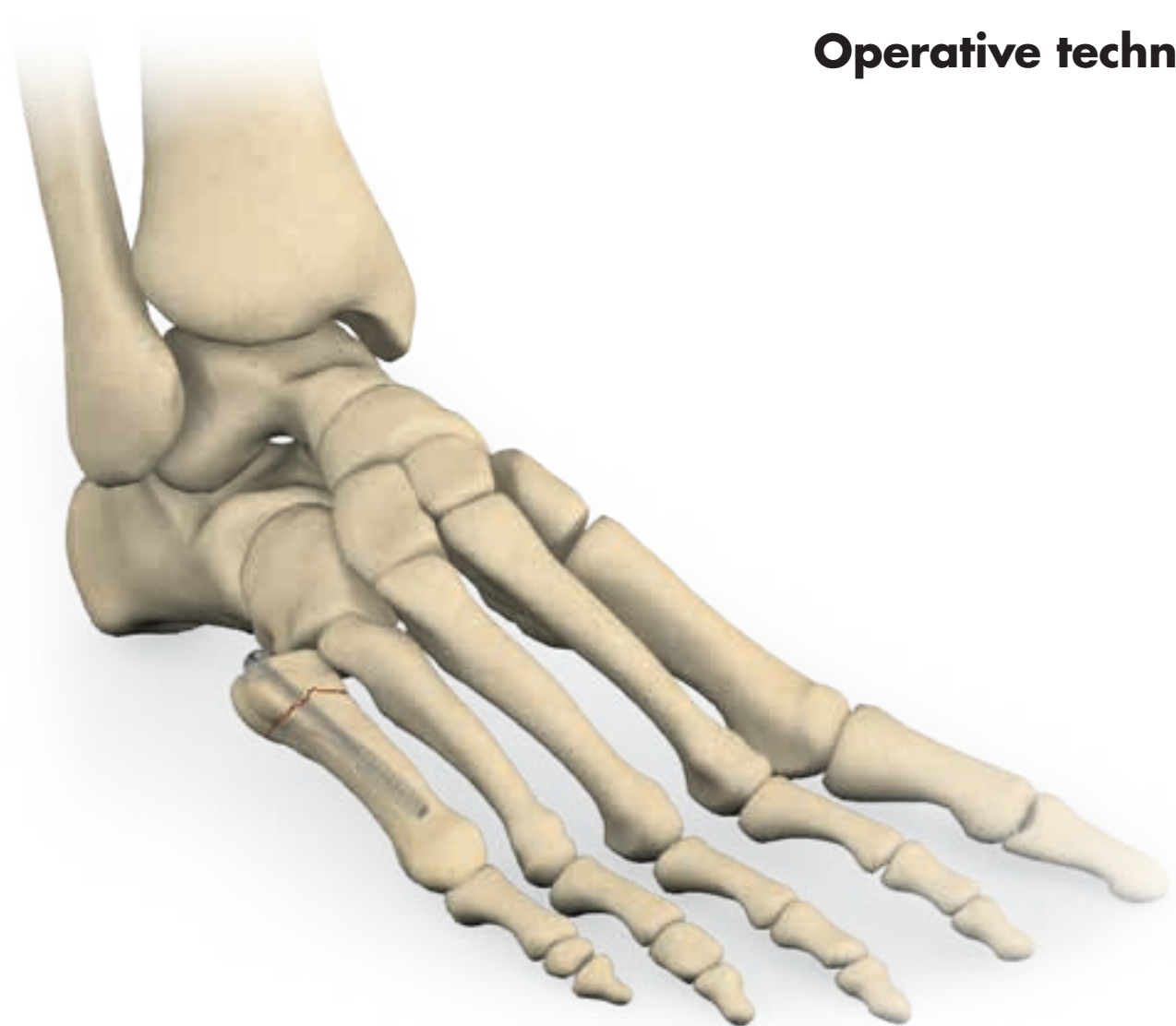


Asnis[®] JFX

Jones Fracture Fixation System

Operative technique



Asnis JFX

Jones Fracture Fixation System

Table of contents

Indications, precautions & contraindications	3
Technical specifications	4
General safety instructions	15
Operative technique	16
Optional steps	28

This publication sets forth detailed recommended procedures for using Stryker's 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.

A workshop training is recommended prior to first surgery. The Stryker instruments are only to be used by a physician with special skills in traumatology and/or reconstructive surgery in a sterile operating room in hospitals or specially equipped offices.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000, OT-RG-1).

Use care when handling or disposing of sharp instruments or implants. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

See package insert (instruction for use/V15011, V15013 and L22000020 and L22000030) for a complete list of potential adverse effects, contraindications, warnings and precautions.

The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Indications, precautions & contraindications

Indications

The Asnis JFX System is intended for the fixation of bone fractures or for bone reconstruction of the 5th metatarsal.

Indications include:

- Fixation of malunions and nonunions
- Acute fractures
- Avulsion fractures
- Repetitive stress fractures
- Jones fractures

Precautions

Stryker systems have not been evaluated for safety and compatibility in Magnetic Resonance (MR) environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

Contraindications

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment.

Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.

Technical specifications Implant

The Ø4.0, 5.0 & 6.0mm solid and cannulated Asnis JFX screws are specifically designed to address Jones fractures.



Figure 1

The system incorporates several specifications intended to allow for screw placement, insertion, fracture stabilization and removal as shown in figure 2:

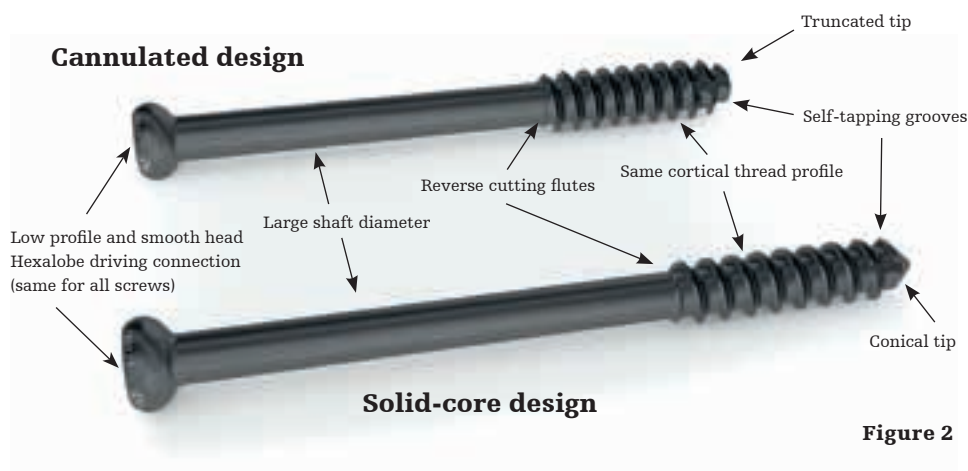


Figure 2

The Asnis JFX System offers 3 diameters and a large range of lengths with 2mm and 5mm increments, in both cannulated and solid core designs, to cover a large range of morphologies:

	Ø4.0mm	Ø5.0mm	Ø6.0mm
Material	Titanium		
Length	From 36 to 50mm each 2mm From 55 to 60mm each 5mm	From 36 to 50mm each 2mm From 55 to 60mm each 5mm	From 36 to 50mm each 2mm From 55 to 65mm each 5mm

*For solid and cannulated screws

Figure 3

Three washers, associated to each screw diameter, are also provided in the kit to spread the load over a larger area.



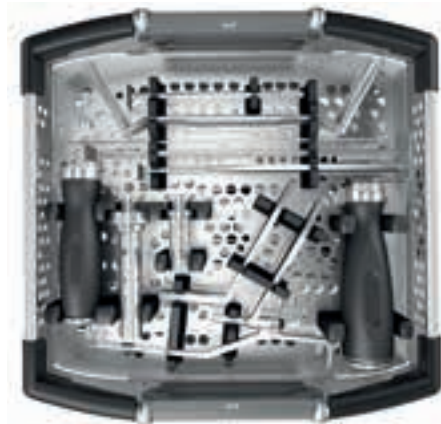
Figure 4

Technical specifications

Instrumentation

Asnis JFX System design

The tray is built in two levels. The top layer contains general instruments whereas the drawer consists of the implants and other instruments.



