CARBOFIX
Orthopedics

Ankle Arthrodesis Nail Procedural Steps

www.carbo-fix.com

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Introduction

The CarboFix™ Implants

The **CarboFix™** Ankle Arthrodesis Nail is made of longitudinal continuous carbon fibers reinforced Polymer (PEEK).

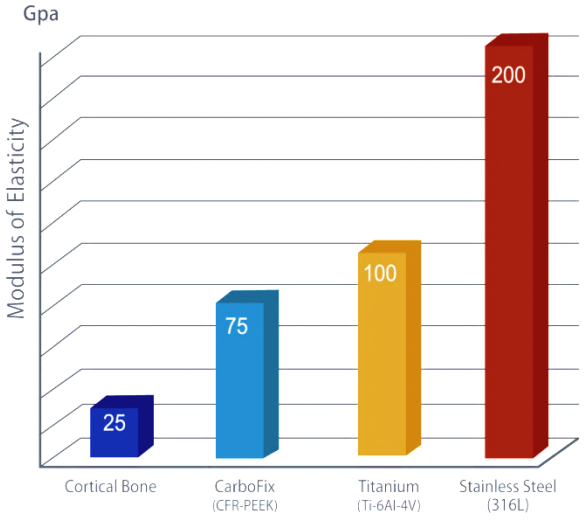
The Carbon Fibers are arranged in a unidirectional longitudinal orientation, as well as in a diagonal orientation, allowing multidirectional strength in all planes.

CarboFix™ is the first implant line to obtain FDA and CE clearance for orthopedic trauma implants made from carbon fiber composite material.

The Advantages of CarboFix™ Implants

Modulus of Elasticity

The **CarboFix™** implants have a modulus of elasticity which is close to that of cortical bone, lowering the risk for stress risers and secondary fractures.



Fatigue Strength

Composite materials are known for their significant fatigue strength. Carbon fiber composite materials are currently being used in critical load bearing structures of commercial airliners (e.g. the wings of the Boeing 787 “Dreamliner”), high performance automobiles and now orthopedic trauma implants.

During fatigue testing the **CarboFix™** 8.5 mm nail withstood 4 million cycles without showing any sign of failure of damage to the nail, which is **4 times** the acceptance criteria for the applicable standard.

Radiolucency

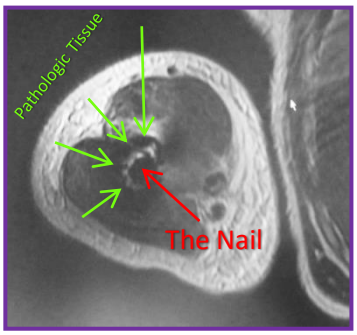
CarboFix™ implants allow for unparalleled intraoperative and post operative imaging.

Metal Nail

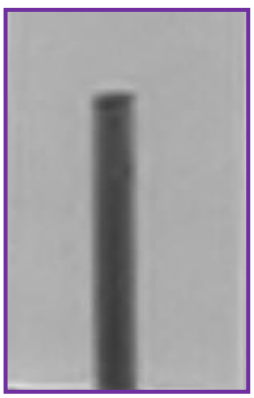
CarboFix™ Ankle Arthrodesis Nail-clear view of the fracture

CT & MRI Imaging

The CarboFix™ implants enable CT and MRI scans with minimal artifacts interference allowing for clear images of the surrounding tissues and the bone. This is clearly an advantage in monitoring fracture healing and pathological tissue.



Titanium Rod Ø5mm in MRI field: demonstrates massive artifacts



Carbon Fibers Rod Ø5mm in MRI field: no artifacts

The Implant

The features of the **CarboFix™** Ankle Arthrodesis Nail:

- Radiolucent: Clear view of the fusion site
- Tibiotalar compression mechanism-nail internal.
- Internal compression up to 7mm.
- External compression using the Insertion Handle.
- The screw holes have an inner thread for enhanced screw fixation to the nail.

* For further information please refer to the product instructions for use at the following link: www.carbo-fix.com/ifu-ank-arth-nail

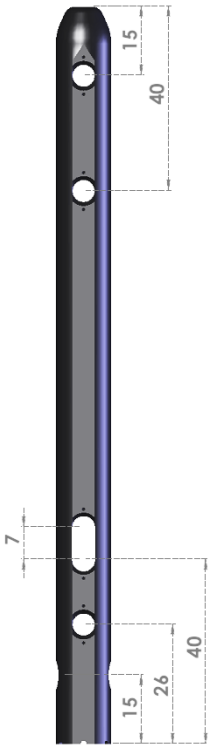
Nail Sizes

The Nails are supplied sterile in different diameters & lengths:

Diameter (mm)	Distal diameter (mm)	Length (mm)
10.0	12.0	160, 200, 240
12.0	12.0	160, 200, 240

