Exclusively foot & ankle

Paragon 28®

SURGICAL TECHNIQUE GUIDE

MONSTER™

SCREW SYSTEM

MINI-MONSTER™

SCREW SYSTEM

Monster® and Mini-Monster® Screws

SURGICAL TECHNIQUE GUIDE

When creating the **PARAGON 28® MONSTER® SCREW SYSTEM** objectives were set to produce a cannulated screw system that is comprehensive, high quality and specifically designed for the unique anatomy of the foot and ankle. Armed with in-depth knowledge of the procedures and challenges that the foot and ankle surgeon faces, we sought to be inclusive and respectful of individual surgeon's preferences knowing that there is more than one way to a successful outcome. We scrutinized every detail that went into the design of the Monster® Screw System and emerged with a screw that comes with a "monster" bite and a noteworthy amount of options.

The **MONSTER® MIDFOOT/HINDFOOT SCREW SYSTEM** offers three different screw diameters in one set. The **MINI-MONSTER™ SCREW SYSTEM** offers five smaller cannulated screw options than the Monster® Midfoot/Hindfoot Screw System. With 8 different screw diameters, multiple thread length options and headed and headless varieties in all diameters, the Monster® and Mini-Monster® screw systems provide a degree of versatility that allows for fixation of osteotomies, fractures and joint arthrodesis in the forefoot, midfoot, hindfoot and ankle.

We invite you to review the remainder of this guide to learn more about the Monster® and Mini-Monster® screw design and features, the accompanying instrumentation and how the screws are provided in sets. Further surgical technique guides under this umbrella document guide more specific procedures using these screws and their instrumentation.

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SURGICAL TECHNIQUE GUIDE: INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

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

INDICATIONS FOR USE (MONSTER®)

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

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

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® 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 and guide wires 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.**

MR SAFETY INFORMATION

The Monster® Screw System has 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 the Monster® Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.

Monster and Mini-Monster Screw Design and Features:

Not Just Another Screw

The Monster and Mini-Monster screws were made with a purpose:

- To deliver a product specifically designed for the foot and ankle surgeon's needs – with a combination of screw types, diameters and lengths to provide remarkable versatility.
- To offer flexibility to surgeons to change the type of screw used intraoperatively between headless and headed as well as partially threaded and fully threaded.
- To provide quality instrumentation for screw placement and insertion including Hintermann retractors, a Parallel K-Wire Guide, and a 3 fluted drill. The 3 fluted drill provided for each screw diameter was tested and designed to remove material in a manner to minimize crumbling without compression of bone prior to screw insertion.
- To supply surgeons with notable screw bite and compression, while controlling costs and maintaining quality.

HEADED SCREW

SCREW HEAD: HEADED SCREW

Rounded for decreased soft tissue irritation when the screw is inserted at an angle, leaving a portion of the screw head proud. The head diameter was optimized to prevent plunging of the screw head into softer bone.

SCREW NECK: HEADED SCREW

Reinforced neck geometry helps to prevent stress risers at a traditional weak point of the screw.

HEADLESS SCREW

SCREW NECK: HEADLESS SCREW

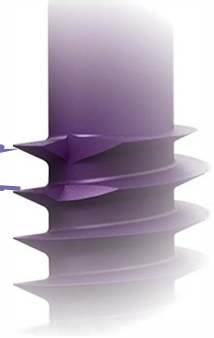
Studies have demonstrated that with traditional headless screws, maximum compression is achieved too early. This results in distal thread stripping when the screw reaches final placement. The Paragon 28 headless screw design provides a tapered neck which enables controlled pre-compression before proximal thread engagement. The pitch ratio and taper were engineered to not exceed (for a given size) the distal thread purchase while achieving maximum compression.

DUAL PITCH THREADS: HEADLESS SCREW

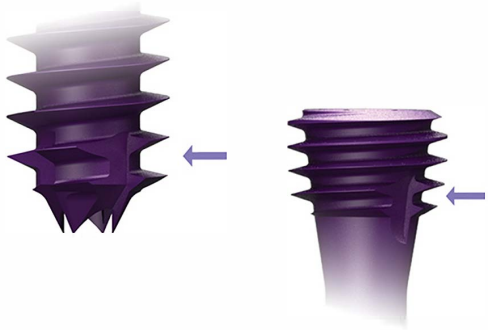
German studies show that the larger pitch differential (between proximal and distal threads) is what contributes to early compression and resultant stripping of the distal threads during final screw insertion to make the screw head flush with bone. The larger the differential between proximal and distal pitch, the more exaggerated this phenomenon.

