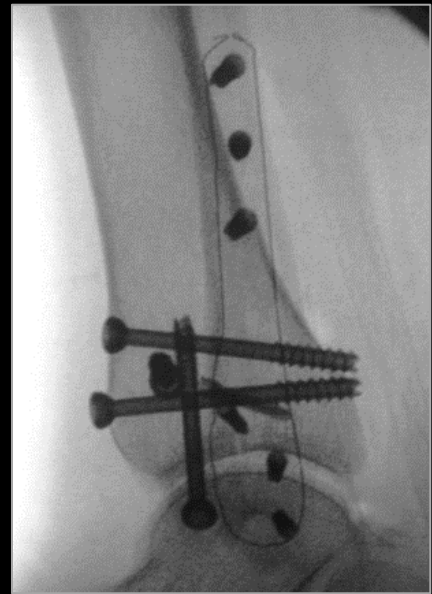




## *Distal Fibula Plate One Third Tubular Plate*

### *Procedure Steps*



# Introduction

## The CarboFix™ Implants

The **CarboFix™** Distal Fibula & One Third Tubular Plates are made out of numerous continuous carbon fibers embedded in polymer (PEEK).

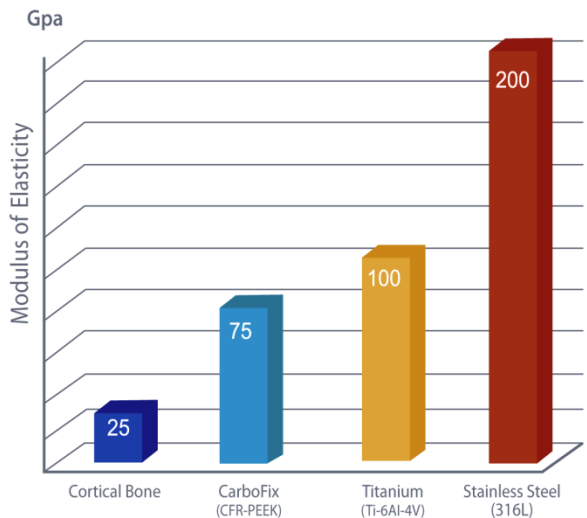
The Carbon Fibers are arranged in a unidirectional longitudinal orientation, as well as in a diagonal orientation, allowing Tri-dimensional bending and rotational strength.

**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

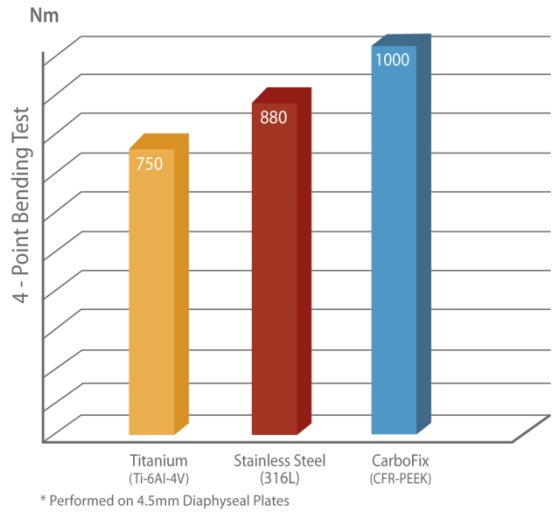
### Modulus of Elasticity

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

The **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

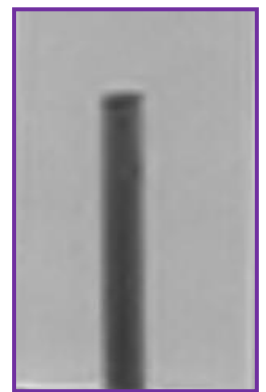
### CT & MRI Imaging

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

\* Please refer to page 17, 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™ Distal Fibula & One Third Tubular Plates

## The Plates

The main features of the **CarboFix™** Distal Fibula and One Third Tubular Plates:

- The Distal Fibula plate is anatomically shaped
- Low profile plate: 2.3mm
- Circumference radiopaque marking outlining the plate contour for positioning & follow-up (A)
- Polyaxial Screw insertion. Screw trajectory up to 10 degrees (B)
- The screw head anchors in the composite material at the desired screw trajectory
- Compatible screw holes for locking or non-locking screws
- Similar instrumentation & procedure steps as conventional metal plates

