



Proximal Humeral Plate Procedure Steps



Introduction

The CarboFix™ Implants

The **CarboFix™** Proximal Humeral Plate is made of numerous endless carbon fibers embedded in polymer (PEEK).

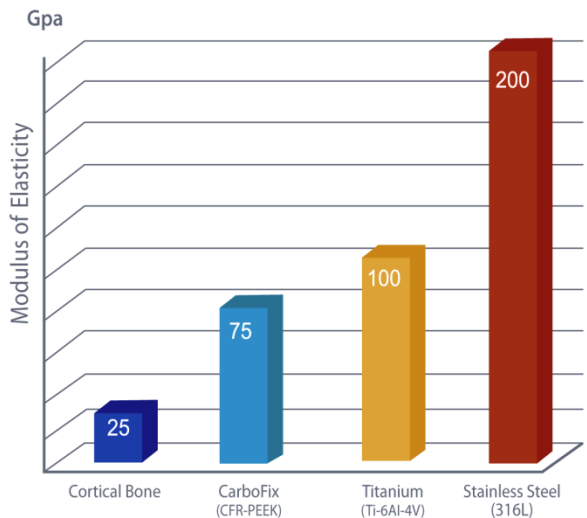
The Carbon Fibers are arranged in a unidirectional longitudinal orientation, as well as in a diagonal orientation, allowing Tri-dimensional bending and rotational strength.

CarboFix™ is the first FDA cleared and CE marked trauma line of intramedullary nails and anatomical plates made of composite material, overcoming the drawbacks of metals.

The Advantages of CarboFix™ Implants

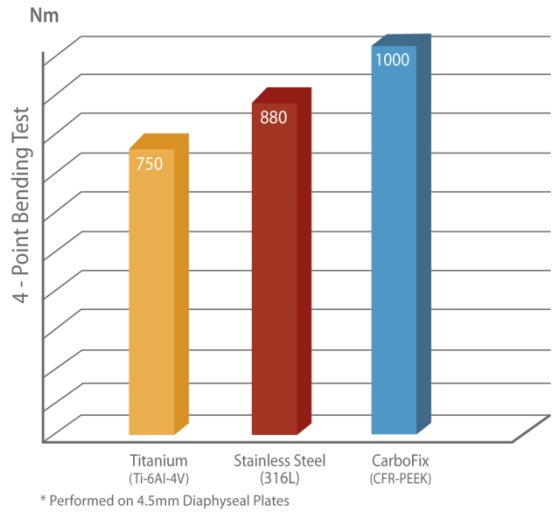
Modulus of Elasticity

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



Bending Strength

In comparison 4-point bending experiments of Diaphyseal plates, the **CarboFix™** plate was 33% stronger than a Synthes titanium plate, and 15% stronger than a Synthes stainless steel plate.



Radiolucency

CarboFix™ implants allow easy positioning and better fracture monitoring during surgery and follow-up.



Metal Plate-fracture view is obstructed



CarboFix™ Plate-clear view of the fracture

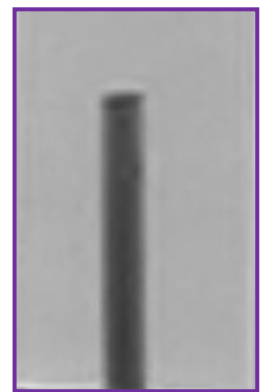
CT & MRI Imaging

The **CarboFix™** implants allow CT & MRI* scans with no artifacts caused by the Carbon Fibers implant.

* Please refer to page 15, and the product IFU.



Titanium Rod Ø5mm in MRI field: demonstrates massive artifacts



Carbon Fibers Rod Ø5mm in MRI Field-no artifacts

Easy Removal

In contrast with titanium, no “Cold Welding” occurs between **CarboFix™** plates & screws, allowing easier hardware removal.

