Exclusively foot & ankle Paragon 28®

SURGICAL TECHNIQUE GUIDE

WEIL OSTEOTOMY

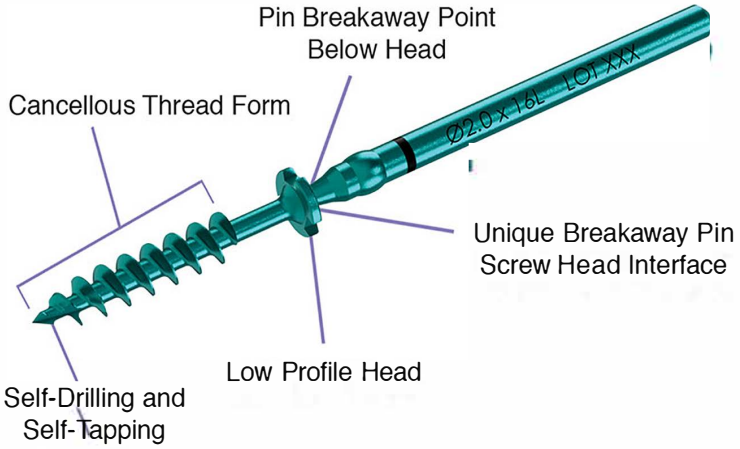
Monster® BITE Snap-Off Screw System

MONSTER™ SCREW SYSTEM

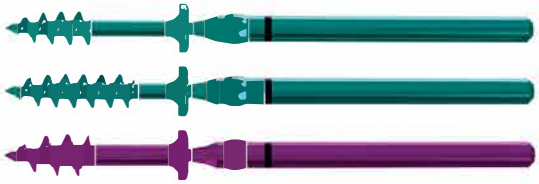
Surgical Technique Guide

Weil Osteotomy

MONSTER® BITE SNAP-OFF SCREW SYSTEM: Screw Features and Optionality



- Unique breakaway pin screw head interface for each length/ thread type that is designed to break as the screw head hits bone
- Made from Titanium Alloy
- 22 total implants in two diameters (2.0 mm and 2.7 mm)
- Designed to supply surgeons with notable screw bite and compression, while controlling costs and maintaining quality



Diameter	Thread Length	Screw Lengths (mm)											
		8	9	10	11	12	13	14	16	18	20	22	24
2.0 mm	Short (1/2 threaded)			●	●	●	●	●	●				
2.0 mm	Long (3/4 threaded)	●	●	●	●	●	●	●	●				
2.7 mm	Short (1/2 threaded)			●		●		●	●	●	●	●	●

DISCLAIMER

The purpose of the Monster® BITE Surgical Technique Guide is to demonstrate the optionality and functionality of the Monster® BITE Snap-Off Screw System and instrumentation. This functionality is demonstrated for a 2nd metatarsal Weil Osteotomy as a representative procedure. Although various screw patterns and methods can be employed for a 2nd metatarsal shortening osteotomy, the fixation option demonstrated was chosen for simplicity of explanation. Other cleared uses for Monster® BITES screws can be employed, appropriate for the size of the device, but are not illustrated in this surgical technique guide. Indications, contraindications and warnings begin on page 3.

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

INDICATIONS FOR USE/INTENDED PURPOSE (Monster®)

System(s)	Indications
Monster Screws Cannulated Screws and Washers in Diameters: 4.5 mm, 5.5 mm, and 7.0 mm	The Monster Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Ligament fixation • Fracture repair/fracture fixation
Mini-Monster Screws Cannulated Screws and Washers in Diameters: 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, and 4.0 mm	The Mini-Monster Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Ligament fixation • Fracture repair/fracture fixation
Mini-Monster Solids Screws Solid Screws and Washers in Diameters: 2.7 mm, 3.5 mm, and 4.2 mm	The Mini-Monster Solids Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Ligament fixation • Fracture repair/fracture fixation
Precision Jones Screws Solid and Cannulated Type II Anodized Screws and Washers in Diameters: 4.0 mm, 4.5 mm, 5.5 mm and 6.2 mm	The Precision Jones Screws of the Monster Screw System are indicated for use in the foot for: • Fracture repair/fracture fixation
Joust Beaming Screws Solid and Cannulated Type II Anodized Screws in Diameters: 5.0mm, 5.5 mm, and 7.2 mm	The Joust Beaming Screws of the Monster Screw System are indicated for use in the foot and ankle for: • Bone reconstruction/osteotomy • Arthrodesis/joint fusion • Fracture repair/fracture fixation
Monster BITES Screws Snap-off Screws in Diameters: 2.0 mm and 2.7 mm	The Monster BITES Screws of the Monster Screw System are indicated for use in the foot for: • Bone reconstruction/osteotomy • Fracture repair/fracture fixation

CONTRAINDICATIONS

Use of the Monster® Screw 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
- Indications not included in the **INDICATIONS FOR USE**

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

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

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® 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® 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 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, guide wires, and sterile packaged instruments are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System. These implants are provided sterile and are not to be re-sterilized.

