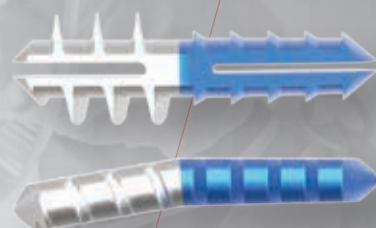


PHALINX[®]

Hammertoe Fixation

SURGICAL TECHNIQUE



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Wright recognizes that 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, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert (151676-0) for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on wmt.com under the link for Prescribing Information.

Please contact your local Wright representative for product availability.

Product Information



PHALINX® 10° Angled Implant X-ray

Device Description

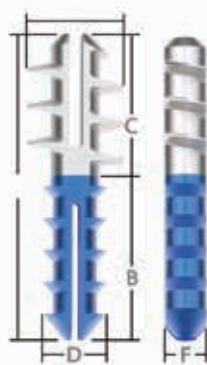
PHALINX® Hammertoe System provides a simple and effective method for hammertoe correction. The implants are manufactured out of implant grade titanium and available in four sizes. The range of sizes accommodate varying anatomical and bone quality needs. Implants are available in 0° cannulated and 10° solid. Color-coding between implants and instruments provides easy navigation of the system.



Straight Cannulated Implant



10° Angled Implant



PHALINX® Implant Dimensions

| Implant Description / Size | Length (mm) | | | Diameter (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 |

Intended Use

Indications

The PHALINX® Hammertoe System is designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

Contraindications

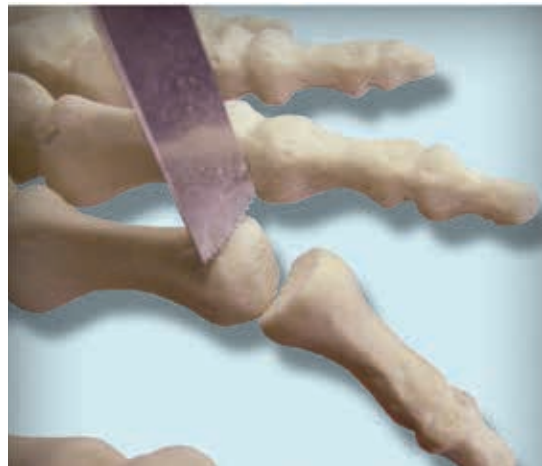
The PHALINX® Hammertoe System implants are contraindicated for use in patients with the following conditions:

- Infection;
- Physiologically or psychologically inadequate patient;
- Irreparable tendon system;
- Possibility for conservative treatment;
- Growing patients with open epiphyses;
- Patients with high levels of activity.

Prior to use of the system, the surgeon should refer to the product instructions for use package insert for warnings, precautions, indications, contraindications and adverse effects. Instructions for use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the instructions for use package inserts are available on wmt.com under the link for Prescribing Information.

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**



NOTE: Approximately 4mm of bone needs to be removed between both cuts - Resection should be slightly less than a traditional arthroplasty.

FIGURE 1

Identify the laser mark on the appropriate size K-wire that corresponds with the implant size selected. Keeping the laser mark proximal drive the K-wire distally 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. **FIGURE 4**



*NOTE: IMPLANT SIZING
*Use the PHALINX®
X-ray Template or place the implant over the joint and check under fluoro. Measure off of the proximal phalanx to determine the correct size implant to use. Always size down if in between sizes.*

FIGURE 2

Attach cannulated planar to the driver handle. Insert the planar over the k-wire, positioned in the middle phalanx, and rotate to remove the cartilage.

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

Using the appropriate size cannulated drill that corresponds with the implant size selected, drill over the K-wire into the intermediate phalanx. The drill is laser marked to indicate drill depth. **FIGURE 5**



FIGURE 5

Using the pilot hole as a guide, drill into the proximal phalanx with the appropriate size drill until the laser mark on the drill is flush with the proximal phalanx. **FIGURE 6**



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

FIGURE 6

The selected size PHALINX® implant is then inserted with the proximal side of the implant (color anodized) into the handle and placed over the K-wire for insertion. While applying pressure screw the implant into the intermediate phalanx. **FIGURE 7**



FIGURE 7

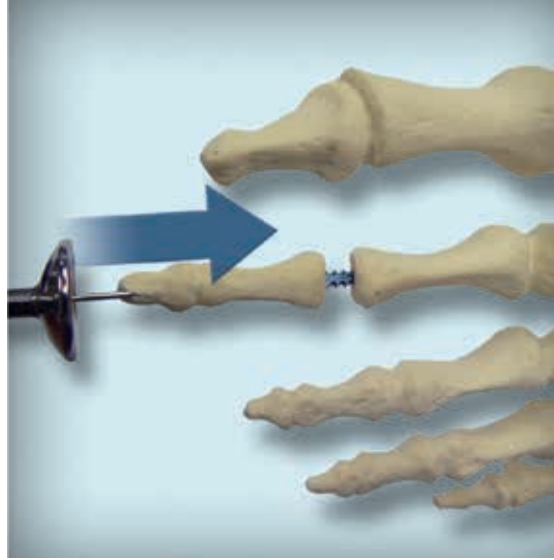
The implant should be screwed into the intermediate phalanx until the distal tip of the handle is flush with the bone. The handle can then be removed from the implant. When re-approximating the PIPJ if the implant protrudes too far proximally it can be inserted further into the intermediate phalanx.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



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

FIGURE 8

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**



NOTE: The implant pickups can be used to stabilize the proximal phalanx while inserting the implant proximally.

