



stryker

Fixos[®]

Midfoot & Rearfoot Screw System

Operative Technique

- **Headless Compression Screws**
 - 4.0mm
 - 5.0mm
 - 7.0mm



Foot & Ankle

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.

CAUTION

The patient is made aware of the risks associated with general surgery, orthopedic surgery, and with general anesthesia.

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Indications and 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

WARNING

The Fixos HCS Systems have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of Fixos HCS Systems in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CAUTION

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

Contraindications

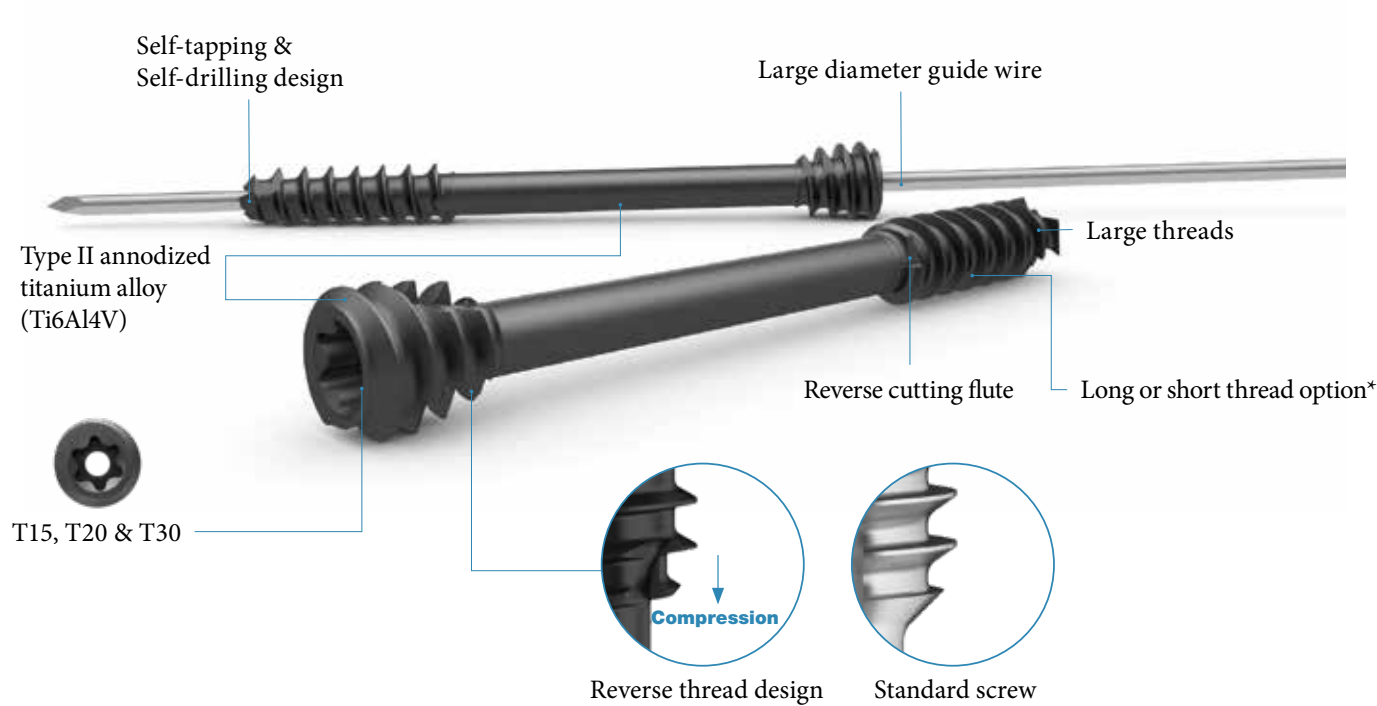
The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- 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 – Technical Details

Created in conjunction with Foot and Ankle specialists, the 4.0, 5.0 & 7.0mm Midfoot and Rearfoot Screw System is designed to allow for reliable, stable and compatible 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 lengths 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 50 to 80mm each 5mm	From 20 to 50mm each 2mm From 50 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 or Unsterile 130mm & 135mm Sterile Only	From 55 to 125mm Sterile or Unsterile 130mm & 135mm Sterile Only