CarboFix™ Ankle Arthrodesis Nail

Nail Design & Dimensions



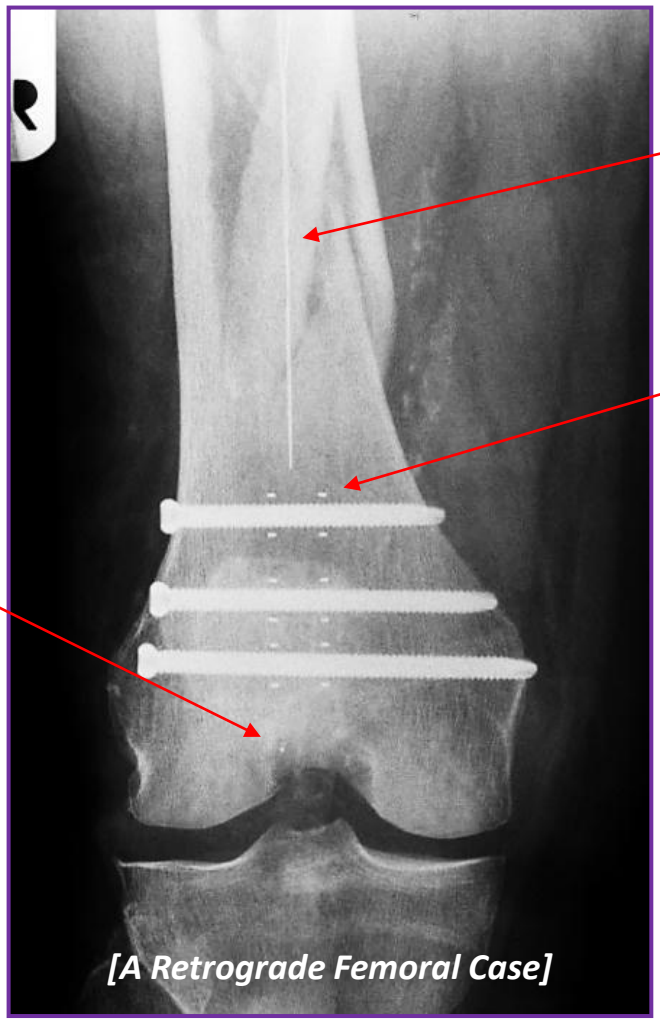
Radiopaque Markers

1. Radiopaque marker along the nail longitudinal axis enables nail visualization under fluoroscopy.

2. Marker at the nail Distal end of the nail indicating the terminal end (distal end) of the nail.

3. Markers, which are located at both sides of each hole.

4. Nail Cap markers, embedded within the nail cap.

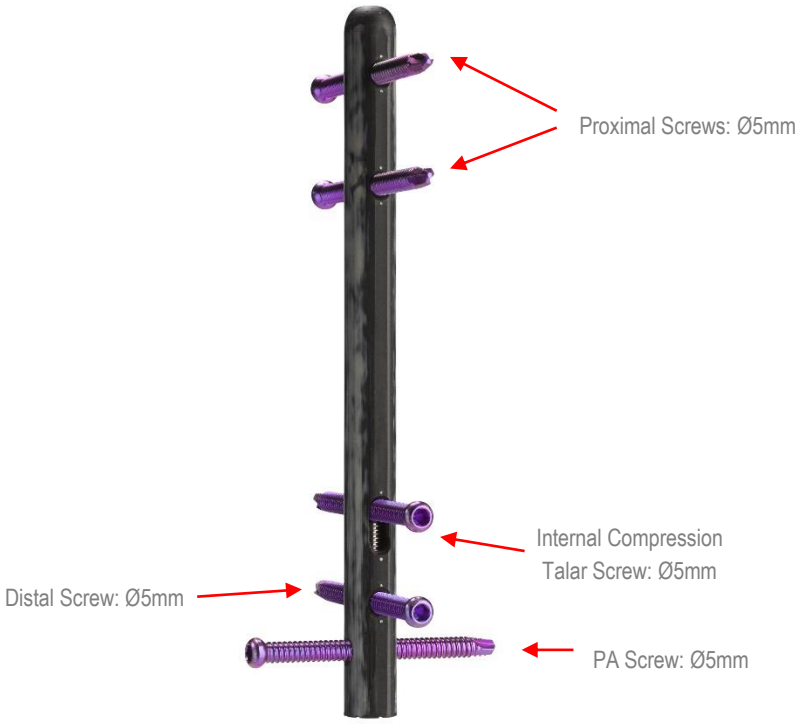


The Screws

All screws, made out of titanium, are provided non-sterile and are contained in the CarboFix Tibia/Femur instrument tray*.

Description	Diameter (mm)	Lengths (mm)	Screw color	Drill Bit Diameter (mm)	
Proximal & Distal Screws	5.0	30-105 30-60mm: 2.5mm increments: In the set 65-85mm: 5.0mm increments: In the Set 90, 100, 105mm: Supplied Sterile	Purple	4.2	

* Screws in length of 90-105 supplied separately packed and sterile



The Ankle Arthrodesis Nail

Instrumentation

Access Ø3.2mm Guide Wire

Marks the entry point and trajectory into the bone.

Entry Portal & Trocar

The Entry Portal is a soft tissue protector during soft tissue tunneling and reaming.

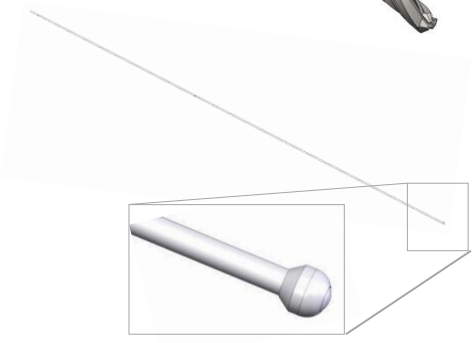
The Trocar is used for soft tissue tunneling at the access point. It is to accommodate a Ø3.2mm Access Guide Wire. The Trocar is locked to the Entry Portal by turning it clockwise.

Ø8x310mm Drill Bit

Used to access the bone. It is to accommodate a Ø3.2mm Access Guide Wire.

*Ball-Tip Guide Wire Ø2.5mm**

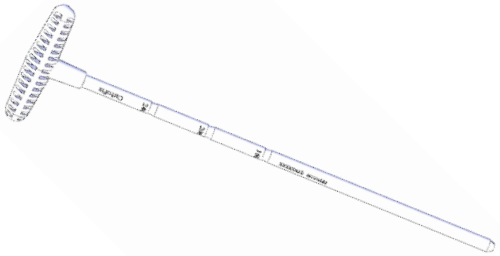
Assists in reduction and reaming. Compatible with conventional reamer sets. Ball Tip diameter Ø4.5mm. Supplied sterile, packed separately for single use.



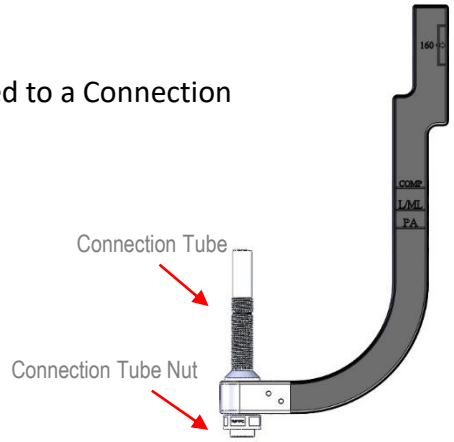
* Packed separately

Nail Length Gauge

Used to determine the required Nail length.