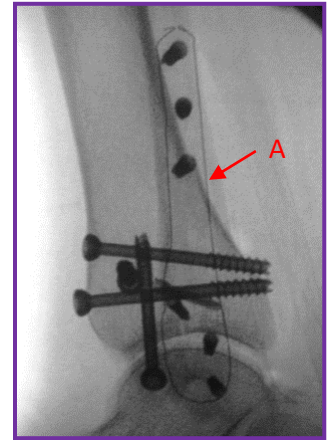
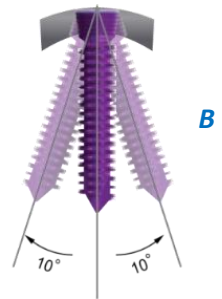


Plate under X-ray



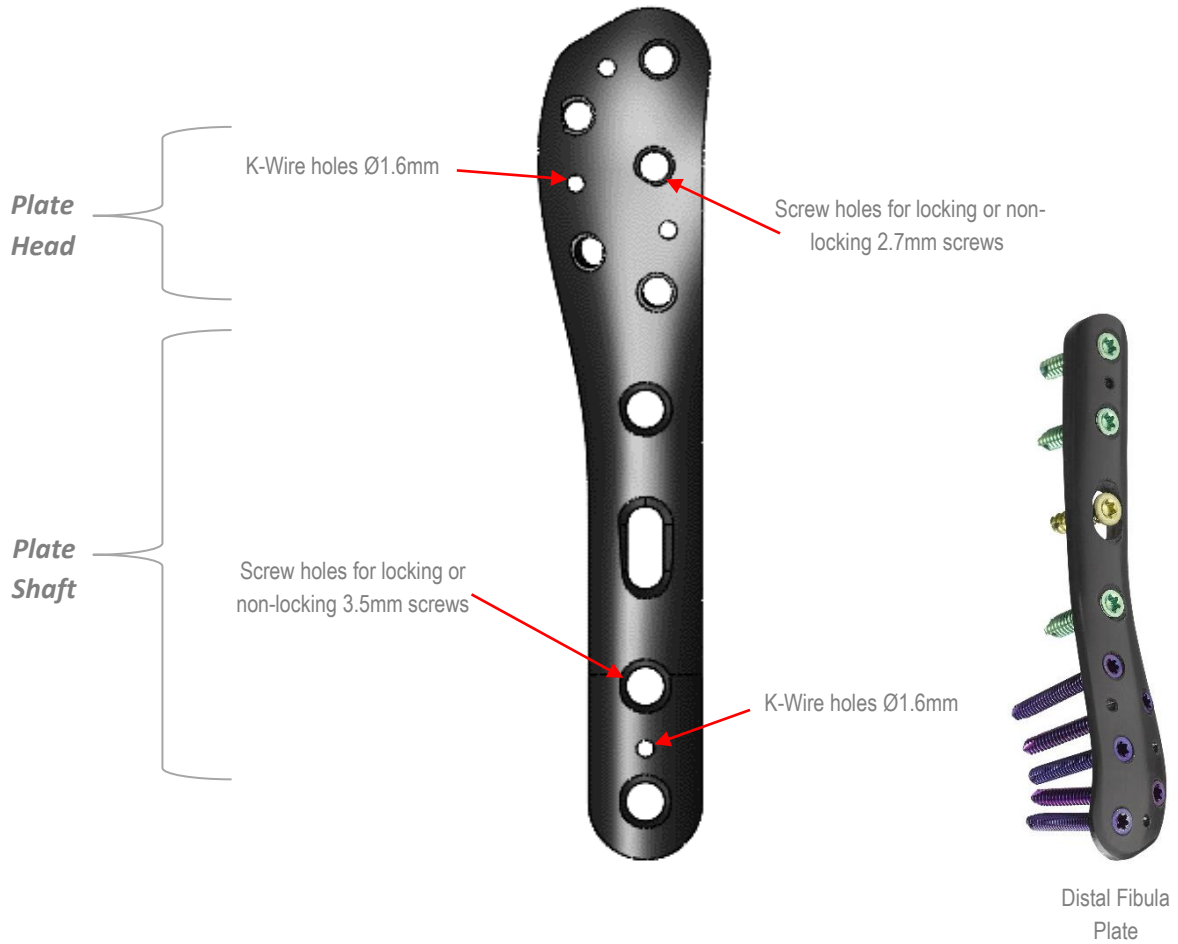
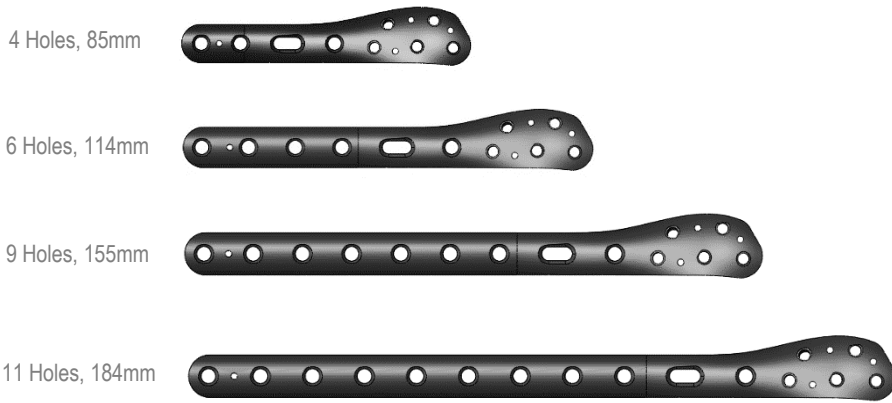
Polyaxial Screws