FIGURE 9

Once the joint is reduced, plantar flex the toe to the desired position. Remove the K-wire. **FIGURE 10**

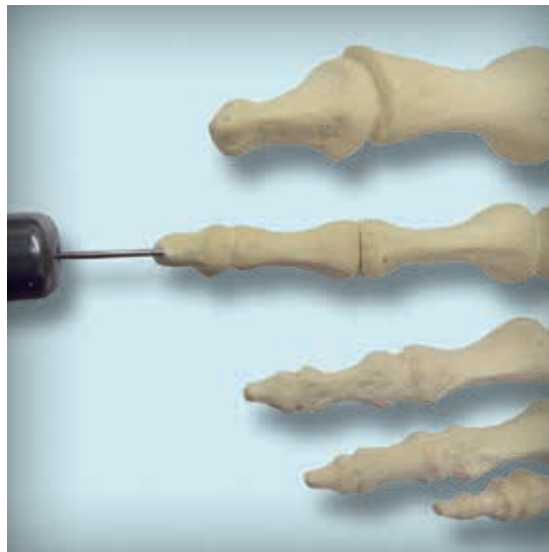


FIGURE 10

PHALINX® 10° Angled Implant Insertion

Remove K-Wire from Intermediate Phalanx.

Using the appropriate size non-cannulated drill that corresponds with the implant size selected, drill into the intermediate phalanx. The drill is laser marked to indicate drill depth. **FIGURE 11**



NOTE: IMPLANT SIZING - Use the PHALINX® X-ray Template or place the implant over the joint and check under fluoro. Measure off of the proximal phalanx to determine the correct size implant to use. Always size down if in between sizes.

FIGURE 11

Using the same drill, drill into the proximal phalanx until the laser mark on the drill is flush with the proximal phalanx. **FIGURE 12**



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

FIGURE 12

The selected size PHALINX® implant is then inserted with the proximal (colored anodized) side of the implant into the handle with the dorsal side of the implant matching up with the “DORSAL” laser mark on the handle. While applying pressure screw the implant into the intermediate phalanx. **FIGURE 13**



FIGURE 13

The implant should be screwed into the intermediate phalanx until the distal tip of 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**



NOTE: “Dorsal,” 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. **FIGURE 15**

Once the joint is reduced. Standard closure can then be performed. **FIGURE 16**

NOTE: The implant pickups can be used to stabilize the proximal phalanx while inserting the implant proximally.

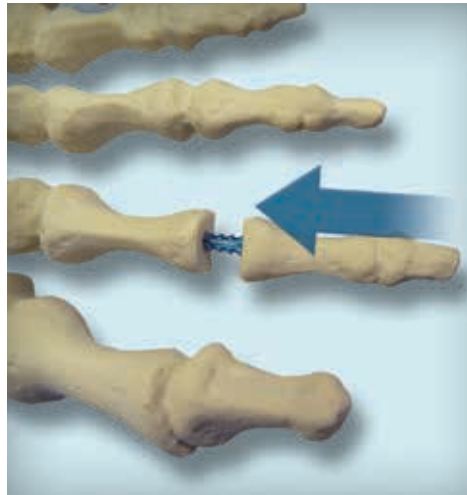


FIGURE 15



FIGURE 16

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.

Ordering Information

PHALINX® Hammertoe Fixation System 4532KIT1/A



1. 45305002 - Implant Impactor

2. Non-Cannulated Drills

| PN | Description |
|----------|----------------------------|
| 45303125 | 2.22mm Drill (Extra Small) |
| 45303145 | 2.45mm Drill (Small) |
| 45303155 | 2.55mm Drill (Medium) |
| 45303165 | 2.65mm Drill (Large) |

3. 45305001 - Drill Handle

4. 45305002 - Implant Pickup Forceps

5. Cannulated Drills

| PN | Description |
|----------|---------------------------------------|
| 45303025 | 2.22mm Cannulated Drill (Extra Small) |
| 45303045 | 2.45mm Cannulated Drill (Small) |
| 45303055 | 2.55mm Cannulated Drill (Medium) |
| 45303065 | 2.65mm Cannulated Drill (Large) |

6. 10° Angled Handles

| PN | Description |
|----------|---------------------------|
| 45304011 | Extra Small Angled Handle |
| 45304012 | Small Angled Handle |
| 45304013 | Medium Angled Handles |
| 45304014 | Large Angled Handles |

7. 10° Angled Implants

| PN | Description |
|--------|--------------------|
| 05-050 | Extra Small Angled |
| 05-051 | Small Angled |
| 05-052 | Medium Angled |
| 05-053 | Large Angled |

8. 0° Cannulated Implants

| PN | Description |
|--------|------------------------|
| 05-040 | Cannulated Extra Small |
| 05-041 | Cannulated Small |
| 05-042 | Cannulated Medium |
| 05-043 | Cannulated Large |

9. Cannulated Angled Handles

| PN | Description |
|----------|--------------------------------|
| 45304001 | Cannulated Extra Small Handles |
| 45304002 | Cannulated Small Handles |
| 45304003 | Cannulated Medium Handles |
| 45304004 | Cannulated Large Handles |

10. K-wires

| PN | Description |
|--------|----------------------------------|
| 05-306 | 0.9mm K-wire (Extra Small/Small) |
| 05-307 | 1.1mm K-wire (Medium) |
| 05-308 | 1.4mm K-wire (Large) |

11. Planars

| PN | Description |
|----------|----------------|
| 45765004 | Planar - 6.5mm |
| 45765005 | Planar - 7.5mm |



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