Insertion Handle Assembly The Handle is connected to a Connection Tube using a Connection Tube Nut.

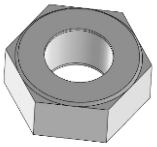


Insertion Handle Extension

Assists in drilling the proximal holes for the proximal screws in nail lengths of 200 & 240mm.

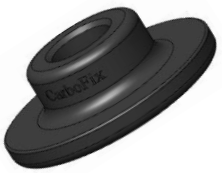
Connection Tube Nut

Secures the Connection Tube to the Handle, as well as part of the external the compression assembly.



Compression Plate

Assembled on the Insertion Handle Connection Tube with a Connection Tube Nut, to allow external compression. Available in Ø40mm & Ø48mm diameter.

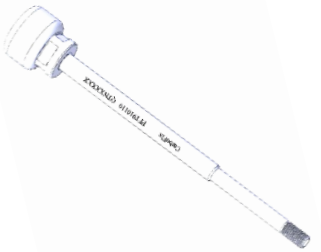


Compression Sleeve

Used when external compression against the calcaneus bone is desired.

Nail Adapter

Connects & locks the Handle Assembly to the Nail

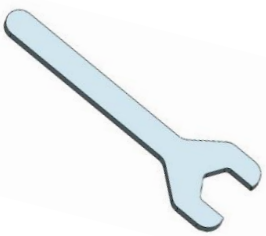


Nail Adapter Pin

Used to tighten/release the Nail Adapter to/from the nail

22” Wrench

For tightening/opening the Compression Plate & Connection Nut

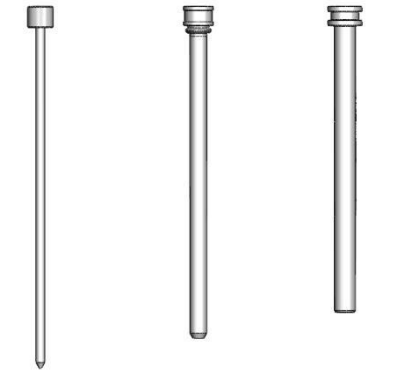


Guide & Drill Sleeves, Trocar

The Guide Sleeve is a working channel through which the Drill Sleeve and the Trocar are inserted.

The Drill Sleeve accommodates the Ø4.2mm Drill Bits.

The Guide & Drill Sleeves lock to each other.



Ø 4.2mm Drill Bit

Used to drill the holes for the screws (screws diameter 5.0mm).

Depth Gauge

Measures the required screw length.

Screwdriver Hex 3.5

Used to insert / remove Screws or the Nail Cap.

Screwdriver Hex 2.5

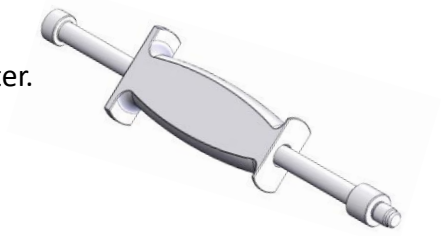
Used for Internal tibiotalr compression.

Nail Removal Adapter

For Nail removal, it is to the Nail's distal end as well as to the Slide Hammer.

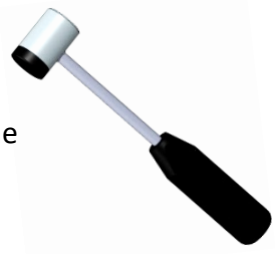
Slide Hammer

Used for Nail removal by connecting it to the Nail Removal Adapter. Optionally, it may be used for Nail insertion. In such cases it is connected to the Nail Adapter.



Mallet

The Mallet may be used during Nail insertion. The plastic side of the Mallet should be used for tapping the Nail Adapter gently.

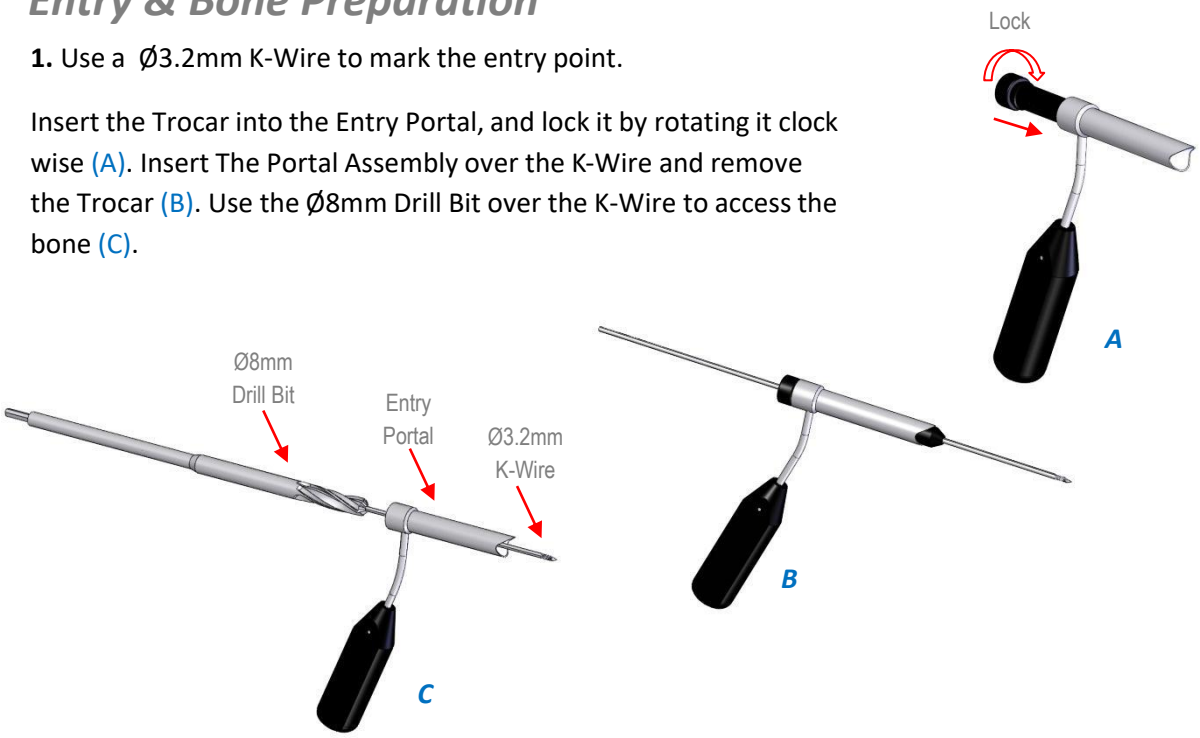


Procedure Steps

Entry & Bone Preparation

1. Use a Ø3.2mm K-Wire to mark the entry point.

Insert the Trocar into the Entry Portal, and lock it by rotating it clock wise (A). Insert The Portal Assembly over the K-Wire and remove the Trocar (B). Use the Ø8mm Drill Bit over the K-Wire to access the bone (C).



