a pilot hole in the proximal phalanx. Reapproximate the PIPJ until the bones are flush. (Figure 3)

Figure 3

With the K-wire pressed into the proximal phalanx, check for dorsal gapping. If necessary, back the wire out of the joint space and make feather cuts to square the joint surface. (Figure 4)

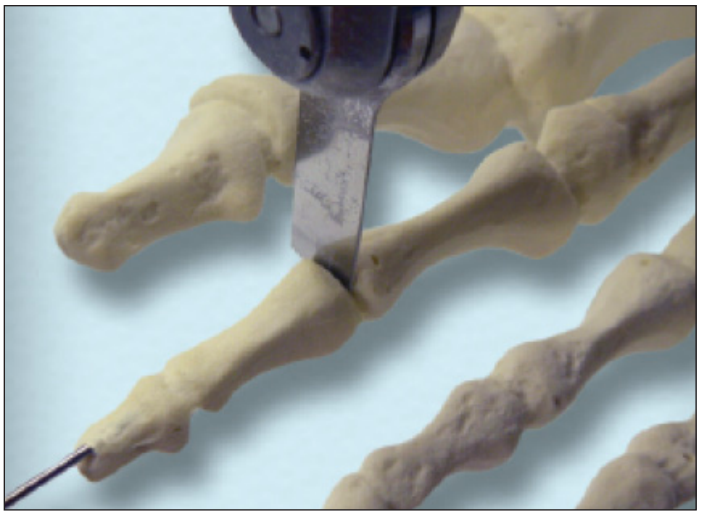


Figure 4

Phalinx Straight Cannulated Implant Insertion

The cannulated drill is preloaded in the drill handle. Manually drill over the K-wire into the intermediate phalanx. The shoulder of the drill is designed to indicate the appropriate drill depth. Drill until the shoulder of the drill is flush against the distal phalanx. (Figure 5)

Drill and Handle

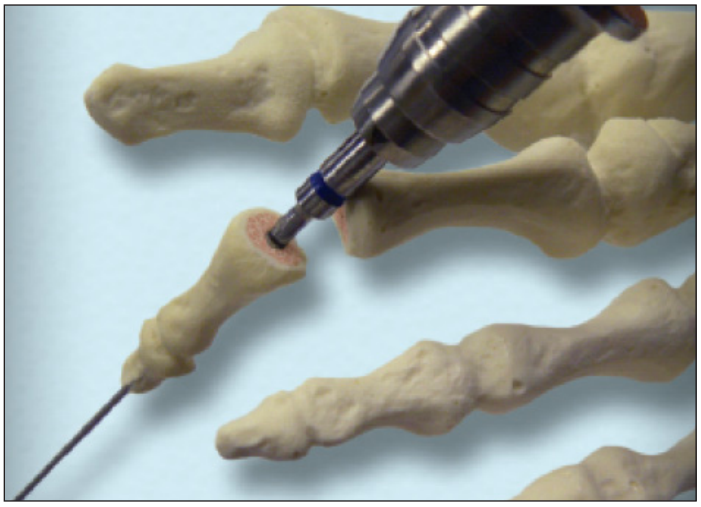


Figure 5

Using the pilot hole as a guide, drill into the proximal phalanx with the appropriate size drill until the shoulder of the drill is flush with the proximal phalanx. (Figure 6)

Optional: A secondary K-wire may be placed proximally prior to pre-drilling to help maintain alignment.

NOTICE

The same drill should be used on both the proximal and middle phalanx.

NOTICE

A Flexor tendon transfer can be performed at this point, prior to inserting the implant.

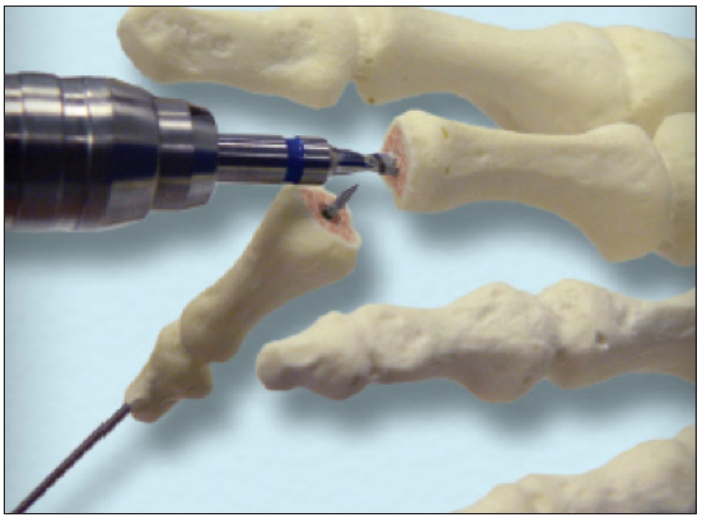


Figure 6

Utilizing the ready to use Phalinx implant inserter, place the implant over the K-wire for insertion. While applying pressure, rotate the implant into the intermediate phalanx. (Figure 7)

