stryker

TruAim™
Lapidus System

TruAim
Lapidus System

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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

TruAim is a sterile, single-use kit.
Do not reuse or reprocess.

⚠WARNING

This product is single-use only and intended for use on one patient, during one procedure. All single-use instruments are defined as biohazard waste and therefore must be disposed of in accordance with the facility's waste disposal procedures.

⚠WARNING

The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

This product is single-use only and intended for use on one patient, during one procedure. All single-use instruments are defined as biohazard waste and therefore must be disposed of in accordance with the facility's waste disposal procedures.

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

Consult Instructions for Use for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

Indications and contraindications

Description

The TruAim Lapidus System is a sterile single-use (single procedure) instrument kit intended to aide in surgical reduction, targeting, and implantation of 4.0mm (cannulated) screws (such as Stryker Asnis III, Fixos 2, DartFire Edge™, PROstep™ Chamfered Screws) and/or 5.0mm screws (such as Stryker Asnis III or Fixos 2) during fixation of Lapidus arthrodesis.

Indication for use

The TruAim Lapidus System enables the implantation of the compatible implant systems.

Contraindications

For specific contraindications, please refer to the contraindications of the compatible implant systems.

NOTICE

For additional information about compatible implant and instrument systems please refer to their respective Instructions for Use (IFU).

Indications and contraindications

User/Patient Safety

⚠WARNING

Before using this instrument, read and understand the instructions. Pay particular attention to warning information.

- This system is for use by qualified personnel trained in the use of surgical instruments and relevant surgical procedures.
- Do not use if packaging is opened, damaged, or show signs of tampering. The packaging of this product should be inspected for compromised sterile barrier.
- Do not use the product if shelf-life expiration date has passed. For shelf-life expiration date, refer to date printed on the product label.
- Do not reuse or reprocess. This product is single-use only and intended for use on one patient during a single procedure. Single-use equipment must be disposed of following the facility's waste disposal policy. All used single-use instruments are defined as biohazard waste and therefore must be disposed of in accordance with facility's procedures.
- Modification or mishandling of the instruments will invalidate the functionality of the instruments and may result in improper function of the instruments.

Instruction for use

Upon removal from packaging, inspect the instruments to ensure there is no damage. If damage is observed, discard the damaged instrument(s) and open a new single-use instrument kit.

After use, dispose the product in accordance with facility's waste disposal policy.

Sterility

This TruAim Lapidus System Instrument Kit (991067S) is supplied by the manufacturer in a sterile condition; it has been sterilized by Gamma radiation.