2. Insert the proprietary Ø2.5mm Ball-Tip Guide Wire into the created canal. Perform reaming. The Ball Tip Guide Wire can be used with any conventional Reamer set. The Guide shaft diameter is Ø2.5mm, and the Ball Tip diameter is Ø4.5mm.

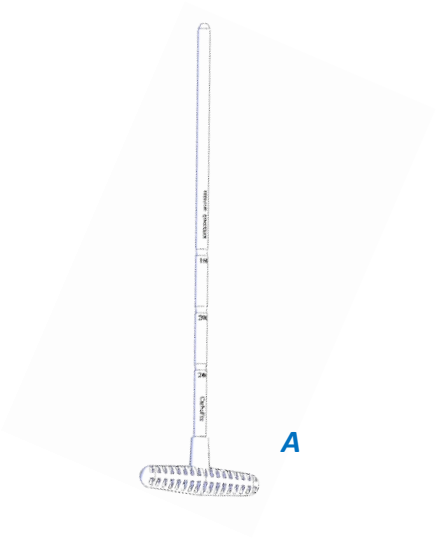
Ø8.0mm & Ø13.0mmDrill bits in the set can be used as well

Final reaming should be 1–1.5mm larger than the selected Nail diameter.

Nail Measurement

3. Measure the required Nail length by inserting the Nail Length Gauge into the created canal (A).

Use the required Nail diameter and length according to the following table:



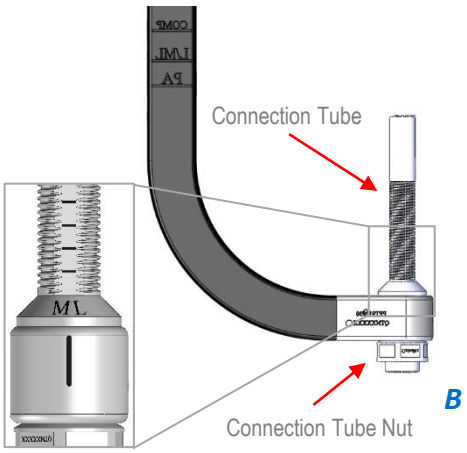
Nail Sizes

Diameter (mm)	Distal diameter (mm)	Length (mm)
10.0	12.0	160, 200, 240
12.0	12.0	160, 200, 240

Nail Insertion

4. Connect the Handle to the Connection Tube and secure it using the Connection Tube Nut (B). The Wrench can be used for tightening.

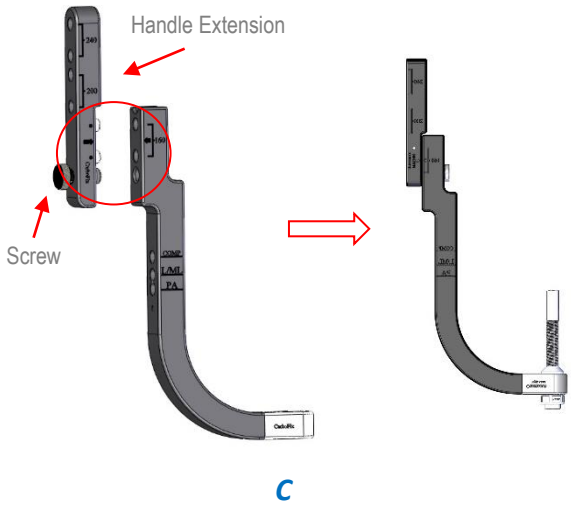
Make sure that the Connection Tube is locked in the **"ML"** position. The Handle orientation should be according to the surgeons preference to insert the proximal screws in medial to lateral approach or vice versa (B).



5. When using the 200mm or 240mm long nails, connect the Handle Extension to the Handle.

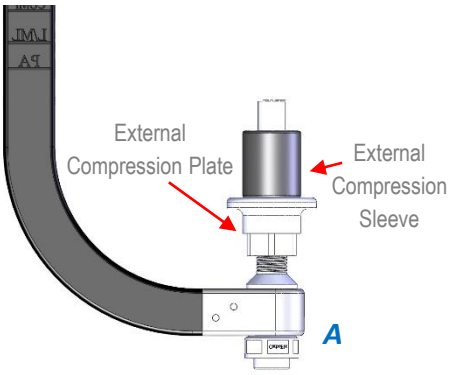
Make sure the arrows on the Handle & Handle Extension are aligned and pointing to each other (C) .

The Handle Extension Screw should be hand tightened.



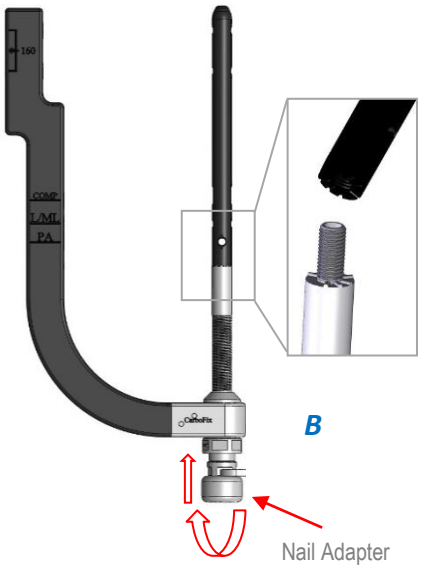
6. Assemble the Compression Plate Assembly over the Connection Tube.