CarboFix™ Proximal Humeral Plate

The Plate

The main features of the **CarboFix™** Proximal Humeral Plate:

- Anatomically shaped
- Low profile plate: 3.7mm
- Circumference radiopaque marking outlining the plate contour for positioning & follow-up (A)
- Compatible plate shaft Screw Holes for locking or non-locking screws
- Similar instrumentation & procedure steps as conventional metal plates

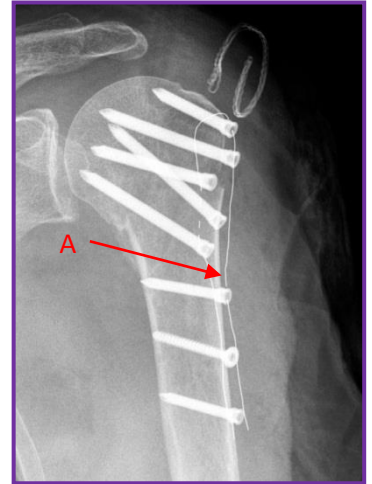
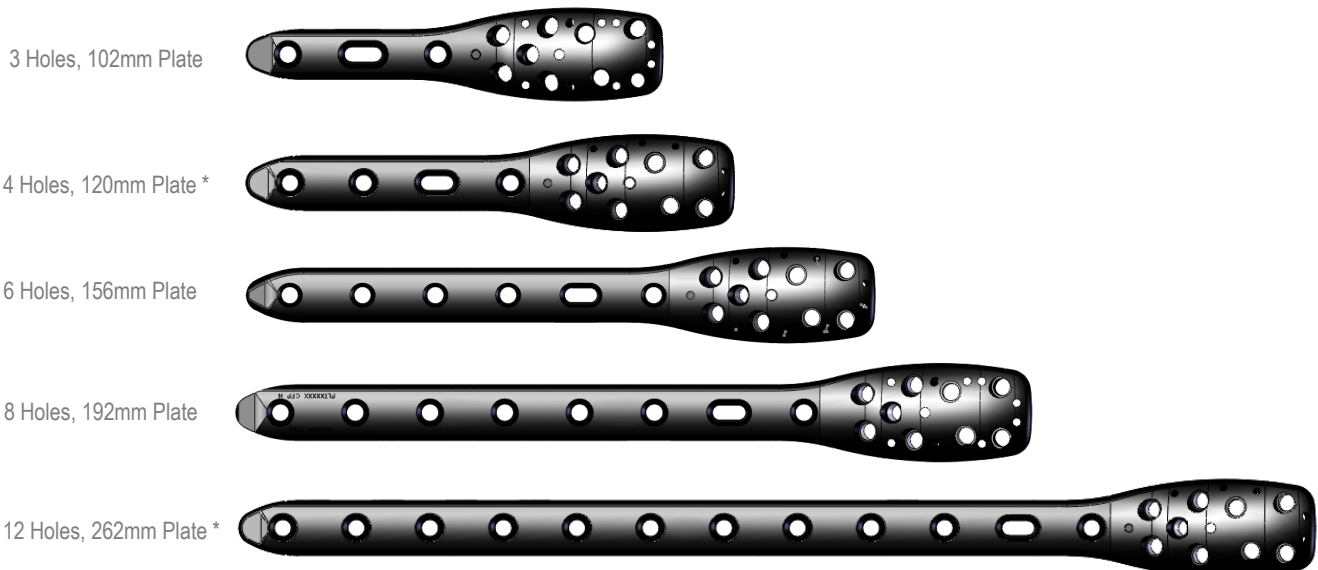


Plate under X-ray

The Plates are universal for left & right humerus, available in 3 different shaft lengths : 3, 6 & 8 holes, as well as 4 & 12 holes as a special order.

Description	Length (mm)	No. of holes (Shaft)
CarboFix Proximal Humeral Plate 3 Holes	102	3
CarboFix Proximal Humeral Plate 4 Holes*	120	4
CarboFix Proximal Humeral Plate 6 Holes	156	6
CarboFix Proximal Humeral Plate 8 Holes	192	8
CarboFix Proximal Humeral Plate 12 Holes*	262	12

* Special Order



The Screws

Proprietary self-tapping titanium screws are used to fixate the plate:

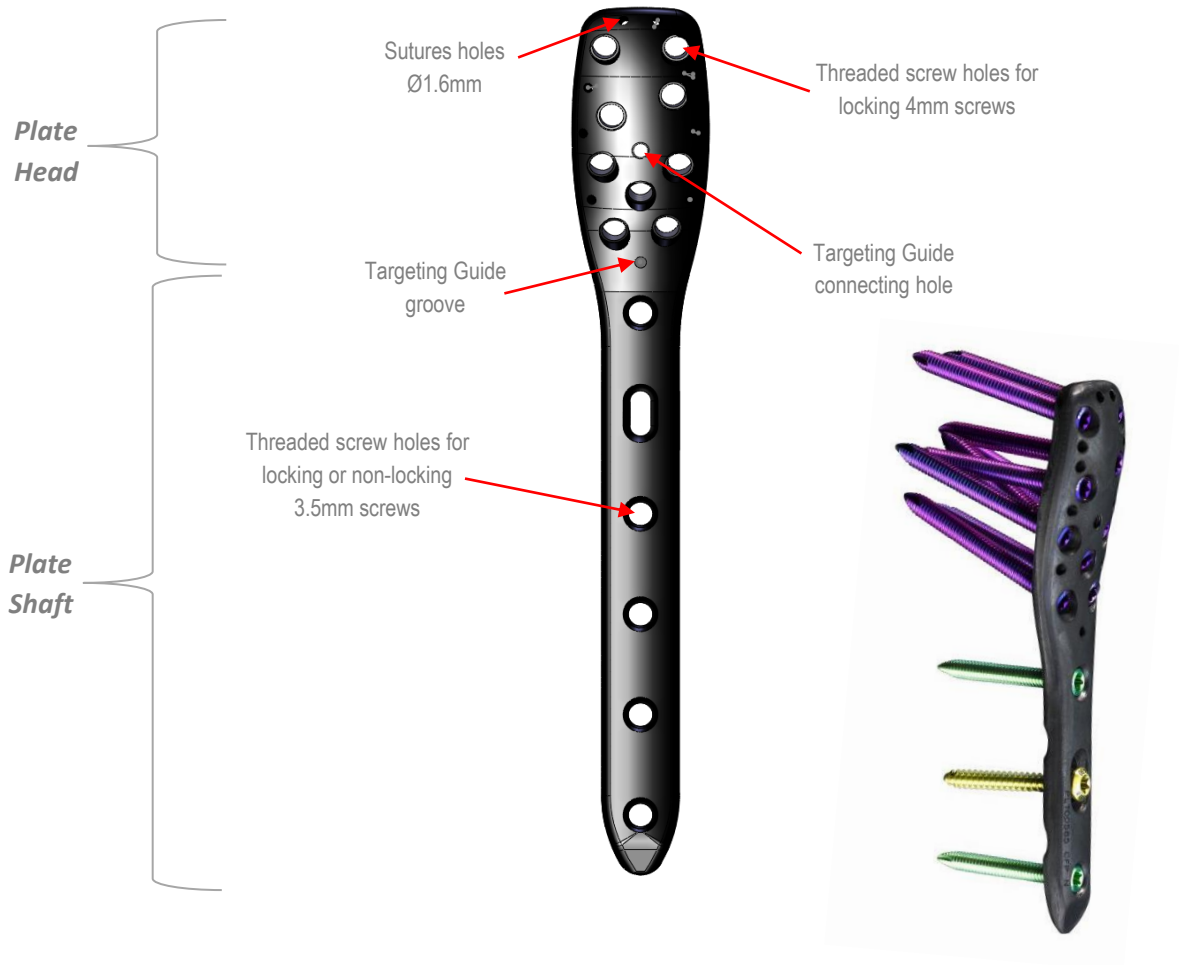


Plate Head




Description	Diameter (mm)	Lengths (mm)	Screw color	Drill Bit Diameter (mm)	
Head Locking Screws	4.0	25, 30-50, 55, 60 (2.5mm increments)	Purple	3.4	

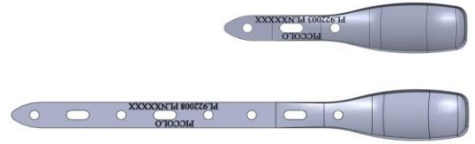
Plate Shaft

Description	Diameter (mm)	Lengths (mm)	Screw color	Drill Bit Diameter (mm)	
Shaft Locking Screws	3.5	22.5-35, 40, 45 (2.5mm increments)	Green	3.0	
Shaft Non-Locking Screws	3.5	22.5-35, 40, 45 (2.5mm increments)	Yellow	2.5	

Instrumentation Set

Metal Plate Template

The metal plate template is used to determine the desired plate length. Templates are available for the 3 holes plate, as well as for the 8 holes plate.



Targeting Guide (Jig)

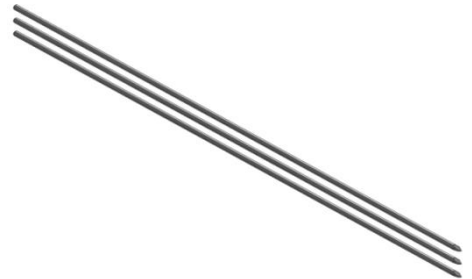
The Targeting Guide (Jig) is mounted on the plate proximal end. It is an aiming device assisting the surgeon in drilling the holes in the correct trajectory.