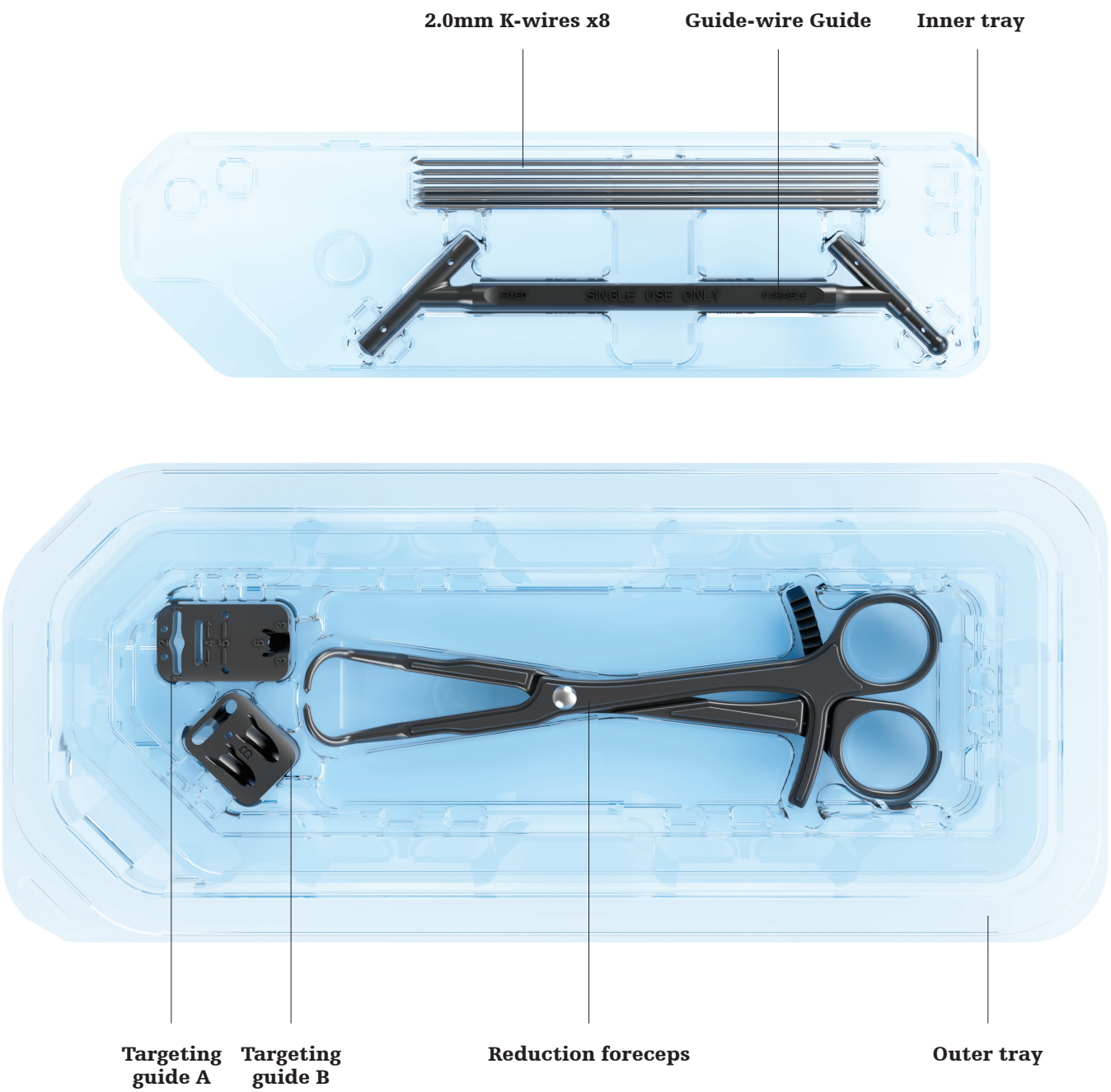
Storage and handling

Devices should be handled with care at all times. Storage zones for surgical instruments should be away from areas of humidity and must be out of contact with UV rays and sources of electro-magnetic radiation.

⚠CAUTION

Use caution when handling sharp instruments and instruments with pinch points such as bone reduction forceps.

Tray Layout


2.0mm K-wires x8
Guide-wire Guide
Inner tray
SINGLE USE ONLY
Targeting guide A
Targeting guide B
Reduction foreceps
Outer tray

Operative technique

'A' Guide

Make a small (12mm) dorsal transverse incision in the medial to lateral direction at the first TMT joint.

After dissection, insert a 2.0x150mm K-wire into the first cuneiform metatarsal joint. Use the K-wire to shield and move the EHL and surrounding nerves laterally. Using power, drive the K-wire into the joint space. This will hold the EHL and nerves in place and away for burring.

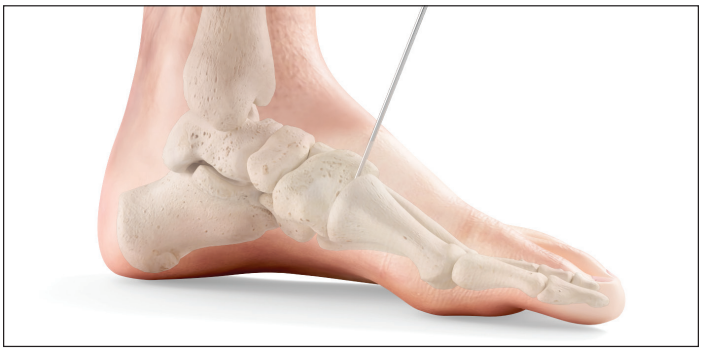


Fig. 1

NOTICE

Ensure the K-wire is in the joint space by taking AP and lateral images. The K-wire should be stable and will be used as a fulcrum for the metatarsal to pivot off while being reduced. This is highly important to the success of the following steps.