At Paragon 28, we have engineered a "Pre-Compression" taper at the neck of the screw to help provide controlled compression. The proximal threads are designed to then "lock" in that compression rather than acting as the source of compression, thereby intending not to exceed what the distal thread purchase can tolerate.

Monster and Mini-Monster Screw Design and Features:

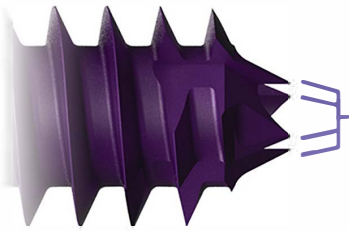


REVERSE CUTTING FLUTES
Self-tapping reverse threads help facilitate screw removal.



FORWARD CUTTING FLUTES:
HEADED AND HEADLESS SCREWS
Allow for the screw to be self-tapping. The “flat” at each flute helps to cut into the bone and create a thread pattern during screw insertion.

SHARP THREADS
Screw threads taper to a size of .02 mm (.0008”) at the crest, allowing for improved definition between the thread and bone interface and increasing the surface area contact, equating to better “bite” in soft or weaker bone.



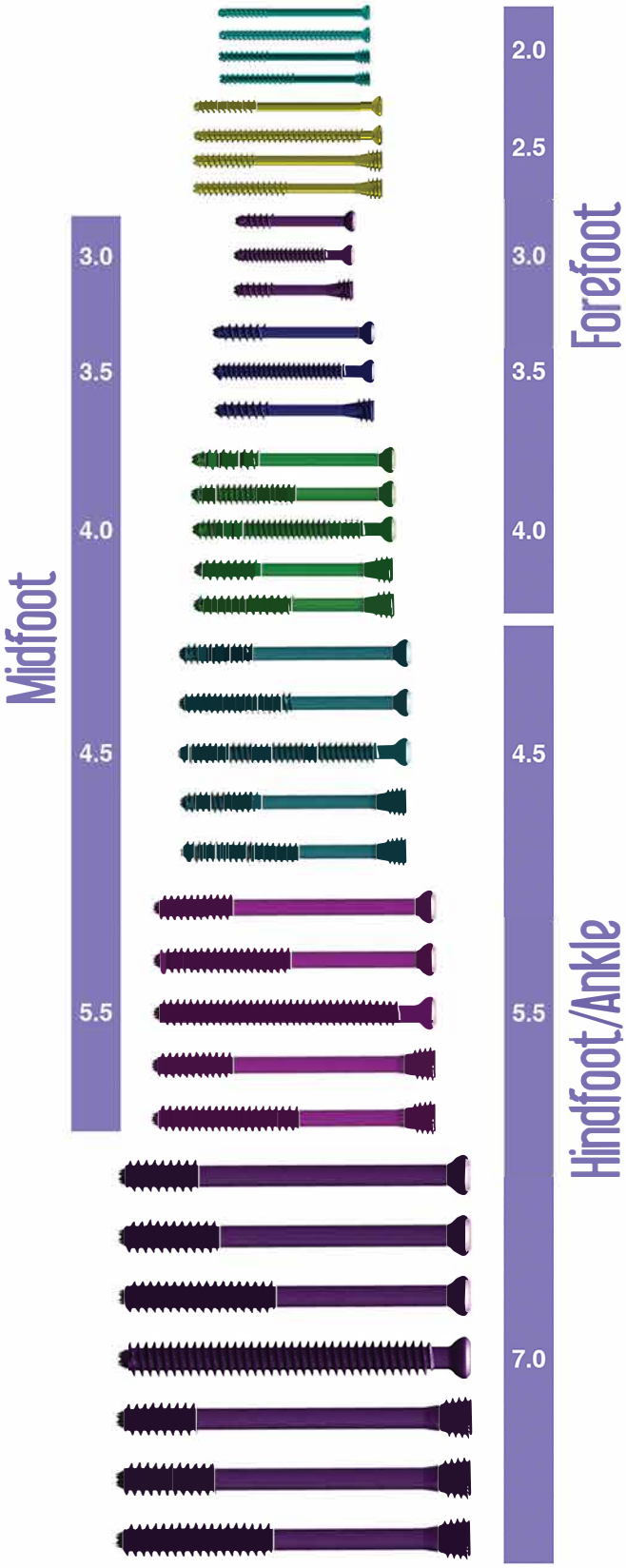
SHARP TIP
The 4 sharp tips are self-drilling and self-tapping. They allow bone to easily escape along the backside of the tip, which requires less torque upon insertion.