Ø1.6mm K-Wire

The Ø1.6mm K-Wire assists the surgeon in positioning the plate, as well as in fracture reduction.

The K-wires may be inserted through the Targeting Guide K-Wire Sleeves. 3 K-Wires are supplied.



Free Hand Drill Sleeve Ø2.5mm

The Free Hand Drill Sleeve is used for drilling the holes for non-locking screws at the plate shaft, using the Ø2.5mm Drill Bit.



Shaft Drill Sleeve Ø3.0mm

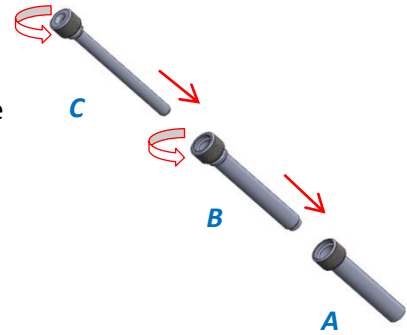
The Shaft Drill Sleeve is used for drilling the holes for locking screws at the plate shaft, using the Ø3.0mm Drill Bit.



Targeting Guide Sleeves

There are 3 Targeting Guide Sleeves:

- **Targeting Guide Screw Sleeve** - inserted into the Targeting Guide designated holes (A).
- **Targeting Guide Drill Sleeve** (Ø3.4mm) - inserted into the Targeting Guide Screw Sleeve (B).
- **Targeting Guide K-Wire Sleeve** (Ø1.6mm) - inserted into the Targeting Guide Drill Sleeve (C).



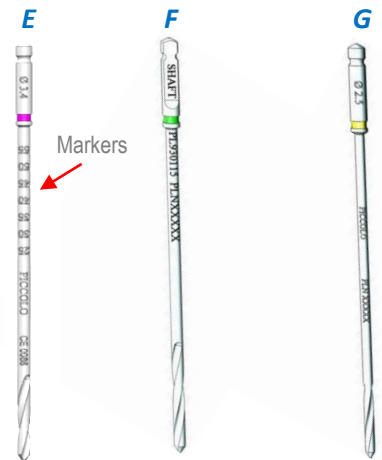
The Sleeves are threaded and lock into each other.

Two sets of sleeves are supplied.

Drill Bits Ø3.4mm, Ø3.0mm, Ø2.5mm

Three different Drill Bits are available:

- **Ø3.4mm**: For drilling the plate proximal screws. Circumference markers on the Drill enable screw length measurement. Marked **Purple (E)**.
- **Ø3.0mm**: For drilling the locking shaft screws. Marked **Green (F)**.
- **Ø2.5mm**: For drilling the non-locking plate shaft screws. Marked **Yellow (G)**.



Please refer to the table on page 4.

Depth Gauge

The Depth Gauge assists in determining the desired screw length.



Screwdriver

For insertion of the plate head (proximal) & shaft screws. The Screwdriver includes a Handle as well as a detachable rod: Tip of the screwdriver is Torx shaped (Torx 15).



Torque Limiter 1.5Nm*

The Torque Limiter is used for manual, as well as for power assisted screw insertion. Connects to the Handle/ Power-drive on one side, and to the detachable screwdriver rod on the other side.



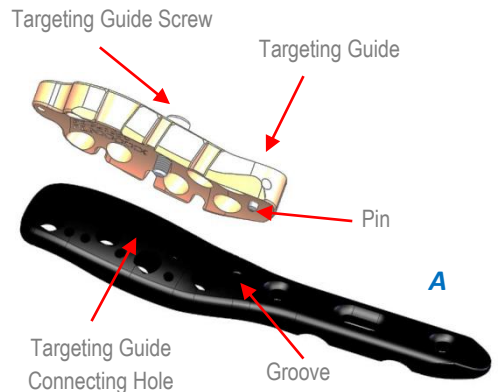
* Optional

Procedure Steps

1. Expose the bone according to routine surgical technique.

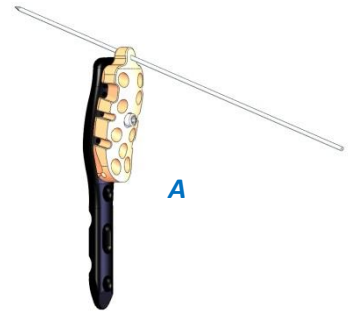
Reduce the fracture and determine the required plate length using the plate templates.