Top layer - general instruments



Drawer - implants and other instruments

Figure 5

Non threaded guide wire Ø2×200mm

The Ø2.0mm Guide Wire (REF 705355) is used for all screw sizes and cannulated instruments

Screw size can be determined intra-operatively without requiring different guide wires.



Figure 6

Sighting arm

The sighting arm (REF 705373) fulfills two main functions.

Under fluoroscopic guidance, it helps the surgeon to target the guide wire into the intramedullary canal of the fifth metatarsal bone, and it helps to determine the appropriate screw length and diameter.

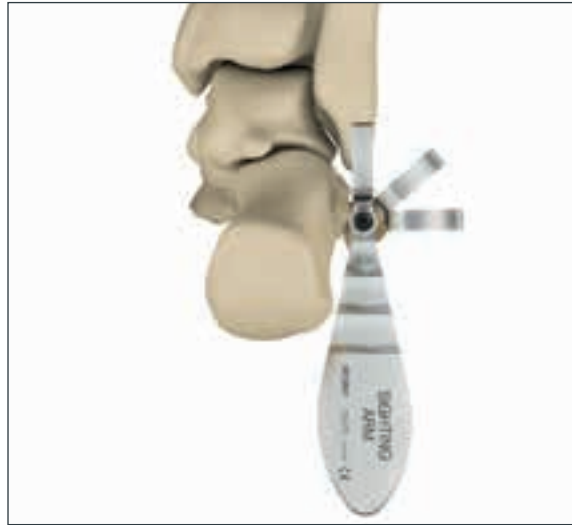


Figure 7

It allows the surgeon to rotate the arm every 45° over the fifth metatarsal bone to check the guide wire position in the antero-posterior, oblique and lateral views.

Pull the trigger to unlock the rotation of the arm, select the appropriate angulation (every 45°) and release it to lock the new position.



Figure 8

Moreover, the sighting arm provides a measuring method to select the appropriate screw size.

The slider is designed to be able to move along the groove of the arm and features a diameter scale corresponding to each screw outer diameter thread (not the core diameter).



Figure 9



Figure 10

The arm is equipped with laser markings associated with each screw length available within the range.



Figure 11

The screw diameter and length should be determined as follows:

Figure 12

Steps description	
1. Guide wire insertion	
2. Sighting arm placement over the guide wire	
3. Screw diameter	<p>Move the slider along the arm until it matches the appropriate screw insertion depth. Assess the most suitable screw diameter to provide adequate screw purchase in bone cortex. In case different diameters are determined in the different views, the smallest one shall be considered in order to avoid cortical breakage.</p>
4. Screw length assessment	<p>In case different lengths are identified in the different views, the shortest one shall be considered in order to avoid cortical infringement due to lateral or plantar metatarsal flares.</p>

Parallel positioning guide

The kit contains a parallel positioning guide (REF 705371) aimed at facilitating the initial insertion of a guide wire or correcting the position of a guide wire inserted with good angulation but not centered in the intramedullary canal (too lateral/medial or plantar/dorsal).

To this end, the device is made of three aligned holes separated by 2.5mm from each other, allowing the surgeon to insert a second guide wire offset by 2.5 or 5mm relative to the first one.



Figure 13

Guide wire correction	
<p>1. Incorrect first guide wire insertion</p>	<p>Example: Guide wire too plantar.</p>
<p>2. Parallel positioning guide placement over the guide wire in the appropriate hole</p>	<p>Example: Guide wire too plantar. Guide wire inserted in the lower hole of the parallel positioning guide to create a dorsal offset.</p>
<p>3. Second guide wire insertion</p>	<p>Example: A second guide wire is inserted in the middle hole while keeping the first guide wire, to create a 2.5mm offset.</p>
<p>4. First guide wire removal</p>	

Figure 14

Drill bit

A Ø3.0mm drill bit with calibrations (REF 705357) is provided in the kit to drill the pilot hole in the intramedullary canal for all screw diameters. It features a scale enabling the surgeon to measure the screw length during the surgery.



Figure 15

Taps

Three taps (REF 705360/ 705361/ 705362) each adapted to a screw diameter are available in the system. Although all screws are self-tapping, taps will be used to evaluate screw diameter and also in cases of high bone density.

All taps are scaled and designed so as to correctly evaluate the appropriate screw length.



Figure 16

Countersinks

The Asnis JFX instrumentation includes three countersinks (REF 705363/ 705364/ 705365) adapted to each screw head, intended to reduce the screw head prominence.

The groove on the countersink provides an indication of the screw head height.

Countersinking should always be performed manually.

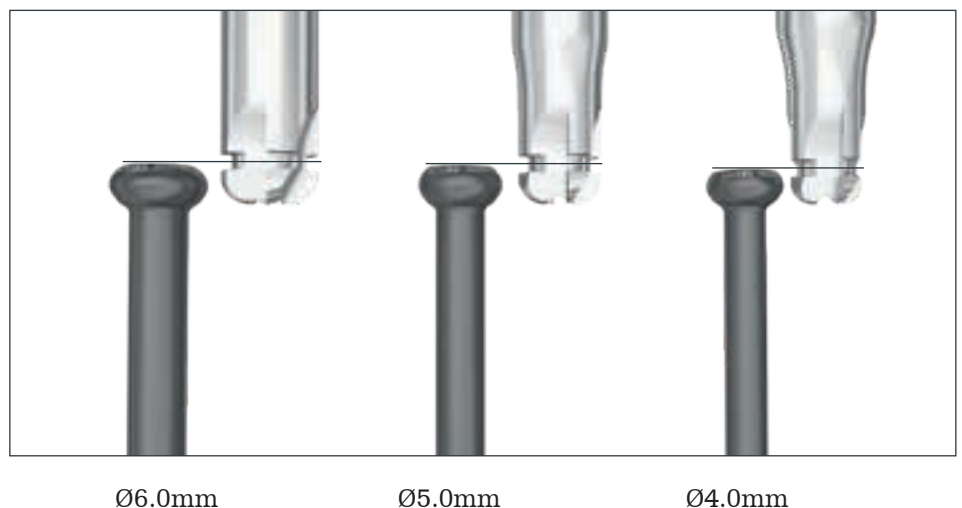


Figure 17

Double protecting sleeve

A double protecting sleeve (REF 705369) is available in the kit to protect the soft tissue during drilling, tapping and countersinking. The device features two sleeves shaped to fit the fifth metatarsal bone.

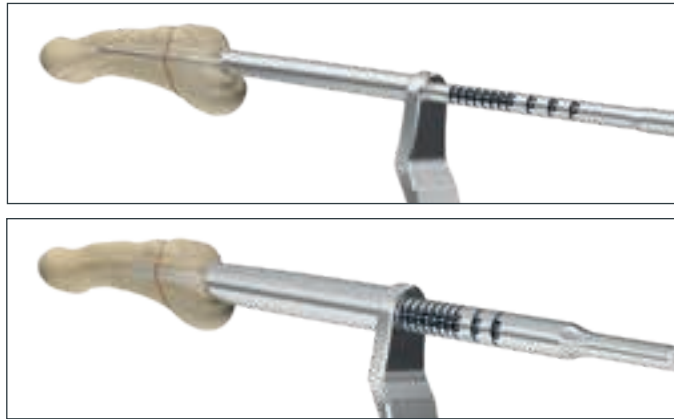


Figure 18

One sleeve is drill bit specific whereas the other one is dedicated for the three taps and three countersinks.