Implant Inserter

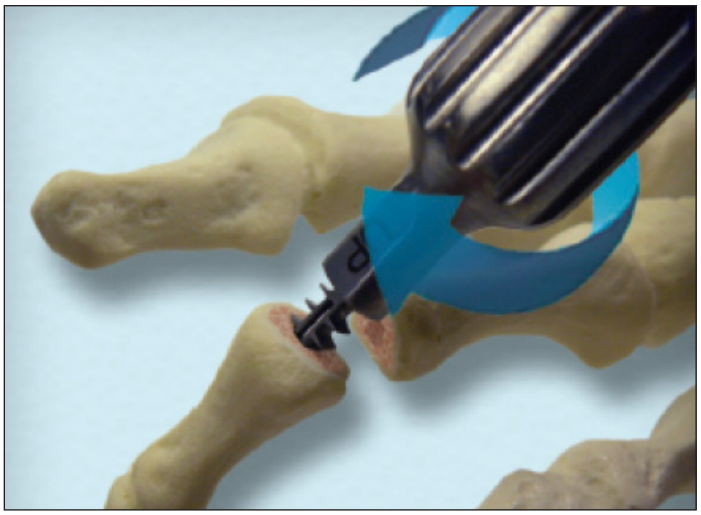


Figure 7

The implant should be screwed into the intermediate phalanx until the distal tip of the handle is flush with the bone. The handle can then be removed from the implant. When re-approximating the PIPJ if the implant protrudes too far proximally it can be inserted further into the intermediate phalanx. (Figure 8)

NOTICE

"UP" on the handle should be facing dorsal to ensure the proper alignment of the implant.

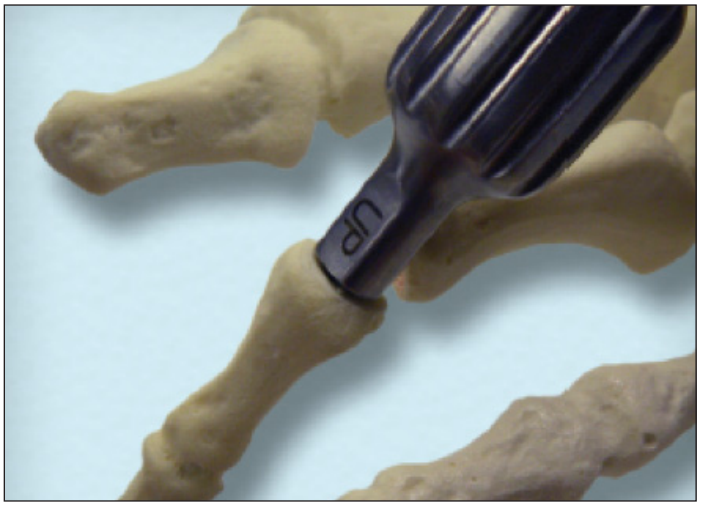


Figure 8

Attach the impactor to the drill handle. Slide the impactor over the distal end of the K-wire and use it to assist in inserting the implant into the proximal phalanx by pressing on the distal tip of the toe. Press the implant proximally until the bones are flush. If unable to re-approximate the PIPJ, sweep collaterals to free up resection. (Figure 9)

Impactor

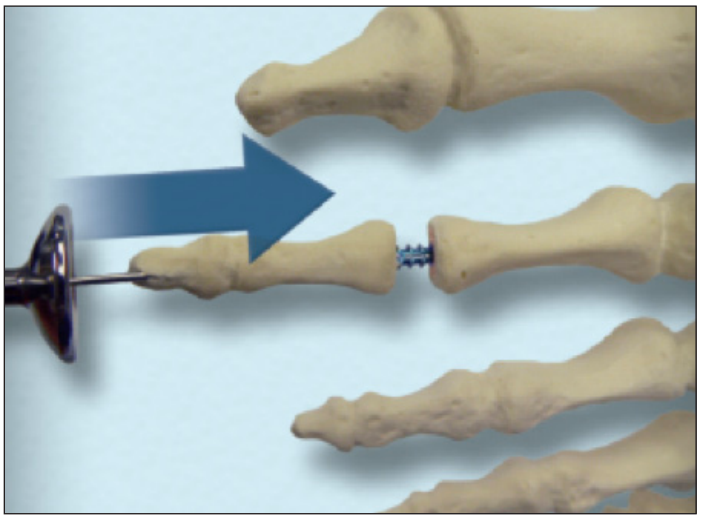


Figure 9

Once the joint is reduced, plantar flex the toe to the desired position. Remove the K-wire. (Figure 10)

Optional: To address MTP joint instability retrograde the k-wire under fluoro until it is placed adequately across the MPJ.