Two templates are available complying with the 3 holes plate, as well as with the 8 holes plate.



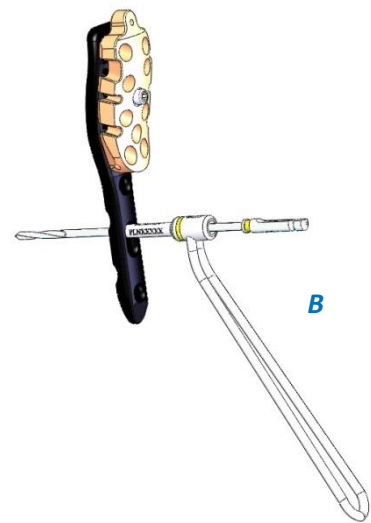
2. Connect the Targeting Guide to the plate head. Align the Targeting Guide to the plate by positioning the Guide's pin into the designated groove in the plate (A). Use the Screwdriver to tighten the Guide to the plate, by screwing the Targeting Guide Screw into the designated hole in the plate.

3. Place the Plate over the bone, approximately 8mm distal to the upper end of the Greater Tubercle. Plate positioning may be assisted by inserting a 1.6mm K-Wire through the proximal hole of the Targeting Guide, so that the wire aims at the proximal joint surface (A).



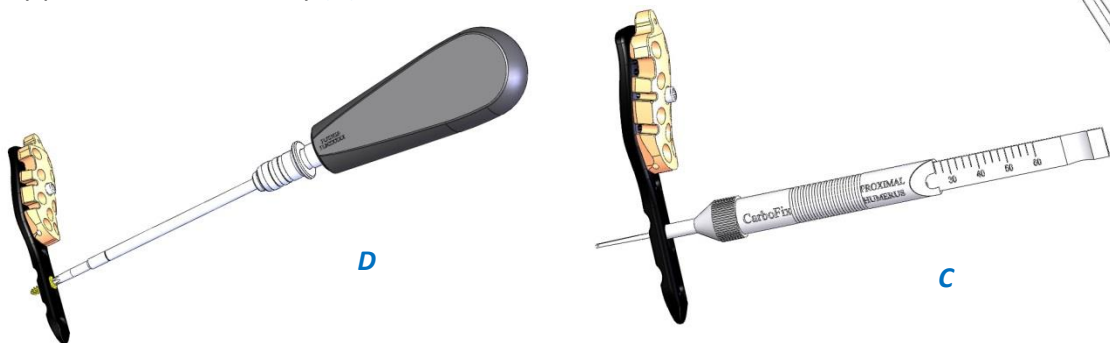
If the use of sutures is desired, they should be threaded through the designated Plate holes prior to the fixation of the plate.

4. For initial fixation and positioning of the plate, use the $\varnothing 2.5\text{mm}$ Drill Bit, (marked **Yellow**) through the Free Hand Drill Sleeve, and drill through an oval hole of the Plate shaft (B).



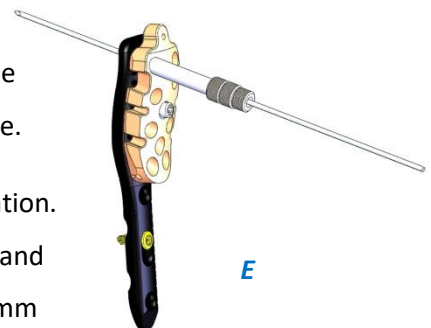
Determine the required non-locking (Cortical) Screw length using the Depth Gauge (C).

Insert the Cortical Screw (**Yellow**) using the Screwdriver.*
Verify placement under X-ray (D).



5. Proximal (head) screws placement: Insert the K-Wire Sleeve into the Drill Guide Sleeve, and insert this assembly into the Screw Guide Sleeve.