* For 7.0mm only

Instrumentation – Technical Details

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

1 or 2 screw diameters:

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

Tray & Contents

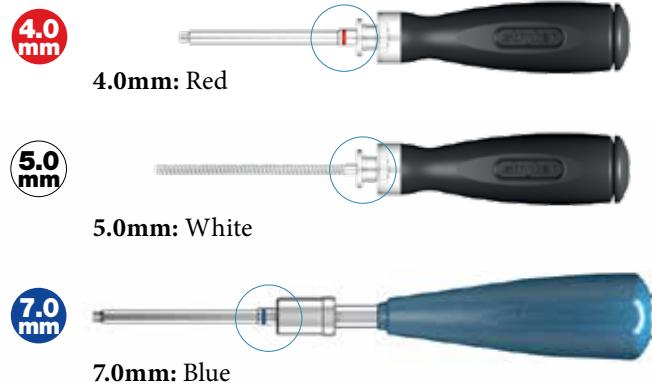


Foot & Ankle Screw System trays feature swing clip locks to create additional modularity and ease-of-use.

Instrumentation – Technical Details

Color Coding

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



Cannulated Countersink

⚠ CAUTION

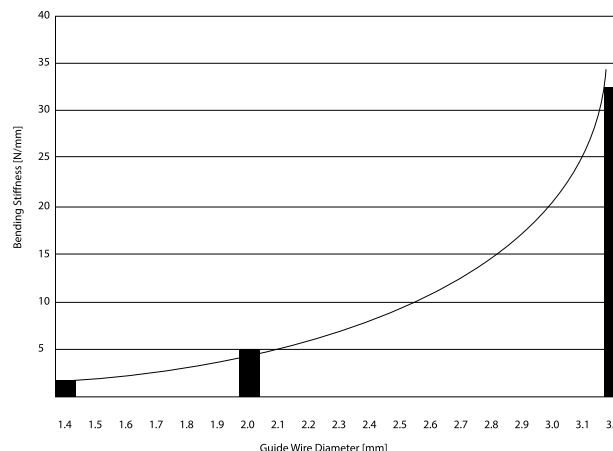
The countersinking is always done manually.

The Cannulated Countersink (REF 705260/705261/705262) is inserted into the bone until the notches are flush with the bone surface.



Large Diameter Guide Wires

Fixos Guide Wires have large diameters to allow for optimal bending stiffness and reduce deflection (see chart).



Bending stiffness:
d= diameter
E= Modulus of Elasticity

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

T15, T20, T30 Screw Head Design



Instrumentation – Technical Details

Direct Measuring Gauge

Measure screw length by using the Direct Measuring Gauge (REF 705266 for 150mm wires / REF 705267 for 230mm wires). Slide the gauge over the guide wire and position directly against the bone.

For accurate screw measurement:

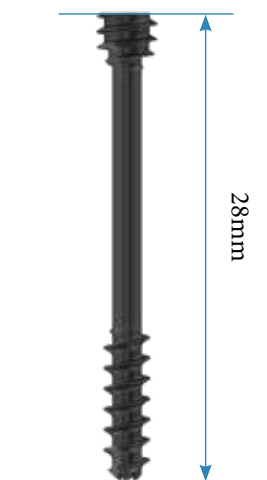
NOTICE

- Appropriately subtract any anticipated shortening due to compression during screw insertion. Choose a screw length inferior to the measurement.
- In the case of an angulated screw measurement, subtract appropriately to ensure a well seated screw head.

CAUTION

The guide wire should not pass through the second cortex.