Right & left Distal Fibula plates are available as follows:

### Distal Fibula Plates

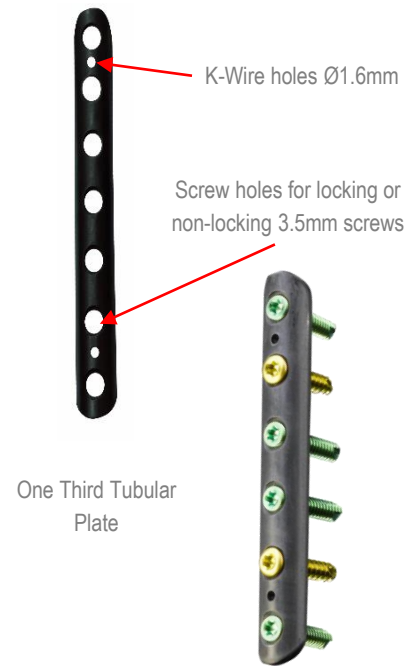
Description	No. of holes (Shaft)	Length (mm)	Right / Left
CarboFix Distal Fibula Plate 4/R	4	85	Right
CarboFix Distal Fibula Plate 4/L	4	85	Left
CarboFix Distal Fibula Plate 6/R	6	114	Right
CarboFix Distal Fibula Plate 6/L	6	114	Left
CarboFix Distal Fibula Plate 9/R	9	155	Right
CarboFix Distal Fibula Plate 9/L	9	155	Left
CarboFix Distal Fibula Plate 11/R	11	184	Right
CarboFix Distal Fibula Plate 11/L	11	184	Left

## Distal Fibula Plates



### One Third Tubular Plates



Description	Length (mm)	No. of holes (Shaft)
CarboFix 1/3 Tubular Plate	56	5
CarboFix 1/3 Tubular Plate	67	6
CarboFix 1/3 Tubular Plate	78	7
CarboFix 1/3 Tubular Plate	98	9
CarboFix 1/3 Tubular Plate	122	11



## The Screws



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

### Plate Shaft Screws (Distal Fibula & One Third Tubular)

Description	Diameter (mm)	Lengths (mm)	Screw color	Drill Bit Diameter (mm)	
Locking plate shaft screws	3.5	10-26 (2mm increments)	Green	2.8	
Non-Locking plate shaft screws *	3.5	10-26 (2mm increments) 30-55 (5mm increments)	Yellow	2.5	