TIP: Internal testing demonstrated improved screw performance when the drill diameter matched the screw inner diameter. Drilling is recommended to optimize thread purchase.

HEXALOBE DRIVER
The largest possible hexalobe driver is used to provide insertion torque without compromising strength.

Screw Optionality

2.0 mm	Headed	Partially Threaded	1 mm increments, 8-20 mm; 2 mm increments, 22-50 mm
2.0 mm	Headed	Fully Threaded	1 mm increments, 8-20 mm; 2 mm increments, 22-50 mm
2.0 mm	Headless	Part Threaded - Short	1 mm increments, 10-20 mm; 2 mm increments, 22-50 mm
2.0 mm	Headless	Part Threaded - Long	2 mm increments, 30-50 mm
2.5 mm	Headed	Partially Threaded	1 mm increments, 10-20 mm; 2 mm increments, 22-50 mm
2.5 mm	Headed	Fully Threaded	1 mm increments, 10-20 mm; 2 mm increments, 22-50 mm
2.5 mm	Headless	Part Threaded - Short	1 mm increments, 10-20 mm; 2 mm increments, 22-50 mm
2.5 mm	Headless	Part Threaded - Long	2 mm increments, 30-50 mm
3.0 mm	Headed	Partially Threaded	2 mm increments, 10-50 mm
3.0 mm	Headed	Fully Threaded	2 mm increments, 10-50 mm
3.0 mm	Headless	Partially Threaded	2 mm increments, 10-50 mm
3.5 mm	Headed	Partially Threaded	2 mm increments, 10-50 mm
3.5 mm	Headed	Fully Threaded	2 mm increments, 10-50 mm
3.5 mm	Headless	Partially Threaded	2 mm increments, 12-50 mm
4.0 mm	Headed	Part Threaded - Short	2 mm increments, 12-50 mm; 5 mm increments, 55-60 mm
4.0 mm	Headed	Part Threaded - Long	2 mm increments, 28-50 mm; 5 mm increments, 55-60 mm
4.0 mm	Headed	Fully Threaded	2 mm increments, 12-50 mm; 5 mm increments, 55-60 mm
4.0 mm	Headless	Part Threaded - Short	2 mm increments, 14-50 mm; 5 mm increments, 55-60 mm
4.0 mm	Headless	Part Threaded - Long	2 mm increments, 28-50 mm; 5 mm increments, 55-60 mm
4.5 mm	Headed	Part Threaded - Short	2 mm increments, 18-50 mm; 5 mm increments, 55-70 mm
4.5 mm	Headed	Part Threaded - Long	2 mm increments, 18-50 mm; 5 mm increments, 55-70 mm
4.5 mm	Headed	Fully Threaded	2 mm increments, 18-50 mm; 5 mm increments, 55-70 mm
4.5 mm	Headless	Part Threaded - Short	2 mm increments, 18-50 mm; 5 mm increments, 55-70 mm
4.5 mm	Headless	Part Threaded - Long	2 mm increments, 30-50 mm; 5 mm increments, 55-70 mm
5.5 mm	Headed	Part Threaded - Short	2 mm increments, 26-60 mm; 5 mm increments, 65-90 mm
5.5 mm	Headed	Part Threaded - Long	2 mm increments, 40-60 mm; 5 mm increments, 65-90 mm
5.5 mm	Headed	Fully Threaded	2 mm increments, 26-60 mm; 5 mm increments, 65-90 mm
5.5 mm	Headless	Part Threaded - Short	2 mm increments, 26-60 mm; 5 mm increments, 65-90 mm
5.5 mm	Headless	Part Threaded - Long	2 mm increments, 40-60 mm; 5 mm increments, 65-90 mm
7.0 mm	Headed	Part Threaded - Short	2 mm increments, 36-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headed	Part Threaded - Med	2 mm increments, 40-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headed	Part Threaded - Long	2 mm increments, 44-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headed	Fully Threaded	2 mm increments, 36-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headless	Part Threaded - Short	2 mm increments, 36-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headless	Part Threaded - Med	2 mm increments, 44-50 mm and 72-90 mm; 5 mm increments, 55-70 mm and 95-130 mm
7.0 mm	Headless	Part Threaded - Long	2 mm increments, 72-90 mm; 5 mm increments, 60-70 mm and 95-130 mm



Monster and Mini-Monster Screw Instrumentation

The instruments described below are specific for each screw diameter within the Monster and Mini-Monster systems. The instruments shown are for the 4.0 mm Mini-Monster screw size as an example.