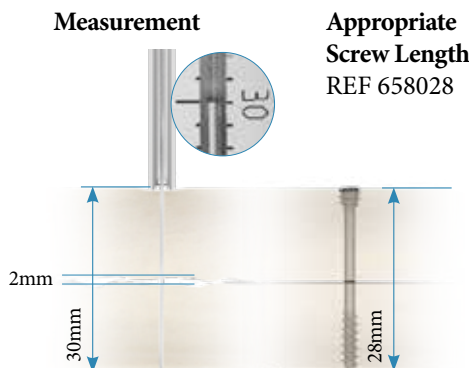
Screw Measurement Examples



REF: 658028

Example 1

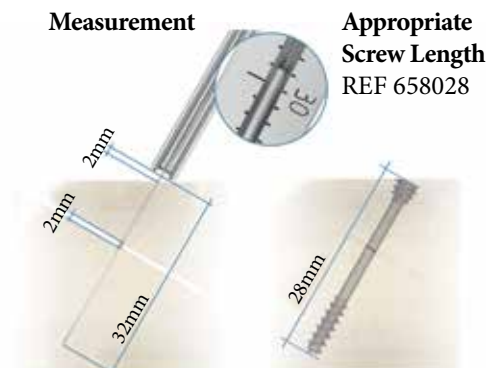
Subtract 2mm to anticipate screw compression



Appropriate
Screw Length
REF 658028

Example 2

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



Appropriate
Screw Length
REF 658028

AO Handles & Ratchet System

Fixos offers a bi-directional ratcheting AO-coupling insert or a standard AO-coupling insert for 4.0 & 5.0mm instruments.

The handles are equipped with a spin-cap to allow proper screw insertion using a two-finger technique. In order to disengage the insert from the handle, press down on the button, located on the distal part of the handle and pull the insert away from the handle.

WARNING

The inserts must be removed from the handles before cleaning.



AO Mechanism (REF 703923)



AO Mechanism with Ratchet (REF 703922)

The ratcheting insert can work in three modes: clockwise ratcheting, counterclockwise ratcheting or neutral.

To switch between the different modes, simply twist the distal part of the insert to the desired driving direction.

NOTICE

- To ensure ratcheting functionality of the insert, perform routine maintenance by applying medical grade lubricant oil through the marked cut-outs.
- Follow the instructions provided in the cleaning, reprocessing, and sterilization guide (OT-RG-1).

Operative Technique

Cannulated & Solid Screwdriver

CAUTION

The Cannulated Screwdrivers shall be used with guide wires only.

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

The Fixos Screw System is intended to be used for various indications, located on page 4, for which the following procedural steps would apply. The operative technique contains examples of the foot indications but can be applied in a similar manner for the other approved indications.

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



WARNING

- Extreme rotation speed during screwing and drilling may lead to increased heat generation.
- Applying excessive torque during screwing may cause damage to the screw head and screw driver, which can lead to difficult screw extraction. Extensive bone damage may require additional surgical measures.
- Pay attention to use protection sleeve to avoid any soft tissue damage.

Operative Technique



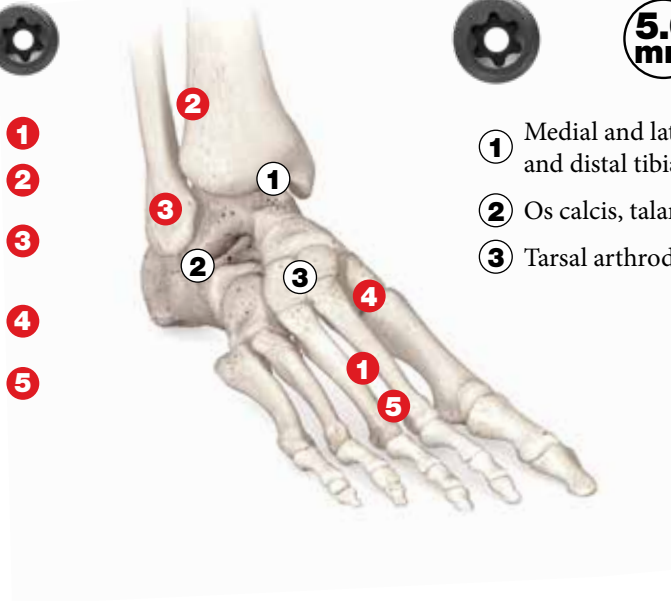
Headless Compression Screws 4.0mm & 5.0mm

Example of applications

4.0 mm



- Fractures of the tarsals and metatarsals ①
- Distal tibia and pilon fractures ②
- Fractures of the fibula, medial malleolus, os calcis ③
- Tarso-metatarsal and metatarsophalangeal arthrodesis ④
- Metatarsal osteotomies ⑤
- Small cancellous fragments of the small and long bones



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

Stabilization

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

In the case of high bone density, the
Drill Bits (REF 702448 / 702453) can be
used prior to inserting the Guide Wire.

