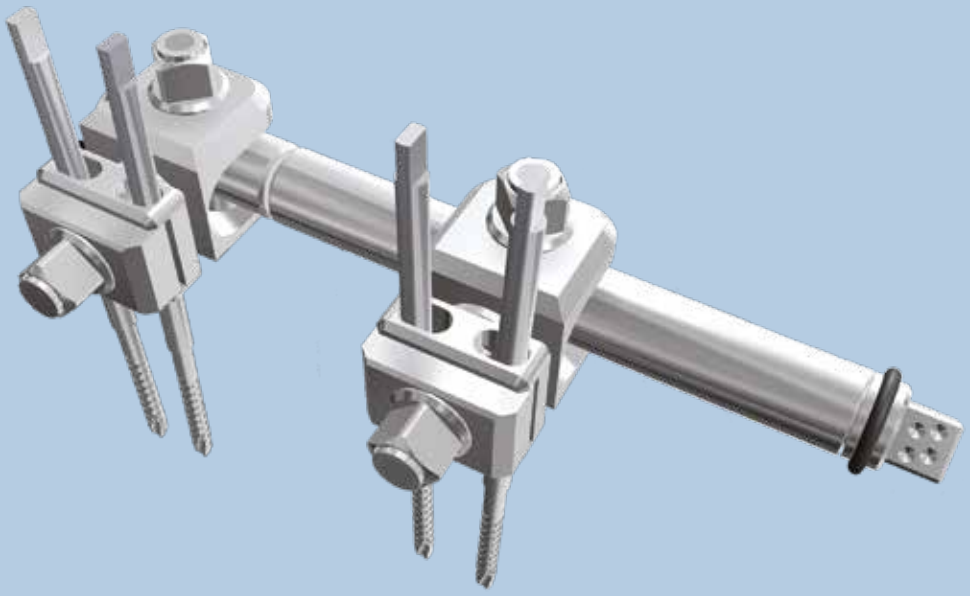
stryker

Hoffmann® II Micro Lengthener

Operative Technique

Small Bone Lengthening Fracture Compression/Distraction



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.

WARNING

- Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- All non-sterile devices must be cleaned and sterilized before use.

WARNING

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.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.

WARNING

- 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 due to medical reasons.

Indications & Contraindications

Indications

The Hoffmann II Micro External Fixation System is intended for use to provide stabilization of open and/or unstable fractures in children and adults where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting or other means of internal fixation and for use in reconstruction procedures in conjunction with commercially available Fixation Pins and/or Kirschner Wires. Specific indications include, but are not limited to:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedure where other treatments or devices have been unsuccessful
- Non-unions and delayed unions
- Compression/distraction and lengthening

Contraindications

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

Conditions presenting an increased risk of failure include:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site
- Previous history of infections
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period
- Malignancy in the fracture area
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen

Introduction & Features

Based on the unique Hoffmann® II Micro™ System for fracture management, Stryker has developed the Hoffmann® II Micro™ Lengthener for metacarpal, metatarsal, or phalangeal lengthening. For arthrodesis or non union cases, it may also be used for compression.

The Lengthener offers the same versatility and ease-of-use that makes the Hoffmann® II Micro™ System a leader in External Fixation for the hand, foot and mandible.

The design of the Pin Clamps allows a minimum pin distance of 2-4 mm, allowing very small segments of bone to be lengthened.

Stryker offers an optional Thumbwheel for the patient to use throughout the lengthening process. This tool will help the patient follow the regime of daily lengthening.

The Micro™ Lengthener is completely compatible with the Hoffmann® II Micro™ System instruments. There are no extra tools needed to assemble the frame.

An advantage is the overall size of the fixator. The low-profile Ø6 mm tube and clamp assembly is one of the most compact devices offered today. This is ideal for patient comfort, while still maintaining secure strength and durability.

The clamps can be positioned in a variety of ways, which allows optimal pin placement, easy frame adaptability, and access to the locking nuts.

Grid on Lengthening Bolt indicates .125 mm compression or distraction and matches grid on Thumbwheel.

