



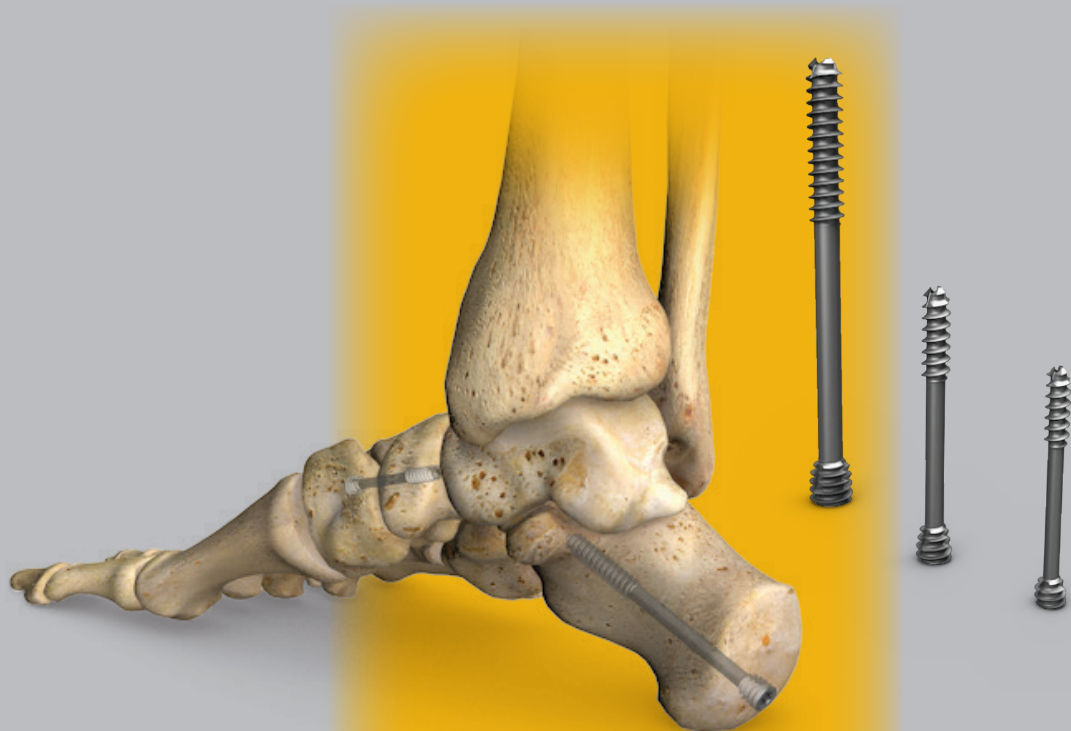
stryker®

Fixos

Midfoot & Rearfoot Screw System

Operative Technique

- Cannulated Compression Screws
4.0mm
5.0mm
7.0mm



Foot & Ankle

This publication sets forth detailed recommended procedures for using Stryker Osteosynthesis 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 performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

See package insert (V15013 and V15011) 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.

Warning:

Fixation Screws:
Stryker Osteosynthesis bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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Indications, Precautions & Contraindications

Indications

Stryker Fixos Screw System is a single use device intended for the fixation, correction or stabilization of small and long bones in adult and adolescent patients. Indications include:

Ø4.0mm Headless Screw

- Fractures of the tarsals and metatarsals
- Fractures of the olecranon, distal humerus
- Fractures of the radius and ulna
- Patella fractures
- Distal tibia and pilon fractures
- Fractures of the fibula, medial malleolus, os calcis
- Tarso-metatarsal and metatarsophalangeal arthrodesis
- Metatarsal and phalangeal osteotomies
- Osteochondritis dissecans
- Fractures of the pelvic ring
- Small cancellous fragments of the small and long bones

Ø5.0mm Headless Screw

- Medial and lateral malleolar and pilon fractures
- Proximal and distal humerus fractures
- Fractures of the olecranon process
- Tibial plateau fractures
- Os Calcis, talar and patellar fractures
- Fractures of the pelvis and acetabulum
- Arthrodesis of the tarsals

Ø7.0mm Headless Screw:

- Tibial plateau fractures
- Ankle arthrodesis
- Calcaneus osteotomies

Precautions

Stryker Osteosynthesis Systems have not been evaluated for safety and use 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 or respective operative technique.

Contact of Fixos Screw with dense bone in a tangential direction may cause a deviation of the screw and/or a bending of the K-Wire, which may result in damage to the implant.

See package insert for warnings, precautions, adverse effects and other essential product information.

Contraindications

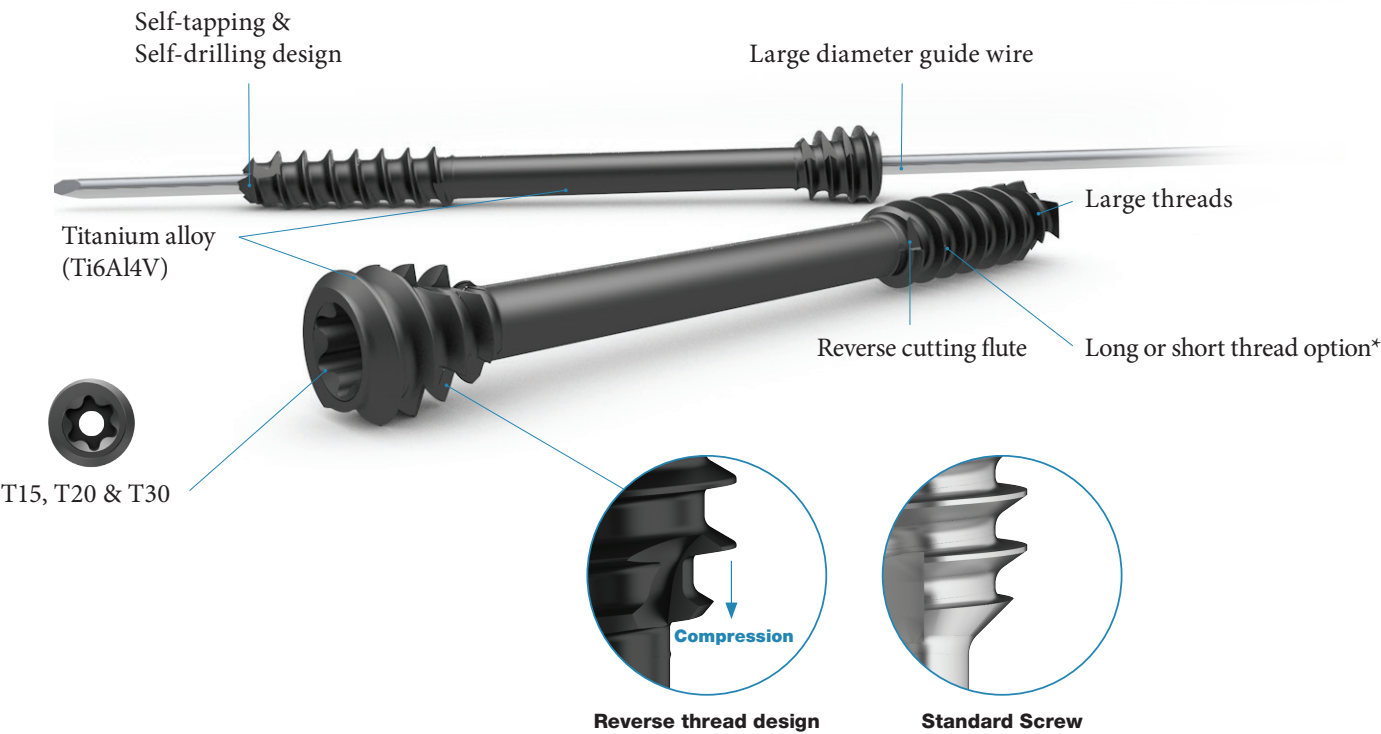
The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- 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 can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity: An overweight or obese patient may produce loads on the implant that may 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.
- 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.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Implant Features