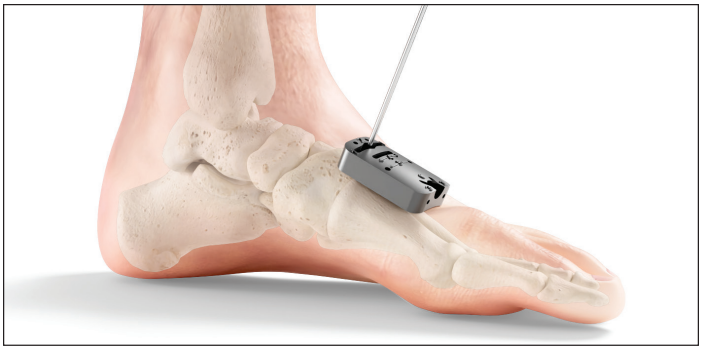


Fig. 2

NOTICE

It is the surgeon's preference if slot #3 2.0 x 150mm K-wires are placed prior to seating the guide.

Place the "A" guide dorsally over the first K-wire on the lateral side of the slot labeled #1.

The guide should be perpendicular to the long axis of the medial cuneiform.

Insert a K-wire through each of the two proximal holes labeled as #2 and into the medial cuneiform to stabilize the guide.

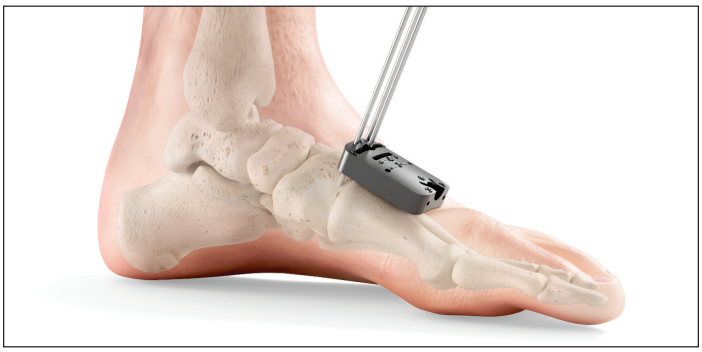


Fig. 3

Under power, drive two K-wires in the distal holes labeled as #3 of the guide until you feel resistance.

This allows for visualization of guide alignment to the first metatarsal and serves as a reference point to qualitatively assess joint correction after reduction takes place.

If needed, surgeons should use wire cutters to cut the K-wires in slot #2 to avoid disturbing their hands while burring.

Insert 2mm x 20mm cutting burr (57SR0220) through the joint slot labeled #1 of the guide. Adjust the length of the burr as needed to count for the 9mm height of the guide in order to reach the most inferior aspect of the joint. Prior to starting the burr, verify in AP and lateral fluoroscopy images that the burr is in correct alignment of the joint space.

⚠CAUTION

Set to 6,000 rpm and use the burr to remove the cartilage from the joint while flushing with irrigation to avoid burning the bone.

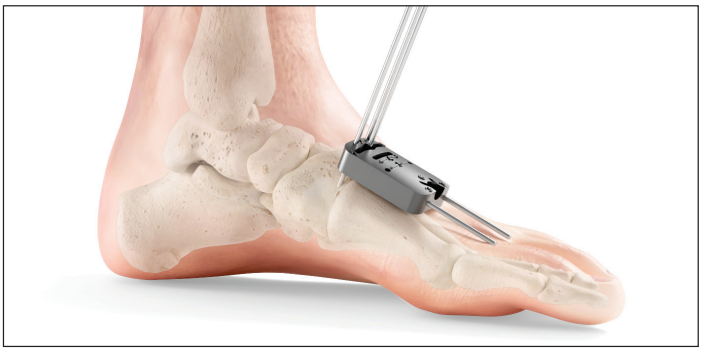


Fig. 4

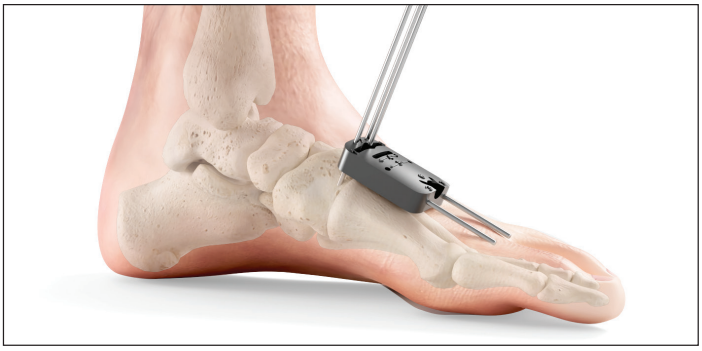


Fig. 5

Fig. 6

Create a minimal incision on the lateral aspect of the second metatarsal. Using the tenaculum, hook under the neck of the second metatarsal and percutaneously on the plantar surface of the first metatarsal as to still allow rotation to occur. For patients with smaller anatomy, the tenaculum can be hooked under the neck of the third metatarsal instead of the second.