MR SAFETY INFORMATION

The Monster® Screw System has been evaluated for safety and compatibility in the MR environment. It has been tested for heating, migration or image artifact in the MR environment. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 3.0 T or less Maximum spatial field gradient of 1900 gauss/cm (19 T/m)

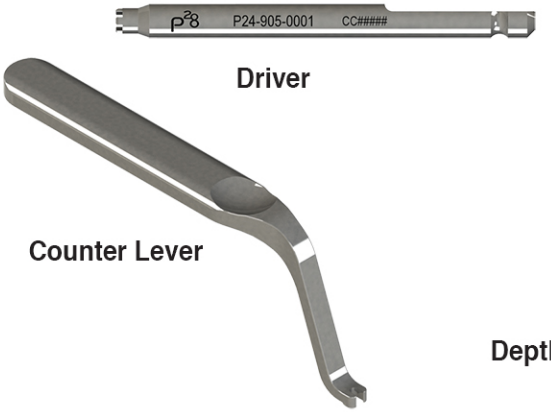
Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

Under the scan conditions defined above, non-clinical testing results indicate the Paragon 28 Orthopedic Screw is expected to produce a maximum temperature rise of less than 7.8°C after 10 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Paragon 28 Orthopedic Screw when imaged with a gradient echo pulse sequence in a 3.0 T MR system.

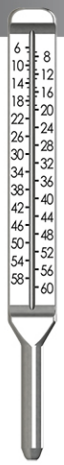
Surgical Technique

INSTRUMENTS



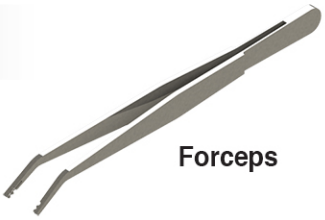
Driver

Counter Lever

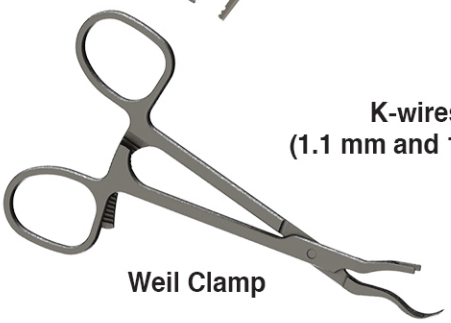


Depth Gauge

Handle
(mini AOSS)



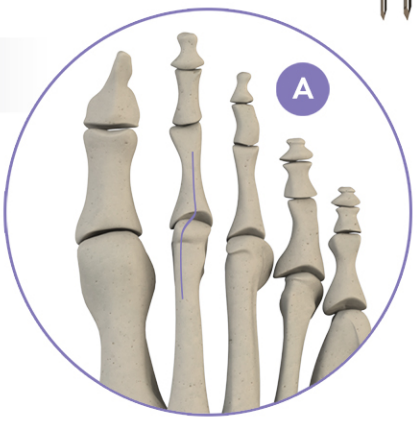
Forceps



Weil Clamp

K-wires
(1.1 mm and 1.4 mm)

INCISION/EXPOSURE



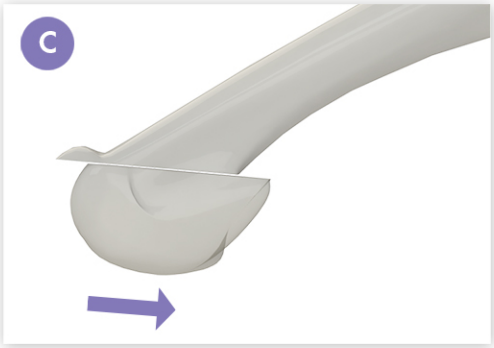
The procedure described can be performed in isolation or combined with other procedures based on patient needs and surgeon discretion.