K-Wires

Smooth K-wires are located in each screw set and are sized to act as a guide wire for the particular screw diameter chosen. Additional K-wires are included to be used as temporary fixation for a fracture site, arthrodesis, or osteotomy—used alone or in conjuction with the Monster or Mini-Monster cannulated screw chosen.

Overdrill

An overdrill is offered for each screw diameter and is sized according to the outer diameter of the screw in the Monster and Mini-Monster screw set. The band on the overdrill corresponds to the color of the screw and connects to the powered driver via a quick-release.

Tap

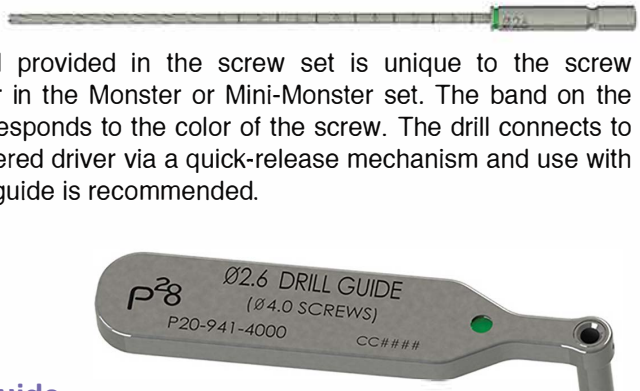
Taps are provided for patients with hard bone and can be used according to surgeon preference. The colored band on the tap corresponds to the color of the screw.

Countersink

Countersinks are available for all Monster and Mini-Monster screw sizes with the colored band corresponding to the screw size. The top countersink is used for a headed screw and the bottom countersink is used for a headless screw. The countersinks connect to the screw driver handle via a quick release mechanism. The countersinks should not be connected to power.

Washer

Domed and flat washers are available for all screw sizes and can be used according to surgeon preference. The washer for a particular Monster or Mini-Monster screw diameter should be the same color as the screw. A washer is recommended in soft bone where the screw head is not well supported by cortical bone. The washer should be oriented such that the text on the washer faces away from the bone.



Drill

The drill provided in the screw set is unique to the screw diameter in the Monster or Mini-Monster set. The band on the drill corresponds to the color of the screw. The drill connects to the powered driver via a quick-release mechanism and use with the drill guide is recommended.

Drill Guide

A drill guide is provided for the Monster and Mini-Monster screw sets, corresponding to the particular screw diameter chosen. The colored dot on the top of the drill guide corresponds to the screw color.

Overdrill Guide

An overdrill guide is provided for the Monster and Mini-Monster screw sets, and is sized to fit the screw outer diameter and the overdrill. The colored dot on the top of the overdrill guide corresponds to the screw color.

Depth Gauge

A depth gauge sized to fit the particular screw size chosen is provided in the screw caddy in the drawer below the screws.

Driver

The driver for a selected screw size will be located within that set. The driver will contain one or more bands to indicate which screw sizes that driver will work with. The driver can be attached to the handle via a quick release mechanism.

TIP: A solid driver is provided in addition to the cannulated driver for the 2.0 mm and 2.5 mm screws. It is to be used when performing final screw insertion and tightening.

