

PICCOLO COMPOSITE® MTP PLATE SYSTEM

Instructions for Use

INDICATIONS

The Piccolo Composite foot and ankle plates are indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 - 21 years) patients, including the foot and ankle, and including in osteopenic bone.

The MTP plates are indicated for treatment of deformations, fractures, nonunions and replantations of the 1st metatarso-phalangeal joint and 1st metatarsal bone.

CONTRAINDICATIONS

1. Active and/or latent infection.
2. Sepsis.
3. Insufficient quantity or quality of bone and/or soft tissue, or severe deformity.
4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
5. General medical conditions that might contraindicate implantation of the device.
6. Cases where the implant would cross open epiphyseal plates in skeletally immature patients.

POSSIBLE ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of the components, possibly with subsequent loss of fixation, attributable to nonunion, osteoporosis, markedly unstable comminuted fractures, or as a result of not following the Warnings and Precautions, or as a result of trauma or excessive activity.
2. Implant migration.
3. Additional bone fractures.
4. Nonunion or malunion.
5. Infections.
6. Vascular damage.
7. Neurological damage.
8. Thromboembolic disease.
9. Delayed healing.

SYSTEM DESCRIPTION

The Piccolo Composite MTP Plate System includes Plates, Screws and Instrumentation (accessories).

IMPLANTS [SINGLE USE]

• Plate

The Plates are made of long carbon fiber reinforced polymer. A tantalum radiopaque marker following the Plate contour provides for visualization under fluoroscopy.

The Plate contour is designed to match the anatomy of the 1st metatarso-phalangeal (MTP) joint.

The Plate provides for round screw holes that can accept both Non-Locking and Locking Screws.

• Screws

Self-tapping titanium alloy Screws, available in varying lengths, to connect the Plate to the bone. Two types of screws are available – Non-Locking Screws and Locking Screws.

In addition, self-tapping and self-drilling titanium alloy Lag Screws (cannulated) are provided.

INSTRUMENTATION

Notes:

1. The Instrumentation Set includes instrument for use with the entire foot/ankle line of Piccolo Composite plates;
2. The Lag Screws and related instruments may be provided in a separate instrumentation tray.

The instruments relevant for use with the MTP Plate include:

• Drill Guides

Free Hand Drill Guides are provided for assisting in drilling the screw holes, as well as for use during the optional introduction of an independent Lag Screw, if required. The Drill Guides may incorporate a direct measurement depth gauge.

• Drill Bits

Intended for drilling the holes for the different Screws (both cannulated and non-cannulated Drill Bits are provided, as detailed through the procedure).

A Countersink is included as well for use during the optional introduction of an independent Lag Screw.

• Depth Gauge

Provided in order to assist the surgeon in determining required Screws (especially the Lag Screw) length, following drilling of the screw holes.

• Screwdrivers

Used to insert or remove the Screws (both cannulated and non-cannulated Screwdrivers are provided, as detailed through the procedure).

• Templates

Used to assess desired Plate dimensions

Additional accessories, such as **K-Wires**, **Guide Wires**, **Forceps**, *etc.*, are also available to assist in the procedure, when required.

Drawings of system components are provided in Figure 1.