The clamps allow insertion of the Apex® Pins in parallel, convergent or divergent directions. Due to the clamp's oblong pin holes, the surgeon can easily insert pins while avoiding soft tissues or obtaining optimal pin/bone interface. It also works well when there is only limited space to insert the pins, which can be the case in phalangeal lengthening.

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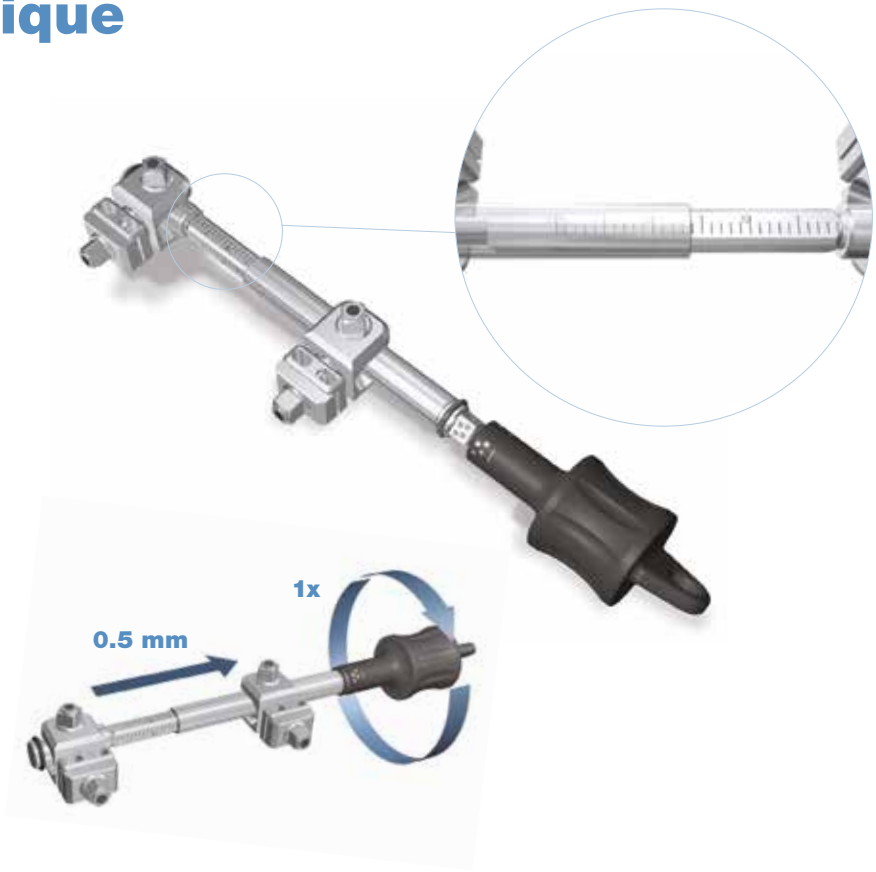
Lengthener Technical Details

The lengthener can distract up to 3.0 centimeters. This is marked on the inner-tube in millimeter increments.

One full turn of the Lengthening Bolt creates 0.5mm of lengthening. The bolt is marked with dimples to help the patient follow the daily lengthening regime.

The titanium Thumbwheel helps the patient with his or her daily regime. The dimples on the lengthening bolt match the markings on the thumbwheel for an easy connection and correct rotation.



⚠CAUTION

The Thumbwheel should only be used with the lengthening bolt. Do not use it to tighten the multi-pin clamps as it does not supply enough torque.

Also, the multi-pin clamps are not designed to be disassembled.

Pin Insertion Guidelines

Two types of half-pins are offered in the system: Blunt/Self-Tapping and Self-Drilling/Self-Tapping.