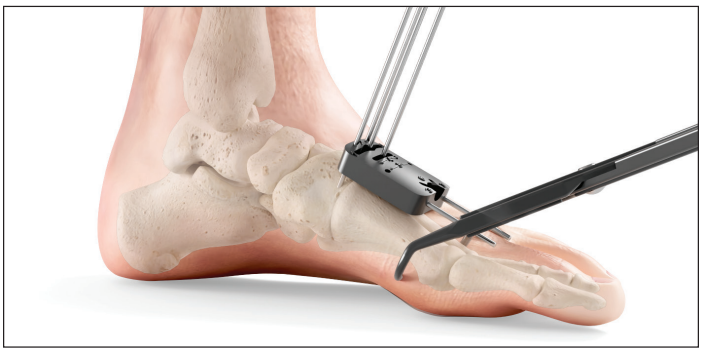


Fig. 7

NOTICE

The tenaculum can sit over or under the #3 slot K-wires. It is recommended to place under if you intend to remove the guide and sweep with curette after burring.

Fig. 8

Bring the first metatarsal to the desired degree of varus correction. Correction should be finished by incrementally burring the joint of the first tarsometatarsal through slot #1 while simultaneously reducing the IM angle with the tenaculum. The alignment wires in the #3 holes can be a visual aid to determining the amount of correction needed from where the first metatarsal was originally positioned.

Insert a 2.0x150mm K-wire through the middle of the rotational correction slot labeled #4. Drive the K-wire into the first metatarsal.

Using the K-wire as a joystick, supinate or pronate the first metatarsal as needed to the desired degree of rotational correction and sesamoid alignment.

Once in the desired position, temporarily stabilize the joint in its corrected orientation by inserting two 2.0x150mm K-wires into the #5 holes and into the first metatarsal as shown.

NOTICE

Start with the medial #5 K-wire. For patient's with small anatomy, one #5 medial K-wire is sufficient.

Remove the K-wire from the #1 slot as well as the #4 slot.

Using an 11 blade, create a minimal incision in the soft tissue through one of the "rabbit ear" features of hole #6 such that the screw head can penetrate through the skin and be seated to the desired depth. Use a hemostat to spread if needed. A cruciate incision can also be made here instead of a linear incision.

Insert the wire guide into hole #6 using the fixed end. Use the variable end if up to 5 degrees of variation is needed. To adjust trajectory, the wire guide does not need to fully sit in hole #6 and can be placed more proximal. Trajectory can be lined up under fluoroscopy with the radiolucent feature of the wire guide.

Insert the **appropriate size K-wire from the screw system** through the wire guide to the desired depth (verified via intraoperative fluoroscopy).

Remove the wire guide and measure the screw length needed with the screw system's depth gauge all the way down to bone.

For screws that are not self-drilling, self-tapping or in the case of hard cortical bone, use the appropriate system's drill and tap as needed. Use the system's cannulated countersink if countersinking is desired.

Insert the proper screw over the K-wire and using a handheld driver, drive through the guide until the screw is fully seated.

Remove all K-wires EXCEPT for the medial wire of hole #2. This wire is necessary for accurate placement of the "B" guide.

Remove the "A" guide by sliding the chip up, leaving just the medial cuneiform fixation wire from the #2 hole. Finish driving the screw if needed and verify via fluoroscopy.