Patient positioning in a supine position with fluoroscopy available is recommended for this procedure. A linear or curvilinear incision is made over the 2nd MTP, but can be varied according to surgeon preference and concomitant procedures being performed. (A) Dissection is carried down to the 2nd MTP joint and head of the 2nd metatarsal.

METATARSAL OSTEOTOMY AND DISPLACEMENT

An osteotomy is made 1-2 mm below the dorsal articular cartilage of the 2nd metatarsal from dorsal distal to plantar proximal at an angle parallel to the weight bearing surface using a sagittal saw. (B) The capital fragment of the metatarsal is shifted proximally. (C)

A Weil clamp can be placed around the osteotomy to temporarily secure the position of the osteotomy if desired. (D) The approximate height of the metatarsal head can be determined by reading the distance off of the Weil clamp (not shown). Alternatively, a k-wire (used for provisional fixation only) can be used with the depth gauge to determine screw length.



Surgical Technique

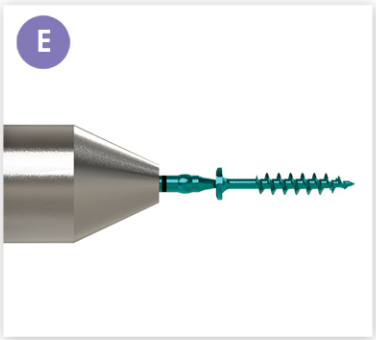
PERMANENT FIXATION USING A MONSTER BITE SCREW

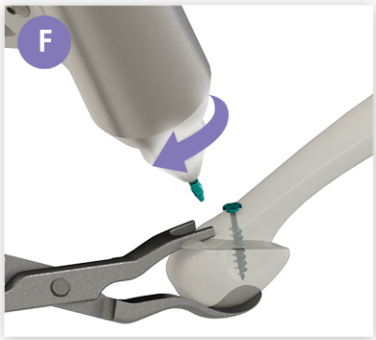
An appropriately sized Monster BITE screw is selected from the Monster BITE screw caddy. The breakaway drive shaft of the Monster BITE screw is inserted into the wire driver. Do not bury the laser mark in the wire driver, but insert the screw such that the laser mark is close to the tip of the wire driver. (E)

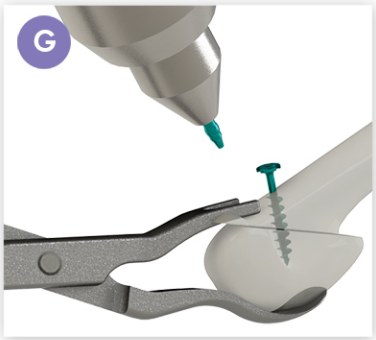
NOTE: The Monster BITE screws are designed to be self-drilling and self-tapping and should be inserted without creating a pilot hole.

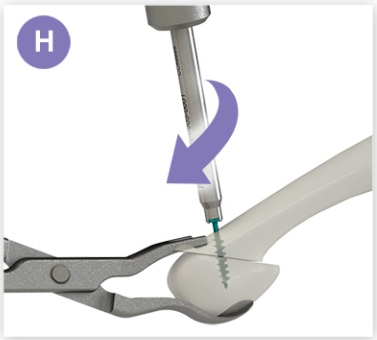
Insert the Monster BITE screw using the wire driver in the forward direction. The pin is designed to break away from the screw head when the screw head hits the bone. (F)

TIP: If the breakaway drive shaft disengages from the Monster BITE screw prior to when the head of the screw is flush to the bone (G), obtain the screw driver from the Monster BITE screw caddy, connect to the handle, and complete insertion of the Monster BITE screw. (H)