\* The 3.5mm Non-Locking screws can be used as Lag or Syndesmotic screws

### Plate Head Screws (Distal Fibula)

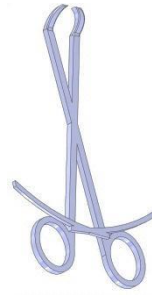
Description	Diameter (mm)	Lengths (mm)	Screw color	Drill Bit Diameter (mm)	
Locking plate head screws	2.7	10-24 (2mm increments)	Purple	2.0	
Non-Locking plate head screws	2.7	12-24 (2mm increments)	Blue	2.0	

# Instrumentation Set

## Reduction Tools

The set includes fracture reduction tools:

- Lobster Claw Forceps
- Pointed Tip Forceps



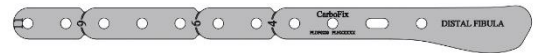
Pointed Tip  
Forceps



Lobster Claw  
Forceps

## Plate Template

The plate template is used to determine the desired plate length. A Template for the Distal Fibula & a Template for the One Third Tubular plates are available.



Distal Fibula Template



One Third Tubular Template

## 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 designated plate holes.



## Free Hand Drill Sleeve Ø2.0mm & 2.5/2.8mm

The Free Hand Drill Sleeve is used for drilling the screw holes .

The Ø2.0mm arm is designed for drilling the Distal Fibula Head screw holes. It has markings to enable measuring the required screw length.

The Ø2.5/2.8mm arm is designed for drilling the Distal Fibula shaft , as well as the One Third Tubular screw holes.



### Free Hand Drill Sleeve Ø2.5mm & 3.5mm

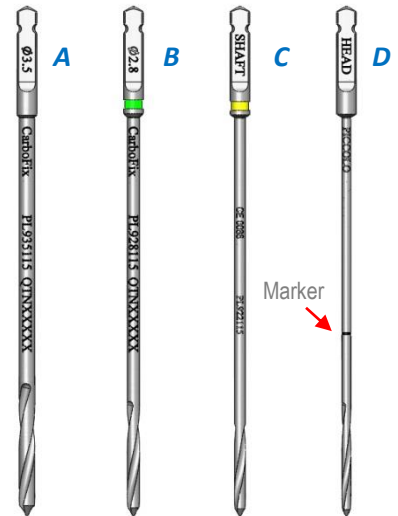
It is used for drilling the holes for a Lag Screw.



### Drill Bits Ø3.5mm, Ø2.8mm, Ø2.5mm, Ø2.0mm

Four different Drill Bits are available:

- **Ø3.5mm:** For drilling the hole for a Lag screw (A).
- **Ø2.8mm:** For drilling the locking shaft screw holes. Marked **Green** (B).
- **Ø2.5mm:** For drilling the plate shaft non-Locking screw holes. Marked **Yellow** (C).
- **Ø2.0mm:** For drilling the Distal Fibula plate head screw holes. Circumference marker on the Drill enables screw length measurement (D).



For Screws/Drill Bits compatibility, please refer to the table in page 5.

### Screwdriver

Two Screwdriver Handles and two Screwdriver bits are available:

- Screwdriver for the Ø2.7mm Head Screws-marked "Head T8" (Torx Size 8), as well as a small Handle
- Screwdriver for the Ø3.5mm Shaft Screws-marked "Shaft T10" (Torx Size 10), as well as a large Handle

The tip of the screwdriver is Torx shaped.





## Depth Gauge

The Depth Gauge assists in determining the desired screw length.



## Counter Sink

Used for preparing a groove in the bone cortex for the Lag Screw head.

The Counter Sink connects to one of the Handles.



# Procedure Steps

1. Expose the bone according to routine surgical technique. Reduce the fracture using reduction tools and determine the required plate length using the plate templates.

- For Distal Fibula Plate sizes please refer to the table on page 3
- For One Third Tubular Plate sizes please refer to the table on page 5



Distal Fibula  
Plate



One Third Tubular  
Plate

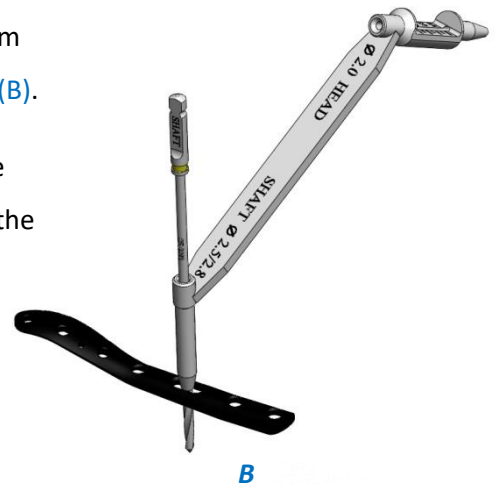
2. Place the Plate over the bone, so it will conform to the surface of the bone. If desired, secure the Plate to the bone with the  $\varnothing 1.6\text{mm}$  K-Wires, placed within the K-Wire holes located along the Plate shaft and/or Plate head (A). If needed, bend the K-wires to facilitate drilling. Verify placement under X-ray.