Designed in conjunction with Foot and Ankle specialists, the 4.0, 5.0 & 7.0mm Midfoot and Rearfoot Screw System allows reliable, stable and straight forward fixation to address a large

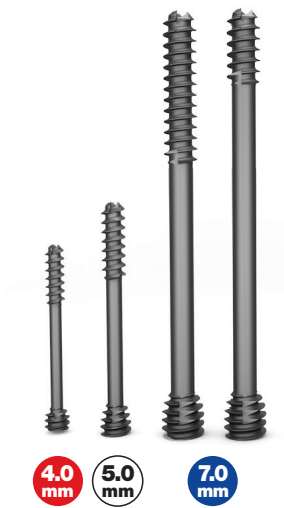
variety of fusions and osteotomies. The system incorporates several features intended to enhance screw placement, insertion, and removal as follows:



The Fixos System, offers 3 diameters and a large range of length with 2mm and 5mm increments:

Fixos Midfoot & Rearfoot Range				
	4.0mm	5.0mm	7.0mm	7.0mm
Material	Titanium			
Thread	1/3 Thread	1/3 Thread	16mm	32mm
Length	From 14 to 50mm each 2mm From 55 to 80 each 5mm	From 20 to 50mm each 2mm From 55 to 90mm each 5mm	From 35 to 135mm each 5mm	From 55 to 135mm each 5mm
Guide wire	1.4 x 150mm	2.0 x 150mm	3.2 x 230mm	3.2 x 230mm
Packaging	Sterile or Unsterile	Sterile or Unsterile	From 35 to 125mm Sterile / Unsterile 130 & 135mm Sterile Only	From 55 to 125mm Sterile / Unsterile 130 & 135mm Sterile Only