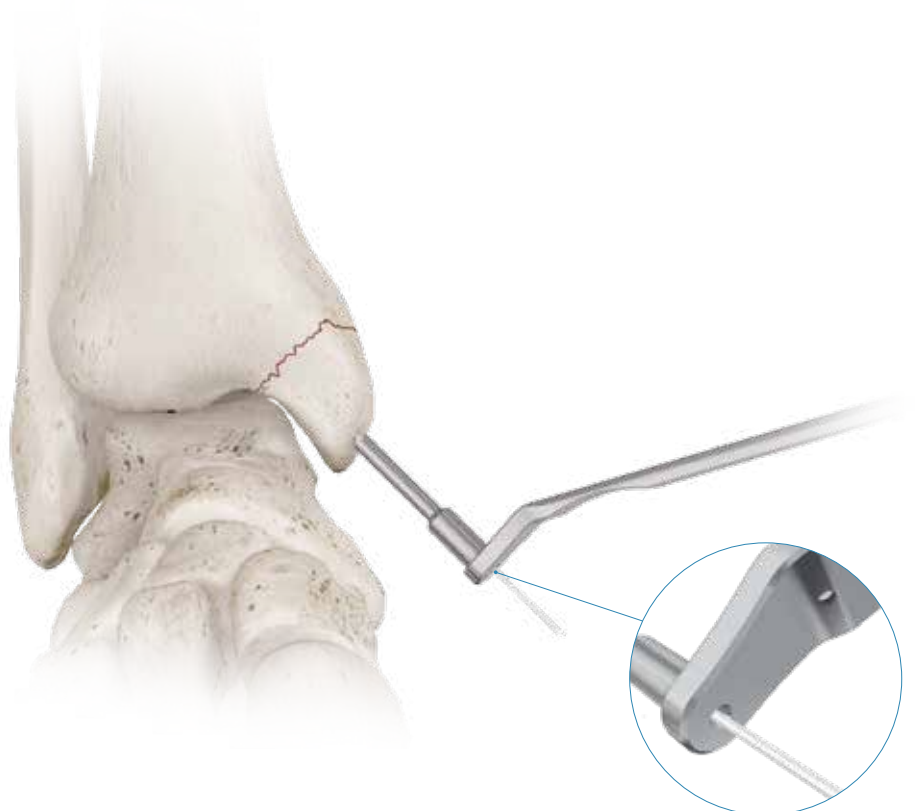
⚠ CAUTION

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.

⚠ CAUTION

In dense bone, puncturing the cortex
with the Drill Bit before inserting
the guide wire may reduce the 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 Ø1.4mm x 150mm (REF 702459) / Ø2.0mm x 150mm (REF 702460).

⚠ CAUTION

Select the appropriate screw length (see pg. 8 for explanation). It is important to adjust the screw length, especially 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 Ø2.7mm / Ø3.5mm (REF 705250 / 705251) and use of the Cannulated Tap Ø4.0mm / 5.0mm (705253 / 705254) is recommended, especially when placing oblique screws.

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

⚠ CAUTION

Do not drill further than the tip of the Guide Wire.