3. For initial fixation and positioning of the plate, use  $\varnothing 2.5\text{mm}$  Drill Bit, (marked **Yellow**) through the appropriate Free Hand Drill Sleeve arm marked  $\varnothing 2.5/2.8$ , and drill through the oval hole of the Plate shaft (B).

Determine the required non-locking Cortical Screw length using the Depth Gauge. Insert the Cortical Screw using the Screwdriver with the larger tip (marked "Shaft T10" ) and tighten it in place (C) \*.

Verify placement under X-ray.



**\* Do not apply high torque during Screw tightening; excessive torque may damage the bone or implant.**



4. To drill the holes for the Distal Fibula "head" screws use the  $\varnothing 2.0\text{mm}$  Drill Bit. Use the  $\varnothing 2.0\text{mm}$  Drill Sleeve arm and position it in the desired angle (D). It can be positioned up to an angle of 10 degrees to each side. Verify drill trajectory and location under X-ray.



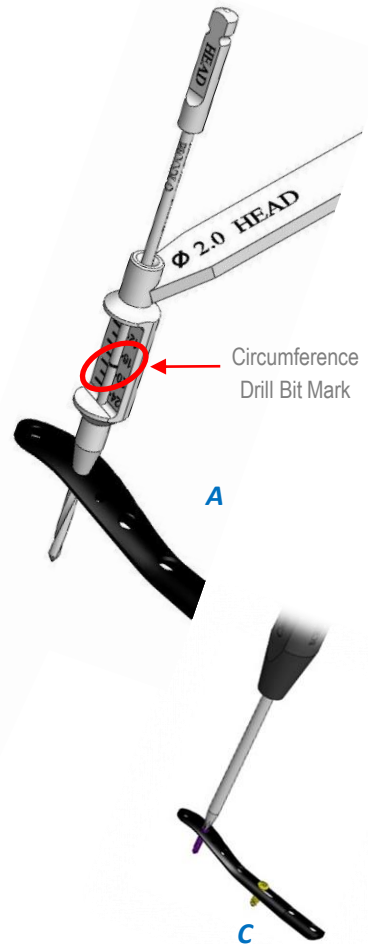
5. Measure the length of the required screw using the markings on the Drill Sleeve and the circumference Drill Bit mark (A).

As alternative, the required length of the screw can be determined by using the Depth Gauge (B).

Choose the desired screw (please refer to the table on page 5) and tighten it in place using the smaller tip Screwdriver tip (marked "Head T8") (C) \* . Verify placement under X-ray.

The Screws shall be tightened until flush with the Plate surface.

Repeat these steps for the rest of the "plate head" holes.



## 6. Distal Fibula Shaft & One Third Tubular Screws:

### Locking Screws:

Place the Drill Sleeve arm tip marked  $\varnothing 2.5/2.8$  in the desired hole of the Plate.

Use the  $\varnothing 2.8$  mm Drill Bit (marked **Green**), placed through the Drill Sleeve, and drill the required hole (D).

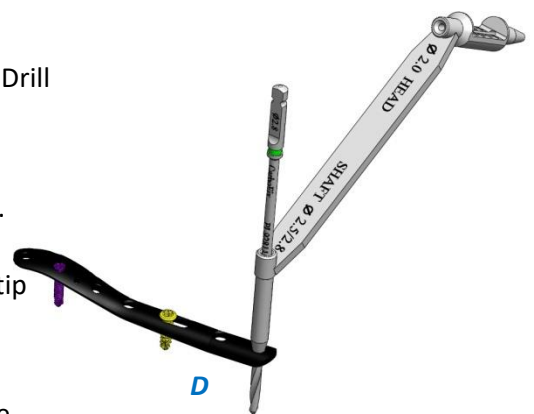
Use the Depth Gauge to determine the required screw length.