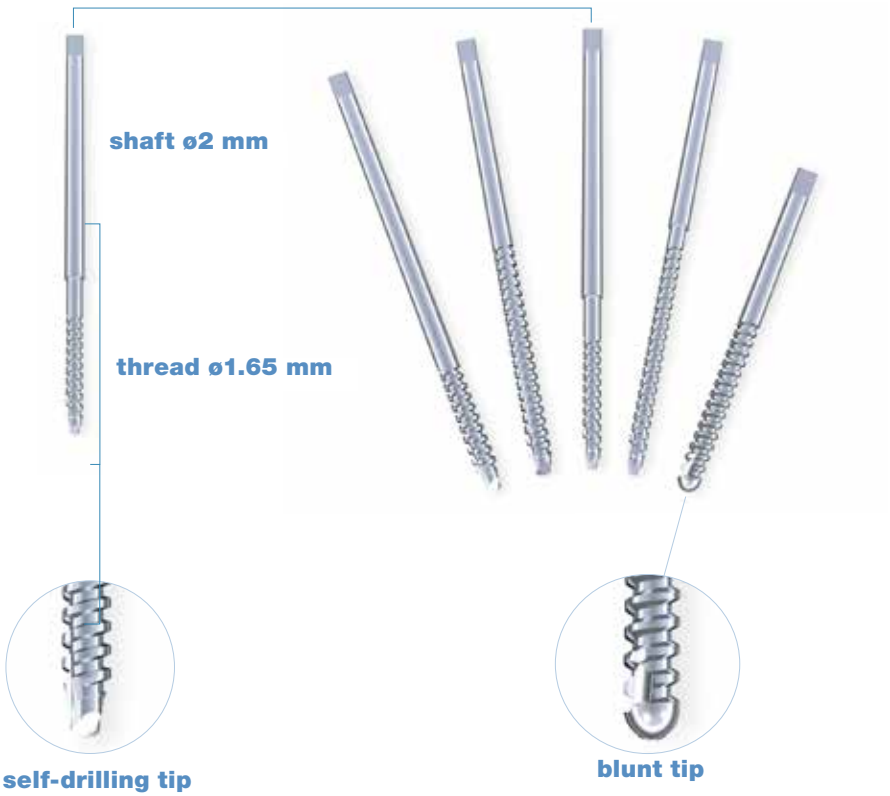
⚠CAUTION

Pre-drilling is necessary when using blunt pins.

It is optional to pre-drill when using Self-Drilling/Self-Tapping half-pins.

- Use a Ø1.6mm K-Wire to pre-drill a Ø2.0mm half-pin
- Use a Ø1.2mm K-Wire to pre-drill a Ø1.65mm half-pin

Blunt/Self-Tapping Half-Pins are offered in Ø2.0mm thread diameter only. Self-Drilling/Self-Tapping Half-Pins are offered in Ø2.0mm and Ø1.65mm thread diameters. All Half-Pins have a Ø2.0mm shaft diameter. For greater frame stability, use Ø2mm pins unless the anatomy requires Ø1.65mm pins.



A (mini) open insertion technique is recommended to avoid unnecessary damage to the soft tissues. A Drill/Insertion Guide is provided in the system to facilitate this technique.

⚠CAUTION

For additional information please refer to the Apex Pin Operative Technique.