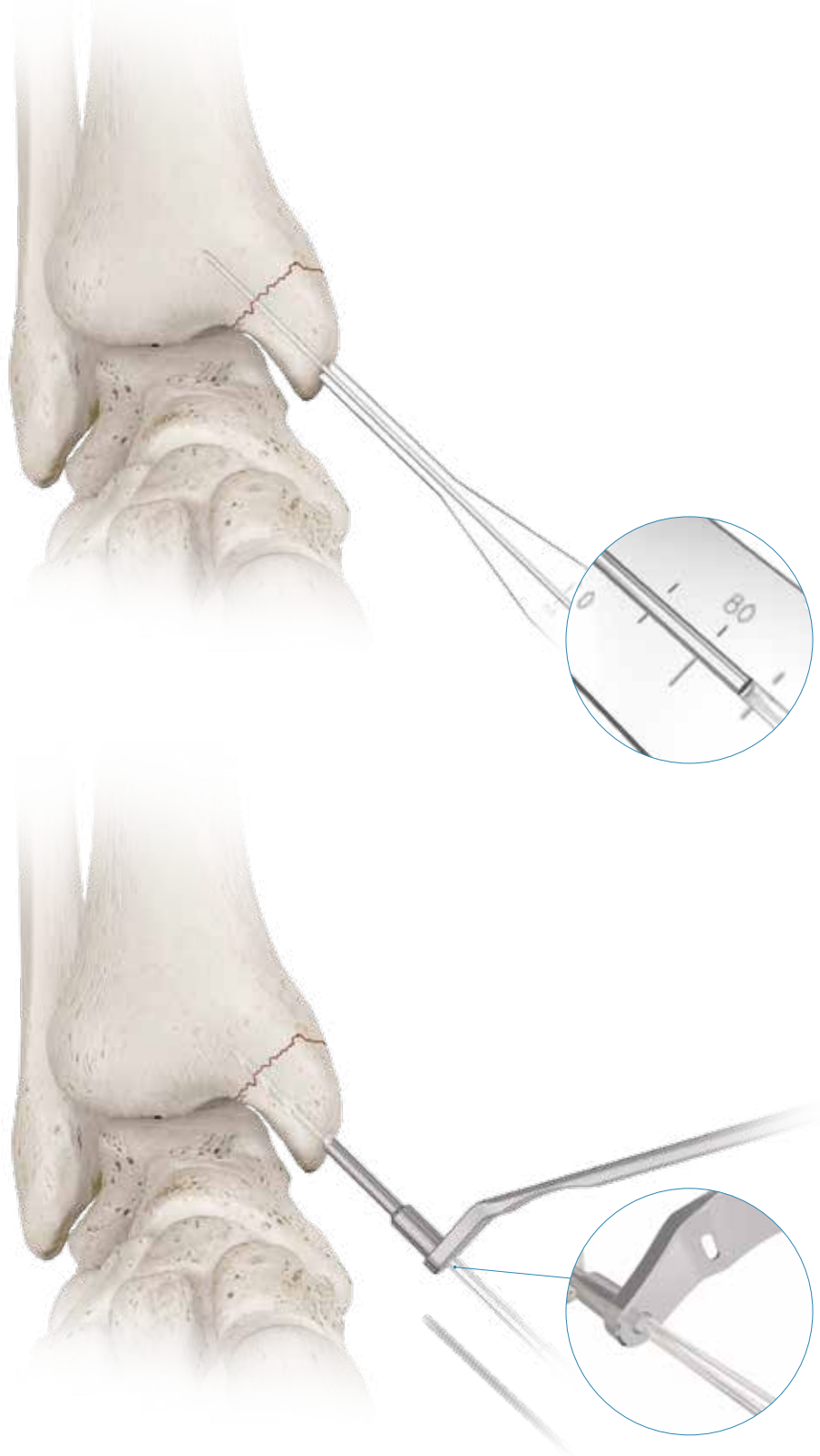
For tapping, insert the Cannulated Tap over the Guide Wire and manually perform the thread cutting.

⚠ CAUTION

- Care should be taken to utilize the cleaning stylet for inter and postoperative cleaning of cannulations.
- Correct inter-operative use of this instrument prevents accumulation of debris.
- If the Guide Wire is stuck in the cannulated instrumentation use the Cleaning Stylet to remove the Guide Wire.

⚠ CAUTION

It is recommended to perform a pre-drilling in dense bone before the screw insertion in order to avoid excessive torque transmission.



Operative Technique

4.0 mm 5.0 mm

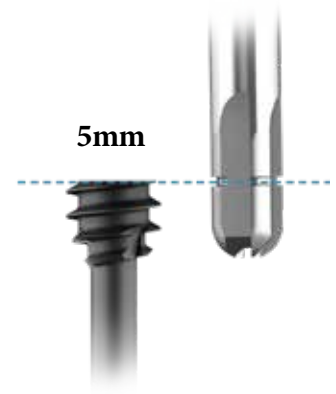
Step 4

Countersinking

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

⚠ CAUTION

During countersinking care should be taken to ensure 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 Handle Large and the corresponding insert (REF 703920 + 703923/703922), and insert the screw into the bone.