* For 7.0 mm only



Instrumentation Features

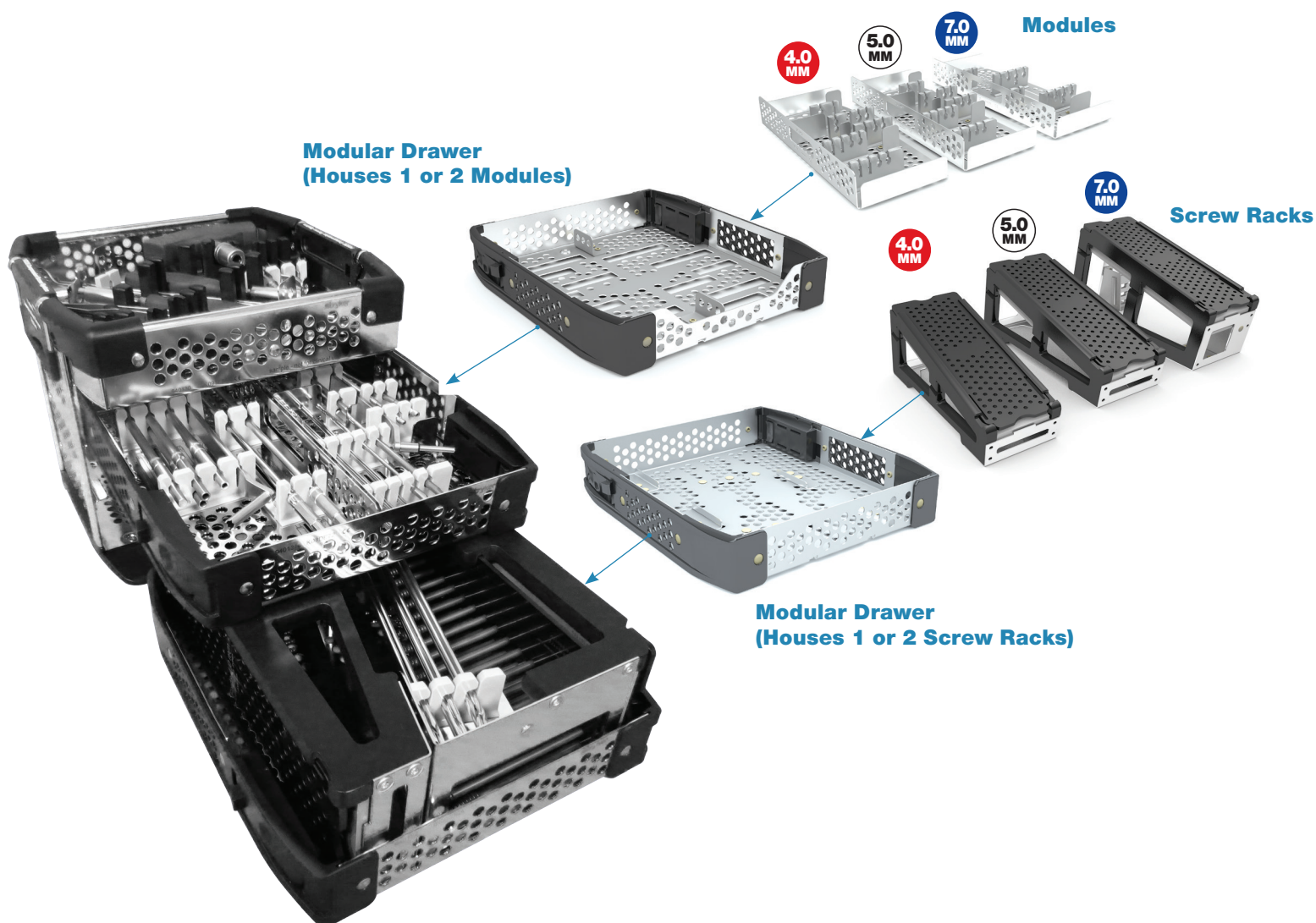
Modular System Design

The tray for the Fixos Screw System utilizes interchangeable instrumentation modules and screw racks to allow you to customize the contents of your tray to better meet your specific needs.

- **Configuration options:**

- 4.0mm
- 5.0mm
- 7.0mm
- 4.0mm & 5.0mm
- 5.0mm & 7.0mm
- 4.0mm & 7.0mm

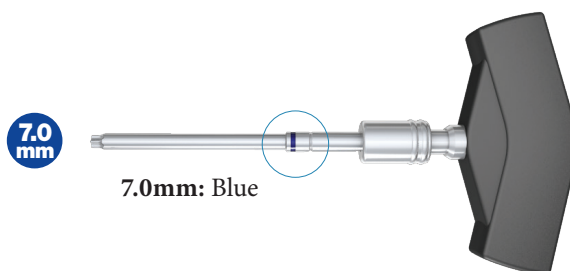
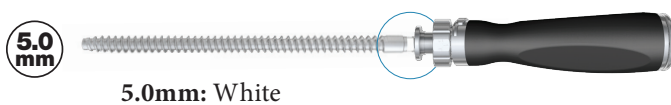
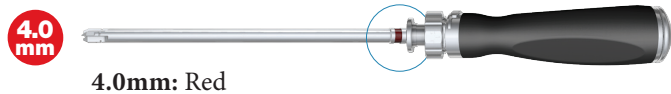
Customize the tray with one or two screw diameters



Instrumentation Features

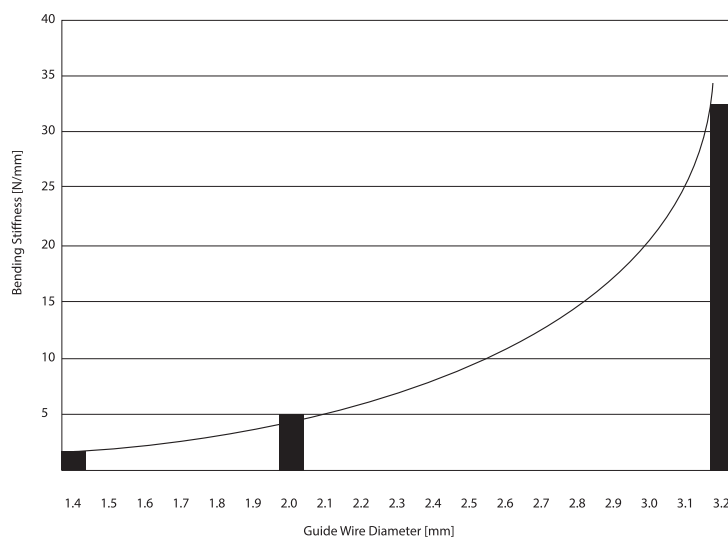
Color Coding

All Fixos Foot Instruments are color coded for easy identification. Instruments have colored stripes to indicate the related screw diameter:



Large Diameter Guide Wires

Fixos Guide Wires have large diameters to provide great bending stiffness and reduce deflection¹.



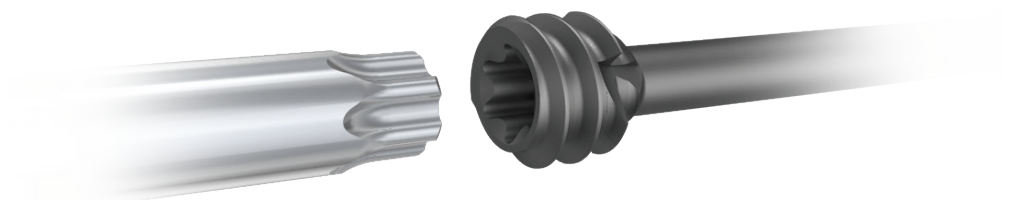
1. Bending stiffness:

d=diameter

E=Modulus of Elasticity

$$K = \frac{E \cdot \pi \cdot d^4}{64}$$

T15, T20, T30 Screw Head Design



Instrumentation Features

Direct Measuring Gauge

Measure screw length by using the Direct Measuring Gauge (REF 705266 for 150mm wires/REF 705267 for 230mm wires). Slide it over the guide wire and position it in direct contact with the bone.

For accurate screw measurement:

- Subtract appropriately any anticipated shortening due to inter-fragmentary or inter-segmentary compression during screw insertion. Choose a screw part number length inferior to the measurement.

- Ensure that the Direct Measuring Gauge is placed perpendicularly to the bone surface for better accuracy. Otherwise subtract appropriately to ensure a well seated head without overpassing the second cortex.
- The guide wire should not overpass the second cortex to obtain valuable measurement.