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Hand

Placement in the Phalanges

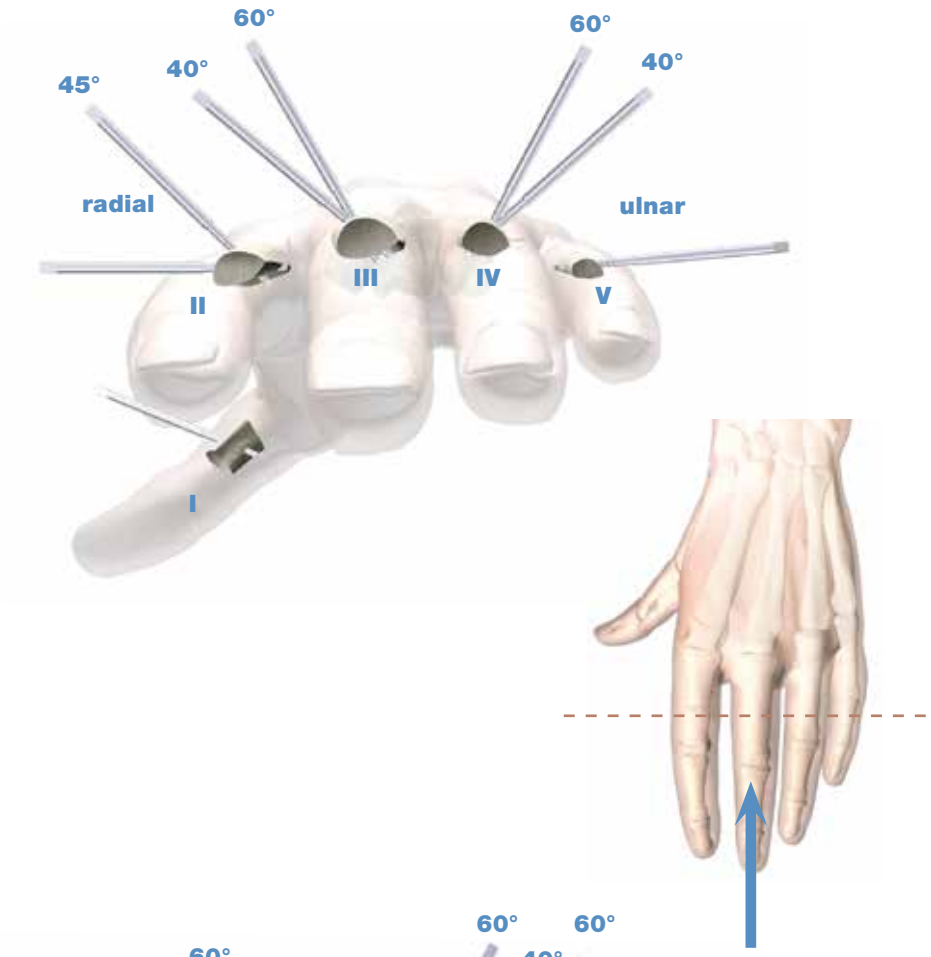
I Insert half-pins from the radial side in the frontal plane.

II Insert 0° to 45° from the frontal plane on the dorsal-radial side.

III Insert 40° to 60° from the frontal plane on the dorsal-radial side.

IV Insert 40° to 60° from the frontal plane on the dorsal-ulnar side.

V Insert from the ulnar side in the frontal plane.



Placement in the Metacarpals

I Insert half-pins from the radial side in the frontal plane.

II Insert 20° to 60° from the frontal plane on the dorsal-radial side.

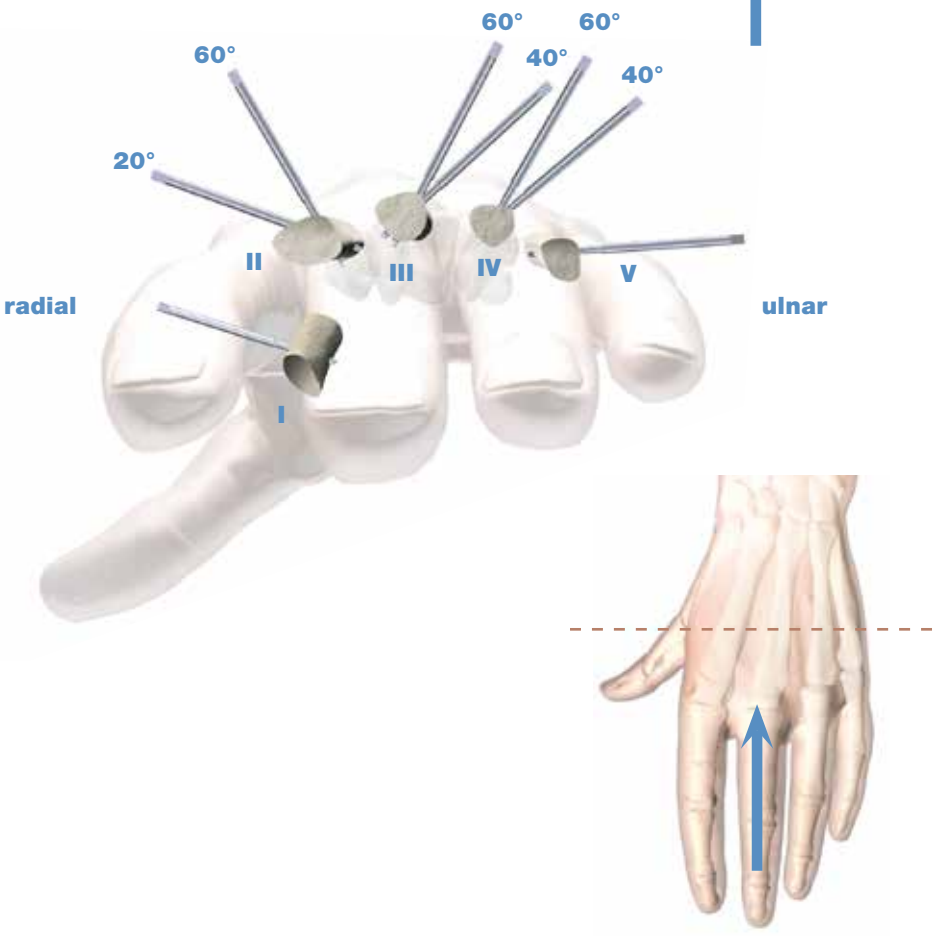
III Insert 40° to 60° from the frontal plane on the dorsal-ulnar side.