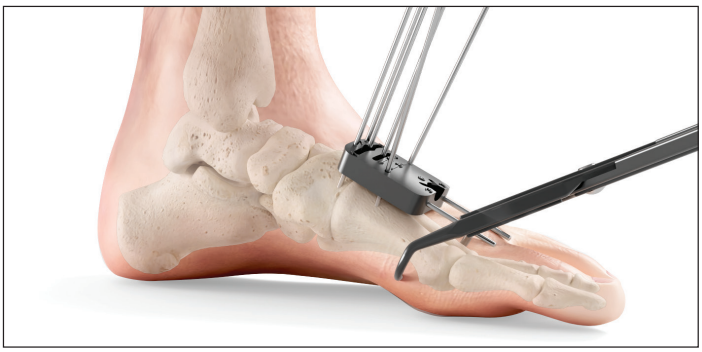


Fig. 9

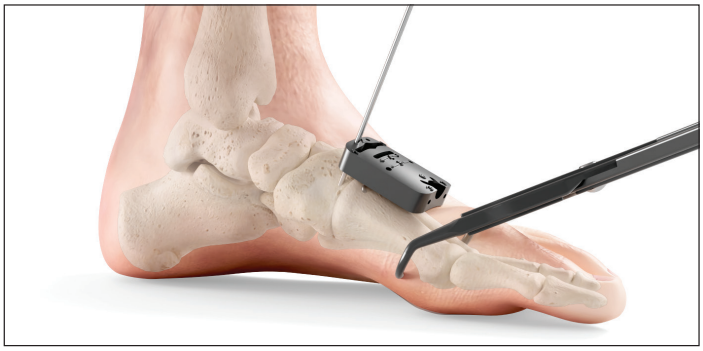


Fig. 10

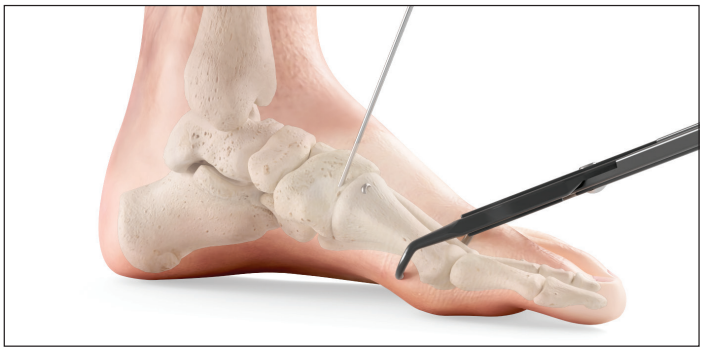


Fig. 11

'B' Guide

Insert a 2.0x150mm K-wire into the #1 hole located on the distal facing surface of the guide. This will be used to align parallel with the first metatarsal but does not need to bisect.

Place the “B” guide over the medial cuneiform K-wire that remained from the “A” guide via the slot labeled #2. Note that the #2 slots are marked with an “L” and “R” for a left vs. right foot.

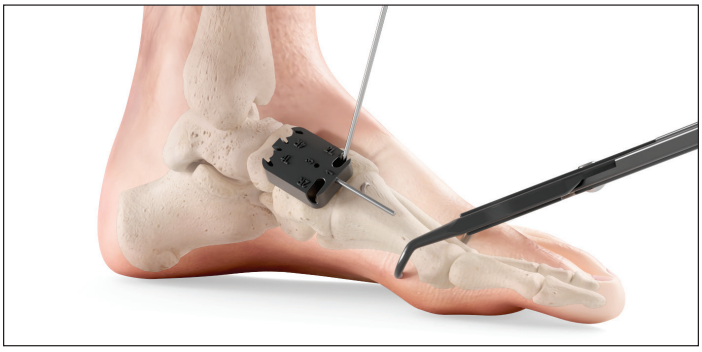


Fig. 12

Precaution

These are not screw slots but serve for correctional rotation purposes. The #2 slot allows the guide to adjust according to the anatomy of the patient's foot and the deformity needing to be corrected. The anterior face of the guide should align with the first TMT joint line and the wire in slot #1 should align parallel to the first metatarsal.

Once the “B” guide is in the proper position, insert a 2.0x150mm K-wire through the central hole labeled #3 to stabilize the guide in the proper position.

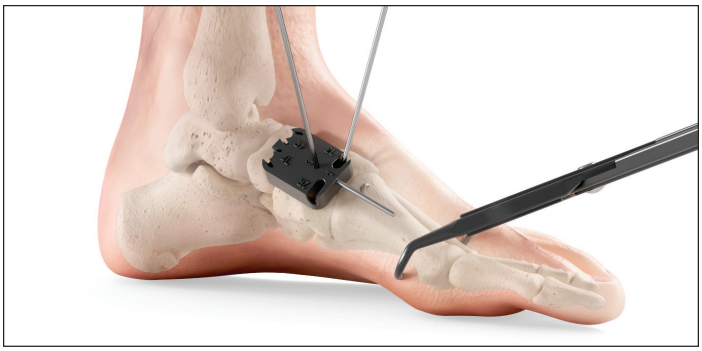


Fig. 13

Using an 11 blade create a minimal incision in the soft tissue through one of the "rabbit ear" features of the appropriate "L" or "R" hole labeled #4. Use a hemostat to spread if needed. A cruciate incision can also be made here instead of a linear incision. Insert the wire guide in the appropriate #4 hole using the fixed end. Use the variable end if up to 5 degrees of variation is needed. If the position of the wire needs to adjust, the K-wire can be inserted through the slot without the use of the wire guide.