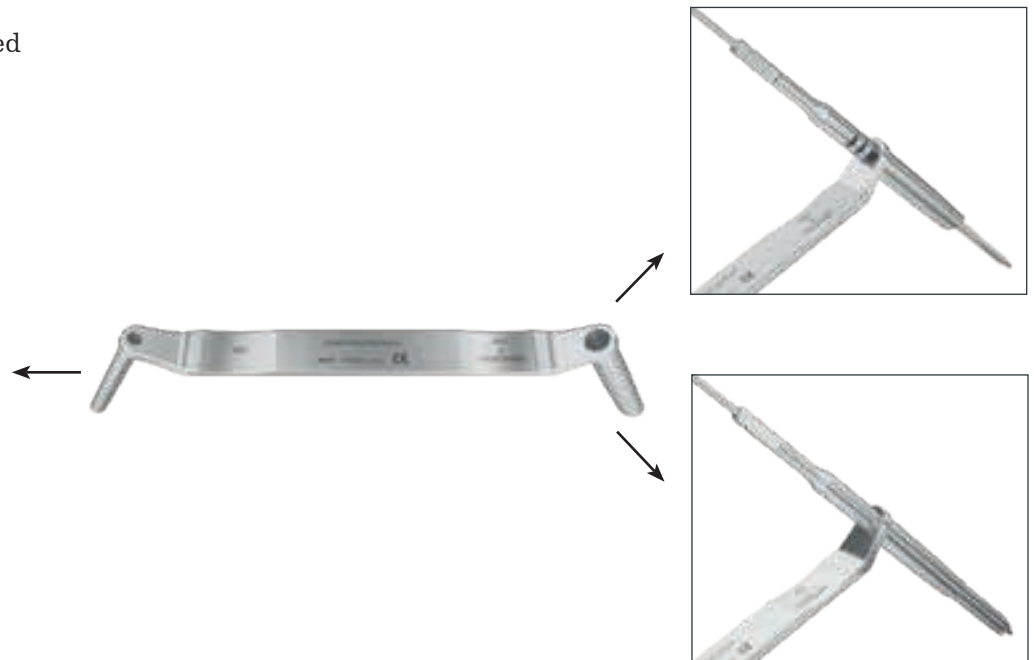


Figure 19

Screwdriver

One cannulated screwdriver (REF 705366) and one solid screwdriver (REF 705214) are provided in the kit. Both of them are compatible with all screw diameters and feature a T20 Torx recess for torque transmission.



Figure 20

Screw size measurement options

The Asnis JFX system offers various options to evaluate screw length and diameter. The drill bit (REF 705357) and direct measuring gauge (REF 705370) are scaled to assess the appropriate screw length

whereas the sighting arm (REF 705373) and the taps (REF 705360/ 705361/ 705362) allow for both evaluating the screw length and diameter. The direct measuring gauge should be used in the case of countersinking or when a washer is used.

All screw length measuring methods measure directly to the tip of the guide wire. This ensures that the final screw position corresponds with the initial tip position of the guide wire.





Instruments	Measurements	
	Length	Diameter
Drill bit (REF 705357) Drill protecting sleeve (REF 705369)		× n/a
Taps (REF 705360, 705361, 705362) Taps protecting sleeve (REF 705369)		× ×
Direct measuring gauge (REF 705370)		× n/a
Sighting arm (REF 705373)		× ×

Figure 21

Modular handle

Asnis JFX offers a fully modular handle system.

This is composed of two handle grip sizes, medium (REF 703921) and large (REF 703920), that can be interchanged with either a bi-directional ratcheting AO-coupling insert (REF 703922) or a standard AO-coupling insert (REF 703923).

Both handle sizes are equipped with a spin-cap to allow insertion using a two-finger technique. In order to disengage the insert from the handle, push down on the button on the distal part of the handle and pull the insert away from the handle.

The inserts must be removed from the handles before cleaning.

The bi-directional ratcheting insert (REF 703922) can work in three modes: clockwise ratcheting, counter-clockwise ratcheting or neutral. To switch between the different modes, simply twist the distal part of the insert to the desired driving direction.

To ensure appropriate ratcheting function, perform appropriate maintenance on the insert by applying medical-grade lubricant oil through the marked cut-outs.



Medium handle

Figure 22



Bi-directional ratcheting AO-coupling insert

Figure 23



Large handle

Figure 24



Standard AO-coupling insert

Figure 25

General safety

instructions

Caution

- Extreme rotation speed during drilling, tapping, countersinking and screw/guide wire insertion may lead to increased heat generation.

Warning

- Applying excessive torque during screw insertion may cause damage to the screw head and screw driver, which can lead to difficult screw extraction. Extensive bone damage may also be a result, requiring additional surgical measures such as supplementary surgery, change in surgical method and/or revision surgery.
- Pay attention to avoid any unexpected soft tissue irritation especially during cutting, drilling, tapping, countersinking and screw/k-wire insertion.

Additional information

Notice

- **Cleaning:**
Care should be taken to utilize the cleaning stylet for intra and post-operative cleaning of cannulations. Correct intra-operative use of this instrument prevents accumulation of debris.
- **Removal:**
It is recommended that the solid screwdriver is used for screw removal.
- **Single use items:**
Discard all single-use implants and instruments utilized during the procedure. Do not reuse these items.

Operative technique

Step 1: Incision

Make a percutaneous lateral incision, approximately 2cm proximal to the base of the 5th metatarsal, carefully avoiding the peroneus brevis tendon and the branches of the sural nerve.

Step 2: Guide wire insertion

Make sure that bone fracture is appropriately reduced and bone fragments are aligned prior to insertion of the guide wire.

Proper positioning of the guide wire into the intramedullary canal is fundamental.

There are two instruments that can be used for initial guide wire insertion, the sighting arm (REF 705373) or the parallel positioning guide (REF 705371).



Figure 26

Step 2a: Sighting arm

1. Introduce the guide wire $\text{Ø}2.0 \times 200\text{mm}$ (REF 705355) into the sleeve of the sighting arm (REF 705373) and target the guide wire "high and inside". A "high and inside" starting point is required so that the placement of the guide wire, drill, tap and implant can match the axis of

the fifth metatarsal bone and follows the true intramedullary canal path which will help prevent deflection or breakage through a cortex. The sleeve should be in contact with the lateral aspect of the cuboid.

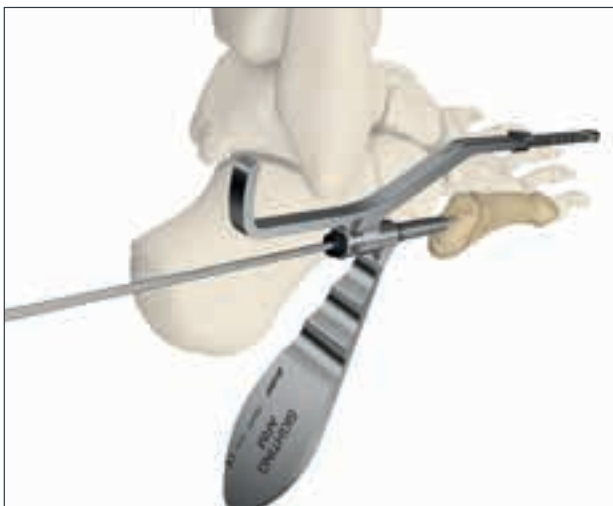


Figure 27



Figure 28

2. Place the tip of the sighting arm sleeve on the tuberosity and insert the guide wire (REF 705355) only 1-2mm into the fifth metatarsal bone to engage the proximal cortex.