Insert the Locking Screw (**Green**) using the larger Screwdriver tip (marked "Shaft T10" ) and tighten it in place \* .

The Screws shall be tightened until flush with the Plate surface.

Verify placement under X-ray.

**\* Do not apply high torque during Screw tightening; excessive torque may damage the bone or implant.**



### Non-Locking Screws:

Place the Drill Sleeve arm tip marked  $\varnothing 2.5/2.8$  in the desired Plate hole (oval or round) and drill through the Plate shaft hole using the  $\varnothing 2.5$ mm Drill Bit, (marked **Yellow**) (A).

Determine the required non-locking Cortical Screw length using the Depth Gauge. Insert the Cortical Screw using the Screwdriver with the larger tip (marked "Shaft T10" ) and tighten it in place\*.

Verify placement under X-ray.

***\* Do not apply high torque during Screw tightening; excessive torque may damage the bone or implant.***



7. Remove any remaining K-Wires. Close the incision according to routine surgical procedure.

# Ordering Information

## Instrumentation

Cat. No.	Description
PL922000	Distal Fibula / One Third Tubular Plate Instrumentation Set (Not Including Screws)

## Plates

### Distal Fibula Plates

Cat. No.	Description	No. of holes (Shaft)	Length (mm)	Right / Left
PDFRN2004	CarboFix Distal Fibula Plate 4/R	4	85	Right
PDFLN2004	CarboFix Distal Fibula Plate 4/L	4	85	Left
PDFRN2006	CarboFix Distal Fibula Plate 6/R	6	114	Right
PDFLN2006	CarboFix Distal Fibula Plate 6/L	6	114	Left
PDRFN2009	CarboFix Distal Fibula Plate 9/R	9	155	Right
PDFLN2009	CarboFix Distal Fibula Plate 9/L	9	155	Left
PDFRN2011	CarboFix Distal Fibula Plate 11/R	11	184	Right
PDFLN2011	CarboFix Distal Fibula Plate 11/L	11	184	Left

### One Third Tubular Plates

Cat. No.	Description	No. of holes (Shaft)	Length (mm)
POTTN2005	CarboFix 1/3 Tubular Plate	5	56
POTTN2006	CarboFix 1/3 Tubular Plate	6	67
POTTN2007	CarboFix 1/3 Tubular Plate	7	78
POTTN2009	CarboFix 1/3 Tubular Plate	9	98
POTTN2011	CarboFix 1/3 Tubular Plate	11	122

## Screws: Plate Shaft (Distal Fibula & One Third Tubular)

### Locking Screw



Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Instrumentation Set
PLCST35100	Locking Screw 3.5X10	3.5	10	5
PLCST35120	Locking Screw 3.5X12	3.5	12	7
PLCST35140	Locking Screw 3.5X14	3.5	14	7
PLCST35160	Locking Screw 3.5X16	3.5	16	5
PLCST35180	Locking Screw 3.5X18	3.5	18	4
PLCST35200	Locking Screw 3.5X20	3.5	20	3
PLCST35220	Locking Screw 3.5X22	3.5	22	3
PLCST35240	Locking Screw 3.5X24	3.5	24	2
PLCST35260	Locking Screw 3.5X26	3.5	26	2

### Non-Locking Screw



Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Instrumentation Set
PNLST35100	Non-Locking Screw 3.5X10	3.5	10	5
PNLST35120	Non-Locking Screw 3.5X12	3.5	12	7
PNLST35140	Non-Locking Screw 3.5X14	3.5	14	7
PNLST35160	Non-Locking Screw 3.5X16	3.5	16	5
PNLST35180	Non-Locking Screw 3.5X18	3.5	18	4
PNLST35200	Non-Locking Screw 3.5X20	3.5	20	3
PNLST35220	Non-Locking Screw 3.5X22	3.5	22	3
PNLST35240	Non-Locking Screw 3.5X24	3.5	24	2
PNLST35260	Non-Locking Screw 3.5X26	3.5	26	2