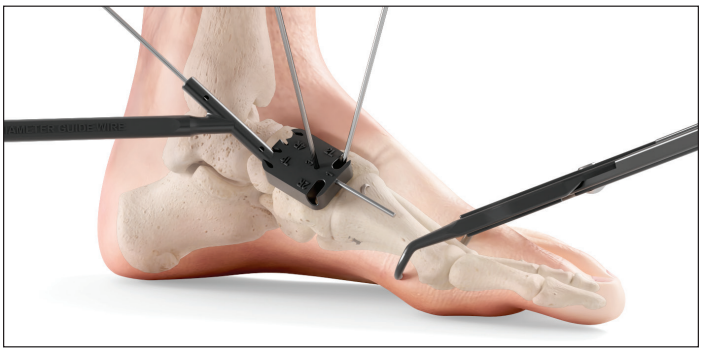


Fig. 14

Insert the **appropriate size K-wire from the screw system** through the wire guide to the desired depth (verified via intraoperative fluoroscopy).

Remove the wire guide and measure the screw length needed with the screw system's depth gauge all the way down to bone.

For screws that are not self-drilling, self-tapping or in the case of hard cortical bone, use system's cannulated drill and tap as needed. Use the system's countersink if countersinking is desired.

Insert the proper screw over the K-wire and using a handheld driver, drive through the guide until the screw is fully seated.

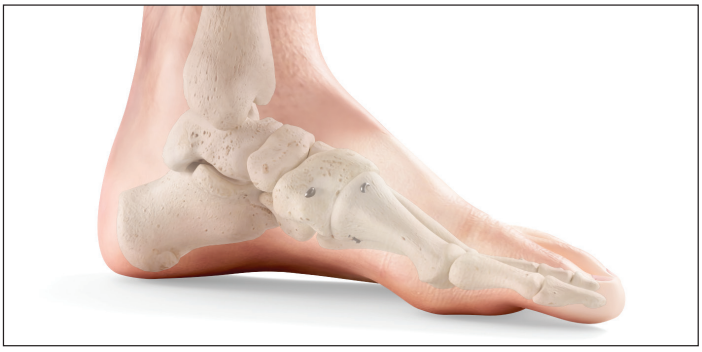


Fig. 15

Images of Final Screw Placement and Positioning

Using fluoroscopy, take AP and lateral images to confirm correct positioning of screws before removing the K-wire holding the guide to the bone.

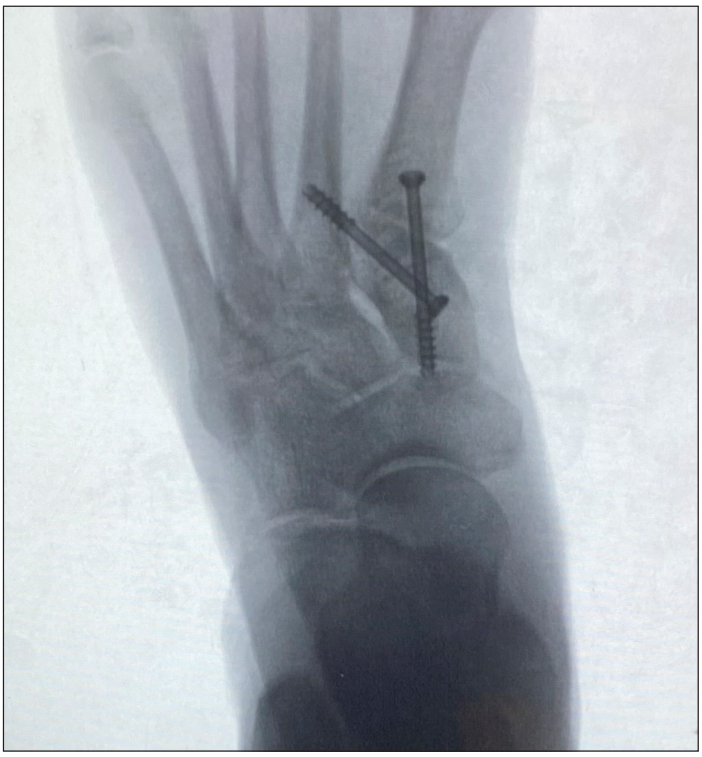


Fig. 16

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Foot & Ankle

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