Monster and Mini-Monster Screw Instrumentation

SCREW MEASUREMENT

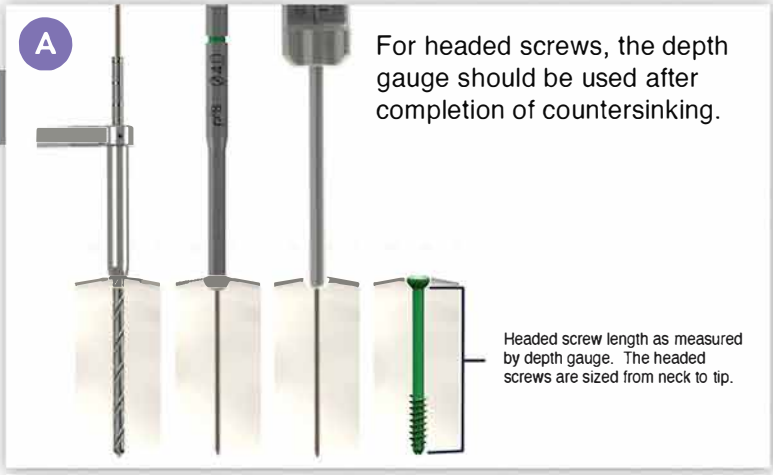
Once the guide wire position and length has been confirmed using fluoroscopy, there are two options for measuring screw length:

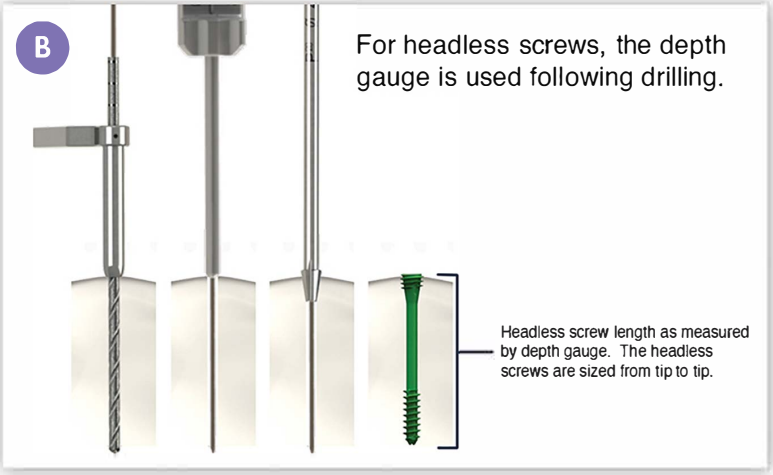
Option 1: Depth Gauge

Headed screw measurement is demonstrated in Figure A. (**A**) Headless screw measurement is demonstrated in Figure B. (**B**)

Option 2: Cannulated Drill Bit Markings

The cannulated drill bit can only be used as a measuring device for screw length when it is used in conjunction with a drill guide (all screw diameters). The screw length is read off the drill guide or tissue protector. The measured screw length will require the subtraction of estimated head height for headed screws. (**C**)





TIP: Because of the superior compression of the Mini-Monster and Monster screws, the instrumentation of each screw diameter has been calibrated to account for any additional compression. Surgeons are encouraged to continue to use their unique method of subtracting a "normal" amount off of their measurement of length based on the particular application.

Monster Screw Instrumentation

The instruments listed below are contained only in the Monster Screw System Midfoot/Hindfoot Set (4.5 mm, 5.5 mm, and 7.0 mm screw diameters).

K-Wire Guide

A K-wire guide (**A**) is available for the Monster Screw Systems that inserts into the drill guide (**B**) for the screw size selected.

With the K-wire guide inserted into the drill guide, the K-wire can be driven into bone with soft tissue protection. (**C**) Both smooth and threaded K-wires are available in the Monster Screw System Case.

Hintermann Retractor

A Hintermann retractor is located at the bottom of the Monster Screw System case. The larger, outside hole accomodates the 2.3 mm wires for the 7.0 mm screw, and alternatively can be used with a Steinmann pin up to 2.4 mm. The smaller, inner hole accomodates 1.6 mm wires (used for the 5.5 mm screw) and smaller.

Jacobs Adaptor

A 3/16" Jacobs Adaptor is available with proper cannulation to fit the instrumentation of any Monster screw size (4.5 mm, 5.5 mm, and 7.0 mm). This adapter can be used to couple the screw driver to the powered driver for powered screw insertion. The driver for a selected screw size will be located within the set. The driver will contain one or more bands to indicate which screw sizes that driver with work with. The driver can be attached to the handle via quick release mechanism **or a power adapter. Final insertion and tightening should be completed by hand with the provided handle.**

Cleaning Stylet

A cleaning stylet is available at the bottom of the Monster screw case for use in circumstances where bone accumulates in the cannulated instrumentation.