Figure 29

3. Rotate the arm of the sighting arm (REF 705373) above the fifth metatarsal (AP view).

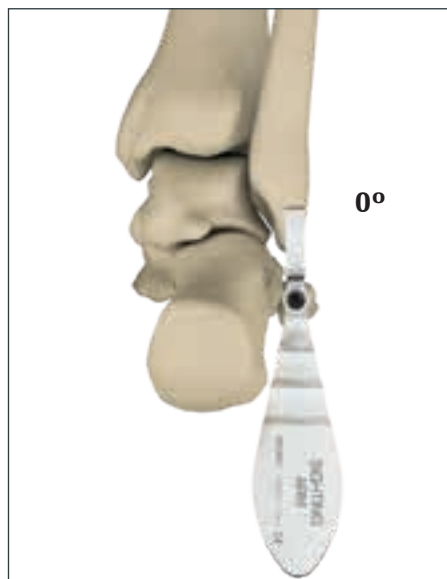


Figure 30

4. Use fluoroscopy to check the alignment of the guide wire (REF 705355) with the intramedullary canal axis on AP view.

The guide wire should be positioned in the center slot of the arm to confirm proper alignment. If necessary, adjust the angle of insertion of the guide wire by moving the handle.



Figure 31

Notice

It is important that the wire is not inserted too deep into the bone to prevent bending when moving the tip of the wire. If so, slightly back-off the wire until it is possible to adjust its angulation without applying excessive force.

5. Rotate the arm and use fluoroscopy to check the alignment of the guide wire (REF 705355) with the intramedullary canal axis on oblique and lateral views.

If necessary, adjust the angle of insertion of the guide wire by moving the handle.

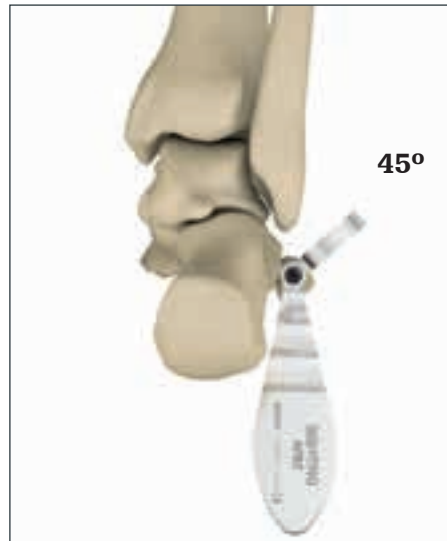


Figure 32

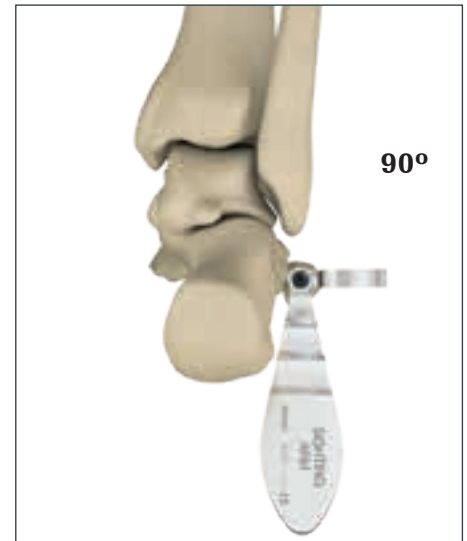


Figure 33

6. Once the guide wire alignment is correct in AP, oblique and lateral views, insert the guide wire (REF 705355) into the fifth metatarsal, taking care not to change the previously determined angulation during insertion.

It is recommended that this step should be monitored under fluoroscopy to ensure good insertion. Under fluoroscopy, check the guide wire position compared to the fifth metatarsal bone in the three different views mentioned above.

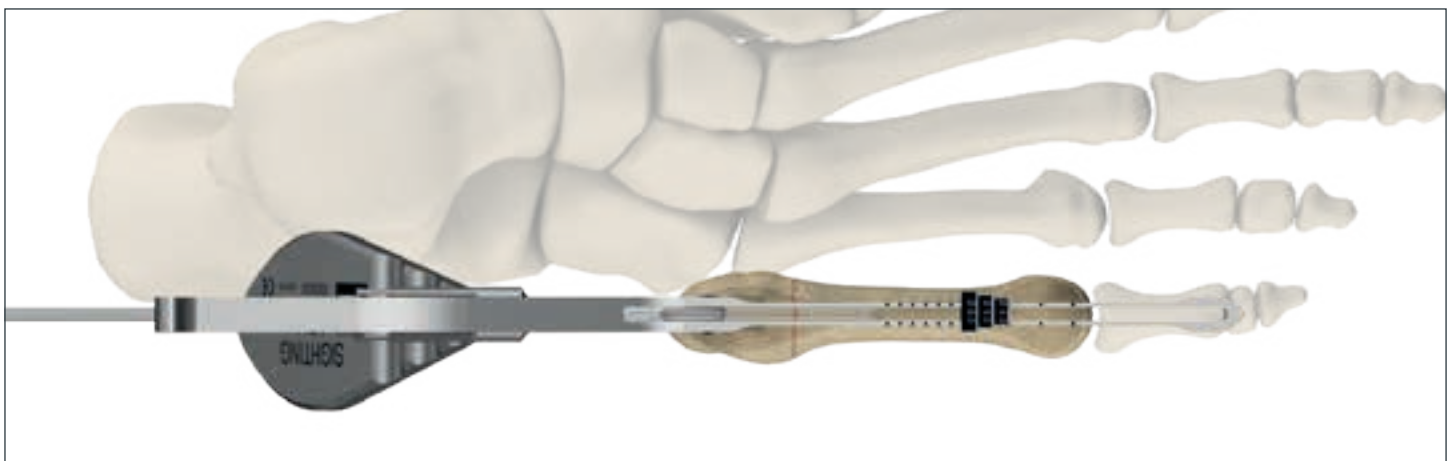


Figure 34

Step 2b: Initial wire placement with the parallel positioning guide (REF 705371)

1. Introduce the guide wire 2.0 x 200mm (REF 705355) into the parallel positioning guide (REF 705371), in the hole closest to the cuboid, and target the guide wire 'high and inside'. A "high and inside" starting point is required so that the placement of the guide wire, drill, tap and implant matches the axis of the fifth metatarsal bone and follows the true intramedullary canal path which will help prevent deflection or breakage through a cortex. The sleeve should be in contact with the lateral aspect of the cuboid.
2. Place the tip of the parallel positioning guide sleeve on the tuberosity and insert the guide

wire (REF 705355) only 1-2mm into the fifth metatarsal bone to engage the proximal cortex.

3. Use fluoroscopy to check the pre-alignment of the guide wire (REF 705355) with the intramedullary canal axis on AP, oblique and lateral views.
4. Once the guide wire alignment is correct in AP, oblique and lateral views, insert the guide wire (REF 705355) into the fifth metatarsal, taking care not to change the pre-determined angulation during insertion. It is recommended that this step should be monitored under fluoroscopy to ensure good insertion. Under fluoroscopy, check the guide wire position compared to the fifth metatarsal bone using an AP, oblique, and lateral view.



Figure 35



Figure 36

Notice

It is important that the wire is not inserted too deep into the bone to prevent bending when moving the tip of the wire. If so, slightly back-off the wire until it is possible to adjust its angulation without applying excessive force.

Caution

The guide wire is inserted across the fracture site and should remain in the intramedullary canal and bridge the fracture, while paying attention to avoid infringing the surrounding cortical bone. It should not go through the metatarsophalangeal (MTP) joint and should stop before the medullary canal of the metatarsal starts to flare.

Optional step (see details in optional steps section):

Parallel positioning guide (optional)

If the primary guide wire angulation is acceptable but its placement is too lateral/medial or plantar/dorsal, the parallel positioning guide (REF 705371) may be used to insert a second guide wire parallel to the initial one and correct the centering axis of the guide wire.



Figure 37

Step 3: Screw diameter and length measurement

Once guide wire positioning has been confirmed centered in the fifth metatarsal shaft, use the sighting arm (REF 705373) to assess the screw length and diameter as follows (Figure 12).