If the surgeon wishes, during external compression, to apply compression directly to the calcaneus bone (rather than to the plantar pad of the foot), the Compression Sleeve shall be placed on top of the Compression Plate Assembly (A) .



7. Pass the Nail Adapter through the Connection Tube and thread it into the distal end of the Nail. Make sure the protrusions on the Connection Tube engage the slots at the distal end of the nail. Tighten the Nail Adapter to the Handle (B).

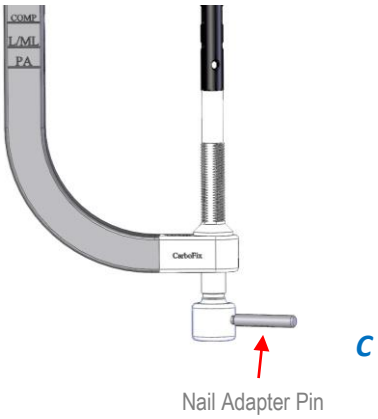
The Nail Adapter Pin can be used for tightening (C).
Do not apply high torque.



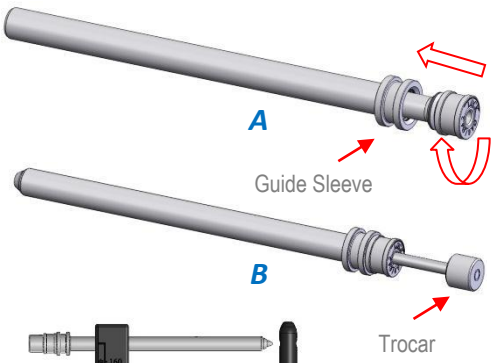
8. Remove the Guide Wire. Insert the Nail into the bone. If the Nail has to be hammered – tap the Nail Adapter with the Mallet. Once Nail insertion is completed – check position.

Important: Do not use excessive force. Use slight strokes only to position the Nail. Do not use oscillating movements to insert the Nail.

Important: The Nail should be countersunk 5mm – 10mm in the plantar cortex of the calcaneus. The Nail may be countersunk more if required, based on the patient anatomy and compression required.



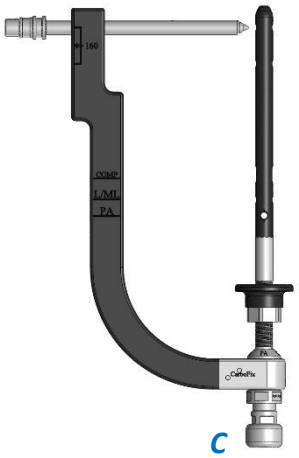
Proximal Screws Insertion



9. Insert the Drill Sleeve into the Guide Sleeve and lock it by rotating it clock wise (A). Insert the Trocar (B).

Cut an incision where proximal interlocking holes are located, and insert the assembly into the appropriate Handle hole, according to the Nail Length (C).

Remove the Trocar.



Drill the screw hole using the ***Ø4.2mm*** Drill Bit marked **Purple** (D).

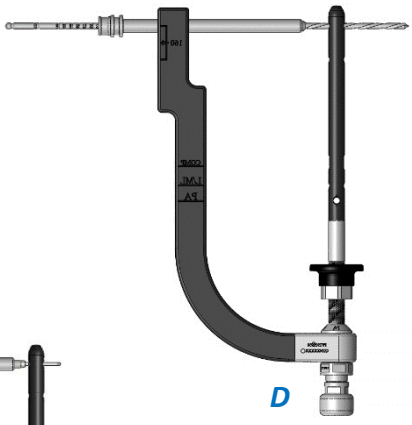
Remove the Drill Bit and Sleeve.

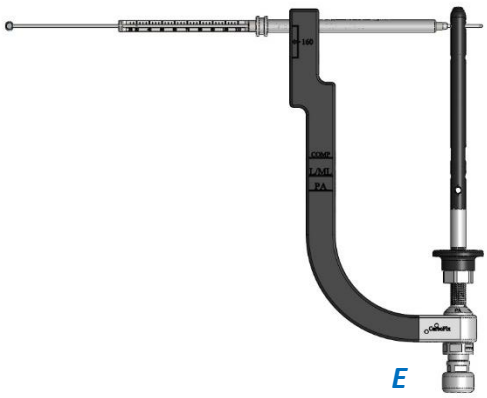
Select the appropriate Screw length using the Depth Gauge (E).

Use ***Ø5.0mm*** *Screws* (**Purple**).

Insert the Screw through the Guide Sleeve, using the Screwdriver.

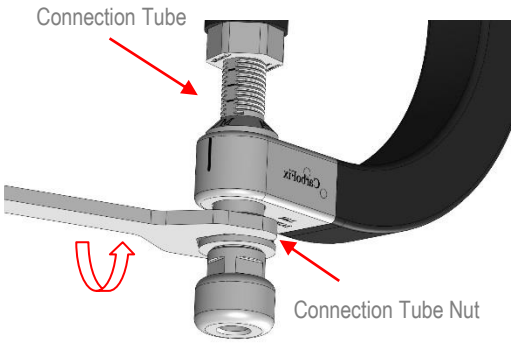
Remove the Screwdriver and Guide Sleeve.





Talar Screw Insertion

10. The Talar Screw should be inserted lateral to medial.
If the Handle orientation has to be changed, release the Connection Nut a little (the Wrench can be used) (A), pull and rotate the Insertion Handle 180˚ to the lateral. Make sure that the Connection Tube is locked in the **"ML"** position.
Tighten the Connection Nut (the Wrench can be used) (B).