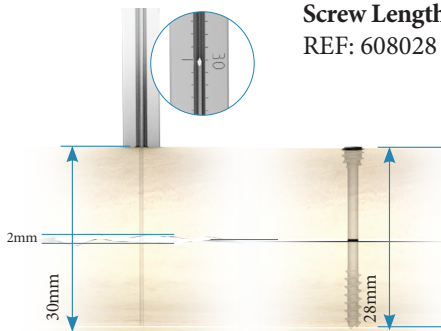
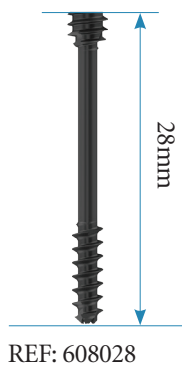
Screw measurement Examples:

Example 1

Subtract 2mm to anticipate screw compression

Measurement

Appropriate
Screw Length
REF: 608028

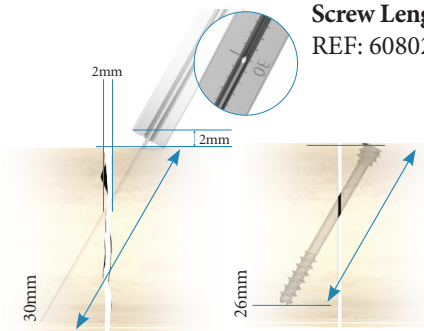


Example 2

Subtract 2mm for gauge positioning error and 2mm to anticipate screw compression

Measurement

Appropriate
Screw Length
REF: 608026



AO Handles, Ratchet System

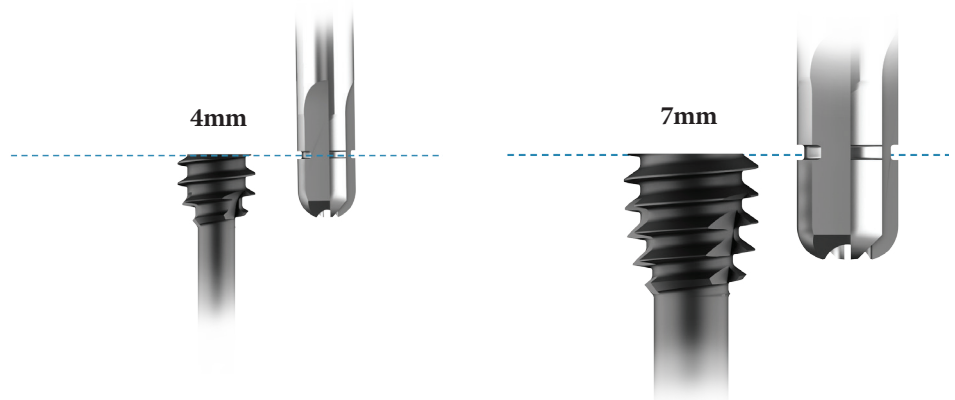
Easy insertion with ratchet system (REF 703922) for 4.0 and/or 5.0mm Fixos screw only.



Cannulated Countersink

The countersinking (REF 705260/705261 /705262) is always done manually.

The countersink is inserted into the bone until the notches are flush with the bone surface.



Operative Technique

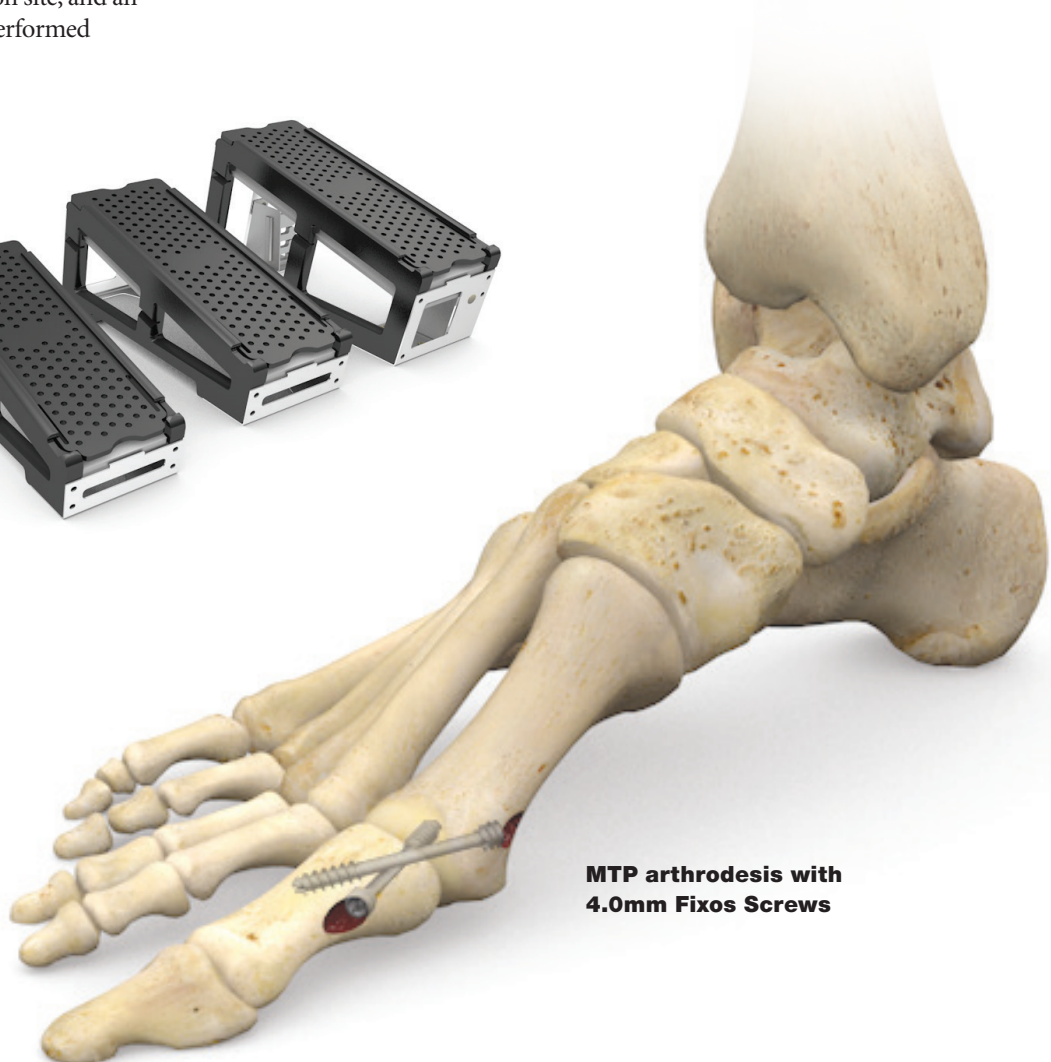
The Operative Technique detailed below is designed to provide a general overview of the instruments and procedure required to implant Midfoot & Rearfoot Fixos Screw System.

The Fixos Screw System is intended to be used for various indications, presented on page 4, for which the following procedural steps would apply. The operative technique is presented for foot indications as an example and can be applied in a same manner for the entire list of indications.