1. Using the AP view under fluoroscopy, make sure the guide wire appears in the center of the slot of the sighting arm (REF 705373) to ensure accurate measurement. Use the diameter scale on the slider of the sighting arm (REF 705373) to assess the best screw diameter to ensure an adequate

cortical purchase. Move the slider along the oblong slot of the arm until the diameter scale reaches anticipated screw distal tip, compared to the bone.

2. Read the distal screw length corresponding to the screw diameter previously determined, on the laser marked scales of the arm.
3. Rotate the arm of the sighting arm (REF 705373) on the oblique and lateral views. Adjust your fluoroscopy position accordingly and check that the guide wire still appears in the center of the slot of the arm.

Ensure the tip of the sleeve is in close contact with the tuberosity for accurate length measurement. Repeat the measurements previously described in step 3.1 & 3.2 in these other views.

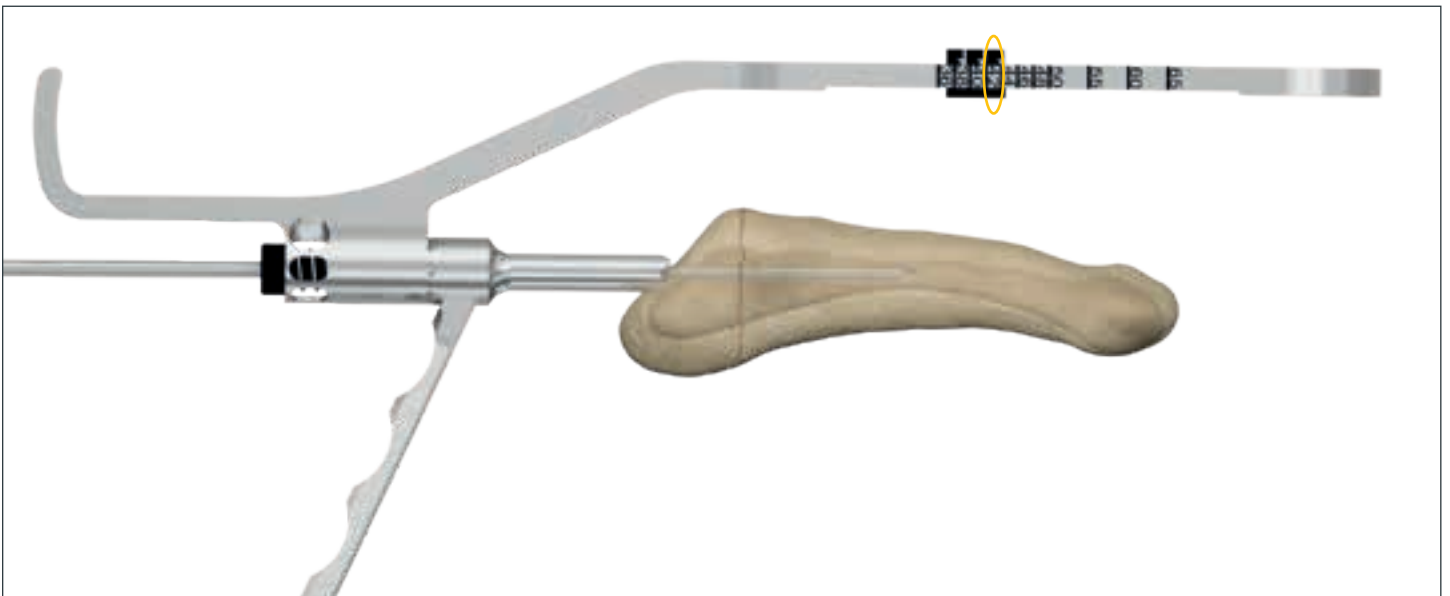
Warning

It is essential to repeat the screw diameter and the distal screw length identification on the lateral view. In order to avoid oversizing of the screw, the smallest measured values between AP and lateral measurements shall be considered to select the screw size.



AP view

Figure 38



Lateral view

Figure 39

Warning

Correct screw diameter selection is fundamental to achieve the best fixation strength. Screw diameter should be maximized depending on each patient's bone size and shape. Always make sure enough room is preserved between screw outer diameter and bone outer dimensions to avoid bone splitting or cracking during screw insertion.



Figure 40



Figure 41

Notice

The average straight segment length (i.e. lateroplantar curvature where the medullary canal begins to flare) of the fifth metatarsal is 52mm and represents 68% of the overall length from its proximal end. Excessive screw length could be avoided by keeping screw length at about 68% of the length of the fifth metatarsal [Ochenjele G., 2014, Radiographic Study of the Fifth Metatarsal for Optimal Intramedullary Screw Fixation of Jones Fracture, American Orthopaedic Foot & Ankle Society].

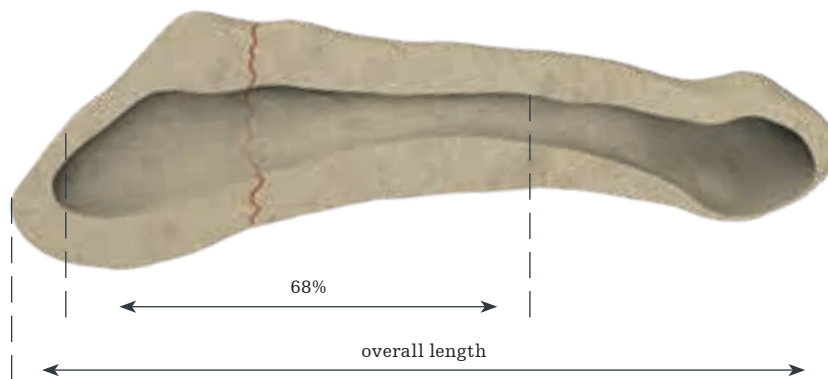


Figure 42

Warning

Attention must be paid to ensure that there is adequate thread engagement in the cortex.

Notice

If the screw diameter selection is not obvious by using the sighting arm, it is recommended to use the taps as trials.

Step 4: Drilling

1. Place the drill sleeve of the double protecting sleeve (REF 705369) over the guide wire Ø2.0 × 200mm (REF 705355).
2. Under fluoroscopic guidance, drill with the cannulated drill bit with calibrations Ø3.0mm (REF 705357) until the distal tip of the drill bit reaches the expected distal tip of the screw.

Take care not to drill through the metatarsophalangeal (MTP) joint.

Check that the tip of the sleeve is in close contact with the tuberosity to ensure accurate length measurement.

Screw length can be reassessed by reading the drill insertion depth from the drill bit calibrations and the back of the drill bit protecting sleeve.