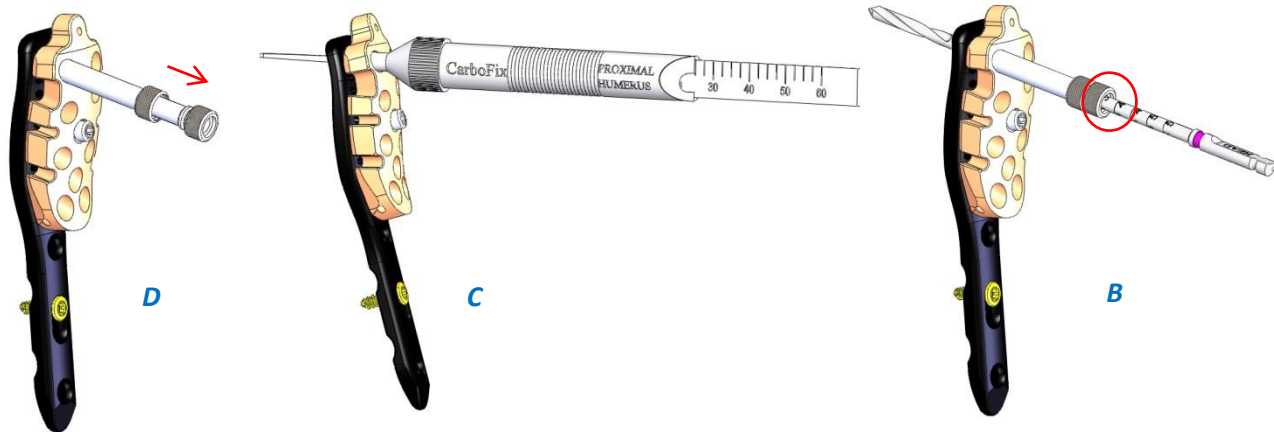
Attach the Sleeve Assembly to the Targeting Guide, at the desired location. Insert a 1.6mm K-Wire through the K-Wire Sleeve under fluoroscopy, and verify that the K-Wire is located in the subchondral bone, at least 5–8mm below the joint surface (E).



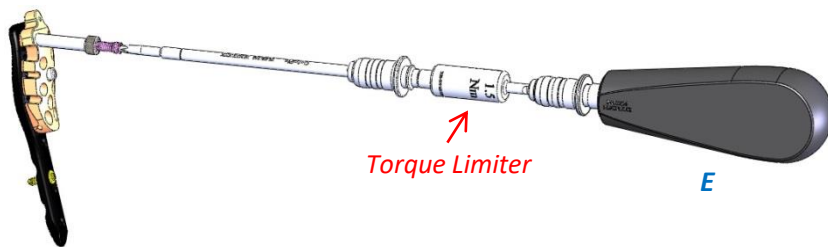
6. Remove the K-Wire & K-Wire Sleeve (A), and use the $\varnothing 3.4\text{mm}$ Drill Bit (marked Purple). Drill the required hole. Verify drill trajectory and location under X-ray.

Determine desired Screw length using the marks on the Drill Bit (B), or measure by using the Depth Gauge through the Targeting Guide (C).

Remove the Drill Bit & Drill Guide Sleeve (D).



If available, attach the 1.5Nm Torque Limiter to the Screwdriver Handle and its rod, and insert the Locking Screw (Purple). Tighten the Screw until the Torque Limiter “clicks”* (E). If a Torque Limiter is not available, tighten the screws until noticeable resistance. Repeat these steps for the rest of the “plate head” holes.



Remove the Screw Guide Sleeve & the Targeting Guide.

Observe the Screws, and if needed, tighten using the Screwdriver without the Torque Limiter, until flush with the plate (F).



*** Do not apply high torque during Screw tightening; excessive torque may damage the bone or implant.
If a Power-drive is used connect it always to the Torque Limiter !**

7. Place the rest of the shaft screws:

Locking Screws:

Connect the Shaft Drill Sleeve to the desired threaded hole of the Plate shaft (A). If needed, the Screwdriver can be used to attach the Shaft Drill Sleeve (B).

Use the $\varnothing 3.0$ mm Drill Bit (marked Green), placed through the Shaft Drill Sleeve, and drill the required hole (C).

Detach the Shaft Drill Sleeve, and measure the desired Screw length using the Depth Gauge.

Insert the Locking Screw (Green) using the Screwdriver and tighten it in place*.

Verify placement under X-ray.

Non-Locking Screws:

Use the $\varnothing 2.5$ mm Drill Bit (marked Yellow), through the Free Hand Drill Sleeve, and drill through the oval or round hole of the Plate shaft (D).

