Exclusively foot & ankle

Paragon 28®

SURGICAL TECHNIQUE GUIDE

Gorilla® TUFFNEK® Screw System

GORILLA®

R3CON PLATING SYSTEM

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. For more information on implant and instrument usability, please see the Gorilla Plating System Surgical Technique Guides (P51-STG-XXXX).

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.

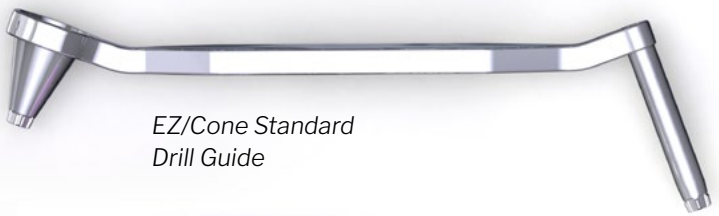
The reinforced, tapered neck is the key feature of TUFFNEK® technology, to improve strength at the highest point of stress in a locking screw.

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

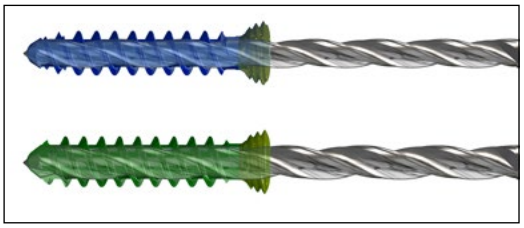
TR-10 Driver

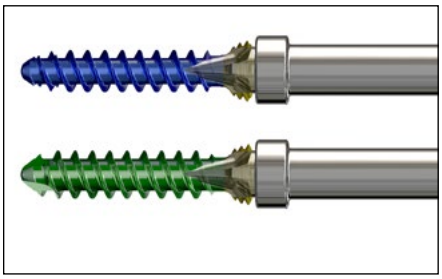
Countersink Punch

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

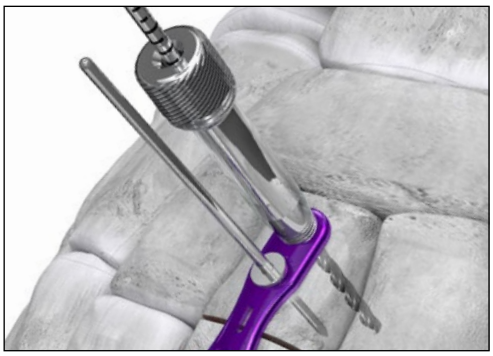
- Prepares the near cortex for the TUFFNEK portion of the screw, allowing screws to seat better in the bone without adding stress to the cortex due to the reinforced necks. The same punch is used regardless of screw diameter.

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.*

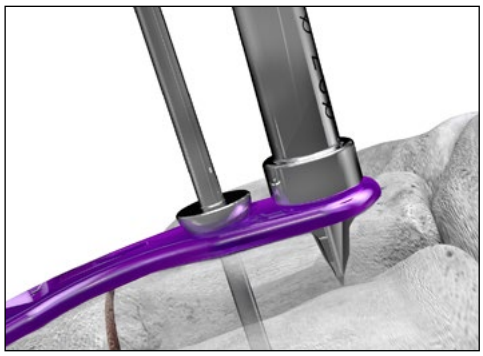
PLATE SELECTION AND FIXATION

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.

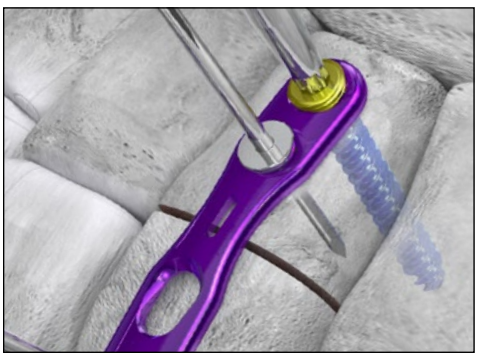
Following incision and bone or joint preparation, secure plate position in desired location with two olive wires.



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.

INDICATIONS FOR USE (GORILLA®):

The Baby Gorilla®/Gorilla® Bone Plates and Bone Screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, talus, and calcaneus, as well as the fingers, hands, and wrists. The system can be used in both adult and pediatric patients. Specific examples include:

Forefoot:

- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Metatarsal or phalangeal fractures and osteotomies
- Lesser metatarsal shortening osteotomies (e.g. Weil)
- Fifth metatarsal fractures (e.g. Jones Fracture)

Mid/Hindfoot:

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Subtalar Fusion
- Medial Column Fusion
- Cuneiform Fracture
- Cuboid Fracture
- Navicular Fracture

Ankle:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures and Osteotomies
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures
- Tibiotalocalcaneal Joint Arthrodesis
- Tibiotalar Joint Arthrodesis
- Tibiocalcaneal Arthrodesis
- Supramalleolar Osteotomy
- Fibular Osteotomy

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic Osteotomy
- Proximal Osteotomy (Chevron and Rotational Oblique)
- Distal Osteotomy (Chevron/Austin)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot:

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Calcaneal Slide Osteotomy

Charcot:

- Medial column fusion (talus, navicular, cuneiform, metatarsal) for neuropathic osteoarthropathy (Charcot)
- Lateral column fusion (calcaneus, cuboid, metatarsal) for neuropathic osteoarthropathy (Charcot)

In addition, the non-locking, titanium screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.

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

CONTRAINDICATIONS:

Use of the Baby Gorilla®/Gorilla® Plating System is contraindicated in cases of inflammation, cases of active or suspected sepsis/infection and osteomyelitis; or in patients with certain metabolic diseases. All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS:

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS:

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- If a stainless steel Gorilla® R3LEASE™ Screw is used, it may only be used standalone.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation.

MR SAFETY INFORMATION:

The Baby Gorilla®/Gorilla® Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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R3CON PLATING SYSTEM

Gorilla® TUFFNEK® Screw System

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

www.Paragon28.com

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DISCLAIMER

The purpose of the Gorilla® TUFFNEK® Screw System Surgical Technique Guide is to demonstrate the optionality and functionality of the Gorilla® TUFFNEK® implants and instrumentation. Although variations in placement and use of the Gorilla® TUFFNEK® implants can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Gorilla® TUFFNEK® screws can be employed, appropriate for the size of the device.