PNLST35300	Non-Locking Screw 3.5X30	3.5	30	2
PNLST35350	Non-Locking Screw 3.5X35	3.5	35	2
PNLST35400	Non-Locking Screw 3.5X40	3.5	40	2
PNLST35450	Non-Locking Screw 3.5X45	3.5	45	2
PNLST35500	Non-Locking Screw 3.5X50	3.5	50	2
PNLST35550	Non-Locking Screw 3.5X55	3.5	55	2

## Screws: Plate Head (Distal Fibula)

### Locking Screw



Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Instrumentation Set
PLCST27100	Locking Screw 2.7X10	2.7	10	4
PLCST27120	Locking Screw 2.7X12	2.7	12	5
PLCST27140	Locking Screw 2.7X14	2.7	14	7
PLCST27160	Locking Screw 2.7X16	2.7	16	7
PLCST27180	Locking Screw 2.7X18	2.7	18	7
PLCST27200	Locking Screw 2.7X20	2.7	20	7
PLCST27220	Locking Screw 2.7X22	2.7	22	5
PLCST27240	Locking Screw 2.7X24	2.7	24	4

### Non-Locking Screw



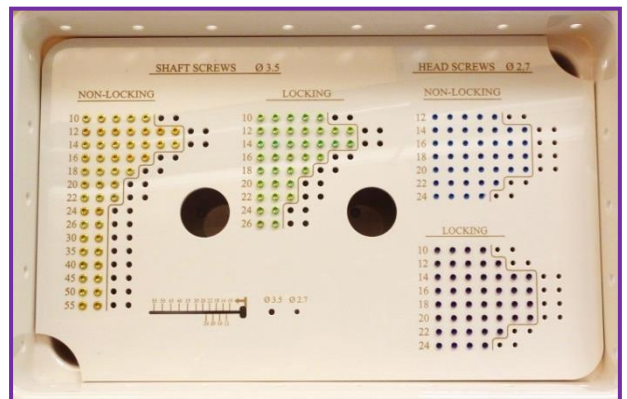
Cat. No.	Description	Diameter (mm)	Length (mm)	No. Screws in Instrumentation Set
PNLST27120	Non-Locking Screw 2.7X12	2.7	12	5
PNLST27140	Non-Locking Screw 2.7X14	2.7	14	7
PNLST27160	Non-Locking Screw 2.7X16	2.7	16	7
PNLST27180	Non-Locking Screw 2.7X18	2.7	18	7
PNLST27200	Non-Locking Screw 2.7X20	2.7	20	7
PNLST27220	Non-Locking Screw 2.7X22	2.7	22	5
PNLST27240	Non-Locking Screw 2.7X24	2.7	24	4

## Miscellaneous

Cat. No.	Description
PL918115	Drill Bit Ø2.0X115mm <i>Single Use</i>
PL922115	Drill Bit Ø2.5X115mm <i>Single Use</i>
PL928115	Drill Bit Ø2.8X115mm <i>Single Use</i>
PL935115	Drill Bit Ø3.5X115mm <i>Single Use</i>
PL921360	K-Wire Ø1.6mm <i>Single Use</i>
PLW35000	Washer

# Instrumentation Set Components

Cat. No.	Description
PLDF0100	Sterilization Box
PLDF0190	Forceps-Lobster Claw
PLDF0200	Forceps-Pointed Tip
PLDF0150	Free Hand Drill Guide/Sleeve $\varnothing$ 2.0 /2.5 & 2.8mm
PLDF0160	Free Hand Drill Guide/Sleeve $\varnothing$ 2.5 & 3.5mm
PL918115	Drill Bit $\varnothing$ 2.0X115mm
PL922115	Drill Bit $\varnothing$ 2.5X115mm
PL928115	Drill Bit $\varnothing$ 2.8X115mm
PL935115	Drill Bit $\varnothing$ 3.5X115mm
PL921360	K-Wire $\varnothing$ 1.6mm
PLDF0240	Depth Gauge
PLDF0250	Screwdriver Rod Torx Size 8
PLDF0260	Screwdriver Rod Torx Size 10
PL921510S	Handle - Small
PL922135	Handle - Large
PLDF0220	Distal Fibula Template
PLDF0230	One Third Tubular Template
PL921770	Counter Sink



Distal Fibula & 1/3 Tubular plates 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](http://www.medicalert.org)) or equivalent organization.



[www.carbo-fix.com](http://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



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