Figure 43

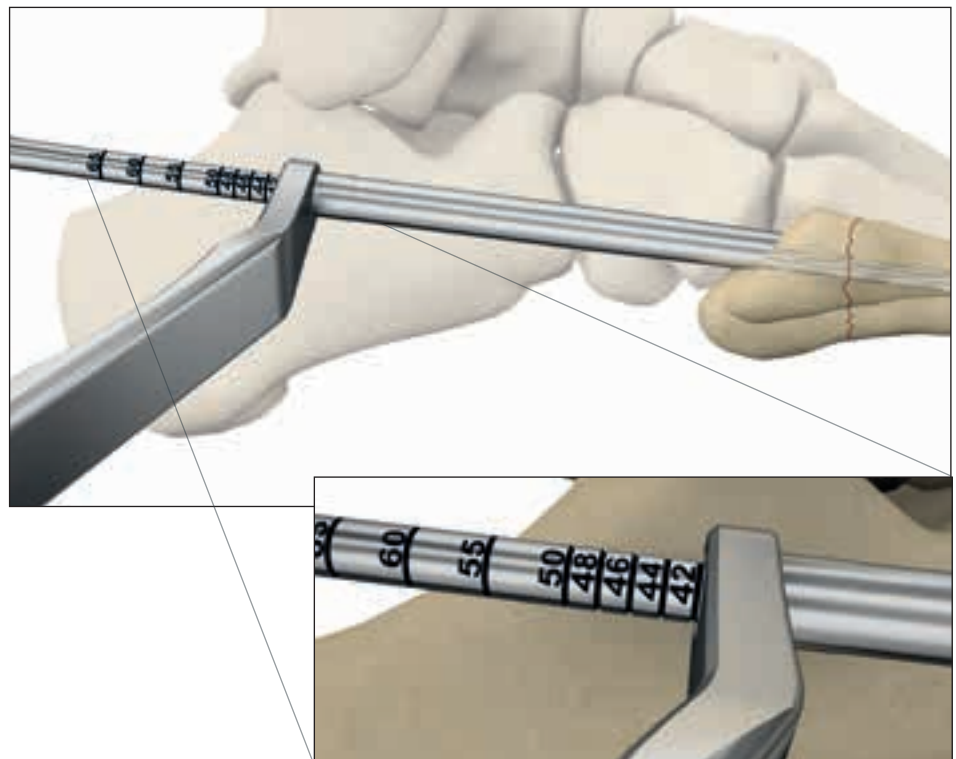


Figure 44

Notice

Excessive rotational speed, when using power-tools, can cause the guide wire to become stuck into the drill bit cannula. Use the cleaning stilet (REF 702493) to remove the guide wire.

Optional steps (see details in optional steps section):

4.1: Tapping (optional): In case of high bone density, or if the screw diameter selection is not obvious by using the sighting arm, tapping is recommended.



Figure 45

4.2: Countersinking (optional): If it is judged necessary by the health care professional, countersinking (REF 705363/705364/705365) is possible.



Figure 46

4.3: Screw length identification with the direct measuring gauge (optional): If not previously determined or if a countersinking (REF 705363/705364/705365) has been performed, the screw length can be measured by advancing the direct measuring gauge (REF 705370) over the guide wire Ø2.0 × 200mm (REF 705355).



Figure 47

4.4: Washer placement (optional): If it is judged necessary by the health care professional a washer can be used. Place a washer (REF 663001/663101/ 663201) of the corresponding screw diameter under the screw head to spread the load over a larger area.



Figure 48

Step 5: Screw placement

It is at the surgeon's discretion to select either a solid or a cannulated screw of $\varnothing 4.0$, $\varnothing 5.0$ or $\varnothing 6.0$ mm.

The adequate screw diameter should appropriately bite in the cortical bone and feel tight within the intramedullary canal. If the screw feels undersized in the canal, remove it and insert a new screw from the next diameter size.

Cannulated screw

Insert the cannulated screw over the guide wire using the screw holder (REF 900105). Use the cannulated screwdriver (REF 705366) with the large or medium handle (REF 703920/ 703921), and insert the screw into the bone until appropriate reduction and compression of the fracture is achieved.

The screw threads should be distal to the fracture line. Confirm screw placement under fluoroscopy. Remove and discard the guide wire.

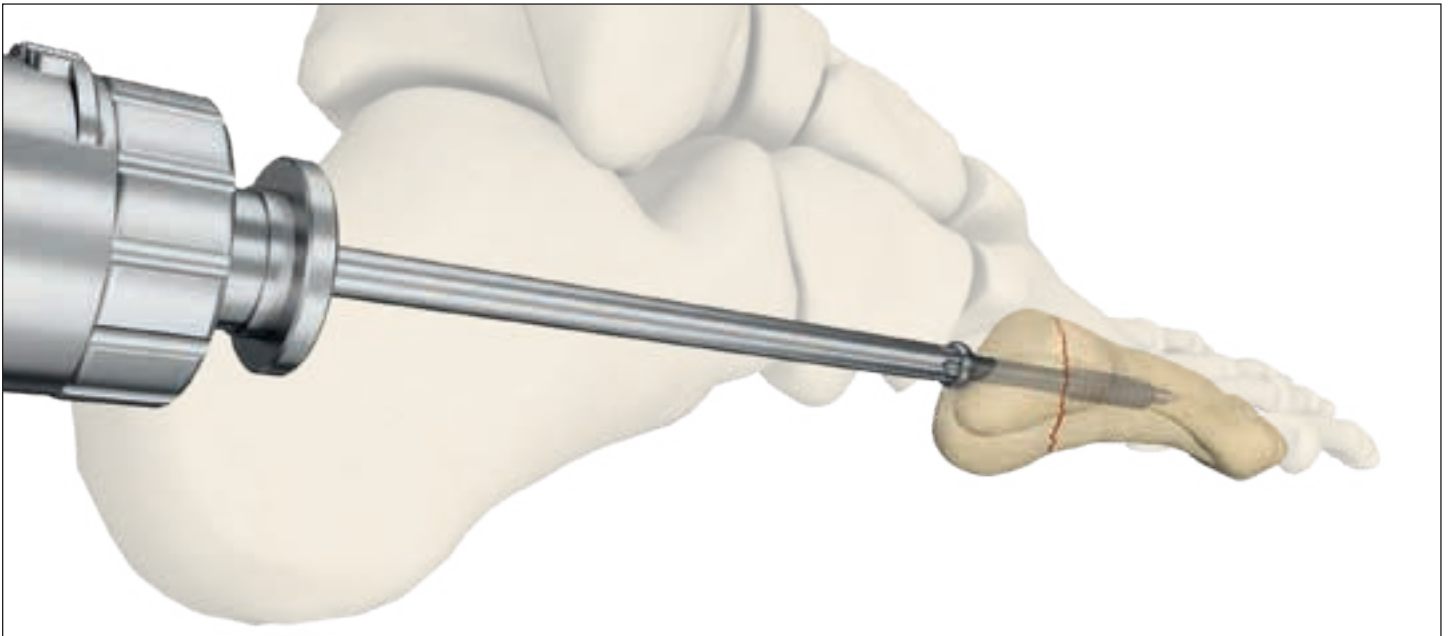


Figure 49

Solid screw

Remove and discard the guide wire and insert the solid screw, using either the cannulated screwdriver (REF705366) or the solid screwdriver (REF 705214) with the handle medium or large (REF 703921/703920), until appropriate reduction and compression of the fracture is achieved.

The screw threads should be distal to the fracture line.

Confirm screw placement under fluoroscopy.