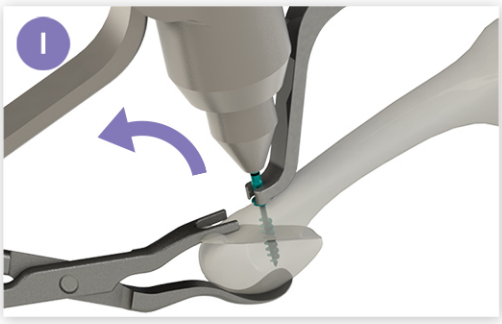


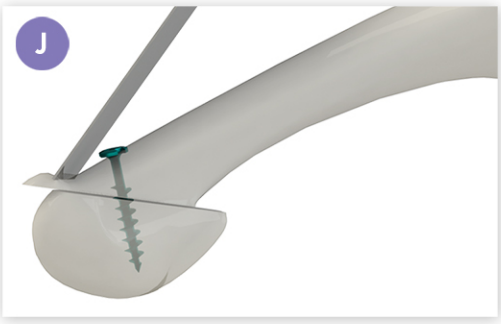


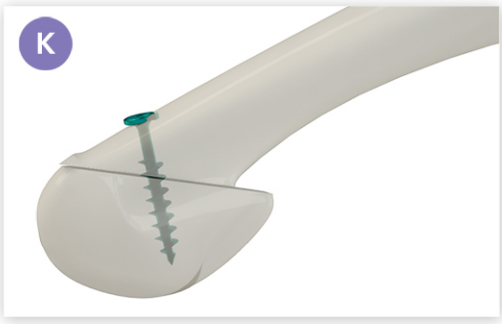




TIP: If the breakaway drive shaft of the Monster BITE screw does not disengage from the screw head prior to the screw head becoming flush with the bone, the breakaway drive shaft can be disengaged by tilting the wire driver. In soft bone or unstable osteotomies, it is recommended to place the counter lever against the head of the screw prior to breaking the breakaway drive shaft using the wire driver, screw driver or surgeon hand. (I) If desired, remove the dorsal eminence on the back of the metatarsal head, using an oscillating saw or bone rongeur. (J) Confirm screw placement using fluoroscopy, if desired. (K)







CLOSURE

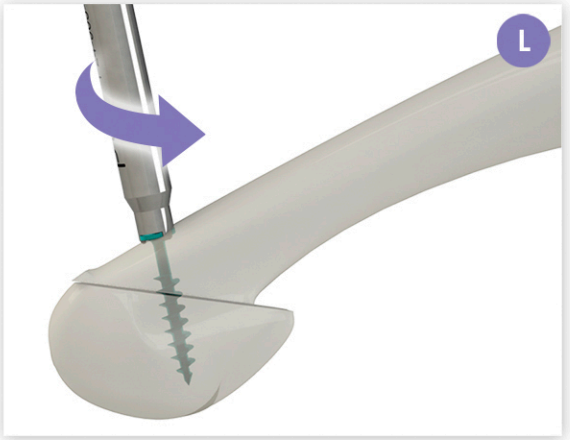
Proceed to incision closure or concomitant procedures at this time.

MONSTER® BITE SCREW REMOVAL

LOCATE SCREW
Utilizing radiographs, determine the location of the implant. Palpate screw head and remove surrounding soft tissue to gain maximum exposure. In cases of bony ongrowth, a dental pick or small rongeur may be used to remove bony matter from the head of the screw to allow the driver to engage.

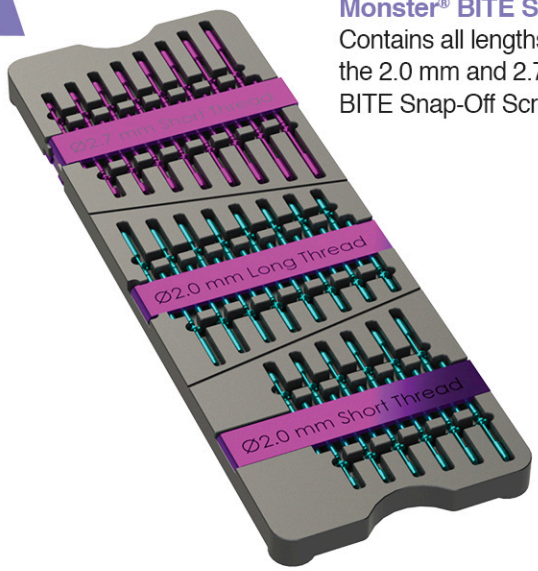
REMOVE SCREW
Use the Monster BITE Screw Driver to engage the head of the screw and rotate counterclockwise by hand until screw is removed. (L)

If the screw head is stripped, engage the proximal shaft of the screw under the screw head with a medium sized Kern forceps and continue turning driver shaft counterclockwise while exerting light pressure upwards with the Kern forceps. If the screw is integrated into bone, core out with appropriate sized trephine drill.



Monster® BITE Snap-Off Screw System

Instrument Caddy
The Monster® BITE Instrument Caddy is a self-contained set that includes all instrumentation necessary for inserting a Monster® BITE Snap-Off Screw. The Monster® BITE Screw Caddy sits atop the instrument caddy and is easily removed to access all instrumentation.



Monster® BITE Screw Caddy
Contains all lengths and options for the 2.0 mm and 2.7 mm Monster® BITE Snap-Off Screws.

MONSTER™
SCREW SYSTEM

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