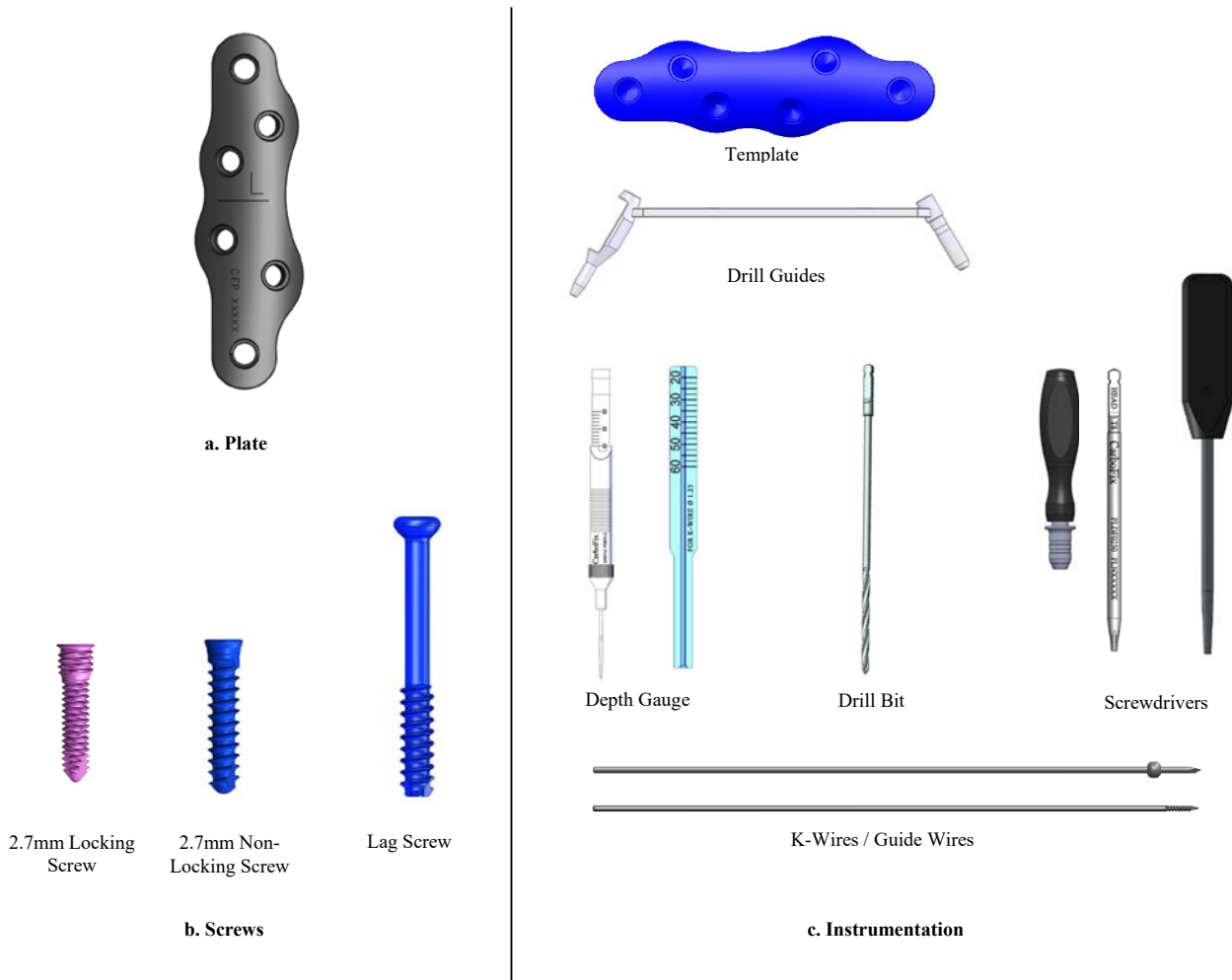


Figure 1: Piccolo Composite® MTP System Components

The following tables detail the available implants. Dimensions in the tables are typical.

Table 1: Piccolo Composite® MTP Plate System - Plates

Thickness [mm]	Width (Max.) [mm]	Length [mm]	Valgus Angle [°]	Dorsiflexion Angle [°]
2.0	15	42	5, 10	0, 5, 10
		50	5, 10	0, 5, 10
		58	5, 10	0, 5, 10
2.0	13	42	5, 10	0, 5, 10
		50	5, 10	0, 5, 10
		58	5, 10	0, 5, 10

Table 2: Piccolo Composite® MTP Plate System - Screws

Screw Type	Screw Diameter [mm]	Screw Length [mm]
Non-locking	2.7	12 – 30, 2mm increments
Locking	2.7	10 – 30, 2mm increments
Lag Screw	Shaft – 2.6; Thread – 4.0; Cannulation - 1.35 Shaft – 2.4; Thread – 3.5; Cannulation - 1.35	20 – 50, 2mm increments

WARNINGS AND PRECAUTIONS

1. For professional use only.
2. Do not use this system without fully reading these instructions for use.
3. The surgeon should be familiar with the general principles and technique of MTP plating and should be familiar with the Piccolo Composite MTP Plate System.
4. Proper handling and storage of the system components is mandatory. Damage or alterations to the system components may produce stresses and cause defects, which could become the focal point for failure.
5. Selection of the correct implants dimensions is most important.
6. The sterile packaging of the relevant system components shall be inspected for visible damage prior to use. Do not use if damage is suspected.
7. Do not use sterile supplied items if the expiration date is overdue.
8. **Do not re-sterilize the sterile-supplied, single use items!**
9. All parts that are provided non-sterile and/or are intended for multiple uses shall be handled per Packaging and Sterilization Section.
10. Do not re-use the system components which are intended for single use. Re-use of items indicated for single use may result in mechanical failure. In the case of implants, re-use may result also in biological implications (e.g., contamination).
11. The integrity of all multi-use instruments, including functionality, where applicable, shall be verified prior to use.
12. The surgeon should be cautious with limb position changing and/or excessive force exertion while accessories are still connected to the implant, in order to avoid tissue and/or device damage
13. Do not use MRI imaging while the system accessory components are connected to the implant.
14. Patients should be cautioned against significant load bearing prior to good callus formation. Patients, who are either non-compliant or predisposed to delayed union or non-union, must have auxiliary support.
15. Periodic x-rays are recommended for at least six months to detect any changes in position, nonunion, loosening, bending or cracking of components.
16. Implants may loosen, fracture, migrate, cause pain or stress shield bone even after a fracture has healed. When considering removal of the implant the surgeon must weigh the risks versus benefits of removal surgery.
17. Patients should be cautioned that even after complete healing there is a higher risk for re-fractures while the implant is in position and soon after removal.
18. Post-operative care and physical therapy should be structured to prevent excessive loading of the operated extremity.
19. The Piccolo Composite MTP Plate System implants assembly has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of the Piccolo Composite MTP Plate System implants assembly in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PROCEDURE**Notes:**

1. Lag Screw introduction must not be carried through the Plate.
The procedure for Lag Screw introduction is provided at the end of the Procedure Section.
2. The Locking Screws provide for multi-axial locking range of $\pm 10^\circ$. Prior to drilling, the Drill Guide shall be placed at the desired angle. The thread at the Screw head shapes the thread of the Plate hole to provide for locking of the Screw to the Plate at the desired angle. Screw insertion into a specific hole is limited to 2 times.