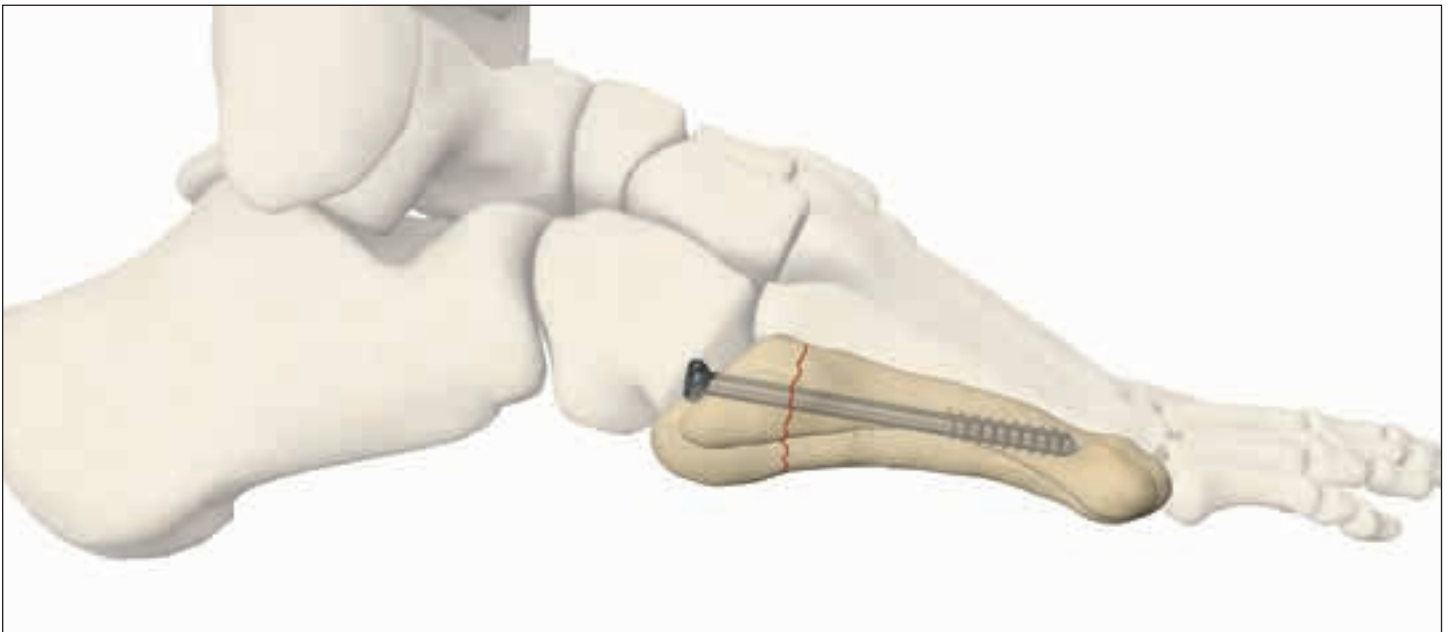


Figure 50

Warning

The AP view can be misleading in regards to screw head location as the base of the fifth metatarsal has a trochanter-like shape plantarly. Therefore, AP, lateral and oblique views should be checked carefully for flush placement of the screw head.

Optional steps

Step 2.7: Parallel positioning guide (optional)

If the primary guide wire angulation is acceptable but its placement is too lateral/medial or dorsal/ plantar, the parallel positioning guide (REF 705371) may be used to insert a second guide wire parallel to the initial one and correct the centering axis of the guide wire (figure 51).

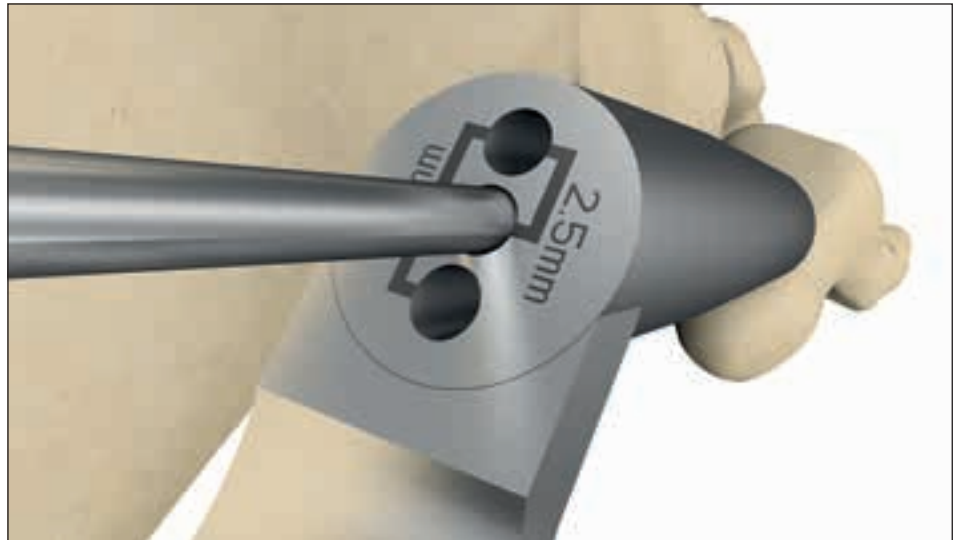


Figure 51

In this case, while leaving in the guide wire (REF 705355) previously introduced in the bone, insert an additional guide wire (REF 705355) with the appropriate offset (2.5mm or 5mm).

Slide back the positioning guide on the guide wires and check the newly inserted guide wire placement under fluoroscopy.

If the newly inserted guide wire position is correct, remove the first guide wire improperly inserted.



Figure 52

Step 4.1: Tapping (optional)

In case of high bone density, or if the screw diameter selection is not obvious by using the sighting arm, tapping is recommended.

If the best screw diameter to be selected needs to be clarified, the taps can be used as trials as they have the same thread profile as the screws.

1. Place the taps/countersinks sleeve of the double protecting sleeve (REF 705369) over the guide wire Ø2.0×200mm (REF 705355) and against the bone.
2. Using the Ø4.0mm cannulated tap with calibrations (REF 705360), manually tap until the distal tip of the tap reaches the expected distal tip of the screw.

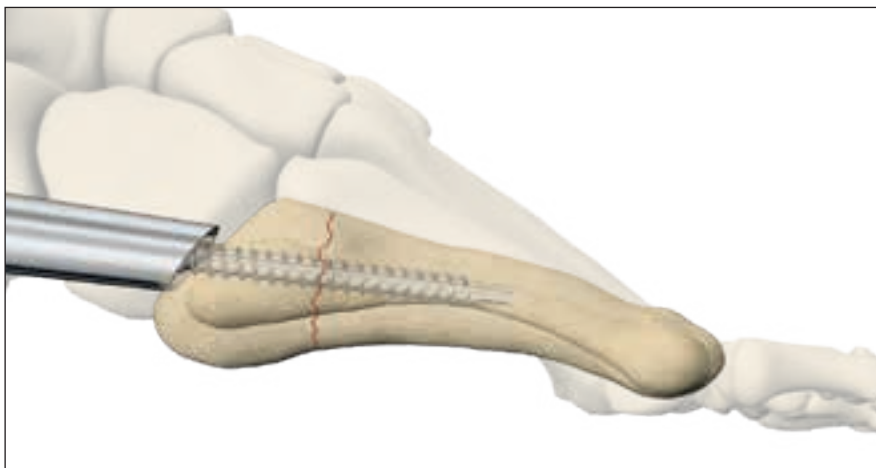


Figure 53

The adequate tap diameter should appropriately bite in the cortical bone and feel tight within the intramedullary canal.

Check placement with fluoroscopy.

3. If tap feels loose in the canal, tap to the next screw diameter size (Ø5.0mm) using the taps/countersinks sleeve (REF 705369) and Ø5.0mm cannulated tap with calibrations (REF 705361).

Check placement with fluoroscopy.

If tap still feels undersized in the canal, repeat this step using the Ø6.0mm cannulated tap with calibrations (REF 705362).

Check that the tip of the sleeve is in close contact with the tuberosity to ensure accurate length measurement.

Screw length can be reassessed by reading the tap insertion depth from the tap calibrations and the back of the taps/countersinks protecting sleeve (REF 705369).



Figure 54



Figure 55

Notice

If the guide wire is stuck in the cannulated instrumentation, use the cleaning stylet (REF 702493) to remove the guide wire.

Step 4.2: Countersinking (optional)

If it is judged necessary by the health care professional, countersinking is possible.

Countersinking is performed manually with the cannulated countersink corresponding to the previously determined screw diameter: countersink (REF 705363) for a Ø4.0mm screw, countersink (REF 705364) for a Ø5.0mm screw, and countersink (REF 705365) for a Ø6.0mm screw.

1. Place the taps/countersinks sleeve of the double protecting sleeve (REF 705369) over the guide wire Ø2.0×200mm (REF 705355) and against the bone.
2. Advance the cannulated countersink over the guide wire Ø2.0×200mm (REF 705355) and manually ream until desired screw head insertion depth has been reached.

Take care not to ream too deep into the bone in order to avoid the screw head sinking into the intramedullary canal. On each countersink, a groove indicates the head height of the corresponding screw diameter.

Warning

Countersinking may influence the previously determined screw length. Use the direct measuring gauge (REF 705370) to re-measure the screw length (See Step 6).