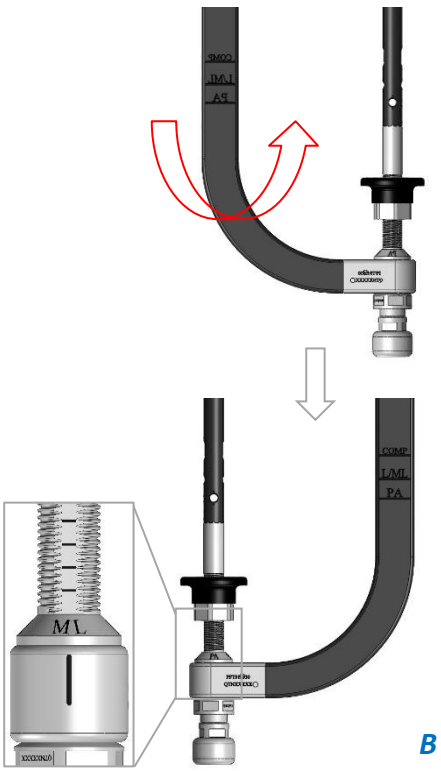


A

11. Insert the Drill Sleeve into the Guide Sleeve and lock it by rotating it clock wise. Insert the Trocar.

Cut an incision where the Talar interlocking hole is located, and insert the assembly into the appropriate Handle hole, marked **"COMP"** (C).

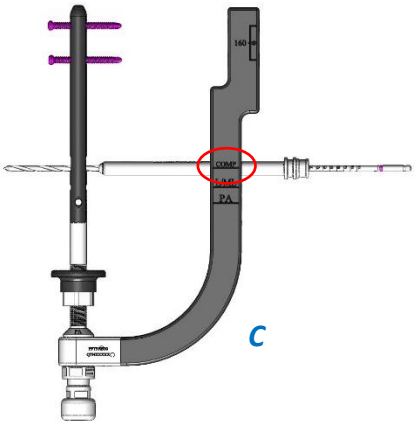
Remove the Trocar.



B

Drill the screw hole using the ***Ø4.2mm*** Drill Bit marked **Purple**.
Remove the Drill Bit and Sleeve.
Select the appropriate Screw length using the Depth Gauge.
Use ***Ø5.0mm*** *Screws* (**Purple**).
Insert the Screw through the Guide Sleeve, using the Screwdriver.

Remove the Screwdriver and Guide Sleeve.

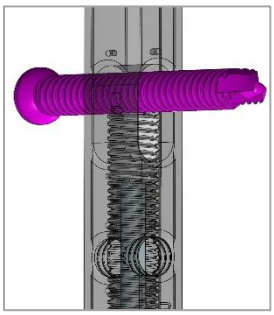


C

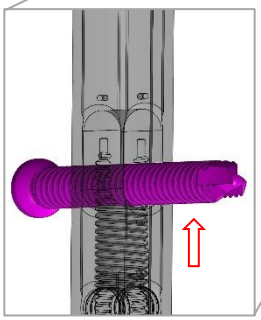
Compression

Internal Compression:

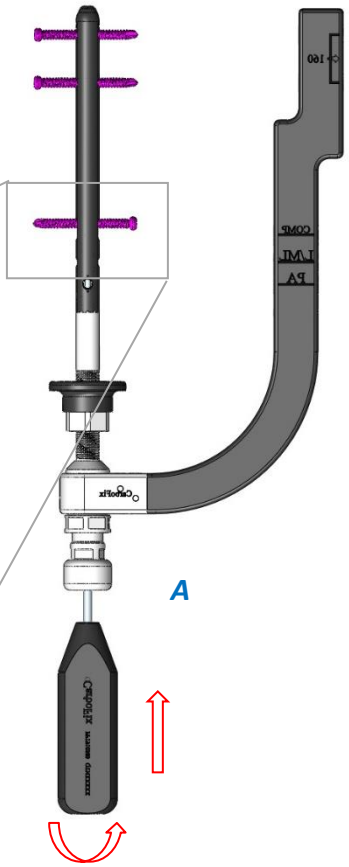
12. Insert the 2.5 Hex Screwdriver through the Nail Adapter and rotate clockwise the internal compression mechanism to achieve up to 7mm compression (A).



Final compression position

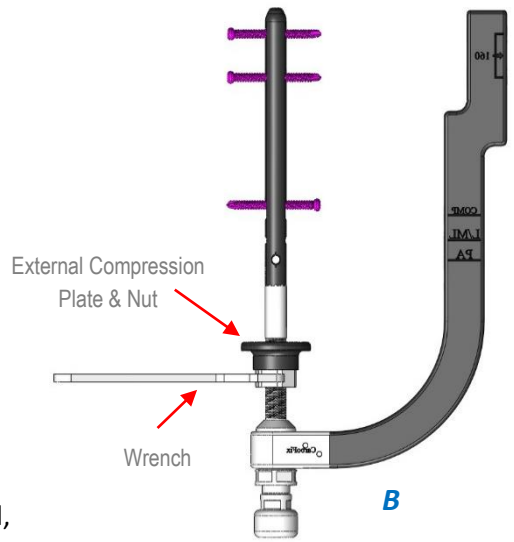


Initial Screw position



External Compression:

13. Rotate the Compression Nut using the Wrench to achieve satisfactory compression at the fusion site (B). Markings on the Connection Tube, in 5mm increments, can be used to indicate the extent of compression.
Care should be taken not to over-tighten the Compression Nut.



Distal Screw Insertion

14. Insert the Drill Sleeve into the Guide Sleeve and lock it by rotating it clock wise. Insert the Trocar.

Cut an incision where the Distal interlocking hole is located, and insert the assembly into the appropriate Handle hole, marked **"L/ML".**

Remove the Trocar.

15. Drill the screw hole using the ***Ø4.2mm*** Drill Bit marked **Purple** (A).

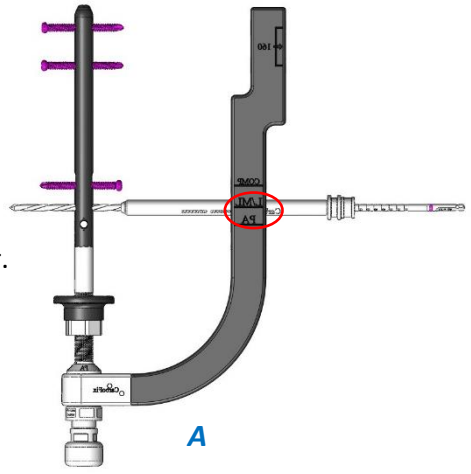
Remove the Drill Bit and Sleeve.