IV Insert 40° to 60° from the frontal plane on the dorsal-ulnar side.

V Insert from the ulnar side in the frontal plane

⚠CAUTION

Make sure to obtain bicortical purchase.



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Foot

A small, limited, open surgical approach allows central pin placement and may help avoid injury to or impingement of important soft tissue structures (tendons, ligaments, nerves and arteries). Half Pin placement should not interfere with soft tissue excursion during range of motion.

NOTICE

Accurate pin size and placement must be determined by the surgeon on a case by case basis.

Placement in the Phalanges

- **I** Insert Half Pins from the medial or dorsomedial side 0-115° from the frontal plane.
- **II** Insert Half Pins medially or laterally 15-45° from the frontal plane.
- **III** Insert Half Pins medially or laterally 15-45° from the frontal plane.
- **IV** Insert Half Pins medially or laterally 15-45° from the frontal plane.
- **V** Insert Half Pins from the lateral to dorsolateral side 0-110° from the frontal plane.

NOTICE

Caution must be taken to avoid all neurovascular or tendonous structures.

Placement in the Metacarpals

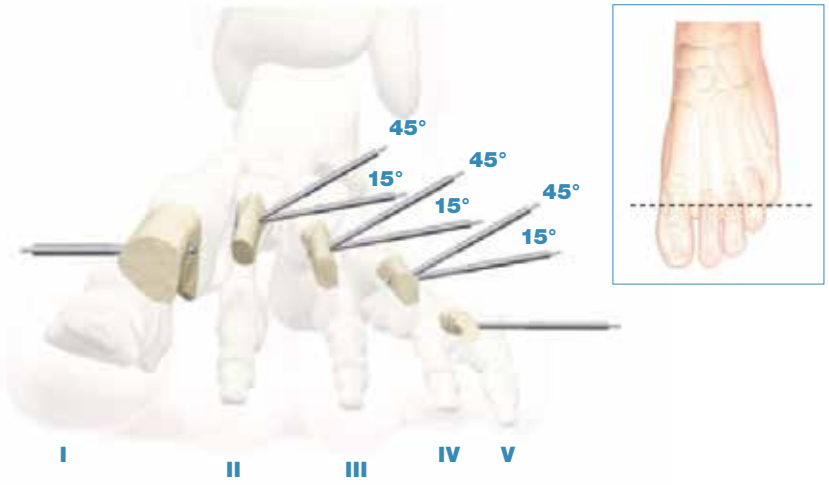
- **I** Insert Half Pins from the medial or dorsomedial side 0-115° from the frontal plane.
- **II** Insert Half Pins medially or laterally 15-45° from the frontal plane.
- **III** Insert Half Pins medially or laterally 15-45° from the frontal plane.
- **IV** Insert Half Pins medially or laterally 15-45° from the frontal plane.
- **V** Insert Half Pins from the lateral to dorsolateral side 0-110° from the frontal plane.

