Paragon 28®

a ZIMMER BIOMET company

SURGICAL TECHNIQUE GUIDE

Gorilla® TUFFNEK® Screw System

PRODUCT DESCRIPTION

The Paragon 28® Gorilla® Plating System was designed to provide solutions to address many foot and ankle indications. The Gorilla® TUFFNEK® locking and non-locking screws coupled with Gorilla® plates provide procedural specific strength for surgeons' foot and ankle reconstructive needs. The TUFFNEK® Screws feature a reinforced, tapered neck, designed to improve strength at the highest stress point in a locking screw. Gorilla® TUFFNEK® screws are offered in locking and non-locking 3.5 mm and 4.2 mm diameters. A compression screw is offered in a 4.2 mm diameter option and is designed for use in the compression slot. The 3.5 and 4.2 mm locking and non-locking screws are compatible in any circular Gorilla® plate screw hole and use the same instrumentation regardless of screw diameter.

SCREW OFFERING

3.5 MM SCREWS

- Locking and Non-Locking
- 2 mm Increments 10-50 mm

4.2 MM SCREWS

- Locking and Non-Locking
- 2 mm Increments 10-50 mm
- 5 mm Increments, 55-70 mm

4.2 MM COMPRESSION SCREW

- 2 mm Increments 10-50 mm
- 5 mm Increments, 55-70 mm

SCREW FEATURES

Titanium nitride (TiN) coated heads allow for TUFFNEK® locking screws to bite into the plate while the tapered shape of the screw head creates a lag effect to lock the plate to the bone.

The reinforced, tapered neck is the key feature of TUFFNEK® technology, to improve strength at the highest point of stress in a locking screw.

Each screw features a tapered screw shaft for improved pullout strength, and tapered screw threads at the distal tip for easier insertion.

INSTRUMENTATION

Threaded Locking Drill Guide

Oblong Compression Drill Guide

EZ/Cone Standard Drill Guide

2.0 mm Drill

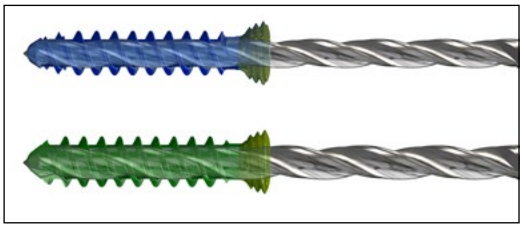
TR-10 Driver

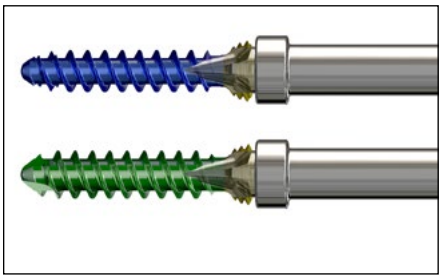
Countersink Punch

INSTRUMENT OPTIONALITY

SINGLE DRILL BIT SIZE

- All screw diameters have a similar tip geometry which allows a single drill bit size to prepare the far cortex for screw insertion.





COUNTERSINK PUNCHING OF SCREWS

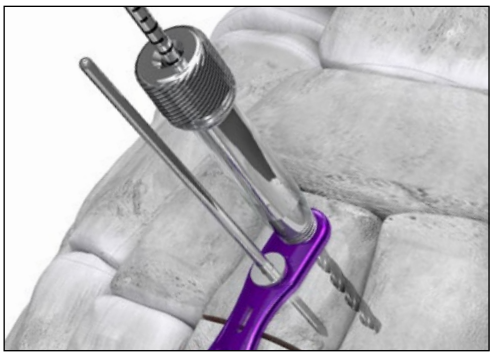
- Prepares the near cortex for the TUFFNEK portion of the screw, allowing screws to seat better in the bone without adding stress to the cortex due to the reinforced necks. The same punch is used regardless of screw diameter.

TIP: *It is strongly recommended to use the punch as it is designed to prevent stress risers in the bone as the neck of the screw enters the near cortex.*

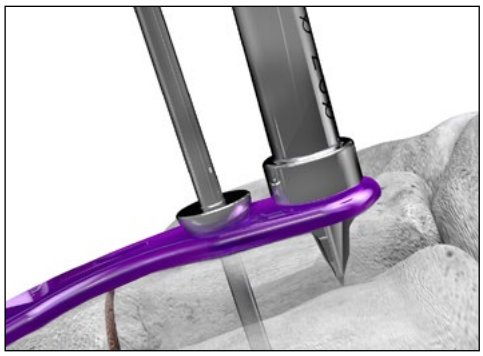
PLATE SELECTION AND FIXATION

The purpose of this portion of the surgical technique guide is to demonstrate the general use of a Gorilla plate with the TUFFNEK screw system while highlighting the available instrumentation.

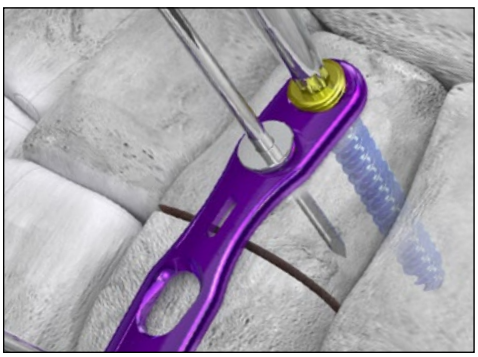
Following incision and bone or joint preparation, secure plate position in desired location with two olive wires.



Using a 2.0 mm drill, drill through the threaded drill guide. All TUFFNEK screws have a similar tip geometry, allowing for a single drill bit size to prepare the distal cortex for insertion.
Remove the threaded drill guide. Measure the screw length using the provided depth gauge.



Attach the punch to the provided handle (not shown). Rotate the punch until adequate bone removal occurs to accept the wider TUFFNEK portion of the screw.



Insert the selected screw. It is advised to avoid final tightening of screws into a locked position until all screws are inserted.

Continue to fill remaining holes of the Gorilla plate with TUFFNEK locking, non-locking or compression screws of choice.

Confirm plate and screw placement using fluoroscopy.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INSTRUCTIONS FOR USE: BABY GORILLA®/GORILLA® PLATING SYSTEM

Indications, Contraindications, Warnings and Precautions relevant to the Baby Gorilla®/Gorilla® Plating System are contained in the Instructions for Use document of the Baby Gorilla®/Gorilla® Plating System P51-IFU-3001.

A patient with the Paragon 28® Baby Gorilla®/Gorilla® Plating System may be safely scanned under the following conditions.
Failure to follow these conditions may result in injury to the patient.

Name/Identification of Device	Paragon 28® Baby Gorilla®/Gorilla® Plating System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spacial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact

If information about a specific parameter is not included, there are no conditions associated with that parameter.

GORILLA®
R3CON PLATING SYSTEM

Gorilla® TUFFNEK® Screw System

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P50-STG-3001 RevD [2026-06-25]

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