PLATING PROCEDURE

1. Expose the bone and prepare it for implantation according to routine surgical procedure.
2. Choose the required Plate (provided templates may be used to assist in required Plate dimensions assessment).
3. Place the Plate over the joint. Verify proper placement, using the line provided on the Plate as a guide.
4. Preliminary fixation of the Plate to the bone is achieved using the K-Wires with stopper through the screw holes of the Plate.
5. Determine the Screws to be used for fixation; if both locking and non-locking ones will be used, the non-locking ones shall be inserted first.
6. Screws insertion:
 - i. Use the $\varnothing 2.0$ mm Drill Bit, through the $\varnothing 2.0$ arm of the $\varnothing 2.0$ & $\varnothing 2.5/\varnothing 2.7/\varnothing 2.8$ Drill Guide, and drill the required hole. Prior to drilling, the Drill Guide shall be placed at the desired angle.
 - ii. Determine desired Screw length using the direct measurement Depth Gauge of the Drill Guide over the $\varnothing 2.0$ mm Drill Bit. Alternatively, use the Screw Depth Gauge.
 - iii. Select the desired Screw.
 - iv. Screw in the Screw, using the Screwdriver (T8), and tighten it in place.
 - v. Repeat the above as applicable, until all desired Screws are inserted.

Note:

Before removing the preliminary fixation K-Wires ensure at least one screw is inserted on each side of the joint.

7. Obtain final radiographic view to assess final reduction and fixation, and to confirm proper implants positioning. Assure fixation stability.
8. Close the incision according to routine surgical procedure.

Note: A Screw Holder (“Screw Spring”), which may be placed at the end of the Screwdriver, may be provided to assist in grabbing Screws out of the Instrumentation Set case.

Note: Do not apply high torque during Screw tightening; excessive torque may damage the bone or implant. The Screws shall be tightened until flush with the Plate surface.

INDEPENDENT LAG SCREW INTRODUCTION – OPTIONAL**Note:**

The Lag Screw is cannulated.

1. Achieve and maintain anatomic reduction according to routine surgical procedure.
2. Insert a 1.25mm Guide Wire to the desired depth. Verify proper placement under fluoroscopy.
3. If desired, use a Countersink to create a recess for the screw head.
4. Measure the desired Screw length with the help of the Depth Gauge, placed over the Guide Wire.
5. Insert the Lag Screw using the cannulated Screwdriver.
6. Remove the Guide Wire.

Note:

In case of dense bone – use the cannulated 2.7mm Drill Bit, through the $\varnothing 2.8$ mm arm of the $\varnothing 2.0$ & $\varnothing 2.5/\varnothing 2.7/\varnothing 2.8$ Drill Guide to drill over the Guide Wire prior to screw insertion.

REMOVAL PROCEDURE

If a case arises where removal of the system is required:

1. Expose the bone along the entire Plate length.
2. Remove the Screws using the Screwdriver.
3. Detach the Plate from the bone.
4. If desired – remove the Lag Screw.
5. Close the incision according to routine surgical procedure.

PACKAGING AND STERILIZATION

The Piccolo Composite MTP Plates are supplied sterile, as well as some of the instruments and Screws may be. Sterilization method for the Plates, Screws and instruments is steam.

The multiple use instruments and, optionally, some single use instruments, are supplied non-sterile. The Screws may be supplied non-sterile as well.

Before each procedure, all non-sterile parts should be cleaned carefully, and sterilized by standard steam double-wrapped in lint-free textile (FDA cleared wrap).

Sterilization parameters (U.S.A.):

132°C, at prevacuum cycle of 4 minutes; drying time shall be 30 minutes.

Further instructions are provided in the Instrumentation Handling Instructions by the company (Ref. 4698).

Note: The sterilization tray can withstand up to 125 steaming cycles of 132°C for 4 minutes at prevacuum cycle.

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 4672411, Israel

Tel: +972-9-9511511
Fax: +972-9-9548939
E-Mail: info@carbo-fix.com

U.S.A. CONTACT:

CarboFix Orthopedics Inc.
7183 Beach Drive SW, Ste 1
Ocean Isle Beach, NC 28469, USA

Tel: 1-800-408 0120
Fax: 877-705 3567
E-Mail: usa@carbo-fix.com

Web Site: www.carbo-fix.com

Patents are pending