PICCOLO COMPOSITE® PLATE SYSTEM – DIAPHYSEAL; NO HOLES
Instructions for Use

INDICATIONS

The Piccolo Composite Diaphyseal Plate is indicated for the fixation of various long bones, such as the humerus, femur and tibia, including osteopenic bone, osteotomies, and nonunions or malunions in adult patients.

These plates are also indicated for fracture fixation of diaphyseal areas of long bones in pediatric patients.

CONTRAINDICATIONS

1. Active and/or latent infection.
2. Sepsis.
3. Insufficient quantity or quality of bone and/or soft tissue, or severe deformity.
4. Conditions that retard healing and conditions causing poor blood supply.
5. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
6. General medical conditions that might contraindicate implantation of the device.

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.

PRINCIPLE OF OPERATION

The Piccolo Composite Plate System implants are introduced in an open procedure. Following fracture reduction the holes are drilled to the plate at the desired location. The holes for the Screws are then drilled, and the Screws are inserted to allow compression and fixation.

SYSTEM DESCRIPTION

The Piccolo Composite Diaphyseal Plate System includes Plate and Screws implants, and Instrumentation.

IMPLANTS [SINGLE USE]

- **Plate**

The Plates are made of long carbon fiber reinforced polymer. The Plate is provided with no holes, except for K-wire holes. A tantalum radiopaque marker following the plate contour provides for visualization under fluoroscopy.

- **Screws**

Self-tapping titanium alloy Screws, available in varying sizes. Two types of screws are available – Non-Locking (Cortical) Screws, and Locking Screws.

INSTRUMENTATION

Multiple Use:

- **Drill Guides**

A set of Drill Guides provided to assist in drilling the different screw holes, as well as for use during the optional introduction of an independent Lag Screw.

- **Screw Depth Gauge**

The Screw Depth Gauge is provided in order to assist the surgeon in determining the required Screw length, following drilling of the screw hole.

- **Screwdriver**

Used to insert or remove the Screws. May be provided as a handle with a rod.

- **Templates**

Used to assess desired Plate dimensions.

Single Procedure Use:

- **Bone Drill Bits**

A set of Drill Bits, provided for drilling the holes for the different Screws. A Countersink may be included as well for use during the optional introduction of an independent Lag Screw.

- **Plate Drill Bit**

A drill bit, provided with a stopper placed over its shaft, to assist in drilling the plate holes.

- **Drilling Tub**

A small container for Plate positioning during plate holes drilling; shall be filled with sterile water/saline, such that the Plate is immersed in the liquid during drilling. The Tub is marked to indicate minimal distance between adjacent holes. The Tub is provided with Spacers to allow easier Plate location.

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

Drawings of system components are provided in Figure 1.