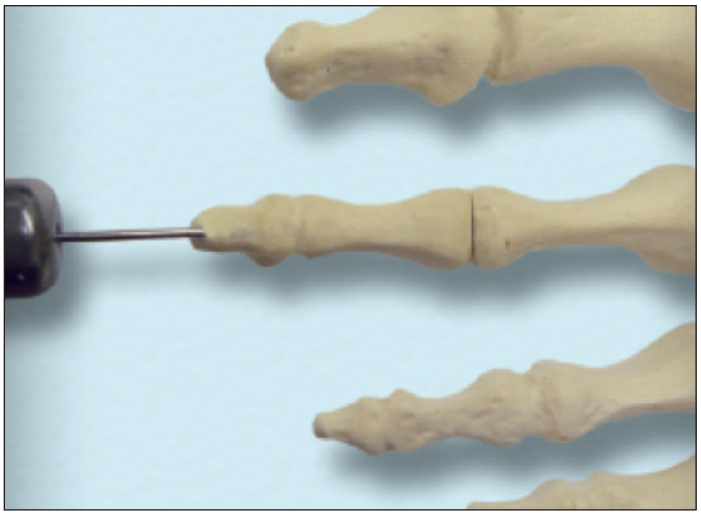


Figure 10

Phalinx 10° Angled Implant Insertion

Remove K-wire from intermediate phalanx.

The cannulated drill is preloaded in the drill handle. Manually drill into the intermediate phalanx. The shoulder of the drill is designed to indicate the appropriate drill depth. Drill until the shoulder of the drill is flush against the distal phalanx. (Figure 11)

Drill and Handle

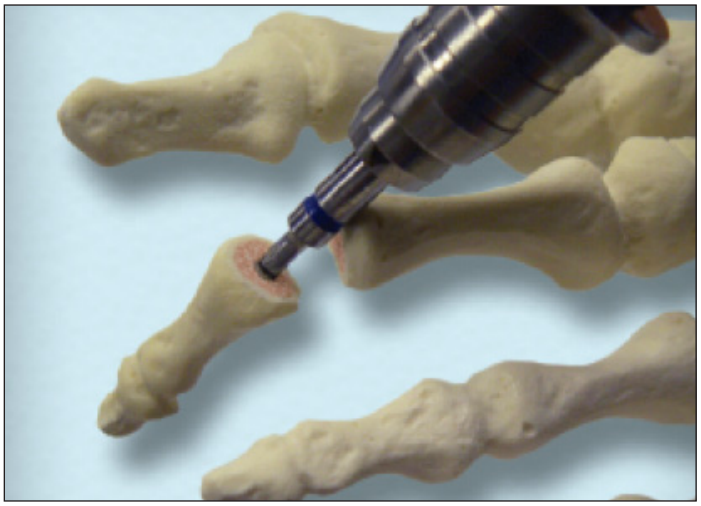


Figure 11

Using the same drill, drill into the proximal phalanx until the shoulder of the drill is flush with the proximal phalanx. (Figure 12)

NOTICE

A Flexor tendon transfer can be performed at this point, prior to inserting the implant.

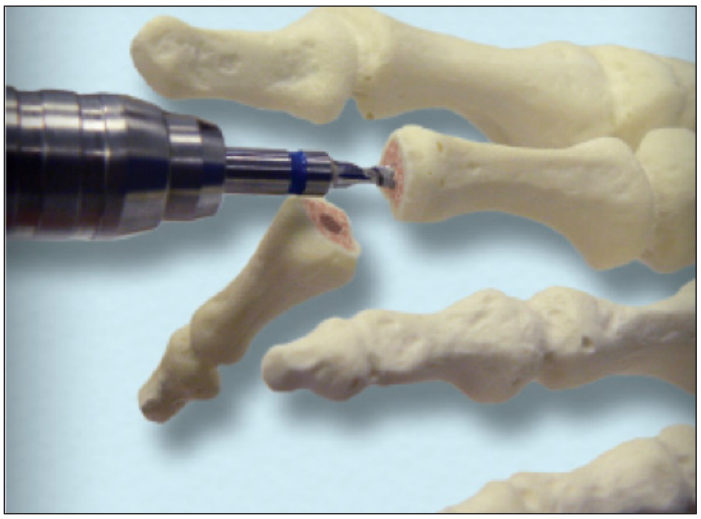


Figure 12

The Phalinx implant is preloaded with the proximal side of the implant (color anodized) in the inserter handle. While applying pressure, use the inserter handle to rotate the implant into the intermediate phalanx. (Figure 13)