Remove the Screwdriver after desired tightening is complete.

⚠ CAUTION

Use image intensification to control reduction and Guide Wire (or Drill Bit) placement.

Remove the Guide Wire. Repeat as necessary for additional screws. Finally, proceed to normal surgical closure.

NOTICE

Avoid screws making contact between them. The implant may be damaged.



Headless Compression Screws 7.0mm

**7.0
MM**

Example of applications

- 1 Calcaneus osteotomies
- 2 Ankle arthrodesis

Step 1

Stabilization

Position the Double Drill Guide Ø3.2mm x 4.9mm (REF 705222) and insert a Guide Wire Ø3.2mm x 230mm (REF 705236) into the bone until the appropriate depth. In the case of high bone density, the Drill Bit Ø3.2mm x 230mm (REF 705232) can be used prior to inserting the Guide Wire.

CAUTION

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.

CAUTION

In dense bone, puncturing the cortex with the Drill Bit before inserting the guide wire may reduce the heat generation and /or deflection of the wire.

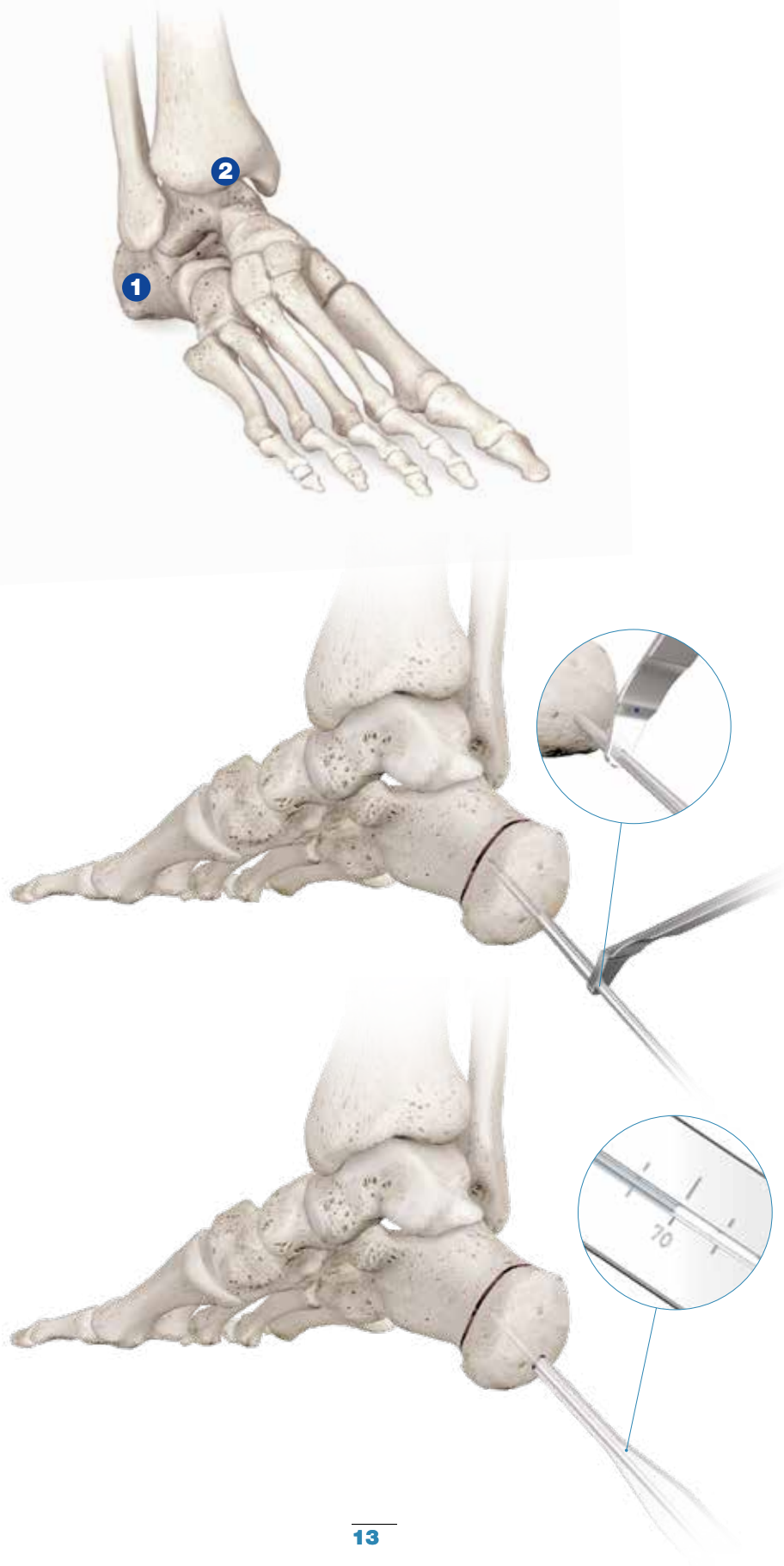
Step 2

Screw Length Identification

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

CAUTION

Select the appropriate screw length (see pg. 8 for explanation). It is important to adjust the screw length, especially 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 4.9mm (REF 705252) and use of the Cannulated Tap Ø7.0mm (REF 705255) is recommended, especially when placing oblique screws. Place the Double Drill Guide Ø3.2mm x 4.9mm (REF 705222), over the Guide Wire and drill with the Cannulated Drill (REF 705252) until the desired depth.

CAUTION

Do not drill further than the tip of the Guide Wire.

CAUTION

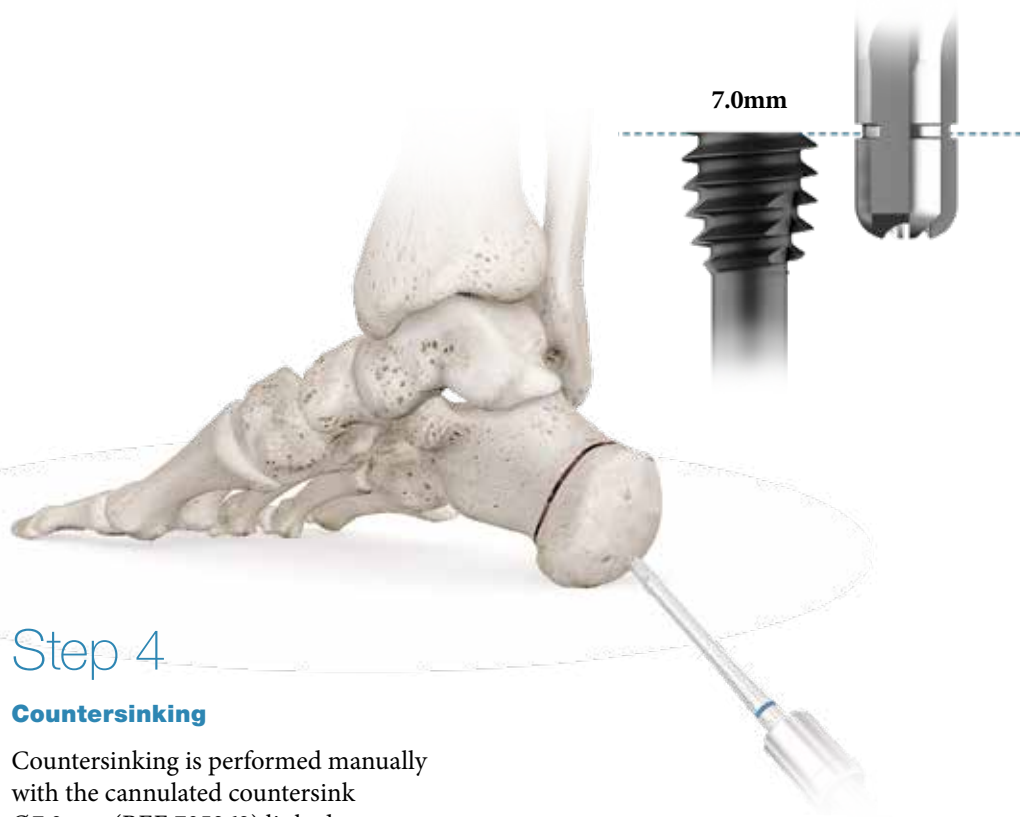
It is advisable to drill/tap hard (dense) cortical bone.