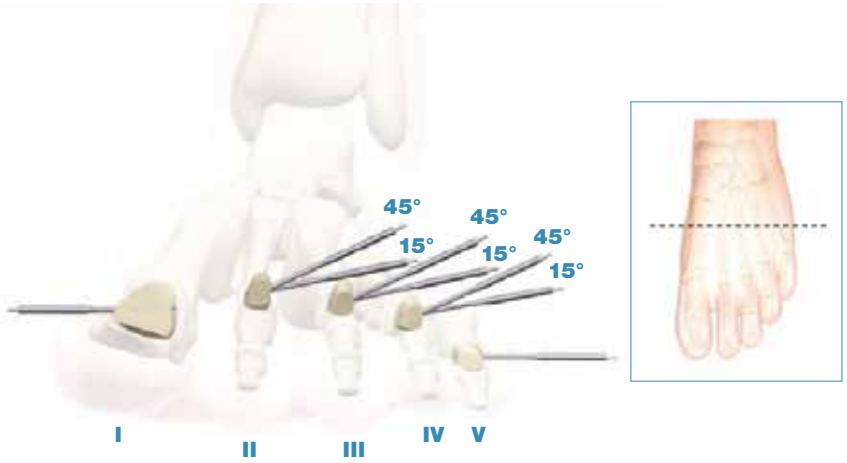
NOTICE

Caution must be taken to avoid all neurovascular or tendonous structures.

Consideration should also be given to any anatomical changes due to the current injury and to planning for any secondary surgeries that may be needed.

A general recommendation is for the pin size to be 1/3 the diameter of the bone treated. The Hoffmann® II Micro™ System is compatible with the larger Hoffmann® II Compact™ System (accepts 3-4mm pins) allowing easy bridging between systems.





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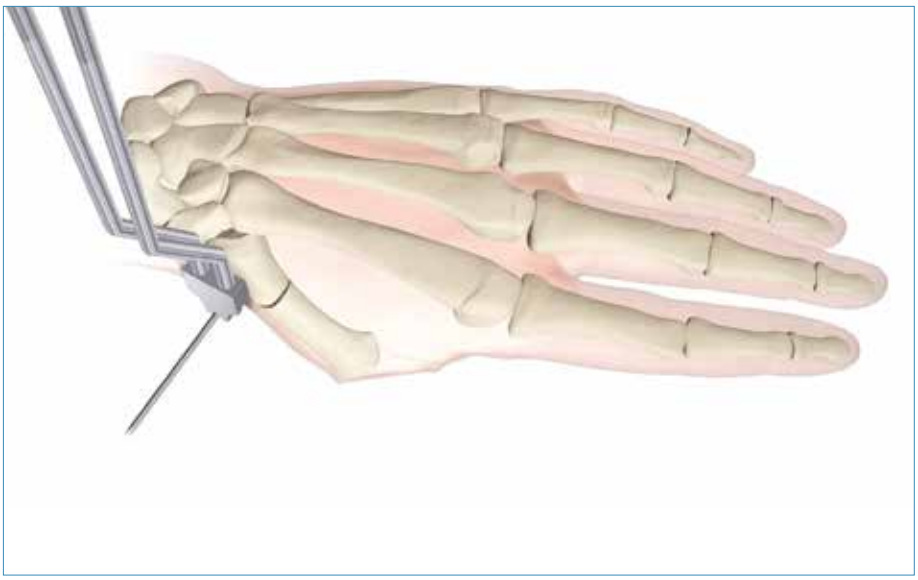
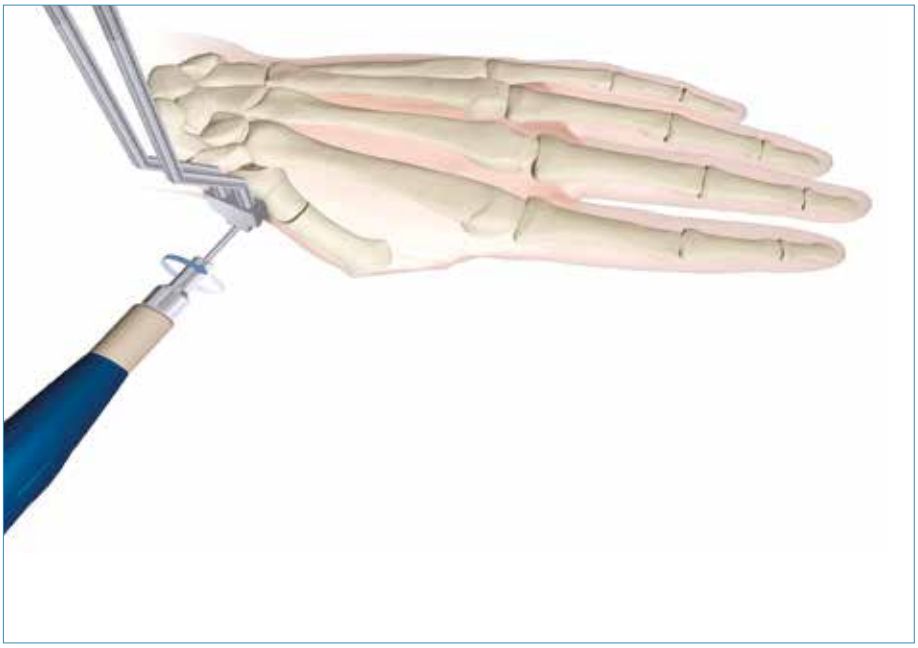
Lengthening of the 1st Metacarpal