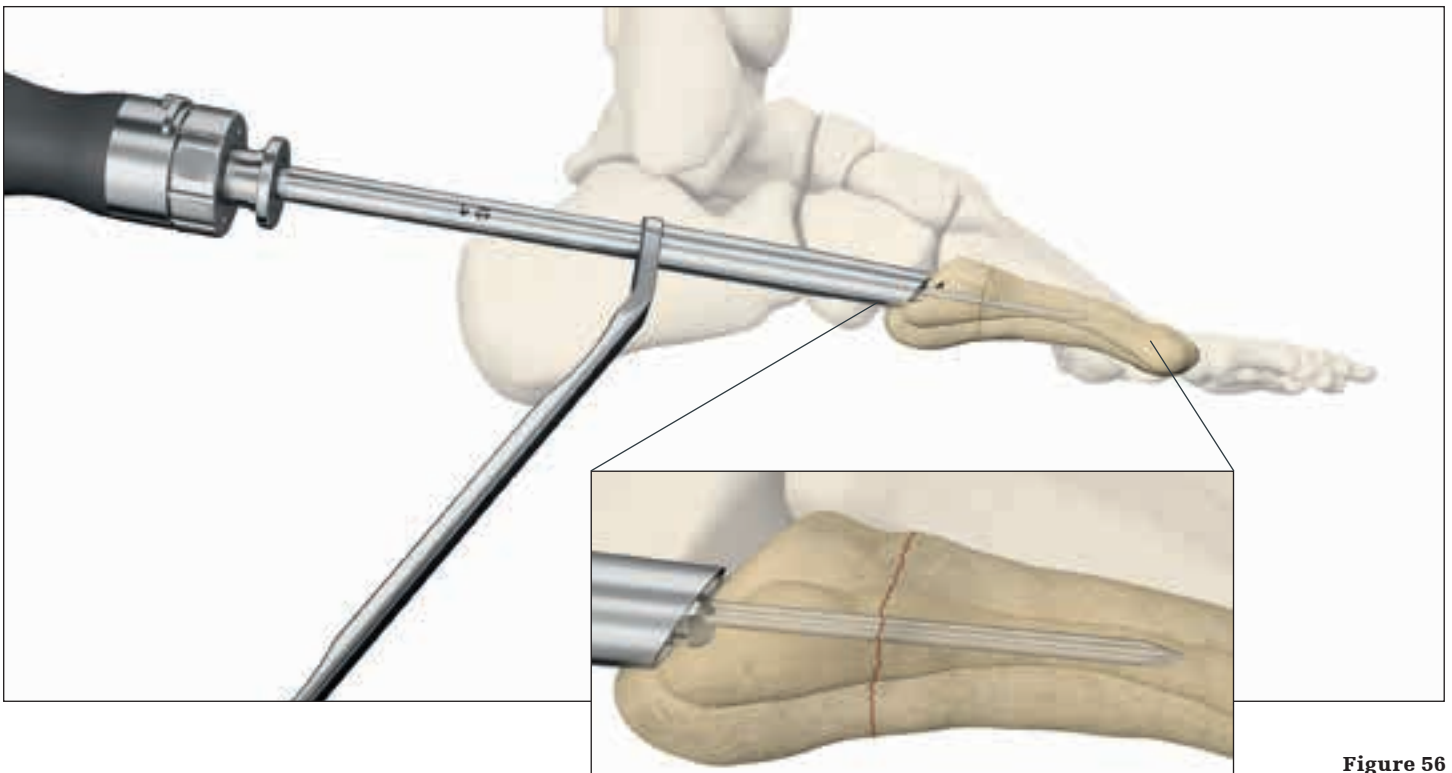


Figure 56

Step 4.3: Screw length identification with the direct measuring gauge (optional)

If not previously determined or if a countersinking has been performed, the screw length can be measured by advancing the direct measuring gauge (REF 705370) over the guide wire (Ø2.0×200mm (REF 705355)).

Check that the tip of the direct measuring gauge is in close contact with the tuberosity to ensure accurate length measurement.

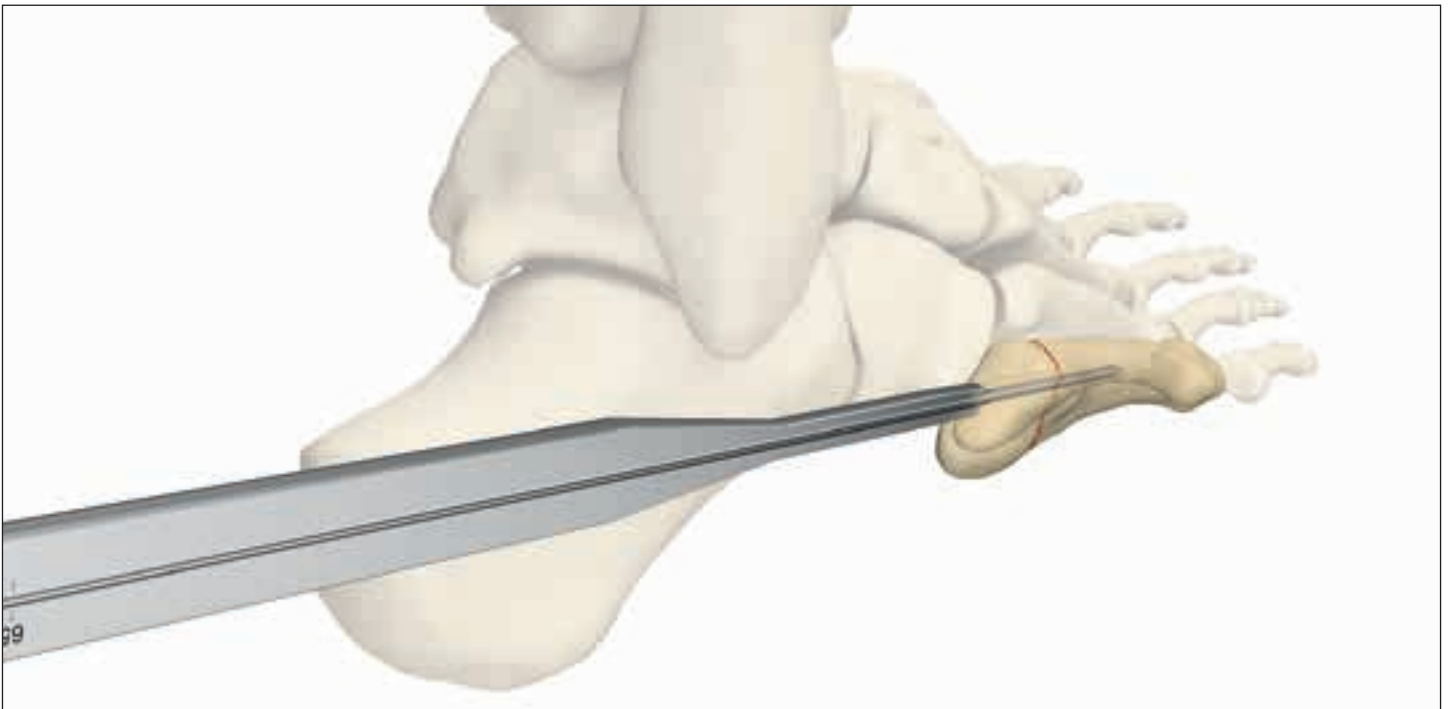


Figure 57

Step 4.4: Washer placement (optional)

If it is judged necessary by the health care professional, the use of a washer is possible.

Place a washer (REF 663001/663101/663201) of the corresponding screw diameter under the screw head to spread the screw load over a larger area, taking care to direct the chamfer of the washer towards the screw head.



Figure 58

Warning

The use of a washer might influence the previously determined screw length. In this case, screw length measurement with the direct measuring gauge (REF 705370) is recommended over the washer (see step 6).

Step 6: screw removal (optional)

Never use a worn or damaged instrument to remove screws.

If screw removal is necessary, use the solid screwdriver (REF 705214) or the removal instruments provided in Stryker's Implant Extraction Set (REF 1806-6152).

Foot & Ankle

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