Planning and preparation with clear identification and classification of the fracture, osteotomy, or fusion site should first be established pre-operatively using the appropriate methods and visualization. Appropriate surgical incisions are made to expose the implantation site, and an osteotomy can then be performed if necessary.

General warning :

- Excessive rotation speed during screwing and drilling may lead to excessive heat generation.
- Excessive torque applied during screwing may lead to screw head or screw driver damage and may make screw extraction difficult. This may lead to extended bone damage which may require additional specific measures (additional surgery, change of surgery method, revision surgery).
- Pay attention to avoid any unexpected soft tissue irritation especially during cutting, drilling, milling and screw/K-Wire insertion.



**MTP arthrodesis with
4.0mm Fixos Screws**

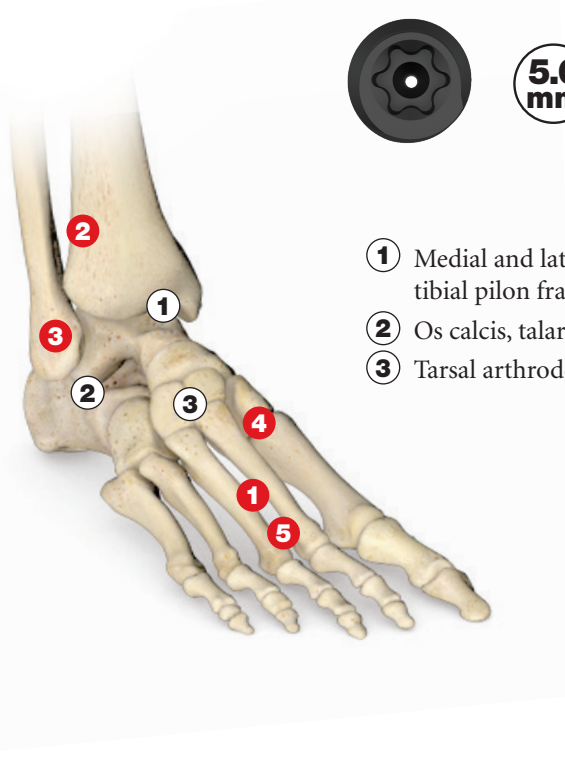
Cannulated Compression Screws 4.0 mm & 5.0mm

Example of applications

4.0 mm



- 1 Fractures of the tarsals and metatarsals
- 2 Distal tibia and pilon fractures
- 3 Fractures of the fibula, medial malleolus, os calcis
- 4 Tarso-metatarsal and metatarsophalangeal arthrodesis
- 5 Metatarsal osteotomies
- Other small fragment, cancellous bone fracture



Example of applications



5.0 mm

- 1 Medial and lateral malleolar and distal tibial pilon fractures
- 2 Os calcis, talar
- 3 Tarsal arthrodesis

Step 1

Joint Stabilization

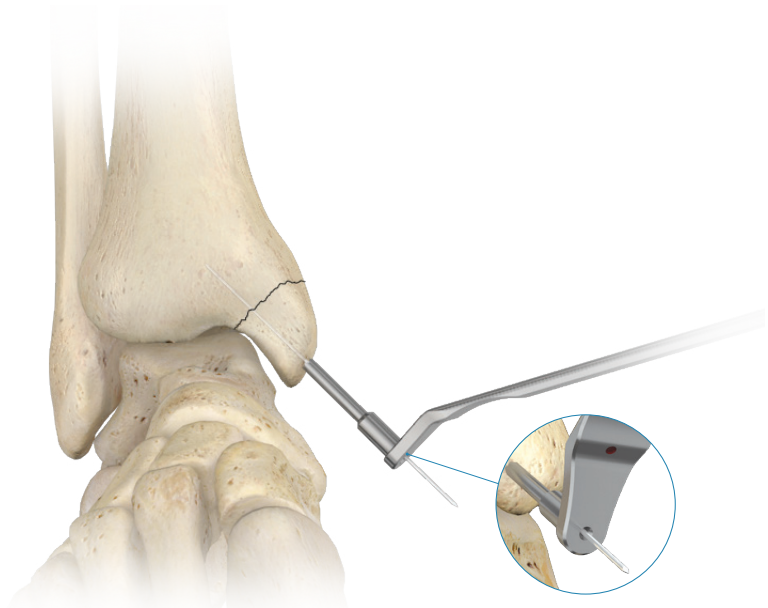
Position the Double Drill Guide
 Ø1.4 x 2.7mm (REF 705220)/
 Ø2.0 x 3.5mm (REF 705221)
 and insert a Guide Wire
 Ø1.4 x 150mm (REF 702459)/Ø2.0 x
 150mm (REF 702460) into the bone
 until the appropriate depth.

In case of hard bone density the Drill Bits (REF 702448/702453) can be also used previously to the guide wire insertion.

Use image intensification to control reduction and Guide Wire (or Drill Bit) placement. Place additional Guide Wire (or Drill Bit) as necessary. Remove the Double Drill Guide.

Note:

In dense bone, puncturing the cortex with the Drill Bit Ø1.4 x 150mm (REF 702448) / Ø2.0x150mm (REF 702453) to initiate the wire may reduce heat generation and/or deflection of the wire.

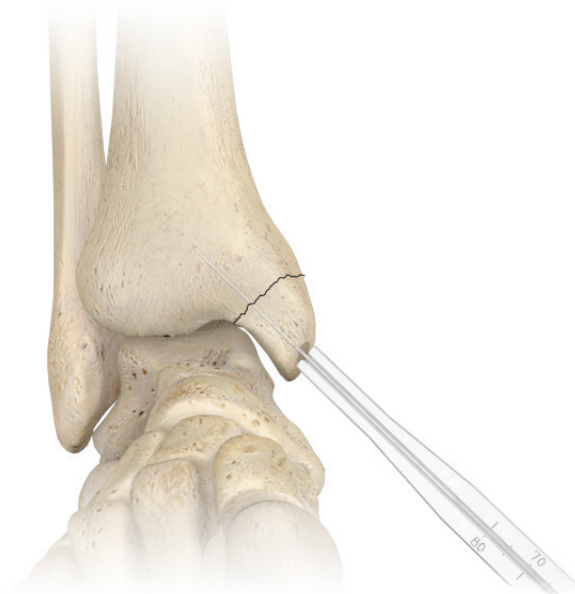


Step 2

Screw Length Identification

Slide the Direct Measuring Gauge - 150mm (REF 705266) over the Guide Wire Ø1.4 x 150mm (REF 704259)/ Ø2.0 x 150mm (REF 704460).