Select the appropriate Screw length using the Depth Gauge.

Use ***Ø5.0mm*** *Screws* (**Purple**).

Insert the Screw through the Guide Sleeve, using the Screwdriver.

Remove the Screwdriver and Guide Sleeve.



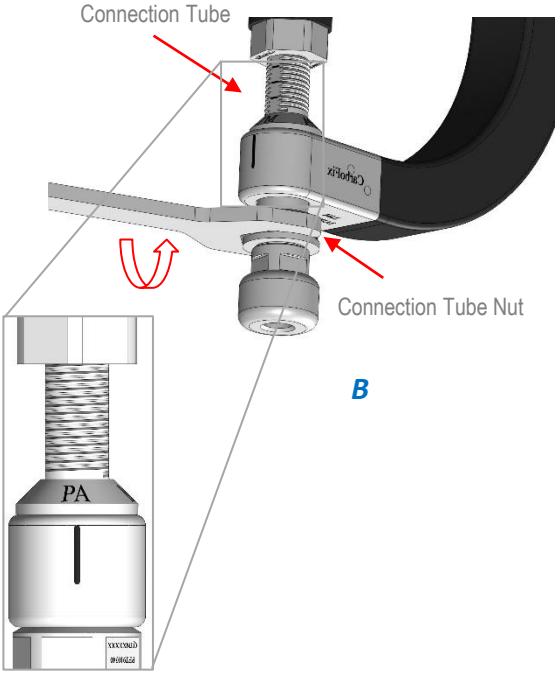
A

PA Screw Insertion

16. The PA Screw should be inserted posterior to anterior.

Release the Connection Nut a little (the Wrench can be used) (B), pull and rotate the Insertion Handle 90˚.

Make sure that the Connection Tube is locked in the **"PA"** position. Tighten the Connection Nut (the Wrench can be used) (C).



B

Drill the screw hole using the ***Ø4.2mm*** Drill Bit marked **Purple** (A).

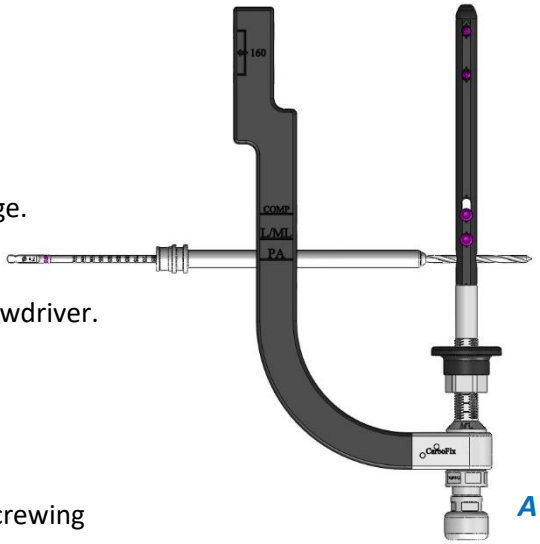
Remove the Drill Bit and Sleeve.

Select the appropriate Screw length using the Depth Gauge.

Use ***Ø5.0mm*** *Screws* (**Purple**).

Insert the Screw through the Guide Sleeve, using the Screwdriver.

Remove the Screwdriver and Guide Sleeve.

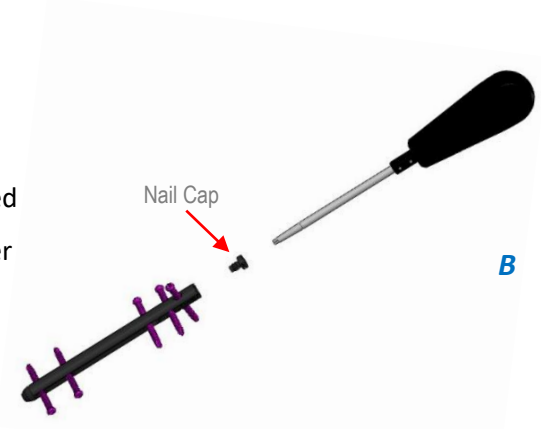


A

17. Disconnect the Insertion Handle from the Nail by unscrewing the Nail Adapter (the 15" Wrench can be used).

Nail Cap Insertion

Nail Cap (supplied separately, packed sterile) can be inserted by using the Screwdriver (B). The Nail Cap is positioned after detachment of the Insertion Handle.



B

There are 3 available Nail Cap lengths: 4, 8 & 12mm

The Nail Cap is radiolucent, made out of composite material, and therefore there are two embedded radiopaque markers for visualization under fluoroscopy.


Nail Cap Visualization in X-ray (Humeral Nail)

Important: Patients should be cautioned against significant load bearing prior to good callus formation.

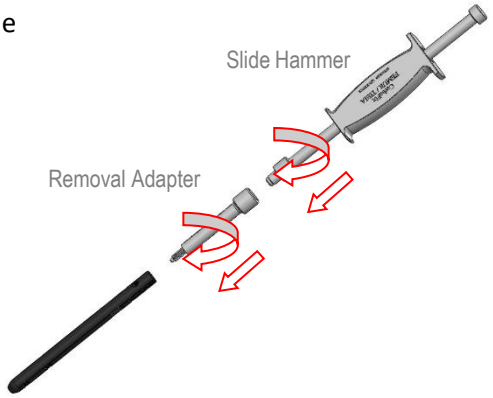
Nail Removal

1. Remove the Nail Cap and the Interlocking Screws by using the Screwdriver.

2. Screw the Nail Removal Adapter onto the nail's distal end.

3. Connect the Slide Hammer to the Nail Removal Adapter.

Use light strokes of the Slide Hammer to remove the Nail from the bone.