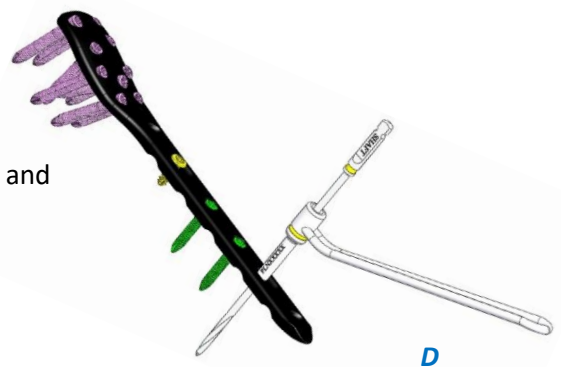
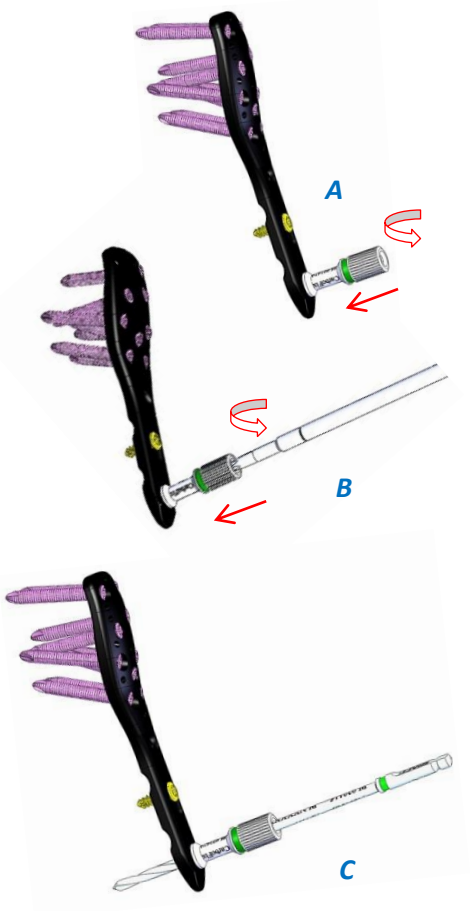
Determine the required Cortical Screw length using the Depth Gauge.

Insert the Non-Locking Screw (Yellow) using the Screwdriver, and tighten it in place.*

Verify placement under X-ray.

8. Remove the Targeting Guide, and close the incision according to routine surgical procedure.

*** Do not apply high torque when tightening the screw; excessive torque may damage the bone or implant.**



Ordering Information

Instrumentation

Cat. No.	Description
PL921020USA	Proximal Humeral Plate Instrumentation Set (Not Including Screws)

Plates

Cat. No.	Description	Length (mm)	No. of holes (Shaft)
PPHNN3503	CarboFix Proximal Humeral Plate 3 Holes	102	3
PPHNN3506	CarboFix Proximal Humeral Plate 6 Holes	156	6
PPHNN3508	CarboFix Proximal Humeral Plate 8 Holes	192	8

Screws: Plate Head

Head Locking Screw



Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Inst. Set
PHTST40250	Head Locking Screw 4.0 L=25	4.0	25	6
PHTST40300	Head Locking Screw 4.0 L=30	4.0	30	6
PHTST40325	Head Locking Screw 4.0 L=32.5	4.0	32.5	6
PHTST40350	Head Locking Screw 4.0 L=35	4.0	35	8
PHTST40375	Head Locking Screw 4.0 L=37.5	4.0	37.5	8
PHTST40400	Head Locking Screw 4.0 L=40	4.0	40	8
PHTST40425	Head Locking Screw 4.0 L=42.5	4.0	42.5	8
PHTST40450	Head Locking Screw 4.0 L=45	4.0	45	8
PHTST40475	Head Locking Screw 4.0 L=47.5	4.0	47.5	6
PHTST40500	Head Locking Screw 4.0 L=50	4.0	50	6
PHTST40550	Head Locking Screw 4.0 L=55	4.0	55	6
PHTST40600	Head Locking Screw 4.0 L=60	4.0	60	6

Screws: Plate Shaft

Shaft Locking Screw



Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Inst. Set
PHTST35225	Shaft Locking Screw 3.5 L=22.5	3.5	22.5	4
PHTST35250	Shaft Locking Screw 3.5 L=25	3.5	25	4
PHTST35275	Shaft Locking Screw 3.5 L=27.5	3.5	27.5	5
PHTST35300	Shaft Locking Screw 3.5 L=30	3.5	30	5
PHTST35325	Shaft Locking Screw 3.5 L=32.5	3.5	32.5	5
PHTST35350	Shaft Locking Screw 3.5 L=35	3.5	35	5
PHTST35400	Shaft Locking Screw 3.5 L=40	3.5	40	4
PHTST35450	Shaft Locking Screw 3.5 L=45	3.5	45	4