Step 1
Drill the first proximal hole at least 5mm from the osteotomy site using the Drill/Pin Insertion Guide and the 1.6mm K-wire. If self-drilling/ self-tapping half-pins are used, it is possible to insert the half-pins without pre-drilling as described in this step.



The drill/pin insertion angle is approximately 0° radial to the frontal plane. Use image intensification to determine proper pin placement, and ensure bicortical purchase.

Step 2
Manually insert the half-pin (blunt or self-drilling/self-tapping) using the Ø2mm Pin Driver and Drill/Pin Insertion Guide.



⚠CAUTION

After final insertion, it is recommended to check the final position under fluoroscopy or X-Ray.

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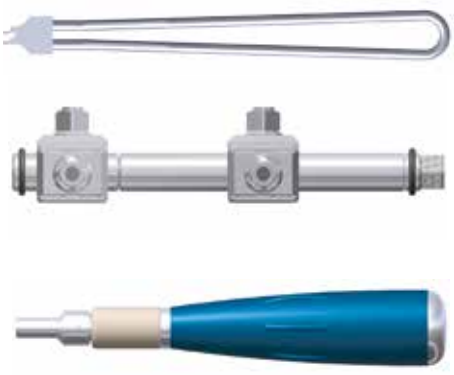
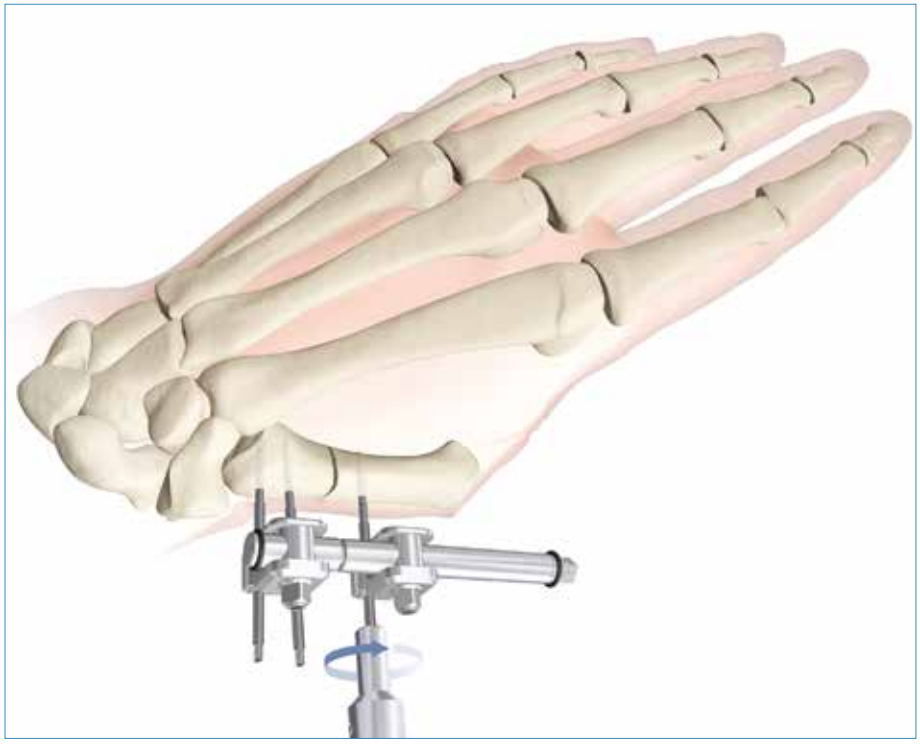
Step 3
Using the Multi-Pin Clamp of the Lengthener as a template, and the Drill/Pin Insertion Guide to protect soft tissue, manually insert the second half-pin through the Multi-Pin Clamp.