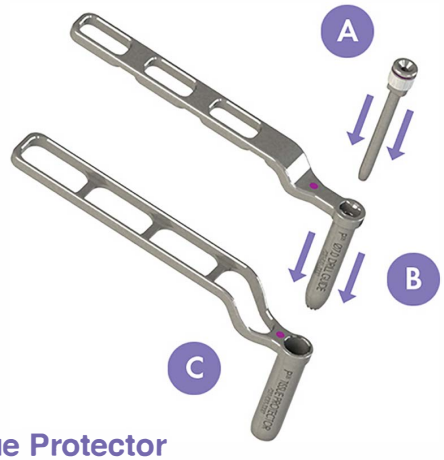
7.0 mm Monster Screw Instrumentation

The instruments below are specific to the Monster 7.0 mm screws. Examples of their application are shown in the Surgical Technique Guide: "Subtalar Joint Arthrodesis".

Parallel K-Wire Guide

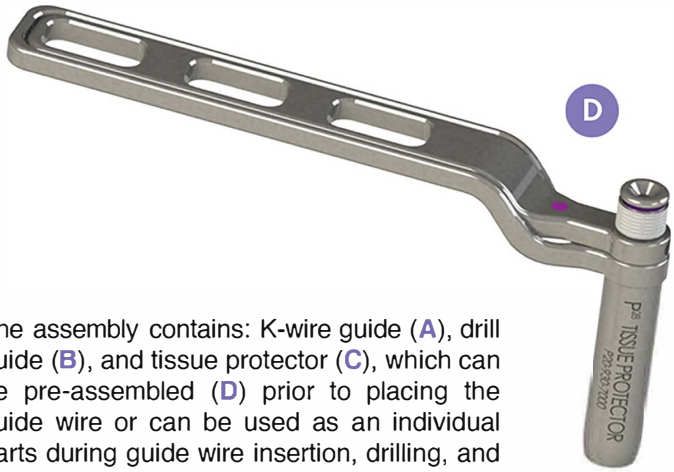
Built for three purposes:

- Assists in spacing and positioning K-wires (guide wires) for the 7.0 mm screws. Prevents screw head contact if minimum distance between wires is met.
- Helps to place a 2nd guide wire when an initial guide wire is inserted with a good trajectory, but an inaccurate position.
- Assists in placing the guide wire for a posterior to anterior screw across the subtalar joint when an anterior to posterior screw has already been placed.



3-in-1 Tissue Protector

Available for minimally invasive insertion of a 7.0 mm screw, offering soft tissue protection during guide wire insertion, drilling, countersinking, and screw insertion.



The assembly contains: K-wire guide (**A**), drill guide (**B**), and tissue protector (**C**), which can be pre-assembled (**D**) prior to placing the guide wire or can be used as an individual parts during guide wire insertion, drilling, and screw insertion.

Countersinks with Stops

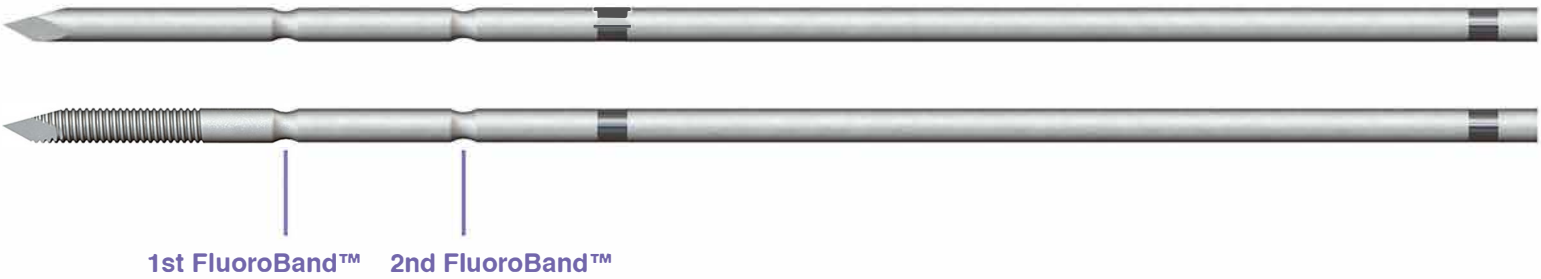
Help prevent accidental overaggressive countersinking by allowing the countersink to penetrate the appropriate amount.

7.0 mm Monster Screw Instrumentation

The instruments below are specific to the Monster 7.0 mm screws. Examples of their application are shown in the Surgical Technique Guide: "Subtalar Joint Arthrodesis".

