PICCOLO COMPOSITE® PLATE SYSTEM - DIAPHYSEAL
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 and placement of the Plate, the holes for the Screws are 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 comprises oval holes and round holes. Both narrow and broad plate designs are available.
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

- **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.

- **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.

- **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.

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.

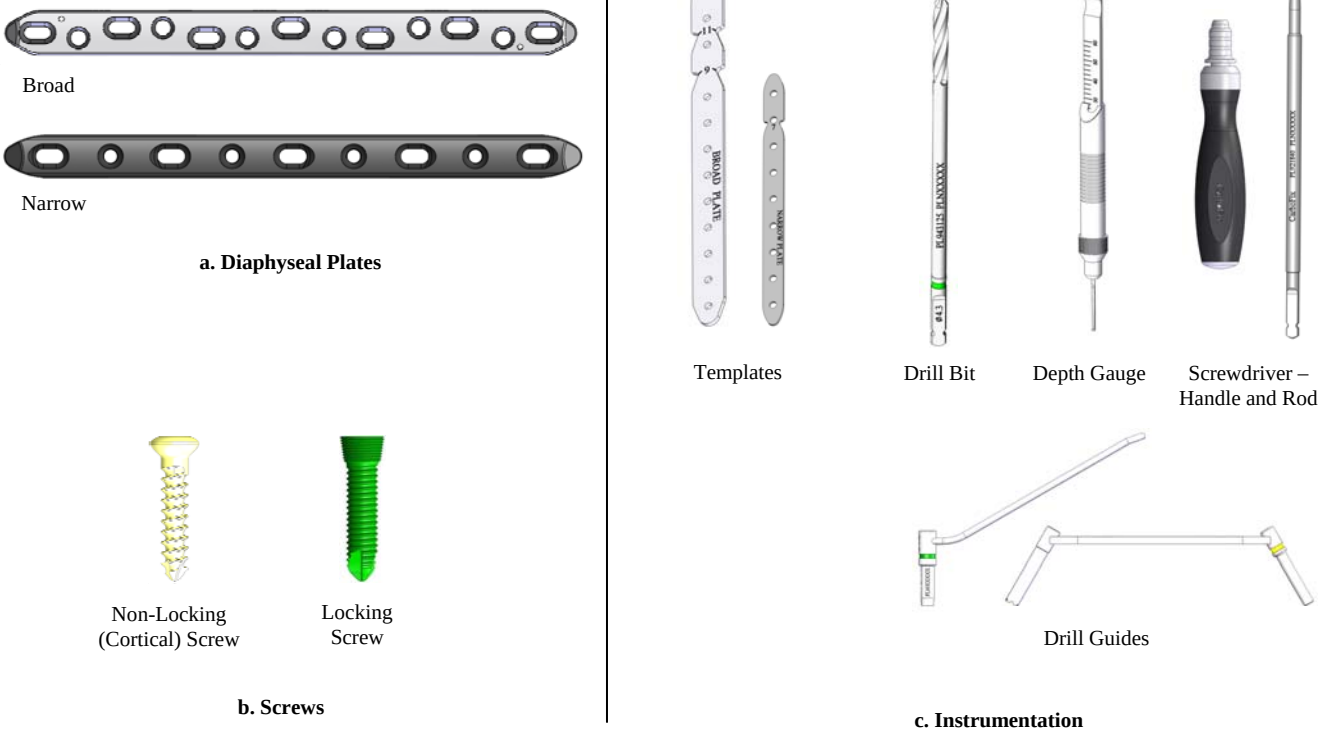

Figure 1: Piccolo Composite Plate System – Diaphyseal; Components

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 - Narrow	7	154	4.7	14.4
	9	190		
Diaphyseal - Broad	9	160	5.3	17.5
	11	185		
	13	220		

Table 2: Piccolo Composite Plate System - Diaphyseal; Screws

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

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.
19. The Piccolo Composite Diaphyseal Plate System implants have not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

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.

PLATING PROCEDURE

1. Reduce the fracture under fluoroscopic control, following standard techniques. Alternatively, reduction can be performed during the operation with the help of the Non-Locking Screws, 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. Place the Plate over the bone and preliminary fix it, if required. In case dynamic compression is desired, verify that the fracture line is located under the center of the plate.
5. Non-Locking Screws Insertion (oval holes):
   a. Use the Drill Guide and place it according to the desired Screw location - if dynamic compression is desired, place the Drill Guide on the edge of the hole; if no dynamic compression is desired, place the Drill Guide such that its rounded distal end engages with the hole.
   b. 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.
   c. Measure the desired Screw length with the help of the Screw Depth Gauge.
   d. Select the desired Non-Locking (Cortical) Screw.
   e. 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 (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.

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Patents are pending