Select the appropriate screw length (Explanations page 8). Length adjustment is particularly important if the tip is close to an articular surface.



Step 3: Optional

Pre-drilling and thread cutting

The self-drilling and self-tapping tip of the Fixos screws is intended for cancellous bone. In dense cortical bone pre-drilling with Cannulated Drill Ø2.7/ Ø3.5mm (REF 705250/705251) and use of the Cannulated Tap Ø4.0/5.0mm (705253/705254) is recommended, especially when placing oblique screws.

Place the Double Drill Guide Ø1.4 x 2.7mm (REF 705220)/Ø2.0 x 3.5mm (REF 705221) over the Guide Wire and drill with the Cannulated Drill (REF 705250/705251) until the desired depth.

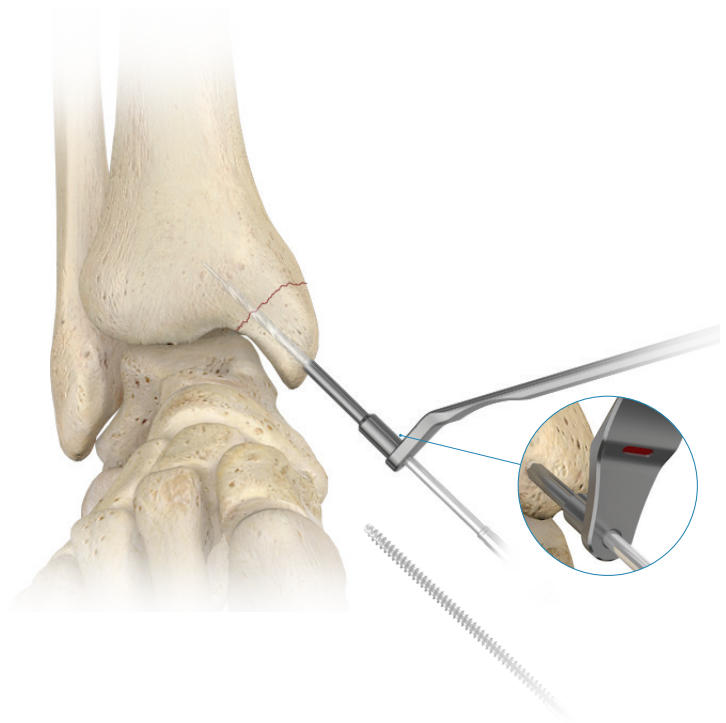
Take care to not drill further than the tip of the Guide Wire. Remove the double Drill Guide.

For tapping, insert the Cannulated Tap over the Guide Wire and perform manually the thread cutting.

Note:

If the Guide Wire is stuck in the cannulated instrumentation use the Cleaning Stylet (REF 702492/702493) to remove the Guide Wire.

Most of the time it is recommended to perform a pre-drilling before the screw insertion in order to avoid excessive torque transmission.



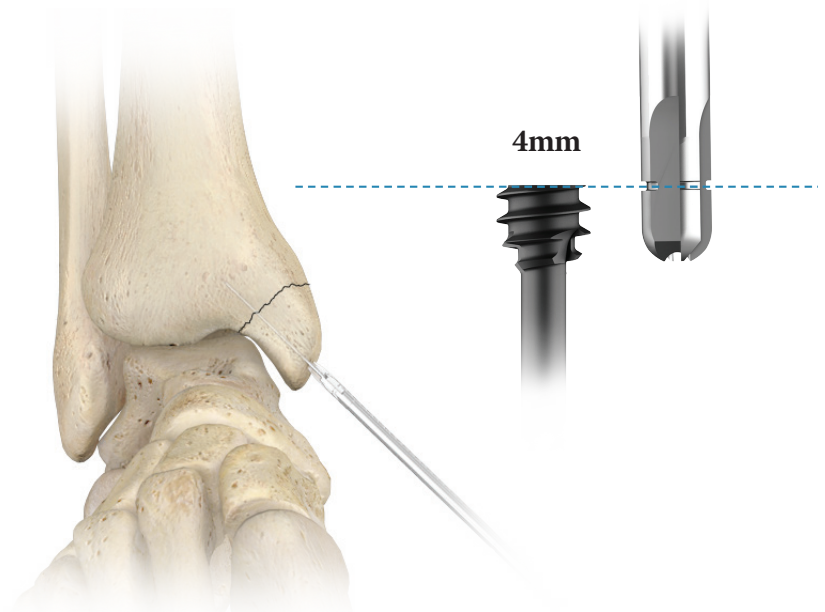
Operative Technique



Step 4

Countersinking

Countersinking is performed manually with the Cannulated Countersink Ø4.0mm (REF 705260)/Ø5.0mm (REF 705261). The Cannulated Countersink is advanced over the Guide Wire Ø1.4 x 150mm (REF 702459)/Ø2.0 x 150mm (REF 702460) until the notches are flush with the bone surface.

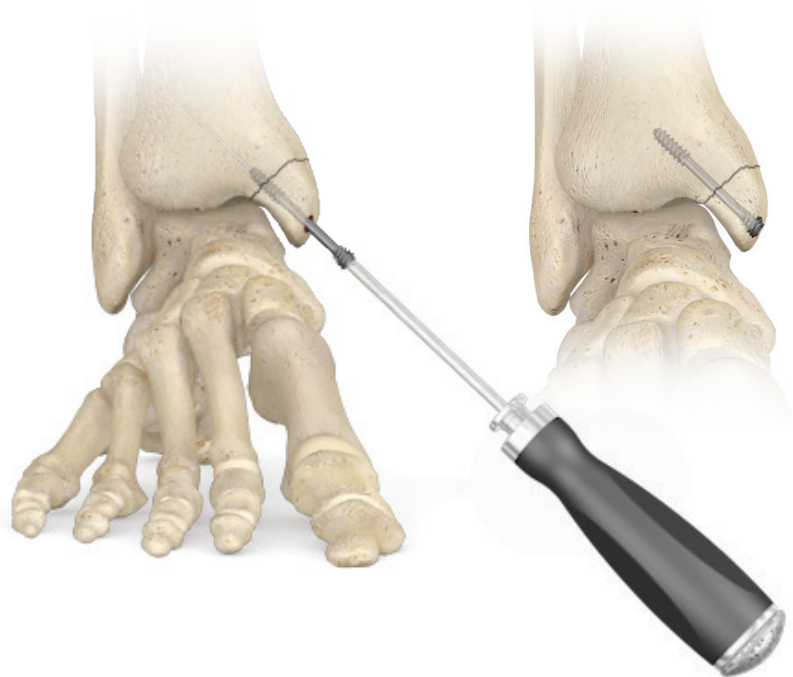


Step 5

Screw Placement

Insert the screw over the Guide Wire using the Screw Forceps (REF 900105). Use the Cannulated Screwdriver (REF 705210/705211) with the Tear Drop Handle T15/T20 (REF 703920 + 703923/703922), and insert the screw into the bone. After final tightening, remove the screwdriver.