CAUTION

- Care should be taken to utilize the cleaning stylet for inter and postoperative cleaning of cannulations.
- Correct inter-operative use of this instrument prevents accumulation of debris.
- If the Guide Wire is stuck in the cannulated instrumentation use the Cleaning Stylet to remove the Guide Wire.

CAUTION

It is recommended to perform a pre-drilling in dense bone 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 Teardrop Handle AO-Medium (REF 1806-6104). The cannulated countersink is placed over the Guide Wire Ø3.2mm x 230mm (REF 705236) until the notches are flush with the bone surface.

Operative Technique

7.0
mm

Step 5

Screw Placement

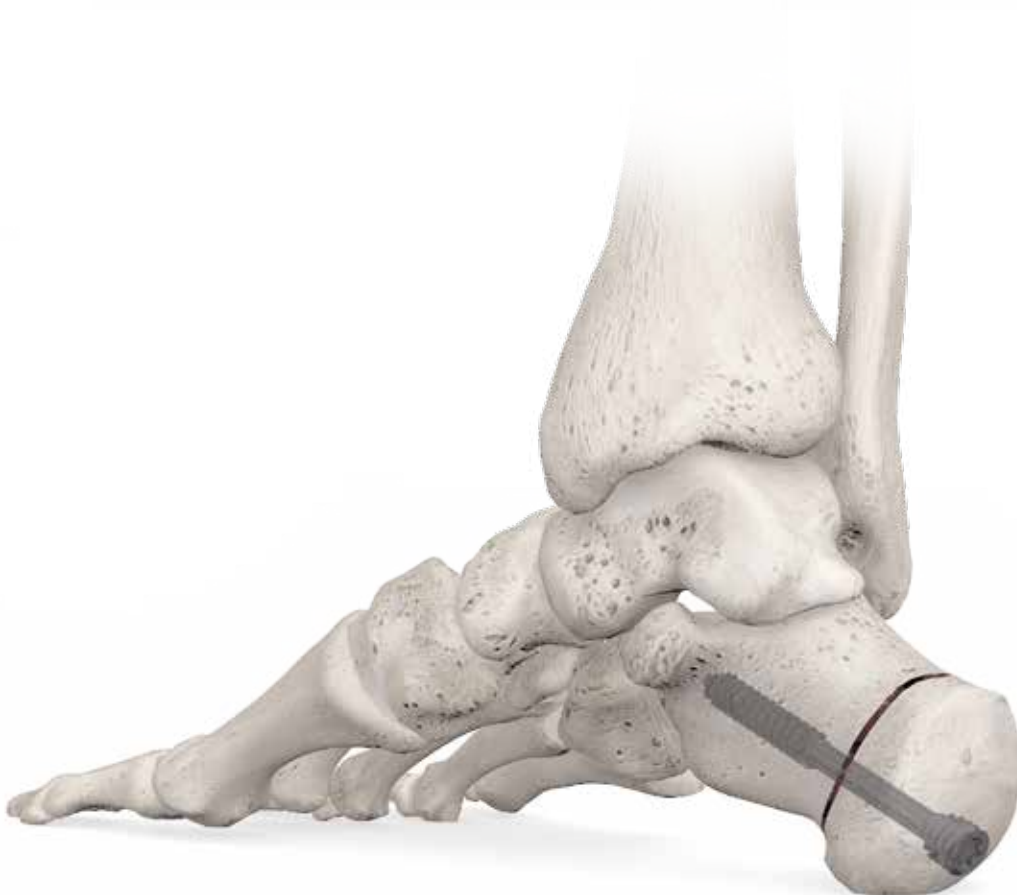
Insert the screw over the Guide Wire using the Screw Forceps (REF 900105). Use the Cannulated Screwdriver T30 (REF 705212) with the Teardrop Handle AO-Medium (REF 1806-6104), and insert the screw into the bone.

Remove the Screwdriver after desired tightening is complete.

CAUTION

Use image intensification to control reduction and Guide Wire (or Drill Bit) placement.

Remove the Guide Wire. Repeat as necessary for additional screws. Finally, proceed to normal surgical closure.



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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.

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