FluoroBand™ Guide Wires

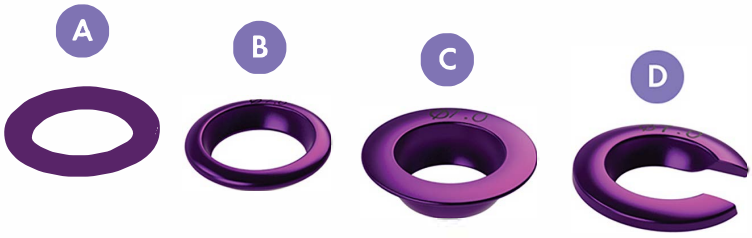
Help to determine if a Short, Medium, or Long Thread Length for a 7.0 mm partially threaded screw could be used across an arthrodesis, fracture or osteotomy site. The FluoroBand™ guide wires are used in place of a standard guide wire, and are available in smooth and threaded options.



The 1st Fluoroband™ is located 20 mm from the tip of the wire. This is the same length as the threaded portion of the Medium Length 7.0 mm Monster Screw. When the 1st Fluoroband™ is not across the arthrodesis, osteotomy, or fracture site, a Short Length 7.0 mm Monster Screw should be used to achieve compression.

When the 1st Fluoroband™ is at or across the arthrodesis, osteotomy or fracture site, a Short or Medium Length 7.0 mm Monster Screw can be used to achieve compression.

The 2nd Fluoroband™ is 32 mm from the tip of the wire. This is the maximum length of the threaded portion of the Long Length 7.0 mm Monster Screw. If the 2nd Fluoroband™ is at or crosses the arthrodesis, osteotomy or fracture site, a Short, Medium or Long Length 7.0 mm Monster Screw can be used for compression.



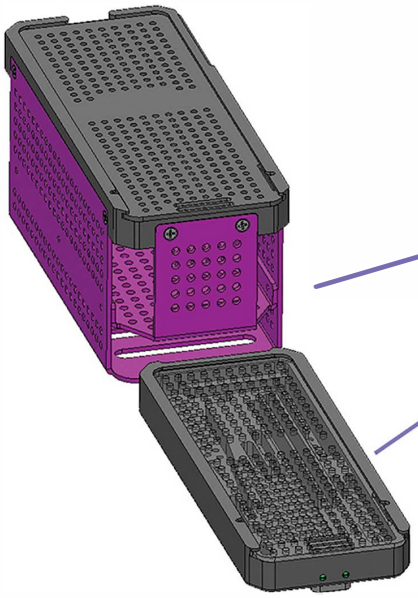
7.0 mm Screw Washer Options

The 7.0 mm Monster Screw System has 4 washer styles available for use:

- Flat (A)
- Domed (B)
- Bowl (C) – The bowl washer allows for the washer to be seated in the countersunk portion of the bone, keeping the screw head lower than a flat or domed washer.
- Split-Flat (D) – The split flat washer allows a washer to be inserted if screw insertion has already begun without the need to back the screw all of the way out.

TIP: The 7.0 mm diameter headed Monster Screw offers a blunt tip to prevent soft tissue irritation when bicortical fixation is preferred. This option is not standard in the set, but can be provided upon request.

Mini-Monster™ System Set



Mini-Monster™ Screw Caddy
Each Mini-Monster™ screw diameter contains an individual caddy for Headed Screws and Headless Screws.

The tray beneath each screw caddy contains the instruments unique to the particular diameter screw chosen.

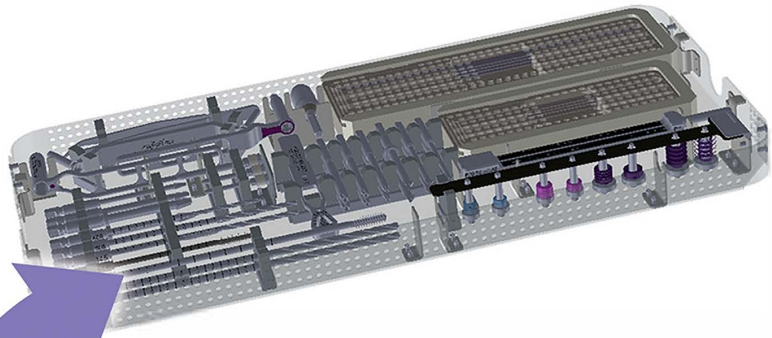
Mini-Monster™ 2-In-1 Option
This "Mini-Monster™ 2-In-1" option allows for two screw caddies to be transported to a surgery. For instance, a surgeon may want a 2.0 mm and a 2.5 mm screw option available for a hammertoe correction case. These two screw diameter options can be brought in the 2-in-1 Caddy.