After final insertion, the position should be checked by fluoroscopy. Remove the Guide Wire. Repeat as necessary for additional screws. Finally, proceed to normal surgical closure.





Example of applications

- 1 Calcaneus osteotomies
- 2 Pilon/Tibial Plafond
- 3 Ankle arthrodesis

Step 1

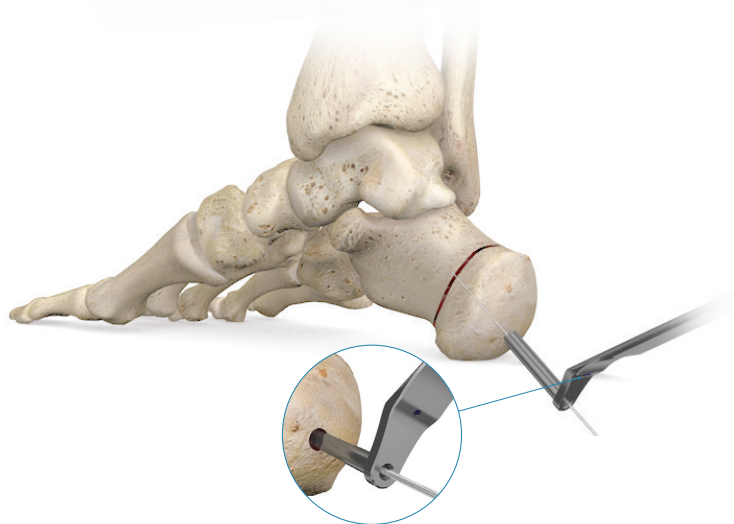
Joint Stabilization

Position the Double Drill Guide Ø3.2 x 4.9mm (REF 705222) and insert a Guide Wire Ø3.2 x 230mm (REF 705236) into the bone until the appropriate depth. In case of hard bone density the Drill Bit Ø3.2 x 230mm (REF 705232) can be also used previously to the guide wire insertion.

Use image intensification to control reduction and Guide Wire (or Drill Bit) placement. Place additional Guide Wire (or Drill Bit) as necessary. Remove the Double Drill Guide.

Note:

In dense bone, puncturing the cortex with the Drill Bit Ø3.2 x 230mm (REF 705232) to initiate the wire may reduce heat generation and/or deflection of the wire

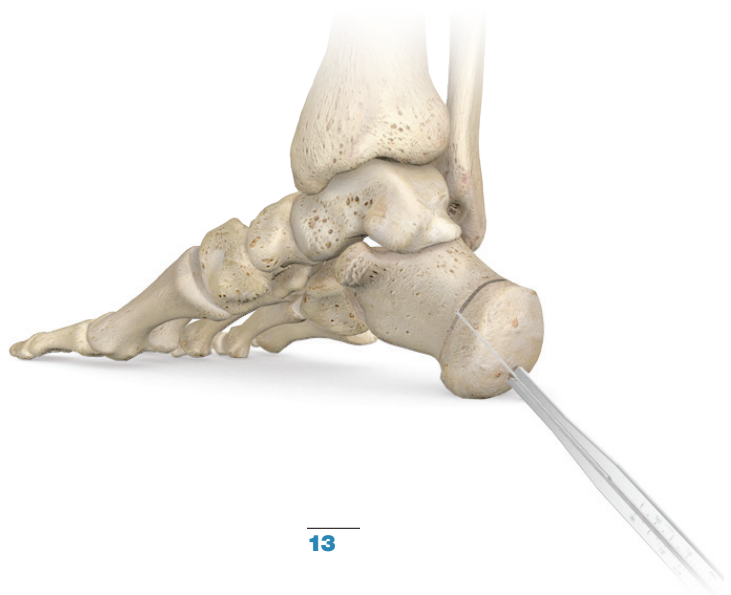


Step 2

Screw Length Identification

Slide the Direct Measuring Gauge 230mm (REF 705267) over the Guide Wire Ø3.2 x 230mm (REF 705236).

Select appropriate screw length (Explanations page 8). Length adjustment is particularly important if the tip is near an articular surface.



Step 3 – Optional

Pre-drilling and thread cutting

The self-drilling and self-tapping tip of the Fixos screws is intended for cancellous bone. In dense cortical bone pre-drilling with Cannulated Drill 4.9mm (REF 705252) and use of the Cannulated Tap Ø7mm (REF 705255) is recommended, especially when placing oblique screws.

Place the Double Drill Guide Ø3.2x 4.9mm (REF 705222), over the Guide Wire and drill with the Cannulated Drill (REF 705252) until the desired depth.