Ordering Information

Ankle Arthrodesis Nails

Cat. No.	Description	Diameter (mm)	Length (mm)	Distal Dia. (mm)
PAAN10160	CarboFix Ankle Arthrodesis Nail 10.0 160mm	10.0	160	12.0
PAAN10200	CarboFix Ankle Arthrodesis Nail 10.0 200mm	10.0	200	12.0
PAAN10240	CarboFix Ankle Arthrodesis Nail 10.0 240mm	10.0	240	12.0
5PAAN10160	CarboFix Ankle Arthrodesis Nail 12.0 160mm	12.0	160	12.0
5PAAN10200	CarboFix Ankle Arthrodesis Nail 12.0 200mm	12.0	200	12.0
5PAAN10240	CarboFix Ankle Arthrodesis Nail 12.0 240mm	12.0	240	12.0

Screws

Ø 5.0 Titanium

Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Inst. Set
PCST50300	CarboFix Titanium Screw, 5.0mm, L30mm	5.0	30	4
PCST50325	CarboFix Titanium Screw, 5.0mm, L32.5mm	5.0	32.5	4
PCST50350	CarboFix Titanium Screw, 5.0mm, 35mm	5.0	35	6
PCST50375	CarboFix Titanium Screw, 5.0mm, L37.5mm	5.0	37.5	6
PCST50400	CarboFix Titanium Screw, 5.0mm, L40mm	5.0	40	6
PCST50425	CarboFix Titanium Screw, 5.0mm, L42.5mm	5.0	42.5	8
PCST50450	CarboFix Titanium Screw, 5.0mm, L45mm	5.0	45	8
PCST50475	CarboFix Titanium Screw, 5.0mm, L47.5mm	5.0	47.5	8
PCST50500	CarboFix Titanium Screw, 5.0mm, L50mm	5.0	50	8
PCST50525	CarboFix Titanium Screw, 5.0mm, L52.5mm	5.0	52.5	8
PCST50550	CarboFix Titanium Screw, 5.0mm, L55mm	5.0	55	6
PCST50575	CarboFix Titanium Screw, 5.0mm, L57.5mm	5.0	57.5	6
PCST50600	CarboFix Titanium Screw, 5.0mm, L60mm	5.0	60	6
PCST50650	CarboFix Titanium Screw, 5.0mm, L65mm	5.0	65	6
PCST50700	CarboFix Titanium Screw, 5.0mm, L70mm	5.0	70	4
PCST50750	CarboFix Titanium Screw, 5.0mm, L75mm	5.0	75	4
PCST50800	CarboFix Titanium Screw, 5.0mm, L80mm	5.0	80	4
PCST50850	CarboFix Titanium Screw, 5.0mm, L85mm	5.0	85	4
PCST50900	CarboFix Titanium Screw, 5.0mm, L90mm	5.0	90	Sterile Packed
PCST50950	CarboFix Titanium Screw, 5.0mm, L95mm	5.0	95	Sterile Packed
PCST51000	CarboFix Titanium Screw, 5.0mm, L100mm	5.0	100	Sterile Packed
PCST51050	CarboFix Titanium Screw, 5.0mm, L105mm	5.0	105	Sterile Packed

Nail Cap

Cat. No.	Description	Diameter (mm)	Length (mm)
PTNC9000	Lower Extremity Nail Cap 4mm	11.0	4.0
PTNC9008	Lower Extremity Nail Cap 8mm	11.0	8.0
PTNC9012	Lower Extremity Nail Cap 12mm	11.0	12.0

Miscellaneous

Cat. No.	Description
PFT912260	Access Guide Wire Ø3.2mmX350mm, ***Sterile & Single Use***
PFT912250	Ball-Tip Guide Wire Ø2.5mmX1000mm, ***Sterile & Single Use***
PFT910370	Drill Bit Ø3.2X270mm-Pointed Tip, ***Sterile & Single Use***
PN942300	Drill Bit Ø4.2X300mm-Pointed Tip, ***Sterile & Single Use***

Instrumentation

Cat. No.	Description
PAA910100USA	Ankle Arthrodesis Instrumentation Set

Instrumentation Set Components

Cat. No.	Description
PFT910355	Sterilization Box
PFT910930	Athrodesis Handle
PFT910120	Athrodesis Connection Tube
PFT910320	Athrodesis Connection Tube Nut
PFT910400	Athrodesis Handle Extension
PFT910110	Athrodesis Nail Adapter
PFT912220	Athrodesis Nail Adapter Pin (Opening Pin)
PFT910340	External Compression Plate 40.0
PFT910480	External Compression Plate 48.0
PFT910130	External Compression Sleeve
PFT910160	Nail Length Gauge
PFT911000US	Drill Bit 4.2x300mm – Pointed Tip (Disposable)
PL980310	Drill Bit 8.0/3.3x365mm (Disposable)
Q9240020US	Guide Sleeve 10.0/8.0mm
PFT910700US	Drill Sleeve 8.0/4.2mm
Q9240390US	Trocar
PFT910390	Wrench 22.0
PFT910380	Athrodesis Long Screwdriver Hex 2.5
PFT912260	Access Guide Wire Ø3.2 mm (Disposable)
PFT917000	Awl 13 mm
PFT912310	Entry Portal
PFT912280	Entry Trocar
PN913220	Drill Bit 13.0x300 mm (Disposable)
PFT912230	Slide Hammer
Q9105110	Mallet
Q9106690FT	Screw Depth Gauge
PFT912210	Screwdriver - Long
PFT912360	Screwdriver - Short
PFT912370	Power Drive Screwdriver
PFT911200	Removal Adapter

Ankle Arthrodesis Instrumentation Set

CARBOFIX
Orthopedics

www.carbo-fix.com

For detailed procedure, indications, contraindications, possible adverse event, warnings and precautions, refer to the Instructions for Use
Caution: In the U.S.A., federal law restricts this device to sale by or on the order of a physician.

MANUFACTURED BY:

CarboFix Orthopedics Ltd.
11 Ha'hoshlim St.,
Herzeliya 46724 , Israel
Tel: +972-9-9511511
Fax: +972-9-9548939
E -Mail: info@carbo-fix.com

U.S.A. OFFICE:

CarboFix Orthopedics Inc.
9983 Traders Lane, Ext. 1
Calabash NC 28467
USA
Tel: 1-800-408-0120
E -Mail: usa@carbo-fix.com

EC AUTHORIZED REPRESENTATIVE:

MEDNET EC-REP IIb GmbH
Borkstrasse 10, 48163 Münster
Germany

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