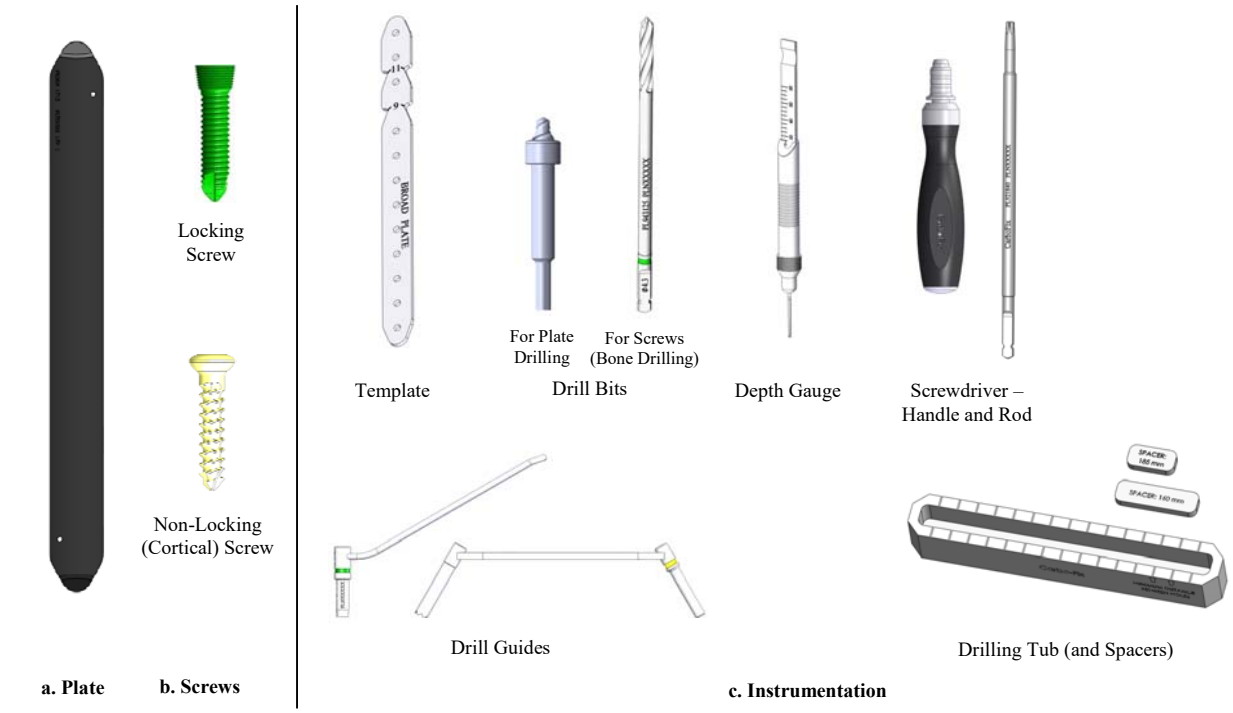


Figure 1: Piccolo Composite Plate System – Diaphyseal; Components

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

Table 1: Piccolo Composite Plate System – Diaphyseal; Plates

Plate Type	No. of Holes	Plate Length [mm]	Plate Thickness [mm]	Plate Width [mm]
Diaphyseal - Broad	Up to 9	160	5.3	17.5
	Up to 11	185		
	Up to 13	220		

Table 2: Piccolo Composite Plate System - Diaphyseal; Screws

Screw Type	Screw Diameter [mm]	Screw Length [mm]
Non-Locking (Cortical)	4.5	20 – 60, in 2.5 mm steps
Locking	5.0	20 – 60, in 2.5 mm steps

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 long bone plating and should be familiar with the Piccolo Composite Diaphyseal 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 Piccolo Composite Plate 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.

MRI INFORMATION 

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

STATIC MAGNETIC FIELD
- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient magnetic field of 720 Gauss/cm (72 mT/cm).
- Whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (*i.e.*, per pulse sequence).
- Normal Operating Mode of operation for the MR system.

MRI-RELATED HEATING
In non-clinical testing, the Piccolo Composite implants produced a temperature rise of less than 1.9˚C scaled to a whole body averaged specific absorption rate (SAR) of 2W/Kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA, Software Numaris/4, Version Syngo MR 2002B DHHS) MR system, and temperature rise of less than 2.4˚C scaled to a whole body averaged specific absorption rate (SAR) of 2W/Kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3-Tesla/128-MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system.

ARTIFACT INFORMATION
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Piccolo Composite Plate System implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.
The image artifact extends approximately 25 mm from the device, when scanned in nonclinical testing using a worst case, gradient pulse sequence in a 3-Tesla/128-MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system with a transmit/receive body coil.

Note: It is recommended that patients register the conditions under which the implant can be scanned safely with the relevant organization.

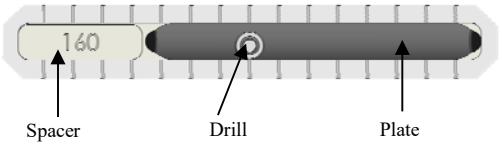
PROCEDURE

Note:

1. The Non-Locking Screw may be used as an independent Lag Screw to reduce fractures prior to fixation with the Piccolo Composite Diaphyseal Plate. Independent 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 ±10°. 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. Reduce the fracture under fluoroscopic control, following standard techniques. Alternatively, reduction can be performed during the operation, following standard techniques.
2. Expose the bone according to routine surgical procedure.
3. Choose the required plate (the Template may be used to assist in required Plate dimensions assessment).
4. Plate Preparation – Drilling:
   a. Place the Plate over the bone and determine the location of the desired holes. A Surgical Marker (pen) may be used for marking holes location on the Plate.
      Note: The distance between adjacent holes, as well as from the proximal and distal ends of the plate to the nearest hole, must be greater than 14 mm.
   b. Verify that the Drilling Tub Insert is located within the Drilling Tub.
      Place the Plate within the designated place in the Drilling Tub. For 160mm and 185mm Plates – locate the relevant Spacer next to the Plate within the Tub, so that the Plate will not be able to move freely during drilling.



   c. Fill the Drilling Tub with sterile water/saline; make sure the Plate is fully immersed in the liquid.
   d. Drill the desired holes in the Plate, using the Plate Drill Bit. Drill until the Drill Bit stopper contacts the plate.
      Note: A Scale showing 14mm increments is provided within the Drilling Tub to indicate minimal distance between holes, as detailed above.
   e. After all holes have been drilled remove the Plate from the Drilling Tub.
   f. Disconnect the Plate Drill Bit from the power drill, insert it through the distal end of each of the created holes, and hand-rotate it in each hole.
   g. Rinse the Plate with sterile saline.
5. Place the Plate over the bone and preliminary fix it, if required. Non-Locking Screws Insertion:
   a. Use the ø3.0 mm Drill Bit, through the ø3.0 arm of the ø3.0/ø4.5 Drill Guide, and drill the required hole. Drill from cortex to cortex.
   b. Measure the desired Screw length with the help of the Screw Depth Gauge.
   c. Select the desired Non-Locking (Cortical) Screw.
   d. Insert the Screw using the ø4.5 Screwdriver Rod and tighten it in place.
6. Locking Screws Insertion:
   a. Use the ø4.3mm Drill Bit, through the ø4.3 Drill Guide, and drill the required hole. Drill from cortex to cortex.
   b. Measure the desired Screw length with the help of the Screw Depth Gauge.
   c. Select the desired Locking Screw.
      Note: Before inserting any Locking Screws, verify that anatomical reconstruction was achieved, and that no additional reduction is required.
   d. Screw in the Locking Screw, and tighten it in place, using the ø5.0 Screwdriver (Torx 25).
7. Obtain final radiographic views.
8. Close the incision according to routine surgical procedure.

Note: Do not apply high torque during screw tightening; excessive torque may damage the bone or implants.

INDEPENDENT LAG SCREW INTRODUCTION – OPTIONAL

1. Achieve and maintain anatomic reduction according to routine surgical procedure.
2. Use the ø3.0/ø4.5 Drill Guide - identify the ø4.5 arm of the Drill Guide, position it against the bone, and using the 4.5mm Drill Bit, drill through the closer fragment. The drill must pass through the entire closer fragment and into the interfragmentary space.
3. Use the other side (ø3.0 arm) of the ø3.0/ø4.5 Drill Guide, and place it as far as possible into the hole created within the closer fragment. Using the 3.0mm Drill Bit, drill through the far fragment.
4. If desired, use a Countersink to accommodate the screw head.
5. Measure the desired Screw length with the help of the Depth Gauge.
6. Select the desired Non-Locking Screw.
7. Insert the Screw using the Screwdriver and tighten it in place. A washer may be used if necessary, due to bone quality.

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. Close the incision according to routine surgical procedure.

PACKAGING AND STERILIZATION

The Piccolo Composite Diaphyseal 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.
Sterilization parameters (outside U.S.A.):

122°C, at prevacuum cycle of 20 minutes, or 132°C, at prevacuum cycle of 4 minutes; an extended cycle (134°C, at prevacuum cycle of 18 minutes) is also possible; drying time shall be 30 minutes.

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

Note:
a. The sterilization tray can withstand up to 125 steaming cycles of 132°C for 4 minutes (or 122°C for 20 minutes, outside the U.S.A.) at prevacuum cycle.
b. Outside U.S.A., the instrumentation set can withstand up to 110 extended steaming cycles (134°C, at prevacuum cycle of 18 minutes).

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