Shaft Non-Locking Screw



Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Inst. Set
PHCST35225	Shaft Non-Locking Screw 3.5 L=22.5	3.5	22.5	4
PHCST35250	Shaft Non-Locking Screw 3.5 L=25	3.5	25	4
PHCST35275	Shaft Non-Locking Screw 3.5 L=27.5	3.5	27.5	5
PHCST35300	Shaft Non-Locking Screw 3.5 L=30	3.5	30	5
PHCST35325	Shaft Non-Locking Screw 3.5 L=32.5	3.5	32.5	5
PHCST35350	Shaft Non-Locking Screw 3.5 L=35	3.5	35	5
PHCST35400	Shaft Non-Locking Screw 3.5 L=40	3.5	40	4
PHCST35450	Shaft Non-Locking Screw 3.5 L=45	3.5	45	4

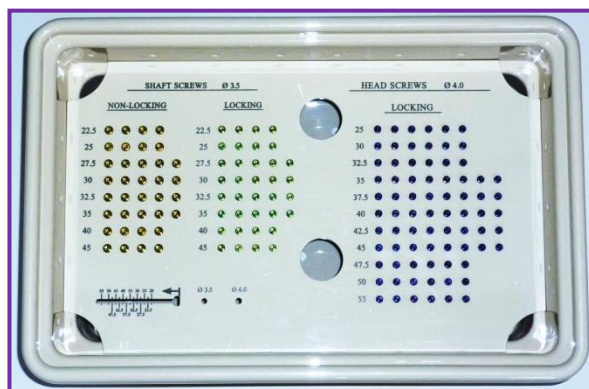
Miscellaneous

Cat. No.	Description
PL922115	Drill Bit Ø 2.5x115mm (marked yellow) <i>Single Use</i>
PL930115	Drill Bit Ø 3.0x115mm (marked green) <i>Single Use</i>
PL934155	Drill Bit Ø 3.4x125mm (marked purple) <i>Single Use</i>
PL921360	K-Wire Ø 1.6mm <i>Single Use</i>

Instrumentation Set Components

Cat. No.	Description	Units in the set
PL921450	Sterilization Box	1
PL921350	Targeting Guide	1
PL921220	Targeting Guide Screw Sleeve	2
PL921230	Targeting Guide Drill Sleeve Ø3.4mm	2
PL921240	Targeting Guide K-Wire Sleeve Ø1.6mm	2
PL921610	Shaft Drill Sleeve Ø3.0mm	2
PL921420	Free Hand Drill Sleeve Ø2.5mm	1
PL934155	Drill Bit Ø3.4 X 125mm (marked purple)	1
PL922115	Drill Bit Ø2.5 X 115mm (marked yellow)	1
PL930115	Drill Bit Ø3.0 X 115mm (marked green)	1
PL921360	K-Wire Ø1.6mm	3
PL921840	Screwdriver Rod Torx 15	2
PL921820	Screwdriver Handle	2
PL921110	Depth Gauge (shaft screws)	1
PL922003	Template Proximal Humerus 3 Holes	1
PL922008	Template Proximal Humerus 8 Holes	1
PL920150	Torque Limiter 1.5Nm (optional)	1

* Maximal Content



CarboFix™ Proximal Humeral Plate Instrumentation Set

Case I

Pre-OP



Post-OP

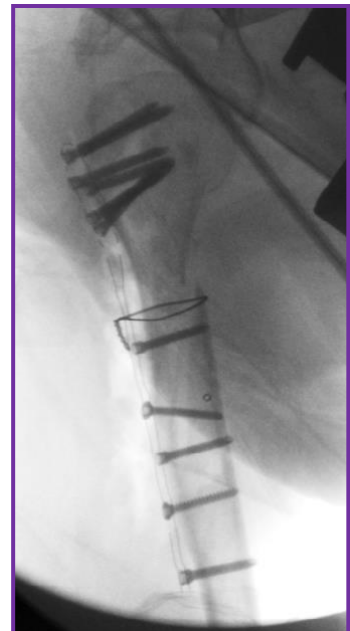


Case II

Pre-OP



Post-OP



MRI INFORMATION



The Piccolo Composite Plate System is MR-Conditional.

Non-clinical testing demonstrated that the Piccolo Composite Plate System is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient magnetic field of 720-Gauss/cm (72 mT/cm).
- Maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg in the First Level Controlled Mode.
- The Piccolo Composite Plate System must be entirely outside the MR scanner bore.

Note:

It is recommended that patients register the conditions under which they can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.



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

Patents are pending



0483