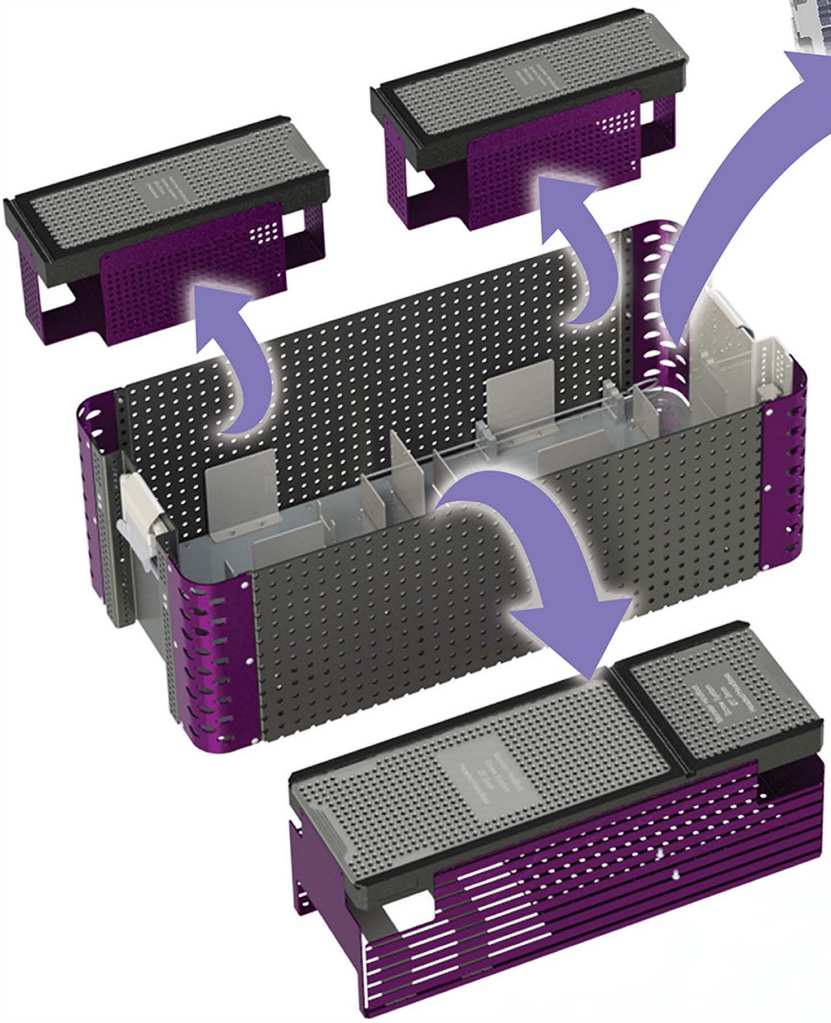
Mini-Monster™ 5-In-1 Option
This "Mini-Monster™ 5-in-1" option allows for five screw caddies to be transported to a surgery. This may be beneficial in a case where multiple procedures are being performed and the optionality of screw diameters is necessary.

Monster® Screw System Midfoot/Hindfoot Set

Monster® Screw System Midfoot/Hindfoot Set

The Monster® Screw System Midfoot/Hindfoot Set contains the caddies for 4.5 mm, 5.5 mm, and 7.0 mm Headed or Headless Screws, as requested. The Hintermann retractor and ratchet handles (small and medium) are located below the screw caddies.





Midfoot/Hindfoot Caddy - Top Tray

The tray that sits atop the screw caddies contains two bins for K-wires: the longer bin containing the guide wires and FluoroBand™ guide wires for 7.0 mm screws and the shorter bin containing the guide wires for the 4.5 mm and 5.5 mm screws. Also contained in this tray are countersinks, washers, drivers, drill guides, taps, depth gauges, the Parallel K-Wire Guide, the Jacobs adapter, and the 3-in-1 Tissue Protector for the 7.0 mm screws.