⚠CAUTION

Pre-drilling is necessary when using blunt pins.

Step 4
Build the same Pin/Clamp construct on the distal side of the osteotomy following steps 1 through 3 ensuring that the lengthener is parallel to the long axis of the bone.



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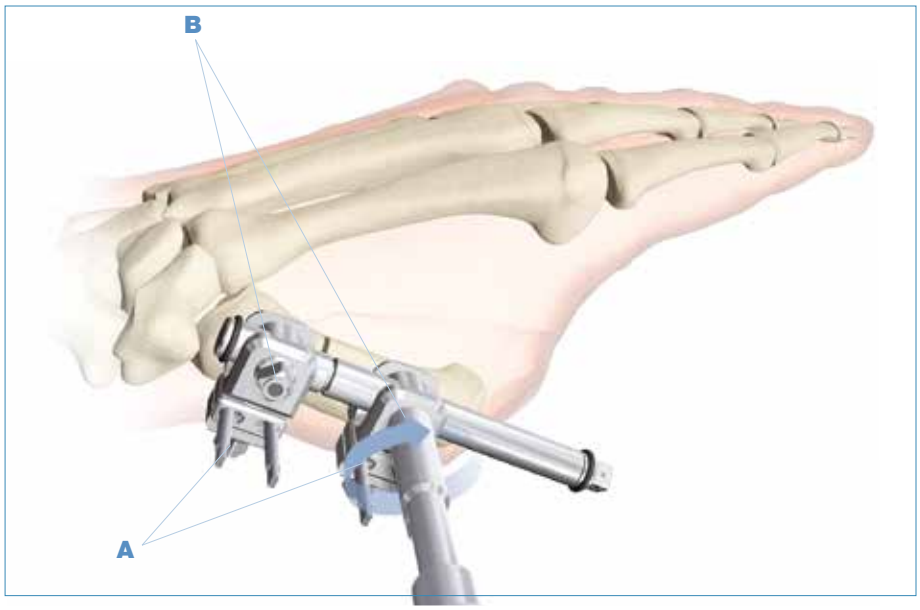
Step 5
After proper alignment is made, tighten Bolts A and B on both clamps.

NOTICE

The 4mm Nut Wrench shown here is designed to allow the proper torque needed to properly tighten bolts A and B. Take care not to over-torque the bolts when tightening with a spanner wrench.



Notes

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the 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. The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com. If saving the Instructions for Use, Operative Techniques, Cleaning instructions from the above mentioned websites, please make sure you always have the most up to date version prior to use.

This document is applicable to US and Canada.

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