Implant Inserter

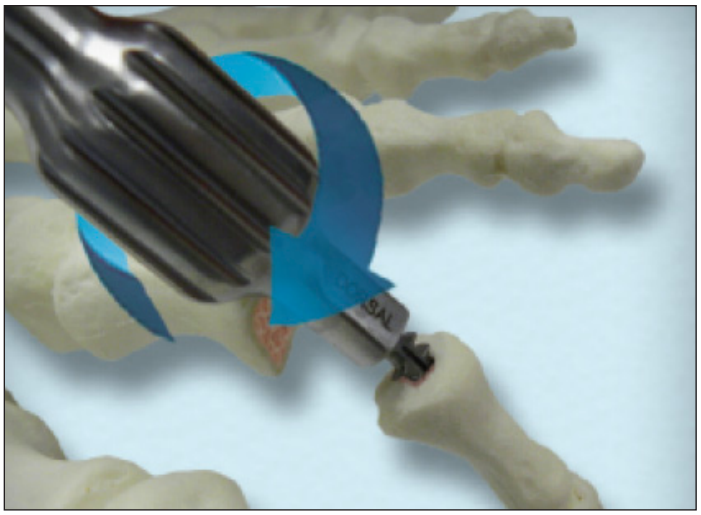


Figure 13

The implant should be screwed into the intermediate phalanx until the distal tip of inserter handle is flush with the bone. The handle can then be removed from the implant. When re-approximating the PIPJ if the implant protrudes too far proximally it can be inserted further into the intermediate phalanx. (Figure 14)

NOTICE

"UP," on handle, should be facing dorsal to ensure proper alignment of the implant.

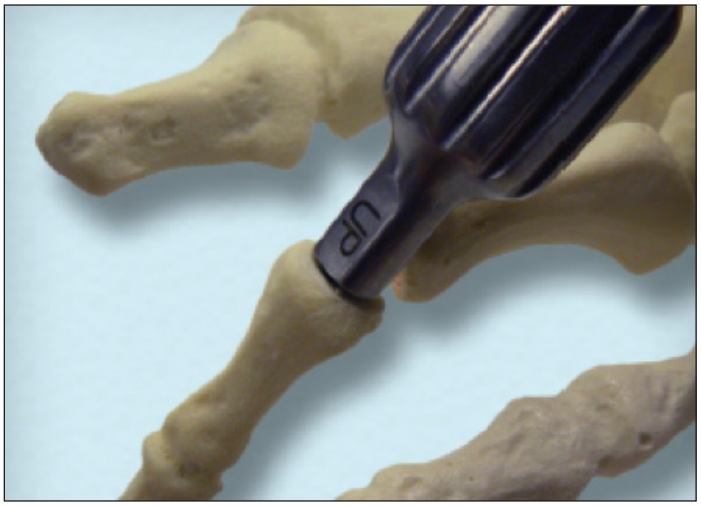


Figure 14

Insert the implant into the proximal phalanx by pressing on the distal tip of the toe. Press the implant proximally until the bones are flush. If unable to re-approximate the PIPJ, sweep collaterals to free up resection. Once the joint is reduced. Standard closure can then be performed. (Figure 15)

Postoperative Protocol

Postoperative care is the responsibility of the medical professional.

Explant Information

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

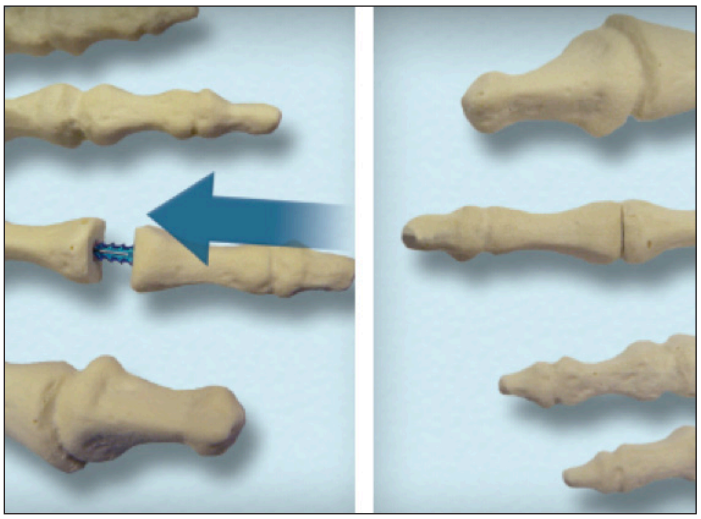


Figure 15

Ordering information

Catalog Number	Description
45A01001	Cannulated X-Small Procedure pack
45A01002	Cannulated Small Procedure pack
45A01003	Cannulated Medium Procedure pack
45A01004	Cannulated Large Procedure pack
45A01011	Angled X-Small Procedure pack
45A01012	Angled Small Procedure pack
45A01013	Angled Medium Procedure pack
45A01014	Angled Large Procedure pack
45A00000	Sterile Sizer

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Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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