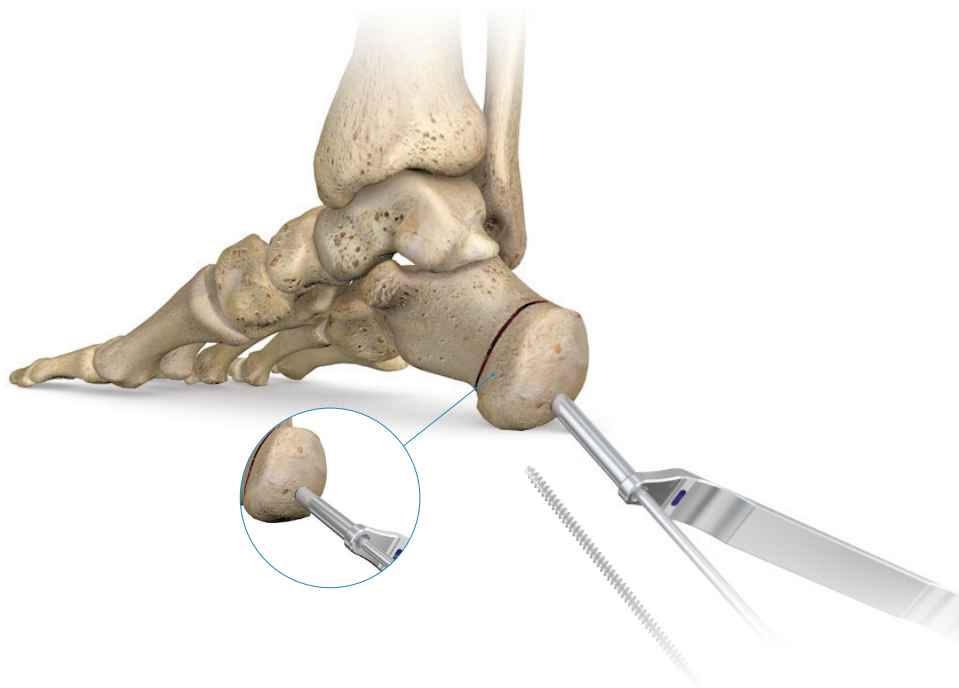
Take care to not drill further than the tip of the Guide Wire. Remove the Double Drill Guide.

For tapping, insert the Cannulated Tap over the Guide Wire and perform manually the thread cutting.

Note:

If the Guide Wire is stuck in the cannulated instrumentation use the Cleaning Stylet (REF 705238) to remove the Guide Wire.

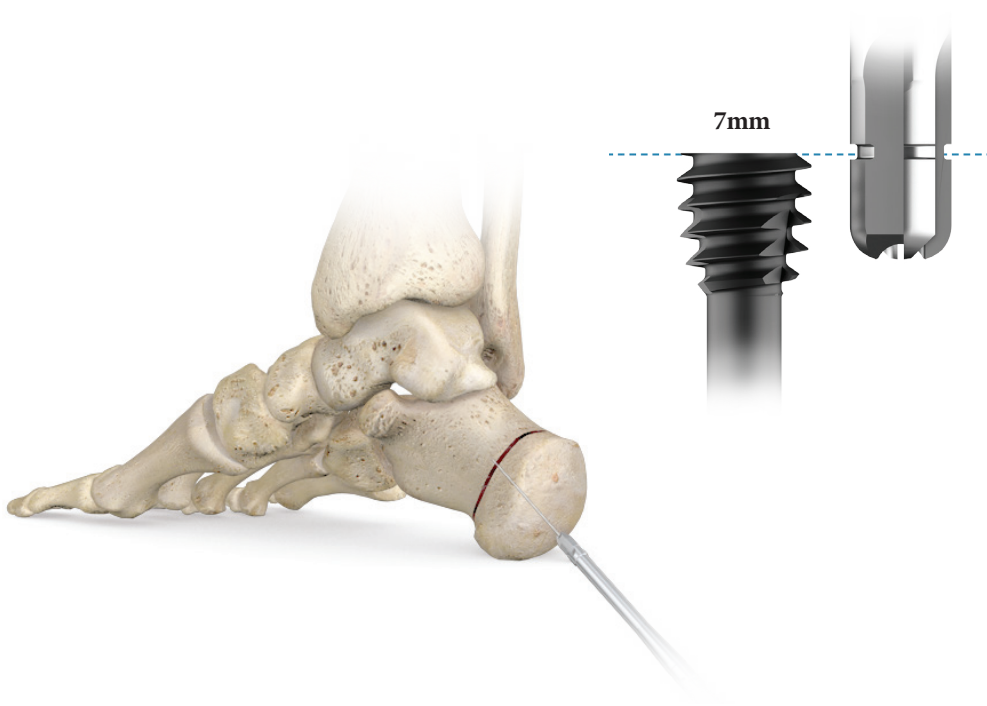
Most of the time it is recommended to perform a pre-drilling before the screw insertion in order to avoid excessive torque transmission



Step 4

Countersinking

Countersinking is performed manually with the cannulated countersink Ø7.0mm (REF 705262) linked to the T-Handle (REF 705268). The cannulated countersink is advanced over the Guide Wire Ø3.2 x 230mm (REF 705236) until the notches are flush with the bone surface.



Operative Technique

7.0
mm

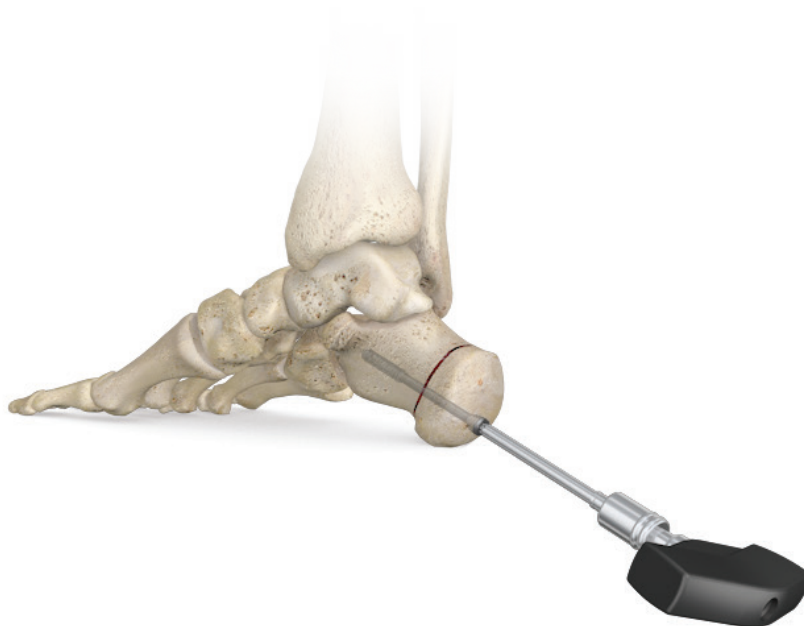
Step 5

Screw Placement

Insert the screw using the Screw Forceps (REF 900105) over the Guide Wire.

Use the cannulated screwdriver T30 (REF 705212) with the T-handle (REF 705268), and insert the screw into the bone. After final tightening, remove the screwdriver.

After final insertion, the position should be checked by fluoroscopy. Remove the Guide Wire. Repeat as necessary for additional screws. Finally, proceed to normal surgical closure.





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